REQUEST FOR PROPOSALS NO. NIH-NINDS-04-05

NINDS PILOT THERAPEUTICS NETWORK CLINICAL OPERATIONS CENTER: NPTUNE COC

DATE ISSUED: May 14, 2004
DATE DUE: June 29, 2004

LADIES AND GENTLEMEN:

The National Institute of Neurological Disorders and Stroke (NINDS), NIH, invites you to submit a proposal in accordance with the requirements of the attached Request for Proposals (RFP) No. NIH-NINDS-04-05.

THIS PROCUREMENT IS FOR FULL AND OPEN COMPETITION. WE ANTICIPATE THAT ANY RESULTANT AWARD WILL BE A PERFORMANCE-BASED CONTRACT. DEPENDING UPON YOUR PROPOSED TYPE OF INCENTIVE, THE CONTRACT WILL BE AWARDED AS EITHER A PERFORMANCE-BASED COST PLUS AWARD FEE TYPE CONTRACT, OR A PERFORMANCE-BASED COST TYPE CONTRACT.

THE EXAMPLE TERMS INCLUDED IN THIS SOLICITATION ARE BASED ON AN AWARD FEE TYPE SCENARIO. HOWEVER, ALL OFFERORS HAVE THE OPTION OF PROPOSING EITHER MONETARY OR NON-MONETARY INCENTIVES. PLEASE REFER TO SECTION L ENTITLED: "INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS", FOR FURTHER GUIDANCE.

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

If you intend to submit a proposal in response to this solicitation, we ask that you inform the Contracting Officer of your intent, by completing the Proposal Intent Response Sheet, Attachment #3, by mailing it to the address below, or by e-mailing it to: hb106s@nih.gov.

In accordance with the Federal Acquisition Regulation (FAR) Clause 52.232-18, "Funds are not presently available for this contract. The Government's obligation under this contract is contingent upon the availability of appropriated funds from which payment for contract purposes can be made. No legal liability on the part of the Government for any payment may arise until funds are made available to the Contracting Officer for this contract and until the Contractor receives notice of such availability, to be confirmed in writing by the Contracting Officer."

It is your responsibility to monitor the web page: http://www.FedBizOpps.gov/ , **OR** http://www.ninds.nih.gov/funding/currentrfps.htm, for any amendments that might be issued under this solicitation.

An original and ten (10) copies of the technical proposal and an original and four (4) copies of the business proposal must be received by the Contracting Officer, no later than 4:30 P.M. (Eastern Standard Time) on June 29, 2004, at the following address:

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

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

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

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

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

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

Your proposal must be prepared in accordance with **Section L** entitled "Instructions, Conditions, and Notices to Offerors", **Section C** entitled "Description/Specification/Work Statement", and will be evaluated pursuant to **Section M** entitled "Evaluation Factors for Award". Please be aware that in addition to hard copies, **Section L 1.a.** also requires you to submit a yearly and cumulative summary of your business proposal on a 3.5"diskette in Microsoft Excel© format.

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

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

Requests for any information concerning this RFP, and all questions should be referred only to Helene Braun, Contract Specialist, who may be reached at hb106s@nih.gov or (301) 496-1813. Discussion with any other individual outside of the Contracts Management Branch may result in the disqualification of a potential offeror's proposal.

Sincerely,

Kirkland L. Davis

Kirkland L. Davis
Chief, Contracting Officer, NINDS

OMB NO. 0990-0115

SOLICITATION

SECTION A – SOLICITATION/CONTRACT FORM

1. Request For Proposal (RFP) Number:	2. Issue Date:	3. Just in Time:	4. Set Aside:
NIH-NINDS-04-05	May 14, 2004	____ NO __X__ YES See Part IV, Section L.	X__ NO ____ YES See Part IV, Section L.

5. TITLE: NINDS PILOT THERAPEUTICS NETWORK CLINICAL OPERATIONS CENTER: NPTUNE COC

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), **June 29, 2004.** 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), DUNS number, and a facsimile number.

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

11. Table of Contents on following page.

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

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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 goal of this contract is to ensure that potential treatments of neurological diseases are tested in pilot clinical trials in a timely and efficient way by developing a network of sites under a single operations center that could implement trials for different neurological diseases. It is anticipated that the award from this solicitation will be a performance-based 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. REPORTING REQUIREMENTS

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

1. Monthly Progress Reports

   The contractor shall describe the activities during the reporting period, and the activities planned for the ensuing reporting period. The reporting period consists of the first full month of performance plus any fractional part of the initial month. As a minimum, this report shall include: (a) a qualitative description of overall progress; (b) an indication of any current problems, which may impede performance, and proposed corrective action; (c) a discussion of the work to be performed during the next reporting period; and (4) recommendations.

2. Annual Progress Reports

   This report shall include a summation of the results of the entire contract work for the period covered.

3. Other Reports:

a. Periodic Study Reports

The exact frequency of these reports will depend on the nature of the study and will be agreed upon by the NINDS and the Contractor. The Project Officer may request, depending upon the study, that these reports include a description of the study progress, quality of data, clinical site performance/compliance, subjects enrolled in the study and their demographic characteristics, subjects screened but not enrolled and reasons why not enrolled, subjects that have completed the study, and anticipated subject enrollment and completion schedules for the remainder of the study, listing of adverse reactions, complications, problems, and their resolution. The report shall present overall study information as well as data for each clinical site. Problems in recruiting and plans for correcting recruiting problems must be included. A brief description of any other impediments to achieving the goals of the contract, any factors having cost implications, and recommendations for resolution should be included. The Contractor shall also provide reports requested by the Data Safety and Monitoring Board (DSMB) according to their specifications. Additionally, study reports may be distributed to other study staff such as the protocol implementation committee at the request of the NINDS.

b. Annual Report for Gender/Minority Tracking

The specific information required in this report is as follows: report date, date enrollment/recruitment was initiated, date enrollment/recruitment was completed, whether a minority sub-population has been identified, and a count of subjects targeted by gender and by ethnic group for each study.

c. Study Final Report

The Contractor shall submit to the NINDS the Study Final Report within three (3) months of completion of each study. This report shall include a summation of the work performed and results obtained. This report shall be in sufficient detail to explain comprehensively the tasks accomplished, results achieved, and shall summarize data and statistical analyses performed in text, tabular and graphical form.

d. Database

At the end of each study, the Contractor shall provide the Project Officer with a final, cleaned, edited, and documented database containing all study data, and all associated programs, source code, codebooks, indices, data tables, documentation, etc., in a format that is readily usable by the NINDS or its designee. A copy of the database shall be made available for public use upon publication of the primary papers, or within 1 year of the end of the original study or at the discretion of the Project Officer. The Project Officer or Contracting Officer may require that the entire database, and all associated programs, source code, codebooks, indices, data tables, documentation, etc., be transferred within 60 calendar days from completion of the study, in a readily usable form to the NINDS or its designee.

e. Trial Material

At the end of the contract period, or when each trial is completed, or at the discretion of the NINDS Project Officer and Contracting Officer, the Contractor shall be prepared to transfer to the NINDS or its designee all trial material including training material, data collection procedures, all data, and any other information, equipment, or procedures necessary to implement and conduct the trial.

f. Study Publications

The contractor shall expeditiously initiate the publication of study results in keeping with the NPTUNE publications policies.

g. Draft and Final Reports

The final report shall include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to comprehensively describe the results achieved.

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

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

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. PACKAGING, MARKING, AND SHIPPING

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

b. Packaging

1. For the purpose of reports, "immediately usable and acceptable condition" includes securing the pages together in a suitable and reasonable manner to be agreed upon by the Contractor and the NINDS Project Officer.

2. Boxes and/or other types of outer packaging, i.e., containers, wraps, etc., shall be suitable to the type of items being transmitted; and the mode of transportation utilized shall assure that such materials be received in an acceptable condition.

c. Marking

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

1. Project Title: "NINDS PILOT THERAPEUTICS NETWORK CLINICAL OPERATIONS CENTER: NPTUNE COC"
2. Contract Number:
3. Name of Contractor:

4. Name of Principal Investigator:

d. Shipping

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

e. See SECTION F for delivery information.

SECTION E - INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

a. The Contracting Officer or a duly authorized representative shall perform inspection and acceptance of all deliverables and services to be provided.

b. For the purpose of this SECTION, the NINDS Project Officer designated in ARTICLE G.2. is the authorized representative of the Contracting Officer.

c. Inspection and acceptance of contract work/deliverables shall be performed at the National Institute of Neurological Disorders and Stroke (NINDS), NIH, 6001 Executive Boulevard, Suite 2225, MSC 9525, Bethesda, Maryland 20892-9525, (for courier service: Rockville, MD 20852). Inspection and acceptance shall be performed using quarterly progress reports, other required reports, and the final report. Site visits will also be employed for this purpose. Acceptance of work and/or report deliverables may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within thirty (30) days of receipt.

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. TERM OF CONTRACT

The contract term is from _____ through _____.

ARTICLE F.2. DELIVERIES

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

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

Item	Description	Reporting Period	Delivery Schedule
(1)	Monthly Progress Report	Monthly	Tenth day of each month, after the inception of the contract, for the entire contract period.
(2)	Annual Progress Report	Yearly	Last day of each contract year.
(3)	Other Reports:		

	1.Periodic Study Reports 2. Annual Report for Gender/Minority Tracking 3.Study Final Report 4.Database 5. Trial Material 6. Study Publications	Duration of contract Yearly Duration of contract Duration of contract Duration of contract Duration of contract	1. To be determined 2. Last day of each year of the contract 3. Within three (3) months of completion of each study 4. Last day of each study 5. To be determined 6. To be determined
(4)	Draft Final Report and Final Report	Duration of contract Duration of contract	Thirty (30) days before last day of contract. Last day of contract.

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

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

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

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. KEY PERSONNEL

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

[To be specified prior to award]

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

ARTICLE G.2. PROJECT OFFICER

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

[To be specified prior to award]

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

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

The Government may unilaterally change its Project Officer designation.

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

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

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

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

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

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

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

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

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

b. The Contractor shall include the following certification on every invoice/contract financing request for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.7 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.7] of the above referenced contract."

OR

ARTICLE G.4. LETTER OF CREDIT PAYMENT

a. Advance payments will be provided under Letter of Credit Number _____, in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments.

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

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

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

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

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

Division of Payment Management
11400 Rockville Pike
Rockwall Building #1, Suite 700
Rockville, MD 20852
(http://www.dpm.psc.gov/support/contact)

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

a. Financial reports on the attached Form NIH-2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the instructions which accompany the form, in an original and two copies, not later than the thirtieth (30) working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph (e) below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the Instructions for Completing Form NIH-2706 instructions entitled "**Preparation Instructions**," all columns A through J shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the *FIRST FULL THREE CALENDAR MONTHS* following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports shall be submitted on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

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

Expenditure Category Percentage of Effort/Hours

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

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

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

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

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

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

ARTICLE G.7. GOVERNMENT PROPERTY

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

ARTICLE G.8. POST AWARD EVALUATION OF PAST PERFORMANCE

a. Contractor Performance Evaluations

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

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

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

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/hotice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan

The Data and Safety Monitoring Plan shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.4. 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**
P.L. 108-199,Title V- General Provisions, Section 510	2004	10/01/2003 – 09/30/2004

ARTICLE H.5. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1) The Small Business Subcontracting Plan, dated _____, is attached hereto and made a part of this contract.

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

b. Subcontracting Reports

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

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

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

April 30th
October 30th

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

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

(2) Summary Subcontract Report, SF-295

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

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

October 30th

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

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

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

ARTICLE H.6. 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**
P.L. 108-199, Title V- General Provisions, Section 505	2004	10/01/2003 – 09/30/2004

ARTICLE H.7. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

b. **Public Law No.**	**Fiscal Year**	**Dollar Amount of Salary Limitation***
P.L. 108-199, Title II - General Provisions, Section 204	2004	Executive Level I

c. Direct salaries which will be paid with FY-04 funds are limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

* For contract expenditures using FY-04 funds, the Executive Level I rate for the period 10/1/03 – 12/31/03 is $171,900. Effective 1/1/04, for contract expenditures using FY-04 funds, the Executive Level I rate was increased to $174,500. Effective 3/3/04, for contract expenditures using FY-04 funds, the Executive Level I rate was increased to $175,700 and will remain at that level until such time as it is determined to raise the Executive Schedule annual rates. See the web site listed below for Executive Schedule rates of pay.

LINK to EXECUTIVE LEVEL SALARIES: http://www.opm.gov/oca/PAYRATES/index.htm

(Click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years.)

ARTICLE H.8. 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.9. PRESS RELEASES

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

b. **Public Law No. and Section No**	**Fiscal Year**	**Period Covered**
P.L. 108-199, Title V - General Provisions, Section 507	2004	10/01/2003 – 09/30/2004

ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.11. ANTI -LOBBYING

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

b. Contract funds shall not be used to pay salary or expenses of the Contractor or any agent acting for the Contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.**	**Fiscal Year**	**Period Covered**
for a., above: P.L. 108-199, Title V- General Provisions, Section 503a	2004	10/01/2003 – 09/30/2004
For b., above: P.L. 108-199, Title V- General Provisions, Section 503b	2004	10/01/2003 – 09/30/2004

ARTICLE H.12. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

ARTICLE H.13. 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.14. SHARING RESEARCH DATA

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

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

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

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

ARTICLE H.15. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: http://www.usfa.fema.gov/hotel/index.htm

ARTICLE H. 16. AWARD FEE (ALL OFFERORS HAVE THE OPTION OF PROPOSING EITHER MONETARY OR NON-MONETARY INCENTIVES.)

Evaluation Guidelines and Procedures for a Performance-Based Cost Plus Award Fee (PBCPAF) Contract

a. Purpose and Results Desired

The purpose of this document is to establish a procedure for evaluating a Contractor's performance to implement Phase I and II clinical trials for neurological disorders. The evaluation will be conducted on a semi-annual basis, (i.e., twice a year) and the Contractor's Award Fee will be based on the quality of services provided, inclusive of deliverables, using a pass/fail rating system.

The Agency'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 the contract awarded as a result of this solicitation. The Agency's decision to pay or not to pay award fee in no way alters the Department's obligation to pay the Contractor for satisfactory deliverables in accordance with the contract awarded as a result of this solicitation. Award Fee is available for services and products identified in the Quality Assurance Surveillance Plan noted below.

The Contracting Officer and the Project Officer and any other Government official (depending on specific expertise specified by the Project Officer) as maybe approved by the Contracting Officer, will serve as the Evaluation Group.

b. Responsibilities of the Award Fee Evaluation Group

The Award Fee Evaluation Group will evaluate the Contractor's technical performance and objectives on a semi-annual basis.

Each member of the Group will evaluate all performance standards using a pass/fail rating scale. The scale will be defined as follows:

DEFINITION OF RATING	RATING	AWARD FEE AMOUNT
Contractor's performance meets the specified standard for each objective, and the monitor can cite few, if any, areas for improvement – all of which are minor.	Pass	Award amount based on rating earned. Superior Performance earns 100% of Available Award Fee
The Contractor's performance does not meet the minimum standard for each objective, and the monitor can cite many areas for improvement, which are not offset by better performance in other areas.	Fail	Satisfactory/Unacceptable Performance earns no Award Fee

Each member of the Group will rate each objective as either "pass or fail". If the Contractor receives a "fail" rating on more than one objective, the overall rating will result in a "fail" for that rating period. Any "fail" rating will result in no Award Fee for that rating period. Any "pass" rating will result in receiving the award fee for that period. The Contractor and the Government agree that the award determinations are not subject to the Disputes Clause.

The overall purpose of the Performance Based Cost Reimbursement contract is to provide a strong incentive and maximum flexibility for the Contractor to achieve superior performance, allowing the Contractor flexibility in performing the work, and encouraging cooperation with the Government. All evaluations will be performed with this purpose in mind. Criticism should be constructive in all points and should be directed toward improvement of technical, management, and administrative conformance with Government objectives and requirements.

On the part of the Government, it is anticipated that the operations of the Group will be to establish and maintain a working relationship with the Contractor that will be conducive to a good business environment and stimulate the free exchange of relevant information. The Group's operation will provide for the establishment of priorities and relative importance of the elements of the work performed.

The Group will include with their evaluation corresponding narrative which supports their rating. In developing remarks, the primary frame of reference will be the trend in level of performance throughout the evaluation period. Specific examples of performance may be used for clarification and emphasis. Remarks will explain reasons for the rating as well as justification for the ratings.

c. Award Mechanism

The award fee will be made semi-annually. The Contracting Officer will inform the Contractor of the amount of the semi-annual award fee along with the narrative explanation of the basis for the award. The payment of the award fee will be made after a Contracting Officer's Authorization (COA) is prepared and signed by the Contracting Officer and an invoice is received from the Contractor for such award fee.

PERFORMANCE STANDARDS AND QUALITY ASSURANCE SURVEILLANCE PLAN

Objective	Measure	Standard	Quality Assurance
			Surveillance Plan
Preparation of Reports	Compliance with Deliverables, see ARTICLE F.2.	No more than one five (5) workday delay per 6-month period.	Review of contract deliverables by PO and CO
Invoice Submission	Accuracy and timeliness of invoices in compliance with Billing Instructions, See ARTICLE G.3.	No more than one (1) invoice per 6-month period requiring suspension or disallowance due to mistakes, incompleteness or unallowable costs.	Review of invoices by PO and CO
Overall Contract Management	Contractor maintains high level of quality assurance responsiveness, and contacts CO/PO immediately with problems, when appropriate.	CO/PO has no more than 3 valid complaints in 6month period, minimal CO intervention required.	Review of contract deliverables by PO and CO

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	Dec 2001	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees
FAR	52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	Jul 1995	Anti-Kickback Procedures
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper
FAR	52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.215-2	Jun 1999	Audit and Records - Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-12	Oct 1997	Subcontractor Cost or Pricing Data
FAR	52.215-14	Oct 1997	Integrity of Unit Prices
FAR	52.215-15	Jan 2004	Pension Adjustments and Asset Reversions
FAR	52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
FAR	52.216-7	Dec 2002	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.219-8	Oct 2000	Utilization of Small Business Concerns
FAR	52.219-9	Jan 2002	Small Business Subcontracting Plan

Reg	Clause	Date	Clause Title
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-26	Apr 2002	Equal Opportunity
FAR	52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-14	Aug 2003	Toxic Chemical Release Reporting
FAR	52.225-1	Jun 2003	Buy American Act - Supplies
FAR	52.225-13	Dec 2003	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
FAR	52.227-14	Jun 1987	Rights in Data - General
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	Jun 1996	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Oct 2003	Prompt Payment
FAR	52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
FAR	52.233-1	Jul 2002	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2001	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
FAR	52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.245-5	Jun 2003	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
FAR	52.246-23	Feb 1997	Limitation of Liability
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	352.216-72	Oct 1990	Additional Cost Principles

Reg	Clause	Date	Clause Title
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT 1/12/04]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS AND MODIFICATIONS OF CLAUSES

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

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

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

FAR 52.219-4, Notice Of Price Evaluation Preference For HubZone Small Business Concerns (JANUARY 1999)

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

- ❑ Offeror elects to waive the evaluation preference.

FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (JUN 2003) Alternate I (JUN 2003).

"(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of 10% to the price of all offers, except--…"

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

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

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

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

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

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

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

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

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

*** (USE BELOW IN NEGOTIATED CONTRACTS THAT ARE EXEMPT FROM CAS REQUIREMENTS SOLELY ON THE BASIS THAT THE CONTRACT IS TO BE AWARDED TO A UNITED KINDGOM CONTRACTOR AND IS TO BE PERFORMED SUBSTANTIALLY IN THE UNITED KINGDOM – SEE 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDITION], SUBPART 9903.201-1(B)(2)) ***

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

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

FAR 52.203-5, Cost Accounting Standards – Educational Institution (APRIL 1998).

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

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

FAR 52.232-18, Availability of Funds (APR 1984).

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

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

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

HHSAR 352.270-8 Protection of Human Subjects (JANUARY 2001)

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

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

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

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

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

There are no applicable clauses in this section.

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

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

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

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

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

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

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

NOTE: Section K - Representations and Certifications - Negotiated Contracts must be completed, signed and included with the Business Proposal. It is available at URL: http://rcb.cancer.gov/rcb-internet/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://rcb.cancer.gov/rcb-internet/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), June 29, 2004**. Delivery and marking of proposals shall be as indicated below:

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

   Technical Proposal: Original plus 10 copies
   Business Proposal: Original and 4 copies**, plus a yearly and cumulative summary of proposed costs on a 3.5" diskette in Microsoft Excel© format.**

2. External Package Marking

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

   RFP No. NIH-NINDS-04-05

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 (Jan 2004)]**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is

not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

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

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

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

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

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

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

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

range to the greatest number that will permit an efficient competition among the most highly rated proposals.

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

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

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

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

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

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offeror's, the Government shall disclose the following information, if applicable:

a. The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
b. The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.
   (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.
   (iv) A summary of the rationale for award.
   (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
   (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

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

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

(End of Provision)

c. **"JUST IN TIME"**

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

Travel Policy. The offeror's (and any proposed management subcontractor's) written travel policy shall **not** be submitted with the initial business proposal.

Annual Financial Statement. The offeror's most recent annual financial statement shall **not** be submitted with the initial business proposal.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal.

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal.

d. **NAICS CODE AND SIZE STANDARD**

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

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

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

e. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

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

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

An offeror who elects to waive this evaluation adjustment must specifically indicate with a statement to this effect on the cover page of its business proposal.

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 October 31, 2004. Depending upon the type of organization selected for contract award, it is anticipated that the award from this solicitation will be a cost reimbursement performance based type contract for a period of five (5) years and could offer either monetary or non-monetary type incentives.

The overall purpose of Performance Based Contracts is to provide a strong incentive and maximum flexibility for the Contractor to achieve superior performance, allowing the Contractor flexibility in performing the work, and encouraging cooperation with the Government.

Each incentive/disincentive should be associated with a monetary value, which the Government will consider during negotiations. The Government encourages you to be creative when developing your incentives, disincentives. This information must be submitted along with your technical and business proposal. The monetary value should be itemized and placed under "Other Direct Cost", in your business proposal.

See SECTION H16., for the description of the Performance Standards and Quality Assurance Surveillance 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 completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the estimated effort for this project as follows: see the table below. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

Labor Category	Percentage of Effort
Professional	75%
Other: Professional Support	250%

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

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

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

(End of Provision)

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

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

(1) Contract Type and General Clauses

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

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in Section L.1.a. entitled, PACKAGING AND DELIVERY OF PROPOSAL. Proposals will be typewritten, paginated,

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

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm (120 days minimum) and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment 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 PART IV, SECTION M of this RFP.

(7) Potential Award Without Discussions

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

(8) Use of the Metric System of Measurement

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

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

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

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

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

(9) Privacy Act – Treatment of Proposal Information

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

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

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

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

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

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

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

-to the cognizant audit agency and the General Accounting Office for auditing.
-to the Department of Justice as required for litigation.
-to respond to congressional inquiries.
-to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(10) Obtaining and Disseminating Biomedical Research Resources

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

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

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

(11) Sharing Research Data

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

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

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. The Clinical Operations Center proposal should describe methods to coordinate the dissemination planning and implementation. The Clinical Operations Center must include a budget and justification for any additional costs of this collaborative effort.

(12) Selection of Offerors

a) The acceptability of the technical portion of each research contract proposal will be evaluated by a technical review panel. The panel will evaluate each technical proposal in strict conformity with the technical evaluation criteria of the RFP, utilizing point scores and written critiques. The technical strengths and weaknesses of each proposal will be addressed by the reviewers and written recommendations provided to the Contracting Officer. Each proposal will be rated as either technically acceptable or unacceptable. Proposals rated technically unacceptable will not be considered further. A separate and independent review of the business proposal will be made by Institute staff and will be subjected to a cost realism and if applicable, a cost analysis. 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 and if applicable, a cost analysis.

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

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

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

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

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

While it is NINDS' policy to conduct discussions with all offerors in the competitive range, NINDS reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct 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 permits tradeoffs among cost or price and non cost factors and allows the Government to accept other than the lowest price proposal.

f) The NINDS reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NINDS' requirements. Synopses of awards exceeding $25,000 will be published on the FedBizOpps web site.

(13) Small Business Subcontracting Plan

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

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

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment 13 to this RFP is an example of such a plan.

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

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

c) The offeror understands that:

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

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

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

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

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses Concerns that each such aspect of the offeror's plan will be judged independent of the other.

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

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors.

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

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

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Concerns as subcontractors.

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

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors have an equitable chance to compete for subcontracts.

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

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

(11) List the types of records the offeror will maintain to demonstrate procedures that have been Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors and award subcontracts to them.

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

(14) HUBZone Small Business Concerns

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

(15) Extent of Small Disadvantaged Business Participation

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

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

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

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

Offerors shall include with their offers, SDB participation targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is 541710, as specified in Section L.1.(d). A total target for SDB participation by the prime contractor, including joint ventures and team arrangements*, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **SDB Participation Plan information may be provided by using Attachment 12, entitled "Small Disadvantaged Business Participation Factor" or in a format developed by the offeror. This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

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

EXAMPLE

Targets for SDB Participation – NAICS Subsector 223

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

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

(16) 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. 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.

(17) Salary Rate Limitation in Fiscal Year 2004

Offerors are advised that pursuant to P.L. 108-199, no NIH Fiscal Year 2004 (October 1, 2003 - September 30, 2004) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-199 applies only to Fiscal Year 2004 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-199 states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES:
http://www.opm.gov/oca/PAYRATES/index.htm

Note to Offerors: The current Fiscal Year 2004 Executive Level I Salary should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2004 Executive Level I Salary rates.

(18) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

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

such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

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

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

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

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

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

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

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

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

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

(4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

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

directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

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

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

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

(19) ROTC Access and Federal Military Recruiting on Campus

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

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

(20) Past Performance Information

Offerors shall mail the Past Performance Information Survey to at least five previous clients (see Section J, Attachment (5) using the criterion below for selection of clients. In addition, offeror's shall submit the following information in their proposal (for both the offeror and proposed major subcontractors). Attachment 6 may be used to request past performance information from previous clients.

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

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

Include the following information for each contract or subcontract:

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

8. North American Industry Classification System (NAICS) Code

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

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

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

(21) 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) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8 (October 1997)

(d) Facilities Capital Cost of Money, FAR Clause 52.215-16 (JUN 2003)

(e) Preaward On-Site Equal Opportunity Compliance Evaluation, FAR Clause 52.222-24, (February 1999)

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

1. Technical Discussions

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

(a) Project Objectives, NIH-1688-1

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

- For an **Institution of Higher Education**: The form MUST be completed in its entirety.

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

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

(b) Statement of Work

i) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

ii) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

iii) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

iv) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

(c) Personnel

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

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

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

i) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

ii) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss their qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

iii) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity must be indicated and the anticipated sources must be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.
-Their availability to the project and the amount of time anticipated.
-Willingness to act as a consultant.
-How rights to publications and patents will be handled.

iv) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

2. **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M).

3. **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points), which is based upon the information contained in the offeror's proposal only.

4. **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

5. **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following 11 paragraphs (5 through 15) shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

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

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

a) Copies of the Department of Health and Human Services (Department), regulations for the protection of human subjects, 45 CFR part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

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

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

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*, telephone: 301-496-7014*), is recommended.

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

f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

*Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human Subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7005. For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/. Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html.

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

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

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

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

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

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

Sources of Materials:

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

Potential Risks:

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

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

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

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

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

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

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

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

Collaborating Site(s)

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

7. **Required Education in the Protection of Human Research Participants**

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

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.
Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at

http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the Contracting Officer with the title of the education program and a one sentence description of the program that the replacement has completed.

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

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

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

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

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

Information Required for ALL Clinical Research Proposals

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

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

The proposal must include the following information:

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

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

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

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

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

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

**See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase II clinical trial.

9. **Inclusion of Children in Research Involving Human Subjects**

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

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

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

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

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

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

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

Justification for Exclusion of Children

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

- The objective of the solicitation is not relevant to children.

- There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.

- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.

- A separate, age-specific study in children is warranted and preferable. Examples include:

  - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or

  -The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or

  - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or

  - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be in the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or

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

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

Definition of a Child

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

10. **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multi-site trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

11. **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g-2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

12. **Research Involving Prisoners as Subjects**

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

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

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

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

1. The sole purposes are:

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

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

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

For more information about this Waiver see http://ohrp.osophs.dhhs.gov/references/fr06-20.pdf

13. **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html) and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and//or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the Project Officer and Contracting Officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funding for any work related to Recombinant DNA Research or a requirement for the Contracting Officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the Project Officer and Contracting Officer. (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)

14. **Human Embryonic Germ Cell (HEGC) Research**

a. Guidelines.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://www.nih.gov/news/stemcell/stemcellguidelines.htm) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice

NOT-OD-02-049, requiring that offerors/Contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines " (http://www.nih.gov/news/stemcell/stemcellguidelines.htm) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

15. **Human Embryonic Stem Cell (HESC) Research**

On August 9, 2001, the President announced the criteria that must be met for Federal funds to be used for research on existing human embryonic stem cell lines. These criteria were subsequently published by the NIH at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. The following eligibility criteria must be met:

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;
2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;
4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;
6. No financial inducements were provided for the donation of the embryo.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry (Athe NIH Registry") that lists the human embryonic stem cells that meet the eligibility criteria. This registry is available at: http://stemcells.nih.gov/registry/.

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal funding.

If a particular human embryonic stem cell line has not been required by the Statement of Work, an offeror proposing research involving human embryonic stem cells must cite a human embryonic stem cell line that is listed in the NIH Registry in its proposal.

c. <u>BUSINESS PROPOSAL INSTRUCTIONS</u>

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

The business proposal must contain sufficient information to allow the Government to perform a basic cost realism analysis of the proposed cost or price of the work. This information shall include payroll documentation, vendor quotes, invoice prices and/or any other information deemed necessary to evaluate the reasonableness of the price or to determine cost realism for all of the basic cost elements. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, and, if applicable, possible base fee and award fee. It is anticipated that the award from this solicitation will be a performance-based type contract, with a term of five (5) years. See SECTION C.1.,Statement of Work, section 3, for the description of the Performance-based Evaluation and Quality Assurance 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.

1) **Direct Labor**

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

2) **Materials**

Provide a summary listing and/or bill of materials for all individual material types and quantities and the basis for the line item cost/pricing estimate. This information should be supported with documentation such as current vendor quotes, invoices based on recent purchases, catalog price lists/schedules, etc. In addition, the Government anticipates that $300,000 per year will support the drug intervention portion of the contract. The offeror shall use the Government's estimate in preparing its proposal for this cost.

3) **Subcontracted Items**

Research subcontracts are those subcontracts awarded under any resultant contract that are directly related to the NINDS' Pilot Therapeutics Network Clinical Operations Center which intends to implement Phase I and II clinical trials for neurological disorders. The Government intends to

fund research subcontracts at a level of $1,000,000 per year. For any given study, the Government anticipates that approximately 10 subcontracts or more depending on the disease could be awarded for the same study. The Government anticipates that $300,000 or less per year will support the cost of the intervention portion of the contract (not the study assessments or patient care costs). The offeror shall use the dollar values above in preparing its proposal for research subcontracts. For all other subcontracts the offeror shall 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 $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4) **Raw Materials**

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

5) **Purchased Parts**

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

6) **Fringe Benefits**

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

7) **Indirect Costs**

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

8) **Special Equipment**

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

9) **Travel**

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

10) **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer

may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(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.(3) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) Total Compensation Plan - Instructions

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

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors INCLUDED IN THE COMPETITIVE RANGE WILL BE REQUIRED TO SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(6) Total Compensation Plan – Evaluation

a) Total Compensation Plan (Professional Employees)

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

b) Cost (Professional Compensation)

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

c) Other (Labor Relations)

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

d) Federal Acquisition Regulation Clauses Incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(7) **Qualifications of the Offeror**

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

(1) **General Experience**

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

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

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

(3) **Performance History**

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

(4) **Pertinent Contracts**

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

(5) **Pertinent Grants**

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

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors, which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(8) **Other Administrative Data**

a) Property

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

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as

desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

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

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

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

b) Royalties

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

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

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

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

d) Financial Capacity

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

e) Incremental Funding

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

HHSAR 352.232-75, Incremental Funding (January 2001)

a. It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs Incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

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

(End of provision)

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

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

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

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

(End of Provision)

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

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

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

(9) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).
b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.
e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions: http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

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

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

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

(11) **Representations and Certifications**

One copy of the Representations and Certifications 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. The Representations and Certifications are available at the following URL: http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

(12) **Travel Costs/Travel Policy**

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

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

a) **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

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

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

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

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

B. TECHNICAL EVALUATION CRITERIA

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

CRITERIA	**POINTS**
1. Understanding the Requirement and Technical Approach	45 points

The proposal must demonstrate a thorough understanding of the requirements of the Statement of Work (SOW) and describe an approach that will demonstrate the ability to achieve the goals outlined in the SOW. The proposal shall present a comprehensive statement of the problem, scope, and purpose of the project to demonstrate an understanding of the requirements from a management and technical standpoint. Proposals must delineate: (1) plans for providing research support for drug/intervention selection (5 points); (2) plans for clinical site selection and retention (10 points); (3) plans for protocol development (10 points); (4) plans for protocol approval and implementation (10 points); (5) plans for data management and electronic communication (5 points); and (6) plans for study meetings and other communications (5 points).

2. Qualifications and Availability of Proposed Personnel	45 points

The proposal must demonstrate evidence of the qualifications, experience, and availability of professional and technical personnel comprising of the necessary project staff.

Personnel proposed to be assigned and available for work under the project shall be evaluated on their demonstrated, documented, and relevant expertise, education, availability, and experience, highlighting that which was obtained within the past three years.

It is anticipated that the success of this project will require a multidisciplinary team. This team should have extensive experience in clinical trials and, preferably, this team should have worked together on previous trials. The team will require a strong, experienced leader/director, preferably, although not necessarily, with a clinical background. There must also be strong statistical expertise, expertise in the design and analysis of pilot clinical trials, expertise in study coordination and clinical operations, and in data management. Additionally experience in working with and coordinating clinical research networks is important. Expertise in pharmacology and in

experimental intervention evaluation is desirable. If not present within the existing team, clear plans should be stated for how this expertise would be obtained.

3. Availability and Utilization of Proposed Facilities and Equipment 10 points

The proposal shall describe the availability and proposed utilization of appropriate facilities and equipment required to successfully perform the work requirements.

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

C. PAST PERFORMANCE

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

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

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

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

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

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

D. SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTOR NON-SCORED

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

Evaluation of the SDB Participation Factor will be assessed based on consideration of the information presented in the offeror's proposal. We request that offeror's provide the "Participation Factor" information on the attached form "Small Disadvantaged Business (SDB) Participation Factor", see Attachment Number 15 to the RFP. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

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

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

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

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

OTHER NON-SCORED FACTORS

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

(1) EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

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

(2) HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

a. Protection of Human Subjects from Research Risks

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

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

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

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

b. Women and Minorities

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

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

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

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

    - inclusion of those groups would be inappropriate with respect to their health; or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

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

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

c. Children

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

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

Based on the reviewers' narrative evaluation of the offeror's response to this evaluation criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable."

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

d. Data and Safety Monitoring

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable."

If the information provided regarding Data and Safety Monitoring is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered "unacceptable," your proposal may not be considered further for award.

STATEMENT OF WORK

I. Objectives

NINDS intends to form a network to perform pilot clinical trials for neurological diseases. The purpose of this network is twofold:

1) To facilitate the early clinical testing of promising compounds for different neurological diseases. The focus here is on the timely translation of pre-clinical results into clinical studies and the efficient conduct of these clinical studies. Pilot clinical trials are defined in this document as studies required to gather the information needed to conduct a definitive efficacy study and fulfill the relevant regulatory requirements. Thus the term pilot clinical trial includes phase I and II studies, although it is anticipated that the majority of studies would be phase II. The interventions studied may be new compounds or compounds that are already FDA approved for other indications. Pilot trials include but are not limited to:

- Studies to refine the intervention strategy - dosage, duration, delivery system, pharmacokinetics and dynamics.
- Studies to define and refine the target population.
- Collection of preliminary data for establishing measures of efficacy and safety.

In preparing for the definitive clinical trial, a pilot study will address questions that are formulated to optimize the design of the eventual trial rather than address the clinical question with lower power.

2) To build and operate a network that will serve multiple different neurological diseases through shared resources and facilitate the study of rare neurological diseases by reaching out to a large number of sites serving different patient populations.

II. Background

Recent progress in neuroscience has led to an explosion in potential pharmacological interventions for neurological diseases that require testing in clinical trials. NINDS is supporting initiatives for drug screening and pre-clinical testing (http://grants.nih.gov/grants/guide/pa-files/PAR-02-139.html). However, many interventions may never reach early phase clinical trials. There are several barriers to entry for pilot clinical trials, including issues of competing interventions, infrastructure and funding, access to patient populations, lack of experienced clinical investigators, and inadequate communication between pre-clinical and clinical researchers. The goal of this project is to ensure that potential treatments are tested in pilot clinical trials in a timely and efficient way by developing a network of sites under a single operations center that could implement trials for different neurological diseases**.** The trials conducted by this network would be studies that are needed to gain the information about the intervention (such as the dose, kinetics, route of administration, safety, and preliminary evidence of activity) needed to design a phase III trial. The proposed network will be a resource to test promising new agents that result from pre-clinical translational research efforts.

The overall objective of the network is to facilitate the timely transition from pre-clinical to clinical studies. Within the network, academic-based and practice-based centers could be pre-qualified, based on simple criteria, to be eligible to participate in pilot trials for one or more diseases. The goal is to have broad participation and representation of different populations and diseases to limit the barriers for sites to enter the network. New sites would be invited to apply to the network at regular intervals. The contractor will maintain eligible sites that may then compete to participate in specific, fully funded studies as the need arises. Each year, the network will potentially run 2 or more concurrent pilot studies. There will be a single operations center that will work with investigators to develop protocols, consent documents and case report forms, facilitate compliance with regulatory requirements, train and monitor study sites, and perform data management and analysis, and coordinate all aspects of the network. It is anticipated that the pilot studies will involve disease areas with little or no previous experience in clinical trials, requiring intellectual leadership – clinical and statistical - on the part of the operating center. The selection of particular interventions for study will be performed by an external advisory committee comprised of

NIH staff and scientists independent of the centers in the network. The network will expedite clinical testing for select, high priority agents and provide clinical trials infrastructure where needed.

The major aims of the network are:

1. To efficiently move promising interventions into early and middle phase clinical trials by:

    a. Assisting in the identification of specific interventions for neurological disease that should be tested in clinical trials.
    b. Conducting efficient trials that will answer the questions necessary to further develop the intervention.

2. Construct and maintain a network that will serve the clinical trial needs of multiple different neurological disorders thereby:

    a. Minimizing the cost of the infrastructure.
    b. Facilitating the study of rare neurological diseases economically.
    c. Facilitating recruitment of a broad range of subjects.

These aims must be achieved while maintaining the highest ethical standards in human subject research, setting a benchmark for the entire neurology research community.

III. Approach:

A. Network Activities

NINDS intends to contract with a single entity to implement two or more pilot clinical trials, concurrently, each year, for five years. The contractor will be required to have the clinical trials experience, flexibility, and leadership ability to deal with numerous challenges and work in disease areas that have not had previous clinical trials. The contractor will need to have experience in designing and executing pilot clinical trials, although this experience may not necessarily be in neurology. Experience in pilot clinical trials includes dose finding and pharmacokinetics studies, studies of safety, tolerability and drug activity. Pilot studies may not require randomization or blinding and innovative approaches to pilot clinical trials will be important.

The main goal of the network is to implement phase I and II studies. These studies would be expected to be small, 30-100 patients and a maximum of 1 to 2 years in duration, with at least 1 trial in progress during each year of the contract. The studies may entail a variety of different agents or even combinations of agents. Some true phase I studies in healthy normals may be needed, but more likely these shall be phase II studies to assess the safety, tolerability, and activity of interventions in the population of interest as well as studies to optimize the dose or route of administration. No comparative efficacy or phase III studies will be conducted under this contract.

B. Research for Drug Selection

NINDS will inform the contractor of the drugs and diseases to be studied. Interventions and diseases to be studied will be determined by NINDS with the input of the external advisory committee (see organization) appointed by NINDS. Information about potential agents may come from several different sources including suggestions from committee members, other investigators, active solicitations, literature reviews, and ongoing NINDS projects. It is expected that NINDS and the committee will meet and specify diseases and interventions for at least the initial trial prior to the contract award. After contract award, the contractor will support the logistics of these meetings as well as the logistics and research of the drug selection process. In particular, the contractor will support the logistics and research required to inform this drug assessment process including: literature searches and reviews, and drafting of summaries covering the rationale, mechanism, pre-clinical and clinical data.

The external advisory committee and NINDS will use these summaries to select agents. Once an agent has been selected for study, the NINDS project officer (PO) and contract officer (CO) will inform the contractor. The contractor will then have 30 days to determine if the network can undertake the conduct of the proposed study and reply with a preliminary study plan, including the sites, protocol outline, and budget. If approval is given by NINDS to continue, the contractor will begin protocol development.

C. Clinical Site Selection and Retention

The network is intended to test interventions for multiple different diseases. However at any given time, it is likely that only a small number of studies will be ongoing, using only a fraction of the sites. More phase II than phase I studies are likely to be conducted, but some sites with adequate staff, facilities, and experience in phase I studies should be sought. Site selection may be a two-stage process: sites may enter the network by meeting some minimum criteria. The Contractor shall be responsible for maintaining the readiness of all sites in the network, representing a broad a range of disease areas and populations. Once a drug/ disease area is identified, sites would then need to be selected by the contractor to participate in that particular study. In order to ensure high quality sites and a fair selection process for participation in a protocol, the Contractor is encouraged to establish evaluation factors for award consistent with the trade off process as promulgated in FAR 15.101-1. Specifically, in the selection process for site performance, the Contractor will be expected to convene an ad hoc independent review group responsible for the assessment of technical proposals as well as the acceptability or unacceptability of each proposal evaluated against specific and advertised/published technical evaluation criteria.

The contractor will need to justify their approach to site inclusion, selection, and retention, which will be a crucial aspect of the network's ability to function. It is anticipated that sites will be added to the network at some regular interval, at least annually, and site selection should be coordinated with the priorities and research opportunities established by NINDS and the external advisory board.

D. Protocol Development

The contractor will identify appropriate sites from the network for each particular study and with the PO's approval will appoint a protocol implementation committee (PIC) to formulate a study design and protocol for each trial. The trials may have shared elements but will need to be adapted to the disease specific requirements. Each trial will have its own planning or development phase.

Other activities during the implementation phase will include development of study policies and operational procedures; training study staff; data management and report generation for the safety monitoring boards; site monitoring, including on-site auditing of source documents and auditing of study agent supply and handling; and overall management of study progress. Early in the implementation phase the contractor will need to obtain the study drug which may be a new compound or an already FDA approved intervention. The interventions may be supplied free of charge by the manufacturer or the contractor may have to purchase them. It is recognized that the costs of the intervention can only be estimated and may vary widely. Specific cost estimates will be provided in the RFP to ensure fair competition. The contractor shall be responsible for assuring appropriate drug supply, packaging and distribution to the sites. All proposed subcontract awards require NINDS consent. Additionally, the contractor should address how they will deal with issues of indemnification and adverse event liability.

E. Organizational Structure (See Figure 1.)

External Scientific Advisory Committee (EAC): This committee consists of scientific advisors who shall provide consultation and guidance on drug selection, and will be organized by the NINDS PO. This committee will be named by the NINDS PO prior to the contract award and will include NINDS staff, external scientists who are representative of the neuroscience community, as well as representatives of the pharmaceutical and biotechnology industries. This committee will meet prior to the contract award to establish working procedures and priorities and will meet at least annually thereafter to update priorities. At the PO's request, this committee may also review aspects of the study design and implementation.

NPTUNE Clinical Operations Center (COC): The contractor for the COC will be the administrative and operational center for the project. The contractor for the COC will be responsible for all subcontracts. The contractor shall a) support the logistics of the drug prioritization process, including meetings, data collection, document preparation support, as well as research activities as described above; b) work with the protocol implementation committee (see below) and NINDS PO to develop the protocol, statistical analysis plan, manual of operations, informed consent documents, and case report forms (CRF's) for each trial; c) lead the implementation of each trial including regulatory communications, centralized data collection, management and quality assurance, training of site personnel and orientation meetings, coordinate drug packaging and distribution, monitor and insure adequate study progress and work with the DSMB to ensure appropriate safety monitoring .

Principal Investigators (PI): The Contractor PI will also be the PI for each study. The contract PI will have overall responsibility for the implementation and integrity of the project and will chair the study steering committee known as the protocol implementation committee (PIC). The contractor will also appoint a primary statistician for each study drawn from the COC and both will be regarded as key personnel (all key personnel will be listed in the RFP). The PI and statistician will participate in publications although specific publication policies will be developed for the network.

Protocol Implementation Committee (PIC): This will be an internal steering committee that shall act as the executive arm of each study. This may be a single committee for several projects or separate committees for each study. This committee will draft protocols, determine operational issues, consider and adopt protocol amendments, monitor study progress and consider recommendations from the DSMB. The PIC membership will at minimum include, the contractor PI (the committee chair) and statistician, one or more site representatives (SR) drawn from the clinical sites, and the NINDS PO (ex officio). The Contractor will provide the logistical support needed for the PIC to carry out its functions.

Clinical Sites (CS): These sites will implement the protocols. Each trial site will have a site PI who will be responsible for the clinical, administrative, and financial execution of the study at that site. This will include: obtaining IRB approval of the protocol and consent; ensuring that study staff are appropriately trained; identification and recruitment of appropriate subjects in a timely manner; IRB approval and dissemination of advertising for the study; proper follow-up of study subjects as specified in the protocol; efforts to retain study participants; reporting of adverse events; overall adherence to the protocol; timely submission of CRF's; financial administration of the study. The site PI will be the primary liaison to the operations center.

Site Representative (SR): The PI will select a SR(s) from the clinical sites, with approval from NINDS, who will work with the PI to provide the clinical knowledge needed for the study. The contractor PI will be responsible for overall study design and implementation and the aspects described above, but the SR will provide advice and assistance on disease specific issues.

Scientific Advisors (SA): In addition to the SR, additional scientific input may be needed about the disease or study intervention. An SA from outside the network may be appointed by NINDS or the SA may be appointed by the PI with approval from NINDS. The SA may sit on study committees including the Steering Committee, and may participate in publications in keeping with the network's publication policies.

Data Safety and Monitoring Board (DSMB): This group will be composed of independent experts appointed specifically by NINDS for each study, or one committee may serve multiple studies. This committee(s) will be appointed after contract award. The DSMB will approve all protocols and protocol changes prior to implementation as well as monitor safety and study performance as specified in NINDS policies on study monitoring.

Other Committees: The contractor will establish other committees, as needed to carryout the mission of the network, such as publications or recruitment committees.

IV. Technical Requirements and Services to be Performed

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 to conduct the pilot clinical trials of one or more neurological diseases. All work under the contract shall be conducted under the general guidance of the PO. The pilot network will involve several temporally overlapping projects and phases. The main tasks and functions to be performed under this contract are described below:

A. Research Support for Drug Selection

The contractor will research and systematically compile information about specific agents requested by the PO and external advisory committee. In this process, the contractor may need to obtain pre-clinical or clinical information about several interventions through literature searches or by contacting investigators or manufacturers. The contractor will also need to have qualified personnel to review and summarize the information, including pharmacologists, clinicians, and clinical researchers. This drug review process will be ongoing and will serve as a

resource for the external advisory board and the network investigators about potential interventions. Specific information that the contractor will research about interventions may include but would not be limited to:

a) Intervention mechanism and rationale
b) Pre-clinical efficacy in animal models
c) Pre-clinical toxicity data
d) Pharmacokinetics
e) Safety and tolerability in humans
f) Evidence of activity in humans

These data will be presented in brief reports for each drug as well as overall summaries of the compounds researched for any given disease area. An example of this work can be seen at Ravina et al. Neurology, 2003; 60:1234-1240.

B. Clinical Site Selection and Retention

Site selection will be a two-step process. First CS will be identified as having the requisite resources for conducting clinical trials such that they may enter the network. Then, upon identification of a specific intervention, CS will be selected to participate in a specific trial.

Step 1: The contractor should seek to include as broad a range of sites as possible such that the network can serve many different diseases and populations including women, children, and minorities, and conduct some phase I studies. Entry to the network should be based on some set of minimal criteria that would identify sites that could potentially participate in pilot trials. These criteria should include the ability to recruit certain patient populations, adequate facilities for pilot clinical trials, and qualified personnel. Application to the network should be made simple to enhance participation. The contractor should explicitly state criteria for entrance to the network and how the process of vetting sites would be conducted. While access to patients with many neurological disorders is critical, the contractor should emphasize the patient population and areas of research prioritized by the EAC, in order to insure that the first trials begin in a timely fashion. The EAC will update the priorities annually and this should be coordinated with ongoing recruitment to the network

Once in the network, a large number of sites may not be selected for participation in the small number of pilot studies to be performed. The contractor should describe how they will maintain site participation in the network and readiness - qualified personnel, access to patients - to participate in trials. Such efforts might include:

a) Annual certification of membership in the network.

b) Different levels of participation in the network, such that sites that are not actively following subject may refer subjects to other sites and receive payment.

c) Additional efforts such as focus groups might be used prior to site selection to determine barriers to joining or remaining in the network.

Step 2: The second step in site selection will be to select sites for particular studies and subcontract with them to participate in a study. The selection of sites and development of protocols and study materials will need to be done in parallel. While step 2 of site selection will require a protocol outline, once selected for the study, CS will then participate in study design through the PIC. The contractor should propose a process for selecting, awarding and managing CS subcontracts that conforms to the requirements of the contract. The contractor shall also state how they propose to deal with potential conflicts of interest for the sites. Sites will need to be reviewed in a timely manner that will ensure equity in selection. The review process should consider the following aspects:

1. Availability of a sufficient number and diversity of potential study participants to ensure prompt enrollment and timely completion of the study.
2. Availability of adequate experienced professional and technical staff to provide scientific and administrative coordination and support to the clinical trial, including site management and quality control expertise, appropriate clinical expertise, and capacity for patient recruitment and follow-up.
3. Adequate facilities, equipment, and support staff to conduct clinical trials and particularly phase I trials that may require in-patient evaluations and adequate resources to support this.
4. Adequate computing resources and support staff, including internet access, and electronic communication capabilities.

5. Any needed capabilities and staff for data collection, entry, editing, electronic transfer, quality control, database management (maintaining security and accessibility), and data backup on site and off site.
6. Evidence of scientific leadership of clinical experience such that the investigator would make a contribution to the design or implementation of the study.
7. Access to a standing Institutional Review Board (IRB) with a multiple project assurance from the NIH Office of Protection from Research Risks (OPRR), or resources to acquire a single project assurance from the OPRR.
8. Agreement to participate as a Site for this trial and follow the protocol.
9. Agreement to comply with all the required Federal Acquisition Regulation (FAR) and Health and Human Services Acquisition Regulation (HHSAR) and flow down clauses that apply to the terms and conditions of the prime contract.
10. Consideration of the costs of the trial as conducted at the site.

The Contractor shall provide a list of recommended CS, their ratings, and all information submitted by prospective CS. The NINDS shall review the proposed recommendations information, consult with scientific advisors, as appropriate, and notify the Contractor of the decision of approval and consent. Within two weeks from receiving the NINDS concurrence, the Contractor shall execute subcontracts to the approved Sites. The following represent some of the expected terms and conditions for the subcontracts to the sites:

Sample Terms & Conditions for Clinical Site Subcontracts

a. At the time of the subcontract award, the CS shall have an available source of research subjects sufficient to meet the needs of the specified protocol.
b. A statement must be included in each subcontract indicating that the CS staff will adhere to the protocol and manual of operations.
c. All research activities conducted at the study Site shall follow the state-of-the-art of Good Clinical Practice guidelines, in order to generate data that can be published in peer-reviewed scientific journals.
d. All institutional, NINDS, and federal regulations concerning informed consent shall be fulfilled. Protocols and patient consent forms shall be approved by the NINDS Human Subjects Clinical Research Panel and by the DSMB (if needed) and appropriate IRBs.
e. All materials/data collected by the site from the specific study funded under this contract shall be property of the NINDS and shall be made available to the NINDS both electronically and in hard copy using standard procedures that safeguard the confidentiality of the research records.
f. It is anticipated that the PO and other Government officials involved in the activities conducted under this contract shall publish study data jointly with the PIs and CS staff. Publications from each study will follow the network's publication guidelines.
g. NINDS or its designees shall have the right to audit patient records and research data at any time during the study.
h. The CS PI shall be responsible for the technical oversight and management aspects of the performance of this subcontract. The CS PI shall be considered Key Personnel and shall not be replaced without prior approval of NINDS.
i. All work under this contract shall be monitored by NINDS and the COC PI.
j. A statement must be included in each subcontract that each investigator agrees and is committed to share, in a timely manner, materials, expertise, and/or data generated in performance of work.

C. Protocol Development

Once the PO has identified a specific disease and intervention and informed the contractor, the contractor will have 30 days to assess the network's readiness and capability to perform the study and develop a protocol outline, budget estimate, and timetable and report to NINDS. If approval is granted by NINDS to proceed, site selection and subsequent protocol development will proceed. NINDS anticipates that there may be 2-3 active concurrent protocols in any calendar year. It is estimated that the preliminary activities prior to initiating the first trial may be up to 12 months after contract award. Subsequently these preliminary activities should be no more than 9 months. This

estimate includes approximately 3 months for site selection and 6 months for developing and finalizing the protocols. Other preparatory activities listed below shall also be completed within this time period. The contractor will also complete a manual of operations (MOP) for each study and handle all regulatory communications and filings and prepare a consent form for each study that is in accordance with all federal guidelines.

At a minimum, each final protocol shall include the following aspects:

1. Trial specific aims and hypotheses
2. Trial design and administrative structure
3. Treatment specifications (with MOP including plans for packaging, distribution, administration) and length of treatment
4. Patient selection criteria with attention to the inclusion of women, children, and minorities and explanations for exclusions
5. Outcome measures
6. Sample size and power calculations and randomization or treatment assignment plan if applicable
7. Clinical and laboratory monitoring procedures
8. Procedures for reporting adverse event and consideration for indemnification
9. Plans for data collection and monitoring
10. Human subjects considerations
11. Plans for safety monitoring
12. Plans for subject retention and minimization of dropouts
13. Statistical analysis plan to include analyses of primary and secondary endpoints
14. Plans for interim analyses and stopping rules and (if applicable)
15. Plans for dealing with clinical emergencies and breaking of blinded treatment (if applicable)
16. Plans for preventing, identifying, and handling protocol violations

Additionally the Contractor shall:

1. Arrange and chair PIC meetings, and draft, revise, distribute all meeting minutes.
2. Arrange and coordinate training of the clinical staff, in order to ensure reliability of evaluation, treatment and assessment procedures.
3. Develop, test/validate, and implement a system for treatment allocation or randomization of eligible subjects as appropriate.
4. Handle all applicable regulatory affairs, communications, and filings, such as INDs, including collection and submission of all regulatory document from the clinical sites.
5. Develop and distribute a detailed manual of all operations and procedures for each study.
6. Develop a timeline with milestones and evaluation criteria against which the progress of the trial will be judged as well as the progress of the overall contract.
7. Obtain drug supply and determine and arrange for packaging, distribution, labeling, storage requirements for sites, and destruction requirements of the appropriate amount of drug or intervention. Develop plan for emergency re-supply of drug.
8. Develop and distribute case report forms.
9. Develop and implement a site monitoring plan and contract with monitors as needed.
10. Develop a system for emergency contacts and unblinding.
11. Develop a data management, entry, and quality assurance plan.
12. Oversee and coordinate subject recruitment.
13. Oversee financial administration each SC and subcontracts.
14. Cooperate with the DSMB to provide the requested information on study safety and performance.
15. Provide regular reports of study progress and performance.
16. Develop a publications policy with the PIC.

D. Protocol Approval and Implementation

The NINDS PO will organize a scientific review of the protocol and study materials and determine the necessary composition of the review panel, which may be the same as the DSMB. This review will result in recommendations to proceed with implementation or to revise and address specific issues. The study materials will also be reviewed by the NINDS Human Subjects Review Panel. Recruitment may begin once the study materials- protocol, consent, manual of operations - have been given approval by NINDS and NINDS appointed committees and appropriate

external panels such as site IRB's and the FDA if there is an IND. Once a study is in progress, no modifications will be made to the study protocol, informed consent, or manual of operations without the consent and approval of NINDS. NINDS and the designated DSMB will monitor the study for safety, performance, and data quality. The contractor shall cooperate with all DSMB requests as communicated through NINDS.

E. Data Management and Electronic Communications

The contractor shall be responsible for providing a data collection and management plan that is suitable for both the network and for each study and will include at a minimum:

1. A system to receive, process, edit, correct, update, store, track, retrieve, and analyze all study data.

2. A method and schedule for transferring data (electronic and/or paper) from the CS to the COC.

3. Produce reports incorporating data within and across all clinical sites as well as different trials.

4. Data entry, verification, and transfer procedures shall be tested prior to patient recruitment to ensure reliable performance.

5. Monitor how accurate, complete and up to date the database is. There shall be a plan for resolving problems identified in the monitoring process.

6. Provide for site monitoring to verify the accuracy and completeness of source documents and CRFs.

7. Have adequate biostatistical expertise available to develop appropriate methods for analyzing and presenting study data.

F. Meetings and Communications

The Contractor shall ensure reliable electronic communications capability among the CS, COC, and study committees. Meetings and calls will be needed and the Contractor will:

1. Schedule and coordinate in person meetings and telephone conferences calls with the PO, other NINDS staff, advisors, and other staff involved in the study, in order to discuss the progress of the study and other project related activities as needed or requested. The frequency of these calls will depend upon the phase of the study, complexity of issues, actual progress, and problems encountered. The Contractor shall prepare minutes of these calls and send them to the PO and other relevant parties within 4 working days after each call.

2. Schedule, coordinate, arrange, participate in, and all conferences necessary for the PIC. These meetings shall be as frequent as required by the phases and progress of the study. The Contractor shall prepare minutes of these meetings and distribute them to the PO and other relevant parties within 7 working days after each meeting.

3. Organize and implement training meetings needed for study investigators, coordinators and other study staff.

4. Attend and participate in the meetings of the EAC requested by the PO. It is estimated the EAC will meet once or twice per year.

G. Terms and Conditions

1. All materials/data collected by the PI from the specific study funded under this contract shall be property of the Federal Government and shall be made available to NINDS electronically and/or as hard copy prior to the end of the contract period or within 30 calendar days of a written request by the PO or CO. The contractor shall use standard procedures to safeguard confidentiality of research records.

2. NINDS or its designees shall have the right to audit patient records and research data, as well as independently access and analyze study data, at any time during the study.

3. The Contractor PI shall be responsible for all aspects of the performance of this contract, including the performance of any subcontracts. Any subcontract requires prior review and approval of the NINDS PO and CO before award.

4. The Contractor, with the PIC and in accordance with network publication policies, shall expeditiously prepare reports on study results for publication in peer-reviewed scientific journals.

5. No data from the primary aims of trials funded under this contract will be presented at meetings or published without prior review and approval NINDS and in keeping with the publications procedures established within the network.

6. The Contractor shall establish procedures to safeguard the confidentiality of any proprietary information provided by the PO or the Sites.

7. NINDS reserves the right to interact directly with the CS and appoint consultants to ensure contract-related activities meet all the requirements agreed to in the contract and are performed in accordance with the standards and requirements of NINDS.

8. The Contractor shall not enter into any subcontract that has not been approval by NINDS.

9. NINDS will approve the NPTUNE publications policy.

H. Deliverables and Publications

In addition to any ad hoc reports requested by the PO, the Contractor shall submit progress (hard copy and electronically) reports covering the work accomplished during each reporting period as outlined below.

1) Periodic Study Reports: the exact frequency will depend on the nature of the study and will be agreed upon by NINDS and the contactor. The PO may request, depending upon the study, that these reports include a description of the study progress, quality of data, CS performance/compliance, subjects enrolled in the study and their demographic characteristics, subjects screened but not enrolled and reasons why not enrolled, subjects that have completed the study, and anticipated subject enrollment and completion schedules for the remainder of the study, listing of adverse reactions, complications and problems encountered and their resolution. The report shall present overall study information as well as data for each CS. Problems in recruiting and plans for correcting recruiting problems must be included. A brief description of any other impediments to achieving the goals of the contract, any factors having cost implications, and recommendations for resolution should be included. The contractor will also provide reports requested by the DSMB according to their specifications.

2) Annual Report for Gender/Minority Tracking will contain the following information: report date, date enrollment/recruitment was initiated, date enrollment/recruitment was completed, whether a minority sub-population has been identified, and a count of subjects targeted by gender and by ethnic group for each study.

3) Study Final Report: The Contractor shall submit to NINDS the Final Report within 3 months of completion of each study. This report shall include a summation of the work performed and results obtained. This report shall be in sufficient detail to explain comprehensively the tasks accomplished, results achieved, and shall summarize data and statistical analyses performed in text, tabular and graphical form.

4) Database: At the end of each study, the Contractor shall provide the PO with a final, cleaned, edited, and documented database containing all study data, and all associated programs, source code, codebooks, indices, data tables, documentation, etc, in a format that is readily usable by NINDS or its designee. A copy of the database shall be made available for public use upon publication of the primary papers, or within 1 year of the end of the original study or at the discretion of the PO. The PO or CO may require that the entire database, and all associated programs,

source code, codebooks, indices, data tables, documentation, etc, be transferred within 60 calendar days, in a readily usable form to NIND or its designee.

5) Trial Material: At the end of the contract period, or when each trial is completed, or at the discretion of the NINDS PO and CO, the Contractor shall be prepared to transfer to NINDS or its designee all trial material including training material, data collection procedures, all data, and any other information, equipment, or procedures necessary to implement and conduct the trial.

6) Study publications: The contractor will expeditiously initiate the publication of study results in keeping with the NPTUNE publications policies.

I. Data Rights

Data developed under this contract will be the property of the NINDS. At the end of each study, the Contractor shall provide the Project Officer with a final, cleared, edited, and documented database containing all study data, and all associated programs, source code, codebooks, indices, data tables, documentation, etc., in a format that is readily usable by the NINDS or its designee. A copy of the database shall be made available for public use upon publication of the primary papers, or within one (1) year of the end of the original study or at the discretion of the Project Officer. The Project Officer or the Contracting Officer may require that the entire database, and all associated programs, source code, codebooks, indices, data tables, documentation, etc., be transferred within 60 calendar days from completion of the study, in a readily usable form to the NINDS or its designee. At the end of the contract period, or when each trial is completed, or at the discretion of the NINDS Project Officer and Contracting Officer, the Contractor shall be prepared to transfer to the NINDS or its designee all trial material including training material, data collection procedures, all data, and any other information, equipment, or procedures necessary to implement and conduct the trial. The Contractor shall maintain and dispose of all study related materials and data in accordance with the standards of Good Clinical Practice. Access to these data must be approved by the NINDS.

Fig1. Overall Organization

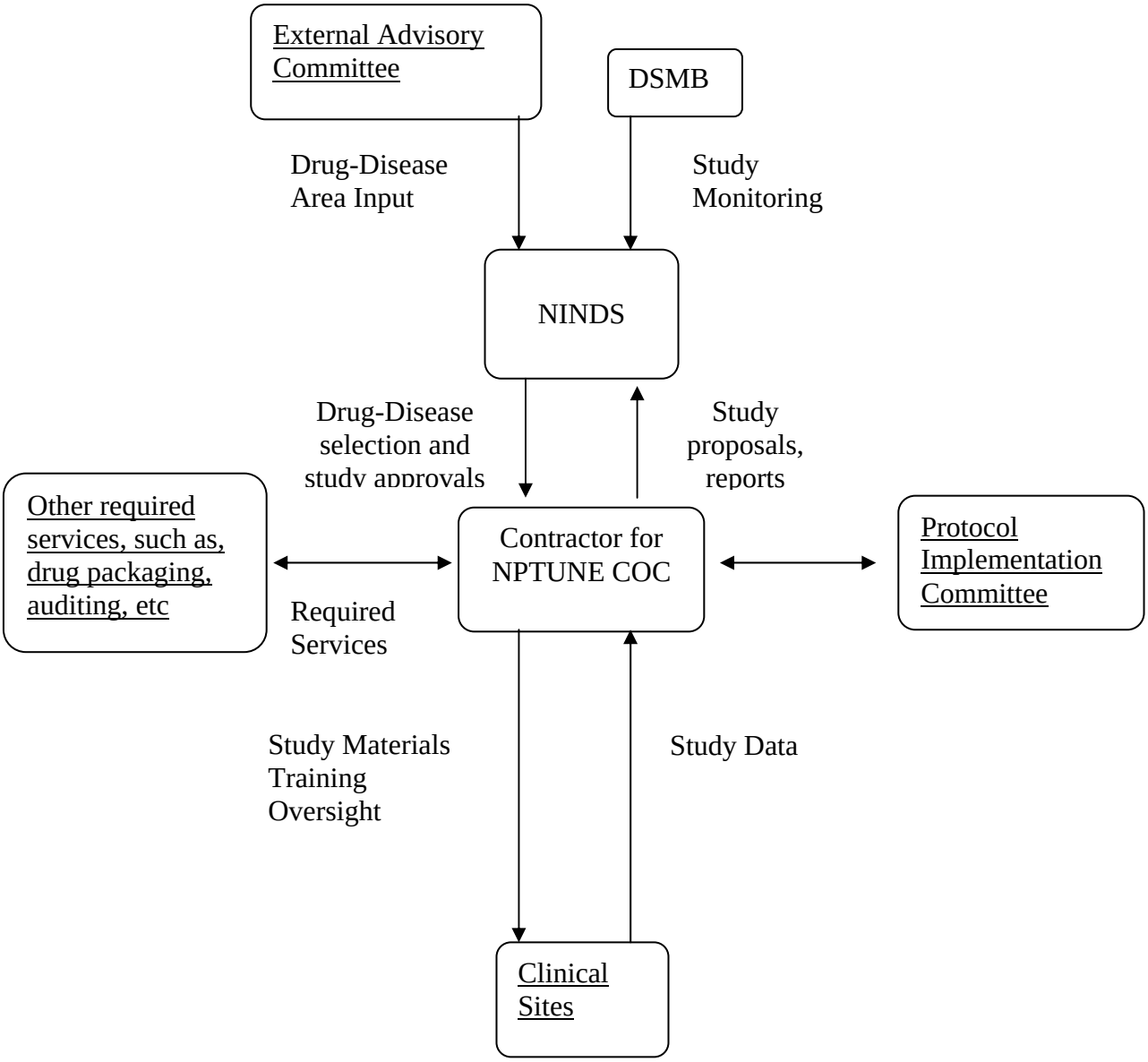
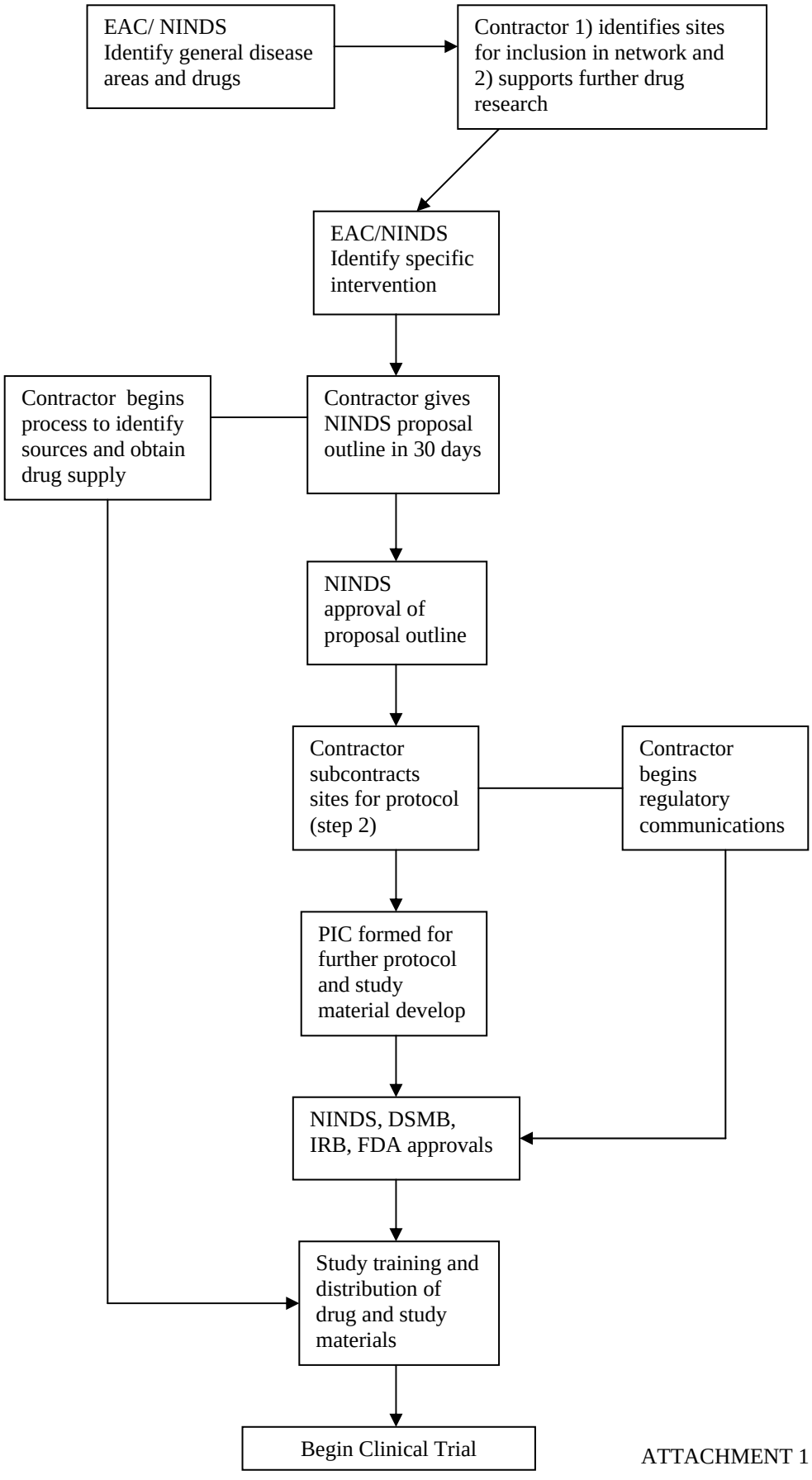


Fig. 2 Drug Selection and Protocol Development



ATTACHMENT 1

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

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

(f) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(g) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

PROPOSAL INTENT RESPONSE SHEET

RFP No. NINDS-

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

==========

[ ] DO INTEND TO SUBMIT A PROPOSAL

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

COMPANY/INSTITUTION NAME:

AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

==========

RETURN TO:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

PROJECT OBJECTIVES

SOLICITATION NUMBER: _____

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

OFFEROR NAME AND ADDRESS:

_____
_____
_____

OFFEROR PHONE NUMBER (WITH AREA CODE)_____

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

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

RFP TITLE: _____

PRINCIPAL INVESTIGATOR: _____

SUMMARY OF OBJECTIVES:

_____

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

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

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

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

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

_____by (Date)_____
(Name)

_____

_____
(Address)

_____
(Fax Number)

This survey pertains to: _____

Department/Component: _____

Contract Number: _____ Date of Survey: _____

Name of Person Completing Survey: _____

Signature of Person Completing Survey: _____

Your Company/Agency: _____

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

Contract Value (including options) : $ _____

Period of Performance (including option periods) : _____

Type of Contract: _____

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

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

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

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

General description of products / services required under the contract:
_____
_____
_____

RATINGS

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

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

QUALITY OF SERVICE

1. Compliance with contract requirements
   0 1 2 3 4 5 N/A

2. Accuracy of reports
   0 1 2 3 4 5 N/A

3. Effectiveness of personnel
   0 1 2 3 4 5 N/A

4. Technical Excellence
   0 1 2 3 4 5 N/A

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

COST CONTROL

1. Record of forecasting and controlling target costs
   0 1 2 3 4 5 N/A

2. Current, accurate and complete billings
   0 1 2 3 4 5 N/A

3. Relationship of negotiated costs to actuals
   0 1 2 3 4 5 N/A

4. Cost efficienciese
   0 1 2 3 4 5 N/A

TIMELINESS OF PERFORMANCE

1. Met interim milestones
   0 1 2 3 4 5 N/A

2. Reliability
   0 1 2 3 4 5 N/A

3. Responsive to technical directions
   0 1 2 3 4 5 N/A

4. Completed on time including wrap-up and contract administration
   0 1 2 3 4 5 N/A

5. Met delivery schedules
   0 1 2 3 4 5 N/A

6. Liquidated damages assessed: Yes No (circle one)

BUSINESS RELATIONS

1. Effective management, including management of subcontracts
   0 1 2 3 4 5 N/A

2. Reasonable/cooperative behavior
   0 1 2 3 4 5 N/A

3. Responsive to contract requirements
   0 1 2 3 4 5 N/A

4. Notification of problems
   0 1 2 3 4 5 N/A

5. Flexibility
   0 1 2 3 4 5 N/A

6. Pro-active vs reactive
   0 1 2 3 4 5 N/A

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

SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS GOALS

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

Comments: (optional) _____
_____
_____
_____
_____

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

Comments: (optional) _____
_____
_____
_____
_____

CUSTOMER SATISFACTION

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

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

ADDITIONAL COMMENTS

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

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

EXAMPLE, REQUEST FOR PAST PERFORMANCE INFORMATION

Date:

Dear Client:

We are currently responding to the DHHS/NIH/NINDS RFP-04-05 entitled: NINDS Pilot Therapuetics Network Clinical Operations Center: NPTUNE COC. The Government is placing increased emphasis in their procurements on past performance as a source selection factor and is requiring that clients of firms responding to NINDS solicitations be identified and their participation in the evaluation process be requested.

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

We thank you for your prompt response in this matter.

Sincerely,

(To be signed by offeror)

Attachment

(SUBMIT WITH TECHNICAL PROPOSAL)

SUMMARY OF LABOR AND DIRECT COSTS

COST ELEMENTS	YEAR 01	YEAR 02	YEAR 03	YEAR 04	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.

Targeted/Planned Enrollment Table

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

Study Title:

Total Planned Enrollment:

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

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

OMB No. 0990-0263 (Formerly OF-310)(1/17/2003)

Approved for use through 7/31/2005

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

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

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

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Applica Proposal Identification No.
[ ] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ]FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:	

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Oth

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

[ ] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No._____, the expiration date_____ IRB Registration No.

[ ] This Assurance, on file with *(agency/dept)*_____,
covers this activity.
Assurance No. _____, the expiration date _____ IRB Registration/Identification No.
(if applicable)

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph .

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

[ ] his activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting)_____ or [ ] Expedited Review on (date)
[ ] If less than one year approval, provide expiration date

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

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

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Sponsored

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

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.

SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN: _____
CONTRACTOR: _____
ADDRESS: _____
_____
DUNN & BRADSTREET NUMBER: _____
SOLICITATION OR CONTRACT NUMBER: _____
ITEM/SERVICE (Description): _____
_____
TOTAL CONTRACT AMOUNT: $_____
Total contract or Base-Year, if options
$_____ $ _____ $_____ $ _____
Option #1 Option #2 Option #3 Option #4
(if applicable) (if applicable) (if applicable) (if applicable)
TOTAL MODIFICATION AMOUNT, IF APPLICABLE $ _____
TOTAL TASK ORDER AMOUNT, IF APPLICABLE $ _____
PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): _____
The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this outline has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable. It is not intended to replace any existing corporate plan that is more extensive. Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract. **If assistance is needed to locate small business sources, contact the Office of Small and Disadvantaged Business Utilization (OSDBU) at (202) 690-7300 or the OPDIV Small Business Specialist at** _____. **Sources may also be obtained from SBA's PRO-Net website**.

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

NOTE TO CONTRACTORS: Please provide your CCR number with your Dunn & Bradstreet number.

Small Business Subcontracting Plan Page 1
March, 2003

1. Type of Plan (check one)

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

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

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

2. Goals

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

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is $ _____ (b + h = a) (Base Year)
FY-___ (1st Option) FY-___ (2nd Option) FY-___ (3rd Option) FY-___ (4th Option)
$ _____ &___% $ _____ &___% $ _____ &___% $ _____ &___%

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB, HUBZone, SDVOSB and VOSB): (% of "a") $ _____ and _____% (Base Year)
FY-___ (1st Option) FY-___ (2nd Option) FY-___ (3rd Option) FY-___ (4th Option)

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

f. Total estimated dollar and percent of planned subcontracting with VETERAN-OWNED SMALL BUSINESSES: (% of "a") $ _____ and _____% (Base Year)
FY-___ (1st Option) FY-___ (2nd Option) FY-___ (3rd Option) FY-___ (4th Option)
$ _____ &___% $ _____ &___% $ _____ &___% $ _____ &___%
g. Total estimated dollar and percent of planned subcontracting with SERVICE-DISABLED VETERANOWNED SMALL BUSINESSES: (% of "a) $ _____ and _____% (Base Year)
FY-___ (1st Option) FY-___ (2nd Option) FY-___ (3rd Option) FY-___ (4th Option)
$ _____ &___% $ _____ &___% $ _____ &___% $ _____ &___%
h. Total estimated dollar and percent of planned subcontracting with "OTHER THAN SMALL BUSINESSES": (% of "a") $ _____ and _____% (Base Year)
FY-___ (1st Option) FY-___ (2nd Option) FY-___ (3rd Option) FY-___ (4th Option)
$ _____ &___% $ _____ &___% $ _____ &___% $ _____ &___%
Notes: 1. Federal prime contract goals are:
SB equals 23%; SDB equals 5%; HUBZone equals 3%, WOSB equals 5% and SDVOSB equals 3%, VOSB equals 3% and can serve as objectives for subcontracting goal development.
2. SDB, WOSB, HUBZone, SDVOSB and VOSB goals are subsets of SB and should be counted and reported in multiple categories, as appropriate.
3. If any contract has more than four options, please attach additional sheets showing dollar amounts and percentages.
i. Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply).
Product/Service
Other
SB
SDB
WOSB
HUBZone
VOSB
SDVOSB

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

_____
k. Indirect costs [ ] have, [ ] have not been included in the dollar and percentage subcontracting goals above (check one).
l. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns.

_____
_____
_____
_____
_____
_____
_____

3. Program Administrator:
NAME/TITLE:
ADDRESS:
TELEPHONE/E-MAIL:
Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? [ ] yes [ ] no _____
(If NO is checked, please indicate who in the company performs those duties, or indicate why the duties are not performed in your company.)
a. Develops and promotes company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns; and assures that these concerns are included on the source lists for solicitations for products and services they are capable of providing; [ ] yes [ ] no
b. Develops and maintains bidder source lists of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns from all possible sources; [ ] yes [ ] no
c. Ensures periodic rotation of potential subcontractors on bidder's lists; [ ] yes [ ] no
d. Ensures that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing; [ ] yes [ ] no
Small Business Subcontracting Plan Page 4
March, 2003
e. Ensures that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns; [ ] yes [ ] no
f. Reviews subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB participation; [ ] yes [ ] no
g. Accesses various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns to include the SBA's PRO-Net and SUB-Net Systems, (http://www.sba.gov), the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce and Federal agencies' Small Business Offices; [ ] yes [ ] no
h. Establishes and maintains contract and subcontract award records; [ ] yes [ ] no
i. Participates in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; [ ] yes [ ] no
j. Ensures that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; [ ] yes [ ] no
k. Conducts or arranges for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; [ ] yes [ ] no
l. Monitors the company's subcontracting program performance and makes any adjustments necessary to achieve the subcontract plan goals; [ ] yes [ ] no
m. Prepares and submits timely, required subcontract reports; [ ] yes [ ] no
n. Coordinates the company's activities during the conduct of compliance reviews by Federal agencies; [ ] yes [ ] no; and
o. Other duties: _____

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

limited to, the following activities:
a. Outreach efforts to obtain sources:
1. Contacting minority and small business trade associations; 2) contacting business development organizations and local chambers of commerce; 3) attending SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB procurement conferences and trade fairs; 4) requesting sources from the Small Business Administrations (SBA) PRO-Net and SUB-Net Systems, (http://www.sba.gov/) and other SBA and Federal agency resources. Contractors may also conduct market surveys to identify new sources, to include, accessing the NIH e-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/). The NIH e-Portals in Commerce is not a mandatory source and may be used at the offeror's discretion.
b. Internal efforts to guide and encourage purchasing personnel:
1. Conducting workshops, seminars, and training programs;
2. Establishing, maintaining, and utilizing SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB source lists, guides, and other data for soliciting subcontractors; and
3. Monitoring activities to evaluate compliance with the subcontracting plan.
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March, 2003
c. Additional efforts:

_____
_____
_____
_____
_____

5. Flow Down Clause
The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $500,000 ($1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (Flow down is not applicable for commercial items/services as described in 52.212-5(e) and 52.244-6(c).)
6. Reporting and Cooperation
The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) submission of Standard Form (SF) 294, "Subcontracting Report for Individual Contracts," and attendant Optional Form 312, SDB Participation Report, if applicable, *(required only for contracts containing the clause 52.219-25)* and SF 295, "Summary Subcontract Report," in accordance with the instructions on the forms; and (4) ensuring that subcontractors agree to submit Standard Forms 294 and 295.
Reporting Period Report Due Due Date
Oct 1 - Mar 31 SF 294 4/30
Apr 1 - Sept 30 SF 294 10/30
Oct 1 - Sept 30 SF 295 10/30
Contract Completion OF 312 30 days after completion
Special instructions for commercial plan: SF 295 Report is due on 10/30 each year for the previous fiscal year ending 9/30.
a. Submit SF 294 to cognizant Awarding Contracting Officer.
b. Submit Optional Form 312, (OF 312), if applicable, to cognizant Awarding Contracting Officer.
c. Submit SF 295 to cognizant Awarding Contracting Officer and to the:
Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
200 Independence Avenue, SW
Humphrey H. Building, Room 517-D
Washington, D.C. 20201
d. Submit "information" copy of the SF 295 and the SF 294 upon request to the SBA Commercial Market Representative (CMR); visit the SBA at http://www.sba.gov/gc and click on assistance directory to locate your nearest CMR.
7. Record keeping
In accordance with FAR 19.704(a)(11), the following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:
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March, 2003

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

_____
_____
_____

8. Timely Payments to Subcontractors

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

9. Description of Good Faith Effort

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

_____
_____
_____

SIGNATURE PAGE

Signatures Required:
This subcontracting plan was submitted by:
Signature: _____
Typed Name: _____
Title: _____
Date: _____
This plan was reviewed by:
Signature: _____
Typed Name: _____
Title: _____**Contracting Officer**_____
Date: _____
This plan was reviewed by:
Signature: _____ _____
Typed Name: _____
Title: _____**Small Business Specialist**_____ __
Date: _____ __
This plan was reviewed by:
Signature: _____
Typed Name: _____
Title: _____**SBA Procurement Center Representative**_____
Date: _____ _____
And Is Accepted By:
Signature: _____
Typed Name: _____
Title: _____
Date: _____

SMALL DISADVANTAGED BUSINESS (SDB) PARTICIPATION FACTOR

1A. OFFEROR'S NAME	2. REQUEST FOR PROPOSAL (RFP) NUMBER		
1B. OFFEROR'S ADDRESS	3. TOTAL SDB PARTICIPATION AT PRIME CONTRACT LEVEL		
	A. NAICS CODE	B. DOLLARS	C. PERCENT
	4. TOTAL SDB PARTICIPATION AT SUBCONTRACT LEVEL		
	A. DOLLARS	B. PERCENT	

5. SDB PARTICIPATION AT SUBCONTRACT LEVEL BY NAICS SUBSECTOR GROUP

A. NAICS SUBSECTOR GROUP	B. DOLLARS	C. PERCENT

INSTRUCTIONS

Item 3. Identify participation, if any, by SDB concerns at the prime contract level by dollar amount and percentage of total contract value. All prime contract dollars must be identified under the NAICS code assigned to the acquisition (see Section L2(a)(15) of the solicitation).

Item 4. Identify participation, if any, by SDB concerns at the subcontract level by dollar amount and percentage of total contract value.

Item 5. Identify, by NAICS Subsector Group, participation of SDB concerns at the subcontract level by dollar amount, and percentage of total contract value. (SDB concerns need not be identified by name.) See http://www.sba.gov/size/NAICS-cover-page.htm for descriptions of the NAICS Subsector Groups.

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

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

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

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

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

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

Billing of Costs Incurred: If billed costs include: (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 name and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number** — Insert the appropriate serial number of the invoice/financing request.

(c) **Date Invoice/Financing Request Prepared** — Insert the date the invoice/financing request is prepared.

(d) **Contract Number, ADB Number and Date** — Insert both the contract number and the ADB number (which appears in the upper left hand corner of the face page of the contract), and the effective date of the contract.

(e) **Payee's Name and Address** — Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee** — Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) **Billing Period** — Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) **Amount Billed for Current Period** — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.

(j) **Cumulative Amount from Inception** — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **Direct Costs** — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(l) **Direct Labor** — Include salaries and wages paid (or accrued) for direct performance of the contract.

(2) **Fringe Benefits** — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property** — Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach the NIH Form entitled, "Report of Government Owned, Contractor Held Property," in accordance with the following instructions:

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

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

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

(4) **Materials and Supplies** — Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) **Premium Pay** — List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee** — List fees paid to consultants. Identify consultant by name or category as set forth in the contract's advance understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) **Travel** — Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs** — List subcontractor(s) by name and amount billed.

(9) **Other** — List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(l) **Cost of Money (COM)** — Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) **Indirect Costs--Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned** — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) **Total Amounts Claimed** — Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments** — Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) **Grand Totals**

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

SAMPLE INVOICE/FINANCING REQUEST

(a) Billing Office Name and Address

NATIONAL INSTITUTES OF HEALTH
National Cancer Institute, RCB
EPS, Room ____
6120 EXECUTIVE BLVD MSC
Bethesda, MD 20892-___

(b) Invoice/Financing Request No.

(c) Date Invoice Prepared

(d) Contract No., ADB No., and Effective Date

(e) Payee's Name and Address

ABC CORPORATION
100 Main Street
Anywhere, U.S.A. zip code

(f) Total Estimated Cost of Contract

(g) Total Fixed Fee

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

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

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

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

_____
Name of Official)

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

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

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

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

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

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

Billing of Costs Incurred: If billed costs include: (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, ADB Number and Date** — Insert both the contract number and the ADB number (which appears in the upper left hand corner of the face page of the contract), and the effective date of the contract.

(e) **Payee's Name and Address** — Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee** — Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) **Billing Period** — Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) **Incurred Cost - Current** — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the current period.

(j) **Incurred Cost - Cumulative** — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **Direct Costs** — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(l) **Direct Labor** — Include salaries and wages paid (or accrued) for direct performance of the contract. For Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.

(2) **Fringe Benefits** — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property** — Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach the NIH Form entitled, Report of Government Owned, Contractor Held Property," in accordance with the following instructions:

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

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

(4) **Materials and Supplies** — Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) **Premium Pay** — List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee** — List fees paid to consultants. Identify consultant by name or category as set forth in the contract's Advance Understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) **Travel** — Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs** — List subcontractor(s) by name and amount billed.

(9) **Other** — List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(l) **Cost of Money (COM)** — Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) **Indirect Costs--Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned** — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) **Total Amounts Claimed** — Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments** — Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) **Grand Totals**

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

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

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

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

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

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Billing Office Name and Address NATIONAL INSTITUTES OF HEALTH National Cancer Institute, RCB EPS, Room 6120 EXECUTIVE BLVD MSC Bethesda, MD 20892- (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._____ ADB 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

PROCUREMENT OF CERTAIN EQUIPMENT

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

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

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

INCLUSION ENROLLMENT REPORT

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

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

	Sex/Gender			
Ethnic Category	**Females**	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

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

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

Racial Categories: Total of Hispanics or Latinos**				
*These totals must agree **These totals must agree				

CONTRACT FINANCIAL REPORT. **Note: Make sure to include ALL necessary expenditure categories for which financial reporting will be required ON THIS ATTACHMENT.) ******

National Institutes of Health FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT, NIH FORM 2706 *Note: Complete this Form in Accordance with Accompanying Instructions.*	**Project Task:**	**Contract No.:**	**Date of Report:**	**0990-0134** **0990-0131**
	Reporting Period:	**Contractor Name and Address:**		

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost--Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Negotiated Contract Amount	Variance (Over or Under) (I - H)
	Negotiated	Actual							
A	B	C	D	E	F	G	H	I	J
								0	
								0	
								0	
								0	

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

GENERAL INFORMATION

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

REPORTING REQUIREMENTS

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

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

REPORTING STATISTICS

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

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

(1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.

(2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

(3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.

(4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of $1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

(5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.

(6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.

(7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.

(8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.

(9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.

(10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.

(11) **Subcontracts.** List each subcontract by name and amount billed.

(12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.

(13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.

(15) **Fee.** Cite the fee earned, if any.

(16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

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

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

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

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

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

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

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

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

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

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

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

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

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of