REQUEST FOR PROPOSALS NO. NIH-NINDS-04-03

NINDS CLINICAL RESEARCH COLLABORATION FACILITY

DATE ISSUED: December 19, 2003
PROPOSAL RECEIPT DATE: March 19, 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-04-03.

THIS ACQUISITION IS ISSUED ON A FULL AND OPEN COMPETITIVE BASIS.

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 Contract Specialist of your intent by completing the Proposal Intent Response Sheet, Attachment 3, by mailing it to the address below or emailing it to dw76q@nih.gov.

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.

Your proposal must be received by the Contracting Officer at the following address, no later than 4:30 P.M. (Eastern Standard Time) on **March 19, 2004**, at:

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 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, Desiree Wheeler at (301) 496-1813), at our buildings guard station. You will then need to personally bring the boxes to Suite 3287. Proposals should NOT be left with the guard.

Your proposal must address the Statement of Work requirements, specified in **Section C** and be prepared in accordance with **Section L** entitled "Instructions, Conditions, and Notices to Offerors". All proposals shall 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 in the block with your name and address on the cover page of your business proposal and annotate "DUNS" or "DUNS + 4" that identifies your name and address exactly as stated in the 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.

Questions concerning this RFP shall be referred only to Desiree Wheeler, Contract Specialist, who may be reached at dw76q@nih.gov or (301) 496-1813 or , Kirkland L. Davis, Contracting Officer, kd17c@nih.gov, (301) 496-1813.

Sincerely,

Kirkland L. Davis
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-04-03	December 19, 2003	NO X YES See Part IV, Section L.	X NO YES See Part IV, Section L.

5. TITLE: NINDS Clinical Research Collaboration Facility

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:

See **Section L.1.a**

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, PACKAGING AND DELIVERY OF PROPOSAL, until **4:30 p.m.** (eastern standard time), **March 19, 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), along with a facsimile address.

10. FOR INFORMATION CALL: Desiree Wheeler, Contract Specialist or Kirkland Davis, Contracting Officer
PHONE: 301-496-1813
E-MAIL: dw76q@nih.gov or kd17c@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.FedBixOpps.gov/, OR you may refer to the Contracts Management Branch web site at: http://www.ninds.nih.gov/funding/currentrfps.htm. Individual notification will not be provided.

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ATTACHMENTS

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 REPRESETNATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE ANTICIPATED TERMS AND CONDITIONS OF ANY RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The specific objective of this contract is to facilitate the efficient execution of NINDS-sponsored clinical research in order to develop and to test more treatments more expeditiously. NINDS-supported investigators will use the Clinical Research Collaboration (CRC) Facility to assist with identification and recruitment of patients for clinical research studies involving the broadest possible range of patients and physicians.

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. TECHNICAL 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.

(a) Quarterly Progress Reports:

Quarterly Progress Reports: Quarterly progress reports shall be due within 10 calendar days of the close of each calendar quarter. This report shall describe the progress on the project during the reporting period and shall include the following: an indication of any current problems that may impede performance and proposed corrective action; description of the work to be performed during the subsequent reporting period;

and any recommendations. Also, the Contractor should provide the list and title of individuals working under the contract who are responsible for the design and/or conduct of the research as described in ARTICLE H.3.

(b) End of Phase Reports:

End of Phase Reports: Before initiating each new phase and 60 days prior to the end of the current phase, a report of accomplishments and plans for the next phase shall be submitted for review and approval by the Project Officer. The Project Officer will have 30 days to review the report; the Project Officer's written approval will be required before the next phase may be initiated.

(c) Final Report:

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

(d) Phase I Reports:

Phase I reports shall be submitted for the following:

(a) Report on the NINDS-sponsored clinical research and CRC collaboration (Objective #1)
(b) Report on incentives and barriers to participation (Objective #2)
(c) Proposal for common data element policies and standards (Objective #5)

These reports shall be in sufficient detail to describe comprehensively the results and barriers for each objective.

(e) Phase II Report:

Phase II Report: This report shall include the development of each component outlined under Objective #5 with detailed plans for protection of confidentiality and human research subjects protection.

Copies of the above reports shall be submitted according to the following schedule:

Reports	Period Covered	Due Date
(1) Quarterly Report	1/1 –3/31 4/1-6/30 7/1-9/30 10/1-12/31	4/10 7/10 10/10 1/31
(2) End of Phase Report	to be determined	60 days prior to end of phase
(3) Final Report	duration of contract	90 days prior to completion of contract
Phase I Reports		
(a) Report on the NINDS-sponsored clinical research and CRC collaboration (Obj #1)	duration of Phase I	90 days prior to completion of Phase I

(b) Report on incentives and barriers to participation (Obj #2)	duration of Phase I	90 days prior to completion of Phase I
(c) Proposal for common data element policies and standards (Obj #5)	duration of Phase I	90 days prior to completion of Phase I
Phase II Report Report on development of each component outlined under Obj. #5 with detailed plans for protection of confidentiality and human research subjects protection	duration of Phase II	to be determined

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 1040A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301/435-1986). In addition, one copy of the annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer at the address listed below. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted within 90 days after contract expiration to the following address:

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

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

ARTICLE C.4. SPECIAL REPORTING REQUIREMENTS

Minimum Information Systems Security Safeguards

The data generated in subcontracts and the information contained in proposals solicited under this contract will be proprietary information requiring, at minimum, the security safeguards listed in this section.

In compliance with the Department of Health and Human Services (DHHS), Automated Information Systems Security Program Handbook (AISSP) Release 2.0, it is required that all DHHS organizations and their employees, including contractors, who are responsible for systems or data, both in hard copy and electronic form meet the requirements of the AISSP. Provide a written explanation addressing how each of the following requirements will be met.

MINIMUM SECURITY SAFEGUARDS

1. Ensure that a complete and current set of documentation exists for all operating systems.

2. Require use of current passwords and log-on codes to protect sensitive AIS (Automated Information System) data from unauthorized access.

3. Establish procedures to register and protect secrecy of passwords and log-on codes, including the use of a nonprint, nondisplay feature.

4. Limit the number of unsuccessful attempts to access an AIS or database.

5. Develop means whereby the user's authorization can be determined. (This may include answer back capability.)

6. Establish an automated audit trail capability to record user activity.

7. Implement methods, which may include the establishment of encryption, to secure data being transferred between two points.

8. Ensure that the operating system contains controls to prevent unauthorized access to the executive or control software system.

9. Ensure that the operating system contains controls that separate user and master modes of operations.

10. Record occurrences of non-routine user or operator activity (such as unauthorized access attempts and operator overrides) and report to the Project Manager

11. Ensure that the operating system provides methods to protect operational status and subsequent restart integrity during and after shutdown.

12. Install software feature(s) that will automatically lock out the terminal if it is not used for a predetermined period of lapsed inactive time, and/or if a password is not entered correctly after a specified number of attempts.

13. Establish controls over the handling of sensitive data, including labeling materials and controlling the availability and flow of data.

14. Require that all sensitive material be stored in a secure location when not in use.

15. Dispose of unneeded sensitive hard copy documents and erase sensitive data from storage media in a manner which will prevent unauthorized use.

16. Prepare and maintain lists of persons authorized to access facilities and AISs processing sensitive data.

17. Establish procedures for controlling access to facilities and AISs processing sensitive data.

18. Furnish locks and other protective measures on doors and windows to prevent unauthorized access to computer and support areas.

19. Install emergency (panic) hardware on “Emergency Exit Only” doors. Ensure that emergency exits are appropriately marked.

20. Install smoke and fire detection systems in the computer facility.

21. Install fire suppression equipment in the computer facility, which may include area sprinkler systems with protected control valves and/or fire extinguishers.

22. Provide emergency power shutdown controls to shut down AIS equipment and air conditioning systems in the event of fire or other emergencies.

23. Establish a fire emergency preparedness plan to include training of fire emergency response teams, development and testing of an evacuation plan, and on-site orientation visits for the local fire department.

24. Secure communication lines.

25. Establish detailed risk management program.

26. Establish Computer Systems Security Plans for sensitive systems.

27. Conduct formal risk analyses.

28. Establish employee security awareness and training programs.

29. Maintain accurate inventory of all hardware and software.

30. Establish security review and certification programs.

31. Establish contingency plan.

32. Establish emergency power program.

33. Ensure that all personnel positions have been assigned security level designations.

34. Conduct periodic security level designation reviews.

35. Ensure that all personnel, including contractors, have received appropriate background investigations.

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 Clinical Research Collaboration Facility"
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 2216, MSC 9520, Bethesda, Maryland 20892-9520, (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.

Reports	Period Covered	Due Date
Quarterly Report	1/1 – 3/31 4/1 – 6/30 7/1 – 9/30 10/1 – 12/31	4/10 7/10 10/10 1/10
End of Phase Report	to be determined	60 days prior to end of phase
Final Report	duration of contract	60 days prior to end of completion of contract
Phase I Reports a. Report on the NINDS-sponsored clinical research and CRC collaboration (Obj #1)	duration of Phase I	90 days prior to completion of Phase I
b. Report on incentives and barriers to participation (Obj #2)	duration of Phase I	90 days prior to completion of Phase I
c. Proposal for common data element policies and standards (Obj #5)	duration of Phase I	90 days prior to completion of Phase I
Phase II Report Proposal on development of each component outlined under Obj. #5 with detailed plans for protection of confidentiality and human research subjects protection	duration of Phase II	to be determined

b. The above reports and instrument 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.

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.10 of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

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

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 CONTRACTOR 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. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the NINDS, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB NO. 0990-0263 (Formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

ARTICLE H.3. 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.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**
   [Applicable information to be included at award]

ARTICLE H.5. NEEDLE EXCHANGE

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

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

ARTICLE H.6. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as Attachment 8.

ARTICLE H.7. ANIMAL WELFARE

All research involving live, vertebrate animals shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.8. OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.9. 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 Block 17, "Remarks," the Contractor shall provide an explanation for any category of small business subcontracting for which there was 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 effect 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 517-D
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) 606-4000, x234 for the correct address if unknown.

ARTICLE H.10. 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" of "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 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***
[Applicable information to be included at award]		

c. Direct salaries which will be paid with FY-03 funds are limited to the Executive Level I rate which was in effect on the date(s) the expense was occurred.

* *For contract expenditures using FY-03 funds, the period 10/1/02 – 12/31/02 the Executive Level I rate is $166,700. Effective 1/1/03, for contract expenditures using FY-03 funds, the Executive Level I rate is increased to $171,900 and will remain at the 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/indix.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.11. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

The Contractor agrees to comply with the Information Technology (IT) systems security and/or privacy specifications set forth herein; the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS Automated Information Systems Security Program (AISSP) Handbook which may be found at the following websites:

Computer Security Act of 1987: http://csrs.ncsl.nist.gov/secp;cy/csa_87.txt
OMB A-130, Appendix III: http://csrs.ncsl.nist.gov/secplcy/a130app3.txt
DHHS AISSP Handbook: http://irm.cit.nih.gov/policy/aissp.html

The Contractor further agrees to include this provision in any subsequent subcontract awarded pursuant to this prime contract. Failure to comply with these requirements shall constitute cause for termination.

The Contractor shall be responsible for properly protecting all information used, gathered, or developed as a result of the SOW. The Contractor shall establish and implement appropriate administrative, technical, and physical safeguards to ensure the security and confidentiality of sensitive Government information, data, and/or equipment.

In addition, during all activities and operations on Government premises, the Contractor shall comply with DHHS, including National Institute of Health (NIH), rules of conduct.

a. Required IT Systems Security Training

The Contractor shall assure that each employee has completed the NIH Computer Awareness Training (http://irtsectraining.nih.gov/) prior to performing any work under this contract.

The Contractor shall maintain a listing by name and title of each individual working under this contract who has completed the NIH required training. Any additional security training completed by Contractor staff shall be included on this listing. The listing of completed training shall be included in the first quarterly technical progress report. (See Article C.2. Technical Reporting Requirements) Any revision to this listing as a result of staffing changes shall be submitted with the next required technical report.

b. Position Sensitivity Designations

The Government has determined that the following position sensitivity designations and associated clearance and investigation requirements apply under this contract:

Level 5C: Sensitive – Moderate Risk (Requires Suitability Determination with a BI)

Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI).

Contractor employees in AIS-related positions shall comply with the DHHS criteria for the assigned position sensitivity designations prior to performing any work under this contract.

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation. Verifications of completed investigations (e.g. copies of certificates of investigations or security clearances) as well as requests for new investigations, shall be submitted to the Project Officer.

c. Commitment to Protect Sensitive Information

(1) Contractor Agreement

The Contractor shall not release, publish, or disclose sensitive information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information:

-18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
-18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
-Public Law 96-511 (Paperwork reduction Act)

(2) Contractor-Employee Non-Disclosure Agreement

Each Contractor employee who may have access to sensitive information under this contract shall complete the attachment entitled “Commitment to Protect Non-Public Information – Contractor Aggreement,” which is referenced in Section J of this contract and available at: http://irm.cit.nih.gov/security/Nondisclosure.pdf

A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

ARTICLE H.12. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L. 105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/.

ARTICLE H.13. 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.14. 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**
[Applicable information to be included at award]

ARTICLE H.15. 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.16. 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.17. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, 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**
[Applicable information to be included at award]

ARTICLE H.18. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

ARTICLE H.19. SHARING RESEARCH DATA

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

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

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	Dec 1998	Pension Adjustments and Asset Reversions
FAR	52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
FAR	52.216-7	Dec 2002	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee

Reg	Clause	Date	Clause Title
FAR	52.219-8	Oct 2000	Utilization of Small Business Concerns
FAR	52.219-9	Jan 2002	Small Business Subcontracting Plan
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-26	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	Oct 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	52.232-12	May 2001	Advance 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	Feb 2002	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)

Reg	Clause	Date	Clause Title
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms
HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.216-72	Oct 1990	Additional Cost Principles
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT 2/20/01]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS AND MODIFICATIONS OF CLAUSES

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

FAR clause 52.232-20, 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…..

[ ] Offeror elects to waive the evaluation preference."

FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (MAY 2001).

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

Alternate I (OCTOBER 1998), FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (OCTOBER 1999).

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 (OCT 1999)

FAR 52.224-1, Privacy Act Notification (APRIL 1984).

FAR 52.224-2, Privacy Act (APRIL 1984).

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

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

[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, 52,30-3, OR 52.230-5.) ***

FAR 52.230-6, Administration of Cost Accounting Standards (APRIL 1996).

FAR 52.239-1, Privacy or Security Safeguards (AUG 1996).

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

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

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

NIH (RC)-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

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

This contract incorporates the following in full text.

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

FAR Clause 52.204-7, CENTRAL CONTRACTOR REGISTRATION (OCTOBER 2003).

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

Central Contractor Registration (CCR) database means the primary Government repository for Contractor information required for the conduct of business with the Government. Data Universal Numbering System (DUNS) number means the 9-digit number assigned by Dun and Bradstreet, Inc. (D&B) to identify unique business entities.

Data Universal Numbering System +4 (DUNS+4) number means the DUNS number assigned by D&B plus a 4-character suffix that may be assigned by a business concern. (D&B has no affiliation with this 4-character suffix.) This 4-character suffix may be assigned at the discretion of the business concern to establish additional CCR records for identifying alternative Electronic Funds Transfer (EFT) accounts (see the FAR at Subpart 32.11) for the same parent concern.

Registered in the CCR database means that--

(1) The Contractor has entered all mandatory information, including the DUNS number or the DUNS+4 number, into the CCR database; and
(2) The Government has validated all mandatory data fields and has marked the record "Active".

(b) (1) By submission of an offer, the offeror acknowledges the requirement that a prospective awardee shall be registered in the CCR database prior to award, during performance, and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement resulting from this solicitation.

(2) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" or "DUNS +4" followed by the DUNS or DUNS +4 number that identifies the

offeror's name and address exactly as stated in the offer. The DUNS number will be used by the Contracting Officer to verify that the offeror is registered in the CCR database.

(c) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one.

(1) An offeror may obtain a DUNS number--

(i) If located within the United States, by calling Dun and Bradstreet at 1-866-705-5711 or via the Internet at http://www.dnb.com; or
(ii) If located outside the United States, by contacting the local Dun and Bradstreet office.

(2) The offeror should be prepared to provide the following information:

(i) Company legal business.
(ii) Tradestyle, doing business, or other name by which your entity is commonly recognized.
(iii) Company Physical Street Address, City, State, and Zip Code.
(iv) Company Mailing Address, City, State and Zip Code (if separate from physical).
(v) Company Telephone Number.
(vi) Date the company was started.
(vii) Number of employees at your location.
(viii) Chief executive officer/key manager.
(ix) Line of business (industry).
(x) Company Headquarters name and address (reporting relationship within your entity).

(d) If the Offeror does not become registered in the CCR database in the time prescribed by the Contracting Officer, the Contracting Officer will proceed to award to the next otherwise successful registered Offeror.
(e) Processing time, which normally takes 48 hours, should be taken into consideration when registering. Offerors who are not registered should consider applying for registration immediately upon receipt of this solicitation.
(f) The Contractor is responsible for the accuracy and completeness of the data within the CCR database, and for any liability resulting from the Government's reliance on inaccurate or incomplete data. To remain registered in the CCR database after the initial registration, the Contractor is required to review and update on an annual basis from the date of initial registration or subsequent updates its information in the CCR database to ensure it is current, accurate and complete. Updating information in the CCR does not alter the terms and conditions of this contract and is not a substitute for a properly executed contractual document.

(g) (1)(i) If a Contractor has legally changed its business name, "doing business as" name, or division name (whichever is shown on the contract), or has transferred the assets used in performing the contract, but has not completed the necessary requirements regarding novation and change-of-name agreements in Subpart 42.12, the Contractor shall provide the responsible Contracting Officer a minimum of one business day's written notification of its intention to

(A) change the name in the CCR database;
(B) comply with the requirements of Subpart 42.12 of the FAR; and
(C) agree in writing to the timeline and procedures specified by the responsible Contracting Officer. The Contractor must provide with the notification sufficient documentation to support the legally changed name.

(ii) If the Contractor fails to comply with the requirements of paragraph (g)(1)(i) of this clause, or fails to perform the agreement at paragraph (g)(1)(i)(C) of this clause, and, in the absence of a properly executed novation or change-of-name agreement, the CCR information that shows the Contractor to be other than the Contractor indicated in the contract will be considered to be incorrect information within the meaning of the "Suspension of Payment" paragraph of the electronic funds transfer (EFT) clause of this contract.

(2) The Contractor shall not change the name or address for EFT payments or manual payments, as appropriate, in the CCR record to reflect an assignee for the purpose of assignment of claims (see FAR Subpart 32.8, Assignment of Claims). Assignees shall be separately registered in the CCR database. Information provided to the Contractor's CCR record that indicates payments, including those made by EFT, to an ultimate recipient other than that Contractor will be considered to be incorrect information within the meaning of the "Suspension of payment" paragraph of the EFT clause of this contract.

(h) Offerors and Contractors may obtain information on registration and annual confirmation requirements via the internet at http://www.ccr.gov or by calling 1-888-227-2423, or 269-961-5757.

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, 17 pages
2. Government Notice for Handling Proposals, 1 page.
3. Proposal Intent Response Sheet, 1 page, (Refer to the cover letter).
4. NIH Form 1688-1, Project Objectives, 1 page, (Refer to Section L.2.b.(1)).
5. Contractor Employee Non-Disclosure Agreement, 1 page, (Refer to Section H.11.d.).
6. National Institutes of Health Customer Survey of Contractor Performance, 5 pages, (Refer to Section L.2.a.(26)).
7. Example, Request for Past Performance Information, 1 page, (Refer to Section L.2.a.(26)).
8. NINDS Privacy Act System of Records, 7 pages, (Refer to ARTICLE H.6.).

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).

9. Targeted/Planned Enrollment Table, 1 page, (Refer to Section L.2.a.(12)).
10. Inclusion Enrollment Report, 1 page, (Refer to Section L.2.a.(12)).
11. Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310). 1 page, (Refer to ARTICLE H.2.).
12. Summary of Labor & Direct Costs (TECHNICAL PROPOSAL), 1 page, (Refer to Section L.2.a.(4)).

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

13. NIH-2043, Proposal Summary and Data Record, 1 page, (Refer to Section L.2.a.(3)).
14. Summary of Annual Costs (BUSINESS PROPOSAL), 1 page, (Refer to Section L.2.c.(2)).
15. Summary of Related Activities, 1 page, (Refer to Section L.2.b.(1)(c)).
16. SF-LLL, Disclosure of Lobbying Activities, 3 pages, (Refer to (FAR 3.803)).
17. Small Business Subcontracting Plan Format, 7 pages, (Refer to Section L.2.a.(19).
18. Small Disadvantaged Business (SDB) Participation Factor, 1 page, (Refer to Section L.2.a.(21)).

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

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

21. NINDS Clinical Research Collaboration Project: Background, Aims, Proposed Structure, and General Policies, 14 pages

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

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - Representations and Certifications, and Other Statements of Offerors

Representations and Certifications - Negotiated Contracts must be accessed electronically from the INTERNET at the following URL: http://amb.nci.nih.gov/forms/rcneg.pdf

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. PACKAGING AND DELIVERY OF PROPOSAL

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

Proposals for furnishing the supplies and/or services in the SCHEDULE will be accepted at the location specified in (3) below, and in the number of copies specified in (1) below, **until 4:30 p.m. (eastern standard time), March 19, 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 15 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-04-03

(3) Address

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

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

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

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

b. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

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

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

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

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

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

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

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

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

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

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

not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does

not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

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

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

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

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

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

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

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

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

can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

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

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

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

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

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

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

(11) The Government may disclose the following information in post award debriefings to other offerors:

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

(End of Provision)

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

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

(End of Provision)

c. "JUST IN TIME"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the

information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted as part of any with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the offeror's travel policy, total compensation plan and small business subcontracting plan will 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 subcontractor's) written travel policy 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 the award may be made in SEPTEMBER 2004. It is anticipated that the award from this solicitation will be a multiple-year with a cost reimbursement type period of performance of five (5) years and 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. P= Professional; NP= Non-Professional.

Offerors are required to furnish their own estimates of effort as related to their technical approach. Example given below:

	Year I	**Year II**	**Year III**	**Year IV**	**Year V**
Phase I	P = 6.75 NP =1.05	P = 0.25 NP = 0.1	P = 0.25 NP = 0.1	P = 0.25 NP = 0.1	P = 0.25 NP = 0.1
Phase II	-	P = 9.4 NP = 2.8	P = 4.5 NP = 1.4	P = 2.5 NP = 0.9	P = 2.5 NP = 0.9
Phase III	-	-	P = 0.9 NP= 0.5	P = 1.75 NP = 1.0	P = 1.75 NP = 1.0
Phase IV	-	-	-	-	P = 3.75 NP = 1.0
TOTAL	P = 6.75 NP = 1.05	P = 9.65 NP = 2.9	P = 5.65 NP = 2.0	P = 4.5 NP = 2.0	P = 8.3 NP = 3.0

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

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the 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, 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 Attachment11, 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.

IMPORTANT NOTE TO OFFERORS: The following 6 paragraphs [(9) through (14)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(9) Human Subjects

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

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (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 will be in one or more of the categories of research in a project may result in delays in the review of a proposal. The NIH 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 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 .

(10) 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 subjects (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 the anticipated benefits to subjects and others.
- Describe treatment and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

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

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

(11) 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:

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 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 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 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 Contracting Officer with the title of the education program and a one-sentence description of the program that the replacement has completed.

(12) 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 in appropriate 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 o fan Institute/Center Director, based on a compelling rational 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 form 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 health services research" (http://www.nih.gov/new/crp/97 report/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 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, Attachment 8)

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, Attachment 8, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

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

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations, see Section J, Attachment 10, entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

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

(13) Inclusion of Children in Research Involving Human Subjects

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *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.

(14) 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, and P.L. 92-218, as amended.

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

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

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

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

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

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

(15) 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

(16) Information Technology Systems Security

a) The Statement of Work (SOW) requires the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the Department of Health and Human Services (DHHS) Automated Information Systems Security Program (AISSP) Handbook, the Government has determined that the following apply:

(1) Category of Safeguarded Information

The safeguarded agency information that the successful offeror will access from an AIS is categorized as Sensitive.

(2) Security Level Designations

Level 3 applies to the sensitivity of the data contained in the AIS and Level 3 applies to the operational criticality of the data processing capabilities of the AIS. The overall security level designation is Level 3.

(3) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each Contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following minimum designations apply:

Level 5C: Sensitive – Moderate Risk (Suitability Determination with an NACIC)

Contractor employees assigned to a Level 6C (High Risk) position are subject to a Background Investigation (BI). Contractor employees assigned to a Level 5C (Moderate Risk) position, with no previous investigation and approval, shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI). Contractor employees

assigned to a Level 1C position (Non-sensitive, i.e. Low Risk) shall be subject to a National Agency Check and Inquiry Investigation (NACI).

If Contractor employees will have access to classified national security information, more intensive investigations will be required. Contractor employees assigned to a Level 4C (Special Access) or Level 3C (Top Secret) position shall be subject to a Single Scope Background Investigation (SSBI). Contractor employees assigned to a Level 2C (Secret or Confidential) position shall undergo an LBI.

The following table summarizes investigation requirements by position risk level.

Required Investigation by Position Risk Level

Level	Description	Required Investigation
6C	Public Trust (High Risk)	BI
5C	Public Trust (Moderate Risk)	NACIC (or LBI)
4C/3C	Special Access/Top Secret	SSBI
2C	Secret/Confidential Access	LBI
1C	Non-sensitive (Low Risk)	NACI

The Contractor shall pay the costs of all required security investigations.

Contractor employees who have previously met investigative requirements within the past five years may only need to be subject to an updated or upgraded investigation.

(b) The offeror's proposal must include:

1. A detailed outline (commensurate with the size and complexity of the requirements of the SOW) of its present and proposed Information Technology systems security program and demonstrate that it complies with the AISSP security requirements of the SOW, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook. At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements of a Security Level Designation
3 identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards.

2. An acknowledgement of its understanding of the security requirements in the SOW.

3. Similar information for any proposed subcontractor having access to an AIS.

In addition, an evaluation will be conducted on the acceptability/unacceptability of your present and proposed Information Technology systems security program.

(4) 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, you must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, you should explain such limitations in its data sharing plans. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-3-032.html

Your plan for the sharing of final research data, or, if data sharing is not possible, your documentation for the inability to share research data, shall be assessed for appropriateness and adequacy. Note: The plan or documentation as to the rationale for not providing a plan shall be evaluated by program staff and shall not be scored. However, weaknesses in a plan or in the rationale for not permitting the sharing of research data may be a part of discussions.

(17) 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.

(18) Small Business Subcontracting Plan

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

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

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment 17 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 Business, 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 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.

HHS expects each activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

Note to Offeror: The anticipated goals for each applicable RFP shall be identified in SECTION L.2. of the specific RFP. _____ % for Small Business; _____ % for Small Disadvantaged Business; _____% for Women-Owned Small Business; _____% for HUBZone Small Business; _____% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(19) HUBZone Small Business Concerns

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

(20) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized 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. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

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 utilize, **provide in one clearly marked section of the Business Proposal,** SDB participation targets, expressed as dollars and percentages of total contract value, in each authorized NAICS Industry Subsector(s), as may be applicable. The applicable NAICS Code for this requirement 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 in the format prescribed in Section J, Attachment 18, entitled “Small Business Subcontracting Plan Factor” using the “Small Disadvantaged Business (SDB) Participation Factor”, Attachment 18, or in a format developed by the offeror.**

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

EXAMPLE

Targets for SDB Participation – NAICS Subsector 223

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

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

(21) 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.

(22) Salary Rate Limitation in Fiscal Year 2003

Offerors are advised that pursuant to P.L. 108-7, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) 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. 108-7 applies only to Fiscal Year 2003 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. 108-7 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: Award herein is anticipated for Fiscal Year 2004. The current Fiscal Year 2003 Salary Rate Limitations 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 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate Limitations.

(23) 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.

(24) 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.

(25) Past Performance Information

Offerors shall mail the Past Performance Information Survey to at least five previous clients (see Section J, ***Attachment 6***) 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. Standard Industrial Code

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

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

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

(26) Electronic and Information Technology Accessibility

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

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

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

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

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(27) 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):

1) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991)

2) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

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

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

5) 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

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

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.

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity 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.

(4) Resumes

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

(2) Technical Evaluation

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

(3) Additional Technical Proposal Information

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

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

(4) Other Considerations

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

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

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

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

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

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

(5) Information Technology Systems Security

Information Technology Systems Security, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation.

(a) **Sensitivity and Security Level Designations.**

The Statement of Work (SOW) requires the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Automated Information Systems Security Program (AISSP) Handbook,* the Government has determined that the following apply:

(1) Category of Safeguarded Information

The safeguarded agency information that the successful offeror will develop or access is categorized as:

[ ] Non Sensitive Information
[X] Sensitive Information
[ ] Classified Information:
[ ] Confidential **[ ]** Secret **[ ]** Top Secret **[ ]** Special Access

(2) Security Level Designations

The information that the successful offeror will develop or access is designated as follows:
Level 5C applies to the sensitivity of the data.
Level 5C applies to the operational criticality of the data.

The overall Security Level designation for this requirement is **Level 5**.

(3) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

[ ] Level 6C: Sensitive - High Risk (Requires Suitability Determination with a BI).
Contractor employees assigned to a Level 6C position are subject to a Background Investigation (BI).

[X] Level 5C: Sensitive - Moderate Risk (Requires Suitability Determination with NACIC).
Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI).

[ ] Level 4C: Classified (Requires Special Access Clearance with an SSBI).
Contractor employees assigned to a Level 4C position are subject to a Single Scope Background Investigation (SSBI).

[ ] Level 3C: Classified (Requires Top Secret Clearance with an SSBI).
Contractor employees assigned to a Level 3C position are subject to a Single Scope Background Investigation (SSBI).

[ ] Level 2C: Classified (Requires Confidential or Secret Clearance with an LBI).
Contractor employees assigned to a Level 2C position shall undergo a Limited Background Investigation (LBI).

[ ] Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).
Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation. In addition, all background investigations needs to be completed prior to award. Please note, the Government prefers an outside contractor perform these investigations.

(b) **Information Technology (IT) System Security Program**

The offeror's proposal must:

(1) Include a detailed outline (commensurate with the size and complexity of the requirements of the SOW) of its present and proposed IT systems security program;

(2) Demonstrate that it complies with the AISSP security requirements, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook.

At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements of a **Security Level 5** identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards.

(3) Include an acknowledgment of its understanding of the security requirements.

(4) Provide similar information for any proposed subcontractor developing or accessing an AIS.

(c) **Required Training for IT Systems Security**

DHHS policy requires that contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the following NIH Computer Security Awareness Training course prior to performing any contract work: http://irtsectraining.nih.gov/. The contractor will be required to maintain a listing of all individuals who have completed this training and submit this listing to the Government.
Additional security training requirements commensurate with the position may be required as defined in OMB Circular A-130 or NIST Special Publication 800-16, "Information Technology Security Training Requirements." These documents provide information about IT security training that may be useful to potential offerors..

(d) **Prospective Offeror Non-Disclosure Agreement**

The Government has determined that prospective offerors will require access to sensitive information described below in order to prepare an offer.

Any individual having access to this information must possess a valid and current suitability determination at the following level:

[ ] Level 6C: Sensitive - High Risk
[X] Level 5C: Sensitive - Moderate Risk

To be considered for access to this sensitive information, a prospective offeror must:

(1) Submit a written request to the Contracting Officer identified in the solicitation;
(2) Complete and submit the "Prospective Offeror Non-Disclosure Agreement" provided as an attachment in Section J of this solicitation; and
(3) Receive written approval from the Contracting Officer.

Prospective offerors are required to process their requests for access, receive Government approval, and then access the sensitive information within the period of time provided in the solicitation for the preparation of offers.

Nothing in this provision shall be construed, in any manner, by a prospective offeror as an extension to the stated date, time, and location in the solicitation for the submission of offers.

(e) **References**

The following documents are electronically accessible:

(1) OMB Circular A-130, Appendix III: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt
(2) DHHS AISSP Handbook: http://irm.cit.nih.gov/policy/aissp.html
(3) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(4) NIH Applications/Systems Security Template: http://cit.nih.gov/security/secplantemp.html
(5) NIST Special Publication 800-16, "Information Technology Security Training Requirements:" http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
(6) NIH CIT-Policies, Guidelines and Regulations:
Table 1 - Categories of Safeguarded Agency Information:
http://irm.cit.nih.gov/security/table1.htm

Table 2 - Security Level Designations for Agency Information:
http://irm.cit.nih.gov/security/table2.htm
Table 3 - Positions Sensitivity Designations for Individuals Accessing Agency Information:
http://irm.cit.nih.gov/security/table3.htm

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

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

(2) Proposal Cover Sheet

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

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required 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" (Section J, Attachment 13) 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.

3. **Subcontracted Items:**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $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) Information Other than 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

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

a) **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.

b) **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.

c) **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.

d) **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.

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

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

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

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

(End of Provision)

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

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

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

(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/EDPclausecover.htm

(10) 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://amb.nci.nih.gov/forms/rcneg.pdf**

(11) 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 evaluation factor. The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. The technical evaluation is more important than past performance, and past performance is more important than cost and price, and cost and price is more important than the Extent of Small Disadvantaged Business Participation Evaluation factor. All evaluation factors other than cost or price, when combined are significantly more important than cost or price. In any event, the Government reserves the right to make an award to that offeror(s) whose proposal provides the best overall value to 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 and the non-scored data sharing and human subject factors 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 and other non-scored factors listed herein. Failure to provide any of the information required to evaluate the proposal may result in less than a favorable evaluation.

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

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 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 which are listed and weighted in the order of their relative importance. The maximum total score possible is 400 points. **Proposals will be judged solely on the written material provided by the offeror.**

Evaluation Criteria (100 maximal points for each phase):

Criteria	Points
1. Understanding of the intent, purpose and scope of each objective and identification and discussion of anticipated major difficulties and problem areas and recommend approaches for their resolution.	15 points
2. Soundness and adequacy of the scientific or technical approach and methods for the successful implementation and completion of work.	35 points
3. Resources and personnel to complete the proposed work. a. Adequacy and soundness of proposed staff time and labor (including proposed use of subcontracts and consultants. b. Adequacy of effort, the availability and experience of the offeror's proposed investigative team needed to successfully complete the proposed work.	30 points total a. 10 points b. 20 points
4. Overall management support, capacity, commitment of facilities, and resources to complete each objective and to integrate them in order to successfully complete the entire phase.	20 points

<u>Phase I.</u> Information gathering, web-site development, common data elements: *100 total points*

Objective #1: Assess current NINDS-sponsored phase III clinical trials and samples of other clinical research grants and phase II trials in order to determine which projects would be feasible for potential CRC collaboration.

Objective #2: Conduct focus group evaluations or other appropriate assessments to determine factors critical for CRC participation by community-based and academic-based neurologists and neurosurgeons, patients with a spectrum of neurological diseases, and research leaders. Plans for inclusion of minority physicians and patients must be addressed.

Objective #3: Create an NINDS CRC website for neurological patients and their physicians (see Statement of Work for specific goals). Familiarity with relevant NIH policies governing websites, particularly security issues and specific plans to protect patient confidentiality must be addressed.

Objective #4: Establish an NINDS CRC Registry to record diagnosis and information relevant to clinical research eligibility regarding patients with neurological disorders.

Objective #5: Develop common data elements policies and standards for CRC research.

<u>Phase II</u>: Developing the key components of the CRC Coordinating Center, initial physician recruitment, and preparing for the pilot phase: *100 total points.*

Objective #1: Develop NINDS-sponsored research projects for pilot testing.

Objective #2: Develop central IRB mechanisms or appropriate alternatives to facilitate multiple simultaneous CRC research projects carried-out by hundreds of investigators that are compliant with federal guidelines pertaining to protection of human research subjects.

Objective #3: Recruit and train an appropriate number of CRC-affiliated physicians:

Objective #4: Develop training and educational materials for CRC physicians, particularly human subject protection education programs and certification relevant to the CRC.

Objective #5: Develop and implement web-based clinical research support systems and services for CRC physicians.

Objective #6: Develop facilities and procedures for handling, distribution and accountability of medications.

Objective #7: Develop educational materials and information about CRC research for neurological patients.

Objective #8: Monitor and update the NINDS CRC website and CRC Registry, including proposals to assess the accuracy of eligibility determinations by patients and physicians and to obtain feedback from those accessing the CRC website

Objective #9: Facilitate close monitoring of phase II activities by NINDS.

Objective #10: Reconsider plans for Phases III and IV based on experience from phase II activities.

Objective #11: Organization of half-day CRC training sessions at large gatherings of academic and community-based neuroclinicians targeted for CRC participation. .

<u>Phase III</u>: Pilot studies: *100 total points*.

Objective #1: Initiation of recruitment and follow-up for the pilot research projects, including description of day-to-day operations of the CRC Coordinating Center, including contingency plans if recruitment and/or study execution is below acceptable rates (to be proposed by the offeror).

Objective #2: Prepare a detailed budgetary analysis of present and future CRC activities.

Objective #3: Facilitate close monitoring of Phase III activities by NINDS.

Objective #4: Assess the satisfaction of research initiators with the CRC pilot studies experience.

<u>Phase IV</u>: Preparation for full-scale CRC operations: *100 total points.*

Objective #1: Recruit additional physician participants in the CRC, focusing on recruitment of minority patients and of physicians caring for children with neurological diseases.

Objective #2: Planning full-scale CRC operations.

Objective #3: Undertake periodic surveys of research leaders, CRC physicians, and patients regarding satisfaction with CRC operations and propose modifications.

Objective #4: Prepare a cost-effectiveness analysis of CRC activities, analysis of the success of the CRC in achieving each its stated aims, proposals for CRC modification, and proposals for measures of CRC success.

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 produce 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. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

In accordance with FAR Part 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract shall be evaluated and scored independent of the technical merit review. Offerors shall submit information on planned SDB participation on the attachment provided clearly marked in 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 considerations 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 18 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 Small Disadvantaged Business Participation Factor will be evaluated by the following two sub-factors:

1) Extent of commitment to use SDB concerns in performance of the contract (in terms of dollars and percentage of total contract value (maximum 3 points); and

2) The complexity and variety of work to be performed by SDB concerns Maximum 2 points).

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

E. OTHER NON-SCORED FACTOR

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. 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 wit h 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.

Attachment 1 – STATEMENT OF WORK

NINDS Clinical Research Collaboration Facility

("CRC Coordinating Center")

Statement of Work

Table of Contents

1 Introduction and Overview

To address the present and future needs of the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, the NINDS Clinical Trials Cluster is requesting proposals to establish and manage a facility to serve as the Coordinating Center for the Clinical Research Collaboration (CRC) project.

Recent progress in neuroscience has led to a rapid increase in the number of neurological treatments that require testing in randomized clinical trials to determine their efficacy and safety. For most NINDS-sponsored clinical research, a recruitment/follow-up infrastructure is developed *de novo* for each individual study. This infrastructure typically requires start-up and recruitment phases lasting several years. The result is slow progress, high costs, and a limited number of studies. A more efficient way of carrying-out clinical research is needed that will involve a broader range of physician participants and neurological patients, significantly accelerate completion of clinical research projects, and speed the implementation of research results into clinical practice.

The overall objective of the NINDS Clinical Research Collaboration (CRC) project is to facilitate the efficient execution of NINDS-sponsored clinical research in order to complete more clinical research projects and to develop and to test more treatments of neurological diseases more expeditiously. NINDS-supported investigators will use the CRC to assist with recruitment of patients for clinical research studies, involving the broadest possible range of patients and physicians. Academic-based and community-based neurologists will recruit and follow patients through access to multiple clinical research protocols coordinated by the CRC.. Researchers will have more ready access to larger groups of patients with the neurological diseases under investigation. Research projects will be developed, funded, analyzed, and reported by independent investigators through the traditional peer-review process, with the CRC facility providing research support services.

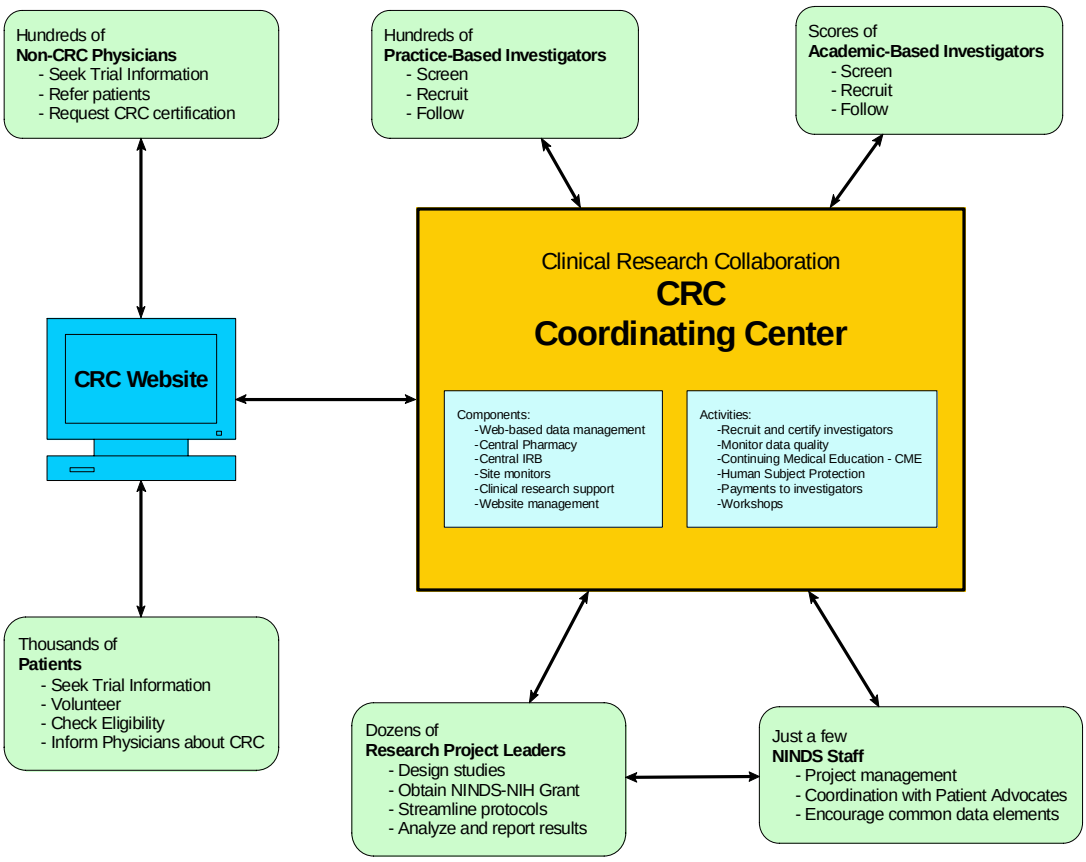
Aims and intended benefits of the NINDS CRC Project include:

1. to expedite recruitment (achieving goals in months rather than years)
2. to involve a wide spectrum of investigators, especially practicing physicians
3. to recruit a broad range of participants, particularly minorities
4. to minimize the cost of the infrastructure, so that overall costs per participant are not increased
5. to make participation in NINDS clinical research more accessible to patients

There are over 12,000 specialty-trained neurologists and neurosurgeons practicing in the U.S. and millions of Americans suffering from debilitating neurological disorders (e.g. epilepsy, Parkinson's disease, stroke, dementia, multiple sclerosis, brain tumor, traumatic brain injury, neuropathies). The CRC will bring together physicians, patients and well-designed clinical research toward the ultimate goal of decreasing the burden of neurological disease expeditiously and efficiently.

NINDS CRC STRUCTURE

2. Scope



General description of the final product of the CRC Coordinating Center contract

This contract is for the CRC Coordinating Center. The envisioned structure of the CRC and Coordinating Center is described below, but the offeror is encouraged to propose alternative strategies to achieve the goals outlined above (i.e. the offeror is not limited to the structure outlined).

The CRC will be developed in four sequential phases, and information and experience gained in the early phases may alter substantially the ultimate structure of the CRC. The currently envisioned CRC structure is described as a conceptual starting point, for refinement and modification as warranted. Flexibility to adapt to the needs of individual clinical research projects is stressed.

The CRC will be a clinical investigator collaboration consisting of community-based and academic-based neurologists and neurosurgeons recruiting thousands of participants annually into multiple investigator-initiated NINDS-sponsored clinical research projects. Linked through the CRC Coordinating Center, CRC physician investigators will choose protocols in which they will participate and will be certified as investigators for individual projects (including human subject protections training and certification). CRC investigators can elect to participate on

different levels, depending on the specific protocol, ranging from screening and referring potential patients to other investigators, to enrolling and following patients themselves. CRC investigators will be able to register their patients (with the patient's consent) including neurological diagnosis, basic demographic information, and other data relevant to research study eligibility for both current and future clinical research projects.

The CRC Coordinating Center will be hub of the project, recruiting and training CRC physician investigators. It will function as the switchboard for protocols, data management, continuing medical education programs, and reimbursement of participating CRC physicians. The Coordinating Center will organize central IRB interactions and provide research support to physicians who may have minimal experience with clinical research. It will monitor data quality and human subject protections, and organize limited on-site monitoring. The CRC Coordinating Center will facilitate the participation of community physicians by minimizing the administrative workload. Because of the scope and complexity of the CRC project, particularly close collaboration between the CRC Coordinating Center and NINDS Staff will be required during each phase of its development. With NINDS Staff, the CRC Coordinating Center will interact with independent research initiators to adapt research projects, to generate project-specific training materials, to cooperate with investigators, to facilitate shipment and handling of drugs in selected trials, and to transmit data to the research initiators for analysis and reporting.

CRC physician investigators will enroll and follow participants in multiple investigator-initiated clinical research projects (clinical trials, epidemiological studies, genetic case series, etc.), coordinated by the CRC Coordinating Center. Research protocols will be developed by independent investigators, funding will be obtained through traditional grant application mechanisms and shared as appropriate for CRC activities, and data will be transferred on an ongoing basis throughout the project from the CRC to the investigators who initiated the research for analysis and reporting (i.e. the CRC will not be the originator of the research projects and will not analyze or report the data). If NINDS clinical research investigators wish, they may request data directly from CRC physician participants without CRC involvement. Collaboration with the CRC will be voluntary, at the discretion of the research initiators, after weighing the advantages and disadvantages for the specific research design. Collaboration with existing disease-specific research networks to support their research needs will be undertaken.

Optimal methods to recompense to CRC physicians investigators will be assessed as part of Phase I. In general, payments from the CRC Coordinating Center to CRC investigators will be based on the time and effort required for training, patient screening and participant enrollment; continuing medical education and esprit-de-corps (from being a member of an important, prestigious collaboration spearheading the advances in neurological treatments) will be additional incentives for CRC physician participation. An important component of the NINDS CRC Project included in this contract is the CRC Website. Patients with neurological disease will directly access information about NINDS-sponsored clinical research through a widely advertised, user-friendly internet website linking them to appropriate research protocols and to local CRC investigators. Using tools on the website, patients or their physicians will be able to assess their potential eligibility for participation in research studies. Links will be provided to the websites of specific research studies, to appropriate patient advocacy groups, and to educational resources. Neurological patients who become aware of CRC research can encourage their physicians to join the collaboration. An associated NINDS CRC Patient Registry will record diagnosis and information relevant to clinical research eligibility for patients with neurological disorders with enrollment through the CRC website as well as other sources.

Patient organizations and patient advocacy groups will be encourage to participate in a modified system of patient registration, with patients who are potentially eligible for CRC research studies referred to CRC-affiliated investigators. Appropriate protection of participants from research risks and preservation of confidentiality will be priorities. Confirmation of an individual's intent to participate will be confirmed. NINDS CRC will maintain the highest ethical standards in human subject research subject protection, setting a benchmark for the neurological disease research community.

2.1 Terms of reference for Offerors

The minimum contract requirements are based on achieving specific objectives that define the scope of the contract. The offeror must submit in detail their proposed approach to achieving each objective and the specific deliverables. *The proposed timelines and guidance that accompany each objective serve to communicate the Government's desired performance and delivery schedule.*

This contract is divided into four sequential phases, with initiation of and funding for the second through fourth phases at the unilateral option of the Government based on successful completion of the earlier phase, the availability of funding, and reassessment of the likelihood of the project achieving the stated benefits outlined above. A separate technical proposal, timeline and budget proposal is requested for each phase. Since the exact structure of the later phases will depend on information and experience gained in the previous phases, proposals for the later phases must permit appropriate flexibility.

2.1a. Alternative proposals

Should an offeror have an alternative approach to achieving the goals of the CRC that is substantially different from the four phases and individual objectives described, the offeror is encouraged to submit an alternative proposal with relevant justification.

2.2 Phases of CRC Development and Specific Objectives

Phase I. Information gathering, initial website development, common data elements.

- five objectives.
- proposed duration: 12 months.

Phase II: Developing the key components of the CRC Coordinating Center, initial physician recruitment, and preparation for the pilot phase

- eleven objectives.
- proposed duration: 18 months.

Phase III: Pilot studies

- four objectives.
- proposed duration: 18 months.

Phase IV: Preparation for full-scale CRC operations

- four objectives.
- proposed duration: 12 months.

Phase I. Information gathering and website development

Objective #1: To determine what fraction of current NINDS-sponsored clinical research projects would be appropriate for potential collaboration with the CRC.

- Assess current NINDS-sponsored phase III clinical trials and samples of other clinical research grants and phase II trials, to determine which projects would be feasible for potential CRC collaboration involving practicing physicians (academically based and non-academically based), and to identify and record features which make research projects more or less amenable to CRC collaboration. The research projects so assessed would not necessarily be part of the phase III or phase IV CRC activities.

- Develop (with input from NINDS Staff) and then to apply criteria for CRC participation to all currently recruiting phase III clinical trials (approximately numbering 28 as of May, 2003) and about half of phase II-III clinical trials (approximately numbering 30 as of May, 2003) and a sample of large-scale non-trial research projects (10 epidemiological, 10 case-control, 10 genetic-based, 10 cohort-based)(100 total research studies). NINDS staff will assist in identifying projects and make the grant files available for review. Protocol evaluation must be undertaken by those with experience in recruitment and execution of clinical research and with initial collaboration of the NINDS staff.

Objective #2: To define incentives and barriers of patients, physicians, and research leaders for participation in the NINDS CRC.

- Perform appropriate social marketing assessments to assess critical factors for CRC participation by practicing non-academic based and academic-based neurologists and neurosurgeons, patients with a spectrum of neurological diseases, and research leaders. Special emphasis on minority patient participation and patient participation from outside of large, urban settings should be included. The importance of alternatives to web-based interfaces with the CRC should be evaluated, as well as the type of research likely to interest potential CRC physician participants. Special aspects and incentives relative to enhancing involvement of minority patients should be explored.

- Develop valid estimates of the rates of patient and physician participation and delineation of critical factors relevant to participation for patients, physicians, and research leaders.

Objective #3: To create a user-friendly website to expedite access to NINDS-sponsored clinical research by patients with neurological diseases, their families, and/or physicians seeking information on behalf of their patients.

- Put into operation a NINDS CRC website that would, for patients with neurological disorders, (a) provide information about current NINDS-sponsored clinical research, (b) assess potential eligibility for participation with a minimum of data entry and a maximum of confidentiality protection, (c) permit registration for future NINDS clinical research studies (NINDS CRC Patient Registry, see Phase I.C, below), and (d) offer links to relevant available Internet information regarding CRC-affiliated physicians conducting the research, disease-specific educational materials, and appropriate support groups. For physicians, the web-site would (a) provide information about current NINDS-sponsored

clinical research, (b) permit eligibility of participation of individual patients to be screened on-line, (c) allow physicians to apply to the CRC and (d) offer links to educational resources and to individuals leading CRC-affiliated research. During phase I and II of CRC development, no active CRC-based research will be ongoing, and the website will provide information and referrals to NINDS-sponsored clinical research projects with the consent and cooperation of the research leaders; this will permit field-testing and refinement of the website to the benefit of the subsequent focus on CRC-affiliated research in phases III and IV.

The website must comply with NIH website policies and minimum security safeguards described in Sections 4.1 and 4.2 regarding access for those with disabilities and with security policies governing access. During the initial period of web-site development, a method of contacting the CRC Coordinating Center for additional questions or problems should allow unanticipated needs or problems to be identified and addressed. Quarterly reports describing CRC website activity and input from those accessing it will be prepared for NINDS CRC Staff.

Objective #4: To create and maintain an NINDS CRC Patient Registry.

- Record diagnosis and information relevant to clinical research eligibility for patients with neurological disorders, with their permission and with appropriate confidentiality protections, and to include mechanisms for verifying an individual's interest in participation and to develop and apply procedures to assess whether registrations are legitimate. Accrual would primarily be through the NINDS CRC Website, but other options for participation should be developed and advertised as well, and collaboration with major patient advocacy groups explored. Individual patient information should be tightly controlled by the CRC Coordinating Center and *not* released directly to NINDS-sponsored investigators without first contacting the patient for permission.

  Contractor would be responsible for ongoing monitoring of patient participation based on hits to the registry website to define reasons why patients elect not to participate (i.e. concerns about confidentiality, ease of use, uncertain benefits) for ongoing effort to improve registry participation.

Objective #5: To develop common data elements policies and standards for CRC research.

- Develop common instruments/nomenclature (e.g. participant features, functional outcome measures) and the use of common data systems for all CRC-related research projects will make CRC participation easier for physician participants and more efficient, and offers potential research advantages. In order to minimize the burden on CRC physicians, collection of adverse event data, response to data queries, and other routine aspects of clinical research will be standardized (as much as possible) for all research projects. Innovative means to reduce the burden of data collection in office practices should be explored (e.g. coordinating research data collection with information required for medical records, insurance, and billing).

- Solicit input from independent clinical research initiators in different areas of neurological research and considering similar initiatives by other NIH institutes, the CRC

Coordinating Center will develop common data elements policies involving participant demographic features and functional outcomes suitable for streamlined research projects. After preparing initial recommendations, review by the CRC Executive Committee and external input will be solicited by the NINDS staff before approval of common data elements policies that will be incorporated as standard CRC operating procedures.

- Develop recommendations for common data elements policies and standards based on the design/scope of the project, experience, and those used in similar projects in other NIH institutes.

Phase II: Developing the key components of the CRC Coordinating Center, initial physician recruitment, and preparation for the pilot phase

Objective #1: To select and develop NINDS-sponsored research projects for the CRC pilot phase.

- In collaboration with the NINDS staff and research initiators who volunteer their projects for CRC collaboration, NINDS-sponsored research projects (divided between clinical trials and other types of research) will be selected for the CRC pilot phase. The appropriate number and spectrum of research should be proposed and justified by the offeror. The selected protocols will be adapted (i.e. "streamlined") as necessary working with the research leaders and NINDS staff, and protocol-specific data forms and educational materials generated to certify CRC physician investigators. At least one high-visibility research project of general interest to the neurology community should be included to engender enthusiasm for subsequent CRC activities and participation, as well as one involving "small" neurological diseases.

- Research study selection, adaptation for the CRC, generation of study-specific data forms and educational materials, and central IRB approval of protocols.

Objective #2: To develop a central IRB mechanism or alternatives to facilitate multiple simultaneous CRC research projects carried-out by hundreds of CRC physicians.

Develop and implement an acceptable central IRB mechanism or other satisfactory options appropriate for CRC structure and function.

Objective #3: To recruit and train CRC-affiliated physicians for participation in the pilot phase.

Community-based physicians will form an important core of CRC investigators, expanding access to the broadest range of patients managed in "real life" community settings. Using information developed in Phase I, Objective #2, practicing physicians will be recruited to participate in the CRC, albeit on different levels for individual clinical research protocols (e.g. registering patients with neurological diseases with the patient's consent, active screening and referral for enrollment, screening, entry and follow-up). The lack of research experience of many community physicians must be addressed through substantial efforts in education, training, careful monitoring, and support services to ensure the quality of CRC studies and the highest ethical standards for conducting research.

Academic-based neurologists and neurosurgeons will be crucial to involve as CRC investigators, serving as research mentors to practice-based colleagues and will bring their research experience. Academic-based CRC investigators should be encouraged to contribute to peer-reviewed CME programs.

Offerors must address intended contractual arrangements and possible incentive schemes for keeping CRC investigators involved as participants under the CRC operations. An estimate of the optimal number and type of physician participants that will be recruited should be provided.

Performance Expectations:

- Train and certify in basic clinical trial principles and human subject protections.
- Train and certify for participation in individual pilot research projects, including data entry.
- Make appropriate contractual arrangements for reimbursement
- Provide certificates of collaboration and office posters

- Prepare and distribute a quarterly newsletter about CRC activities to CRC physicians to stimulate continuing interest.

Objective #4: To develop training and educational materials for CRC physicians.

Ongoing training of CRC physician participants is crucial for the quality of the research, for human subject protection, and for physician motivation. Consequently, training courses and on-line training with Continuing Medical Education (CME) credit awards are likely to be an important aspect of the CRC. As incentive for physician participation, the concept of the CRC as a "clinical learning network" should be an attractive aspect to encourage CRC participation. CME will be offered without charge to CRC participants, primarily on-line but in other venues developed as well. High-quality CME will include research training, research ethics and human subject protections, and state-of-the-art reviews relevant to CRC research. Training in specific CRC research protocols will follow selection and adaptation of those to be used in the pilot phase.

Sources of CME programs and patient information materials could include:
1. NINDS staff (including collaboration with the Office of Human Research Protection).
2. Independent research initiators funded by NINDS (particularly for project-specific programs).
3. CRC-affiliated physician investigators.
4. CRC Coordinating Center experts.

Potential collaboration with the American Academy of Neurology CME programs could be explored.

Offerors must describe plans for implementation of the training program, including accreditation for awarding physician continuing medical education credits.

Objective #5: To adapt existing web-based clinical research support systems and services to facilitate participation of CRC physicians in NINDS-sponsored research.

Proposed minimum requirements include facilitating:

- data entry at clinical sites, data transfer, and data management
- training and availability of appropriate research support personnel
- programming and activation of specific research protocols
- monitoring of data quality, including limited on-site monitoring
- monitoring of human subject protections
- mechanisms for data transfer to the research initiators
- data back-up and security procedures
- handling and monitoring of patient confidentiality issues
- randomization programs with appropriate protections

Objective #6: To develop appropriate facilities, policies, and procedures for handling, distribution, and accountability of study medications.

- To aid NINDS investigators in development of adequate mechanisms for drug handling, distribution and accountability applicable to and adequate for multiple CRC participants.

Performance Expectations:

- Approval of procedures by an expert consultant in drug handling and distribution chosen by the NINDS staff;
- Satisfactory rating by CRC physicians and NINDS-supported investigators during pilot phase.

Objective #7: To develop educational materials and information about CRC research projects for neurological patients.

For patients with neurological disorders, informational materials about the CRC and its mission, about their neurological disorder, and about available NINDS-sponsored clinical research projects (both affiliated with the CRC and others) will be developed and made accessible to encourage their participation. These will be developed with the cooperation of the NINDS Office of Communications and Public Liaison. Many materials are already available.

- High-quality patient information materials to inform about CRC activities and encourage participation, available both in web-based and printed versions.

Objective #8: To monitor and update the NINDS CRC website.

These activities will include periodic assessment of the accuracy of eligibility determination by patients and physicians, modifications based on feedback from patients and physicians following approval by NINDS CRC Staff, timely addition of new information, and quarterly reports to NINDS about website activities.

- Solicit and analyze feedback from those accessing the CRC website;
- Submit quarterly reports to NINDS;

- Develop methods to assess the accuracy of eligibility determinations by patients and physicians;
- Timely modification of website following NINDS approval of recommended changes.

Objective #9: To facilitate close monitoring of phase II activities by NINDS.

- Submission of quarterly reports to NINDS staff regarding the progress of each phase II CRC component.

Objective #10: To critically reconsider plans for phases III and IV based on experience from phase II activities.

- Prepare a detailed report of CRC activities after all phase II activities have been initiated, including budgetary aspects and proposed modifications for phases III and IV.

Objective #11: To organize half-day CRC training sessions in association with meetings at which large numbers of potential CRC physicians would attend.

The purpose of these training sessions is to inform neurologists, neurosurgeons and other attendees about the CRC and stimulate interest in physician participation. Attendance will be free of charge, with CME credit awarded. The programs will be developed with the cooperation of NINDS staff and include presentations about the CRC, research methods, evidence-based therapeutics, results of CRC-affiliated research, and perhaps neurological controversies (to entice attendance). The contractor would advertise the workshop and solicit the level of expected attendance by distribution of the program to meeting attendees, arrange a suitable room, audiovisual support and coffee break, arrange for CME credit, solicit and collate feedback from attendees. Targeting neurology/neurosurgical trainees is particularly important to stimulate their interest in future participation in the CRC. No travel or other expenses for attendees will be paid; the budget proposal should include travel expenses and an honorarium for four speakers. Collaboration with the meeting organizers to include the workshop on-site/within the meeting program should be sought. Training sessions will commence during phase II and continue each year for the duration of the CRC contract.

Phase III: Pilot studies and additional CRC physician recruitment

Objective #1: To initiate recruitment and follow-up for the pilot research projects developed in Phase II.

- Successful recruitment;
- Adequate follow-up and study execution parameters;
- Adequate data quality;
- CRC physician satisfaction.

Objective #2: To generate detailed budgetary estimates for ongoing Phase III and Phase IV activities.

Based on the accumulative experience with CRC Coordinating Center activities, a detailed budgetary analysis with projections for phase IV activities will be generated for consideration by the CRC Executive Committee.

Objective #3: To facilitate close monitoring of Phase III activities by NINDS.

- Submission of quarterly reports to NINDS staff regarding the progress of each phase II component.

Objective #4: To assess the satisfaction of research initiators with the CRC pilot studies.

At this point in CRC development, evaluation will be undertaken to determine whether the CRC is meeting the needs of the research leaders whose projects are involved in the pilot studies and to elicit their recommendations for modifications.

- Initiate surveys of CRC research leaders involved in the pilot studies;
- Prepare a report for the NINDS staff, to include suggested procedural modifications.

Phase IV: Preparation for full-scale CRC operations

Objective #1: To recruit an additional cadre of physicians for full-scale CRC operations.

Physician recruitment should focus on those serving minority patients and on those caring for children with neurological diseases. An estimate of the optimal number and type of physician participants that will be recruited should be included and justified.

Objective #2: To plan for full-scale CRC operations involving multiple NINDS-sponsored clinical research projects, hundreds of CRC-affiliated physicians, and thousands of participants.

According to a timeline proposed by the contractor and approved by NINDS, solicit and develop additional clinical research projects to be carried-out by the CRC physicians recruited and trained in phases II and III. Specific research projects will be selected in collaboration with NINDS staff and the number and type agreed upon by the contractor and NINDS staff, and with the approval of the research initiators.

Objective #3: To assess satisfaction of CRC physicians, patients, and research initiators.

Initiate periodic surveys of CRC research leaders, physicians and patients to be forwarded to NINDS CRC Staff along with suggested procedural modifications.

Objective #4: Assessment of success of the CRC in meeting its major aims.

After the initial year of phase IV activities, prepare a cost-effectiveness analysis of CRC activities, analysis of the success of the CRC in achieving each of its stated aims, and generation of an application to obtain grant support for the continued operations of the CRC.

3. General Requirements

Independently, and not as an agent of the Government, the contractor shall exert its best efforts to achieve the specified objectives and to furnish the necessary services, qualified personnel, material, equipment and facilities required to serve as the CRC Coordinating Center.

The contractor will adhere to all applicable federal guidelines governing research involving human subjects and protection of patient confidentiality.

3.1. Information Technology Systems Security

The contractor is required to develop or access a Federal Automated Information System. Based on security guidelines contained in the DHHS Automated Information Systems Security Program Handbook (http://irm.cit.nih.gov/policy/aissp.html), the Government has determined that Level III minimum security safeguards are applicable. The applicant should describe the appropriate security safeguards applicable to each phase of the contract. (See SECTION C, ARTICLE C.4. for the listing of the Level III minimum safeguards).

3.2. Electronic and Information Technology (EIT) Standards

Proposals submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards described in Section 508 of the Rehabilitation Act of 1973 (http://www.section508.gov).

3.3. Ownership and Property

All research data generated as part of the CRC contract shall be the property of NINDS and the research initiators (per contract) and must not be disclosed to other parties without the specific written consent of NINDS.

All data and database systems and/or platforms, data forms, and software generated as part of the CRC contract shall be the property of the NINDS. In the event that the contract is terminated by the Government for any reason, all such material generated or collected under the contract shall be expeditiously forwarded to parties designated by NINDS.

3.4. Applicable Reference Document

NINDS Clinical Research Collaboration Project: Background, Aims, Proposed Structure and General Policies. This document describes and provides additional details about the NINDS CRC Project. (Attachment 21). Any inconsistencies between this document and the Statement of Work, the Statement of Work shall prevail.

4. Notes/Guidance Disclaimer

The sole purpose of "Notes and Guidance" is to provide the Contractor with additional information that may be useful in developing a plan to perform the work required by this Contract. The Contractor may not rely on the information contained in the "Notes and Guidance" as a material representation by the Government. No information contained in "Notes and Guidance" establishes a contractual requirement on either party to this contract.

4.1. Notes/Guidance – General

Because of the nature of this contract, information and experience gained during the initial phases will critically influence the specific activities, timeline and budget of the later phases. Extraordinary collaboration between NINDS and experienced professionals from the contracting entity will be required to plan and successfully carry-out the full-scale operation that comprises phase IV. Hence, the contractor will be partner in the design of the later phases of the project, and those with interest and expertise in planning and initiation of large scale clinical research will be particularly valuable to the project.

The number and type of personnel needed to achieve the performance requirements are likely to change and to fluctuate during the different phases of the project.

5. Glossary of Terms and Abbreviations

AAN – American Academy of Neurology (www.aan.org).

CME – Continuing medical education

IRB – Institutional review board governing research in human subjects

NINDS – National Institute of Neurological Disorders and Stroke

OHRP – Office for Human Research Protections (of the US Department of Health and Human Services), http://ohrp.osophs.dhhs.gov

Research initiator – the principal investigator or steering committee chair of the clinical research projects undertaken by the CRC who is responsible for independently gaining NINDS peer-review approval and funding, for data analysis, and for publication of the results of the research. Clinical research done by the CRC will be not be initiated by the CRC per se, but rather the research will emerge from the usual peer-review mechanisms independent of and prior to direct CRC involvement.

Attachment 2 – 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 315.305 (3)(f)

Note: This notice is for the Technical Evaluation Review Group who will be reviewing the proposals in response to this RFP.

(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.)

Attachment 3 – PROPOSAL INTENT RESPONSE SHEET

RFP No. NINDS-04-03

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:

Desiree wheeler
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

Attachment 4 – NIH FORM 1688 –1

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.

Attachment 5 – CONTRACTOR EMPLOYEE NON-DISCLOSURE AGREEMENT

Access to sensitive information from the files of the [indicate the NIH component] is required in the performance of my official duties, under Contract Number [indicate the contract number] between [indicate the NIH component] and my employer, [indicate your organization's name]. I, [indicate your name], on this ____ day of [indicate the month] 20__, hereby agree that I shall not release, publish, or disclose such information to unauthorized personnel, and I shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

I affirm that I have received a written and/or verbal briefing by my employer concerning my responsibilities under this agreement. I understand that violation of this agreement may subject me to criminal and civil penalties.

Signature of Contractor Employee: _____
Name of Contractor Employee: _____
Date: _____

Signature of Witness: _____
Name of Witness: _____
Date: _____

Copies retained by: Project Officer
Contractor's Project Manager
Contractor Employee

Attachment 6 – PAST PERFORMANCE INFORMATION

NATIONAL INSTITUTES OF HEALTH CUSOMER 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): _____ %

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 at the end of this survey.

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

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

4. Cost efficiencies
   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

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:

	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."				

Attachment 7 – EXAMPLE, REQUEST FOR PAST PERFORMANCE INFORMATION

Date:

Dear Client:

We are currently responding to the DHHS/NIH/NINDS RFP-04-03 entitled: NINDS Clinical Research Collaboration Facility. 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

Attachment 8 – NINDS PRIVACY ACT SYSTEM OF RECORDS NOTICE

09-25-0200 SYSTEMS LISTING

SYSTEM NAME:

Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at NIH and Contractor research facilities which collect or provide research data for this system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored, is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Adults and/or children who are the subjects of clinical, basic, or population-based research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: name, study identification number, address, relevant telephone numbers, social security number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including curricula vitae); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Research and Investigation," "Appointment and Authority of the Directors of the National Research Institutes," "National Cancer Institute," "National Eye Institute," "National Heart, Lung and Blood Institute," "National Institute on Aging," "National Institute on Alcohol Abuse and Alcoholism," "National Institute on Allergy and Infectious Diseases," "National Institute of Arthritis and Musculoskeletal and Skin Diseases," "National Institute of Child Health and Human Development," "National Institute on Deafness and Other Communication Disorders," "National Institute of Dental and Craniofacial Research," "National Institute of Diabetes, and Digestive and Kidney Diseases," "National Institute of Drug Abuse," "National Institute of Environmental Health Sciences," "National Institute of Mental Health," "National Institute of Neurological Disorders and Stroke," and the "National Human Genome Research Institute" of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c,

285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S):

To document, track, monitor and evaluate NIH clinical, basic, and population-based research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (A) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR Part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR Part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.
2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.
3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is, therefore, deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.
4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social security numbers, date of birth and other identifiers may be disclosed: (1) to the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.
6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in research studies.

7. PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.
   PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).
8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.
9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.
10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.
11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:
Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEVABILITY:
During data collection stages and follow-up, retrieval is by personal identifier (e.g., name, social security number, medical record or study identification number, etc.). During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

1. Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.
2. Physical Safeguards: Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.
3. Procedural Safeguards: Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act

requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

4. Implementation Guidelines: These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and the HHS Automated Information Systems Security Program Handbook.

RETENTION AND DISPOSAL:
Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1B "Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions.

SYSTEM MANAGER(S) AND ADDRESS(ES):
See Appendix I for a listing of current System Managers. This system is for use by all NIH Institutes and Centers.

NOTIFICATION PROCEDURE:
To determine if a record exists, write to the appropriate IC Privacy Act Coordinator listed below. In cases where the requester knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requester must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.
Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to designate, in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship.
If the requester does not know which Institute or Center Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address: NIH Privacy Act Officer, Office of Management Assessment, 6011 Executive Blvd., Room 601L, Rockville, MD 20852.

NIH Privacy Act Coordinators
Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, Clinical Center (CC), Building 10, Room 1N208, 10 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Center for Complementary and Alternative Medicine (NCCAM), Building 31, Room 2B11, 31 Center Drive, Bethesda, MD 20892-2182.
Privacy Act Coordinator, National Cancer Institute (NCI), Building 31, Room 10A34, 31 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Center on Minority Health and Health Disparities (NCMHD), Democracy Plaza II, Room 800, 6707 Democracy Boulevard, Bethesda, MD 20892-5465.
Privacy Act Coordinator, National Center for Research Resources (NCRR), Rockledge I, Room 5140, 6705 Rockledge Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Eye Institute (NEI), Building 31, Room 6A32, 31 Center Drive, Bethesda, MD 20892-2510.
Privacy Act Coordinator, National Human Genome Research Institute (NHGRI), Building 10, 3C710, 10 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Heart, Lung, and Blood Institute (NHLBI), Building 31, Room 5A33, 31 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute on Aging (NIA), Gateway Building 31, Room 2C234, 7201 Wisconsin Avenue, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 400, 6000 Executive Boulevard, Bethesda, MD 20892-7003.
Privacy Act Coordinator, National Institute of Allergy and Infectious Diseases (NIAID), 6700-B Rockledge Drive, Room 2143, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Natcher Building, Room 5AS49, 45 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute of Biomedical Imaging and Bioengineering (NIBIB), Building 31, Room 1B37, 31 Center Drive, Bethesda, MD 20892-2077.
Privacy Act Coordinator, National Institute of Child Health and Human Development (NICHD), Building 31, Room 2A11, 31 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, Office of Extramural Affairs, National Institute on Drug Abuse (NIDA), Neuroscience Center, 6001 Executive Boulevard, Room 3158, Bethesda, MD 20892-9547.
Privacy Act Coordinator, National Institute on Deafness and Other Communication Disorders (NIDCD), Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute of Dental and Craniofacial Research (NIDCR), Natcher Building, Room 4AS25, 45 Center Drive, Bethesda, MD 20892-6401.
Privacy Act Coordinator, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Building 31, Room 9A47, 31 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, Research Triangle Park, NC 27709.
Privacy Act Coordinator, National Institute of General Medical Sciences (NIGMS), Natcher Building, Room 2AN32, 45 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute of Mental Health (NIMH), Neuroscience Center, 6001 Executive Boulevard, Room 8102, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute of Neurological Disorders and Stroke (NINDS), Building 31, Room 8A33, 31 Center Drive, Bethesda, MD 20892.
Privacy Act Coordinator, National Institute of Nursing Research (NINR), Rockledge II, Room 710, 6701 Rockledge Drive, Bethesda, MD 20892.

RECORD ACCESS PROCEDURE:
Same as Notification Procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:
Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:
The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:
None.
Appendix I: System Manager(s) and Address(es)

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.
Computer Systems Analyst, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 344, 6130 Executive Boulevard, Bethesda, MD 20892.
American Burkitt's Lymphoma Registry, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Suite 434, 6130 Executive Boulevard, Bethesda, MD 20892.
Chief, Genetic Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute (NCI), Executive Plaza South, Room 7122, 6120 Executive Boulevard, Bethesda, MD 20892-7236.
Program Director, Research Resources, Biological Carcinogenesis Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 540, 6130 Executive Boulevard, Bethesda, MD 20892.
Chief, Environmental Epidemiology Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 443, 6130 Executive Boulevard, Bethesda, MD 20892.
Associate Director, Surveillance Program, Division of Cancer Prevention, National Cancer Institute (NCI), Executive Plaza North, Room 343K, 6130 Executive Boulevard, Bethesda, MD 20892.
Head, Biostatistics and Data Management Section, Center for Cancer Research, National Cancer Institute (NCI), Building 6116, Room 702, 6116 Executive Boulevard, Bethesda, MD 20892.
Chief, Clinical Research Branch, Center for Cancer Research, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), 501 W. 7th Street, Room 3, Frederick, MD 21702.
Deputy Branch Chief, Navy Hospital, NCI-Naval Medical Oncology Branch, Center for Cancer Research, National Cancer Institute (NCI), Building 8, Room 5101, Bethesda, MD 20814.
Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 804, 6130 Executive Boulevard, Bethesda, MD 20892.
Director, Extramural Clinical Studies, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), Fort Detrick, Frederick, MD 21702.
Clinical Operations Manager, National Eye Institute (NEI), Building 10, Room 10S224, 10 Center Drive, Bethesda, MD 20892.
Director, Division of Biometry and Epidemiology, National Eye Institute (NEI), Building 31, Room 6A52, 31 Center Drive, Bethesda, MD 20892.
Associate Director, Office of Clinical Affairs, National Heart, Lung, and Blood Institute (NHLBI), Building 10, Room 8C104,10 Center Drive, Bethesda, MD 20892-1754.
Senior Scientific Advisor, Office of the Director, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute (NHLBI), Federal Building, Room 220, 7550 Wisconsin Avenue, Bethesda, MD 20892.
Chief Laboratory of Epidemiology, Demography and Biometry, National Institute on Aging (NIA), Gateway Building, Room 3C309, 7201 Wisconsin Avenue, Bethesda, MD 20892.
Chief, Research Resources Branch, Intramural Research Program, National Institute on Aging (NIA), 5600 Nathan Shock Drive, Baltimore, MD 21224.
Clinical Director, National Institute on Aging (NIA), 5600 Nathan Shock Drive, Baltimore, MD 21224.
Deputy Director, Division of Biometry and Epidemiology, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 514, 6000 Executive Boulevard, Bethesda, MD 20892-7003.
Deputy Director, Division of Clinical and Prevention Research, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 505, 6000 Executive Boulevard, Bethesda, MD 20892-7003.
Chief, Respiratory Viruses Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), Building 7, Room 106, 7 Memorial Drive, Bethesda, MD 20892.
Chief, Hepatitis Virus Section, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), Building 7, Room 202, 7 Memorial Drive, Bethesda, MD 20892.
Chief, Biometry Branch, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), 6700-B Rockledge Drive, Room 3120, Bethesda, MD 20892.
Clinical Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Building 10, Room 9S205, 10 Center Drive, Bethesda, MD 20892.
Chief, Contracts Management Branch, National Institute of Child Health and Human Development (NICHD), Executive Plaza North, Room 7A07, 6130 Executive Boulevard, Bethesda, MD 20892.
Director of Intramural Research, National Institute on Deafness and Other Communication Disorders (NIDCD), Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.
Chief, Scientific Programs Branch, National Institute on Deafness and Other Communication Disorders (NIDCD), Executive Plaza South, Room 400C, 6120 Executive Boulevard, Bethesda, MD 20892-7180.

Clinical Director, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room 1N117, 10 Center Drive, Bethesda, MD 20892-1191.

Chief, Scientific Review Branch, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room 1N117, 10 Center Drive, Bethesda, MD 20892-1191.

Research Psychologist, Gene Therapy and Therapeutics Branch, National Institute of Dental and Craniofacial Research (NIDCR), Building 10, Room 1N105, 10 Center Drive, Bethesda, MD 20892-1190.

Chief, Clinical Investigations, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Building 10, Room 9N222, 10 Center Drive, Bethesda, MD 20892.

Chief, Phoenix Clinical Research Section, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Phoenix Area Indian Hospital, Room 541, 4212 North 16th Street, Phoenix, AZ 85016.

Chief, Diabetes Research Section, Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Natcher Building, Room 5AN18G, 45 Center Drive, Bethesda, MD 20892-6600.

Privacy Act Coordinator, Office of Extramural Affairs, National Institute on Drug Abuse (NIDA), 6001 Executive Boulevard, Room 3158, Bethesda, MD 20892-9547.

Chief, Epidemiology Branch, National Institute of Environmental Health Sciences (NIEHS), P.O. Box 12233, Research Triangle Park, NC 27709.

Director, Intramural Research Program, National Institute of Mental Health (NIMH), Building 10, Room 4N224, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Mental Health (NIMH), Neuroscience Center, Room 8102, 6001 Executive Boulevard, Bethesda, MD 20982.

Privacy Act Coordinator, National Institute of Neurological Disorders and Stroke (NINDS), Building 31, Room 8A33, 31 Center Drive, Bethesda, MD 20892.

Chief, Epilepsy Branch, National Institute of Neurological Disorders and Stroke (NINDS), Neuroscience Center, 6001 Executive Boulevard, Suite 2110, Bethesda, MD 20892-9523.

Assistant Director, Clinical Neurosciences Program, Division of Intramural Research, National Institute of Neurological Disorders and Stroke (NINDS), Building 10, Room 5N234, 10 Center Drive, Bethesda, MD 20892.

Acting Chief, Laboratory of Central Nervous Systems Studies, Intramural Research Program, National Institute of Neurological Disorders and Stroke (NINDS), Building 36, Room 4A21, 36 Convent Drive, Bethesda, MD 20892-4123.

Clinical Director, National Human Genome Research Institute (NHGRI), Building 10, Room 10C101D, 10 Center Drive, Bethesda, MD 20892.

Deputy Director, Division of Extramural Research, National Institute of Neurological Disorders and Stroke (NINDS), Neuroscience Center, Room 3307, 6001 Executive Boulevard, Bethesda, MD 20892.

Director, Office of Clinical and Regulatory Affairs, Division of Extramural Research and Training, Democracy Plaza II, Room 401, 6707 Democracy Boulevard, Bethesda, MD 20892-5475.

Privacy Act Coordinator, National Institute of Biomedical Imaging and Bioengineering (NIBIB), Building 31, Room 1B37, 31 Center Drive, Bethesda, MD 20892-2077.

Privacy Act Coordinator, National Center on Minority Health and Health Disparities (NCMHD), Democracy Plaza II, Room 800, 6707 Democracy Boulevard, Bethesda, MD 20892-5465.

Attachment 9 – TARGETED/PLANNED ENROLLMENT TABLE

This report format should NOT be used for data collection 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			
Ethic 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."

Attachment 10 – INCLUSION ENROLLMENT REPORT

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

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

Ethnic Category	Sex/Gender			
	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				

Attachment 11 -- Protection of Human Subjects

Assurance Identification/IRB Certification/Declaration of Exemption

(Common Rule)

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

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or 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 Other

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

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

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

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

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

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

[ ] 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 by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(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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Attachment 12 – SUMMARY OF LABOR AND DIRECT COSTS

(SUBMIT WITH TECHNICAL PROPOSAL)

COST ELEMENTS	YEAR 01	YEAR 02	YEAR 03	YEAR 04	YEAR 05	TOTAL
DIRECT LABOR (List individuals 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.

Attachment 13 – NIH 2043, PROPOSAL SUMMARY AND DATA RECORD

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH **PROPOSAL SUMMARY AND DATA RECORD**	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.

Attachment 14 – SUMMARY OF ANNUAL COSTS

(SUBMIT WITH BUSINESS PROPOSAL)

COST ELEMENTS	YEAR 01	YEAR 02	YEAR 03	YEAR 04	YEAR 05	TOTAL
DIRECT LABOR (List individuals by name/labor category. Indicate hours, % effort, and rates 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	$	$	$	$	$	$

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.

Attachment 15 – 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.		

Attachment 16 – 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

Attachment 16 – DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity:_____ Page _____ of _____

Attachment 16 – DISCLOSURE OF LOBBYING ACTIVITIES

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.

Attachment 17 – SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN: _____

CONTRACTOR: _____

ADDRESS: _____

_____

DUNN & BRADSTREET NUMBER and CCR NUMBER: _____

SOLICITATION OR CONTRACT NUMBER: _____

ITEM/SERVICE (Description): _____

_____

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

$ _____	$ _____	$ _____	$ _____	$ _____
Option # 1 (if applicable)	Option # 2 (if applicable)	Option # 3 (if applicable)	Option # 4 (if applicable)	Option # 5 (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 Regulation (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 need 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 *The NIH Small Business Office,* 6100 Executive Blvd. Room 6D05, Bethesda, Maryland 20892-7540, Phone: (301) 496-9639, Fax: (301) 480-2506, E-mail: sbmail@od.nih.gov**. Sources may also be obtained from SBA's PRO-Net website.**

NOTE TO CONTRACTORS: Please provide your CCR number with your Dunn & Bradstreet number.

1. **Type of Plan (check one)**

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

[ ] ***Mater 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 pan 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 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 9SDVOSB), 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 type of concerns under this contract is
$ _____ (b + h = a) (Base Year)

FY - ___ (1ST Option)	FY - ___ (2nd Option)	FY- ___ (3rd Option)	FY- ___ (4th Option)	FY- ___ (5th Option)
$ _____ & _____ %	$ _____ & _____ %	$ _____ & _____ %	$ ___ & ___ %	$ _____ & _____ %

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

FY - (1ST Option)	FY - (2nd Option)	FY- (3rd Option)	FY- (4th Option)	FY- (5th 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)	FY- ___ (5th 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)	FY- ___ (5th Option)
$ _____ & _____ %	$ _____ & _____ %	$ _____ & _____ %	$ _____ & _____ %	$ _____ & _____ %

e. Total estimated dollar value and percent of planned subcontracting with HUB-Zone SMALL BUSINESSES:
(% of "a") $ _____ and _____ % (Base Year)

FY - ___ (1ST Option)	FY - ___ (2nd Option)	FY- ___ (3rd Option)	FY- ___ (4th Option)	FY- ___ (5th Option)
$ _____ & _____ %	$ _____ & _____ %	$ _____ & _____ %	$ ___ & ___ %	$ _____ & _____ %

f. Total estimated dollar value 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)	FY- ___ (5th Option)
$ _____ & _____ %	$ _____ & _____ %	$ _____ & _____ %	$ ___ & ___ %	$ _____ & _____ %

g. Total estimated dollar value and percent of planned subcontracting with SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESSES: (% of "a") $ _____ and _____ % (Base Year)

FY - ___ (1ST Option)	FY - ___ (2nd Option)	FY- ___ (3rd Option)	FY- ___ (4th Option)	FY- ___ (5th Option)
$ _____ & _____ %	$ _____ & _____ %	$ _____ & _____ %	$ ___ & ___ %	$ _____ & _____ %

h. Total estimated dollar value 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)	FY- ___ (5th 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

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 Describe efforts 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.

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:

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 benefit**s. 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, women-owned, 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: _____

Attachment 18 – 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.

Attachment 19 – NIH (RC) 7

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.

Attachment 20 – NIH (RC) 4

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

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

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

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

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

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

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

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

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

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

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

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the contractor (e.g., resolution of all suspensions and audit exceptions).

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

(a) **Designated Billing Office Name and Address:** Enter the designated billing office and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) **Invoice/Financing Request Number:** Insert the appropriate serial number of the invoice/financing request.

(c) **Date Invoice/Financing Request Prepared:** Insert the date the invoice/financing request is prepared.

(d) **Contract Number, 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 Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

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

- The item number for the specific piece of equipment listed in the Property Schedule.

- The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule.

- Be preceded by an asterisk (*) if the equipment is below the approval level.

(4) **Materials and Supplies:** Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) **Premium Pay** ? List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract's Advance Understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed.

(9) **Other:** List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(l) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) **Indirect Costs—Overhead:** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) **Fixed-Fee Earned:** Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(p) **Adjustments:** Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) **Grand Totals**

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

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

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

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

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

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Billing Office Name and Address

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

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

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

(b) Invoice/Financing Request No. _____

(c) Date Invoice Prepared _____

(d) Contract No.
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

Attachment 21 - NINDS Clinical Research Collaboration Project: Background, Aims, Proposed Structure, and General Policies

Summary

The overall objective of the NINDS CRC Facility is to facilitate the efficient execution of NINDS-sponsored clinical research in order to test more treatments, more expeditiously. Hundreds of academic-based and practice-based neurologists will recruit and follow patients through access to multiple clinical trial protocols. The CRC Facility will assist RO1-investigators with the execution of clinical trials and will involve the broadest possible range of patients and physicians. The CRC Facility will be a web-based network, distinctly different from traditional disease-specific investigator research networks. The CRC Facility will serve as the switchboard to coordinate clinical research projects developed and funded by independent RO1 investigators. There will be multiple pathways to CRC Facility access, several levels of physician participation, the flexibility to adapt to the needs of specific research studies, and ongoing continuing medical education (CME) as a prominent component.

Specific Aims

1. to expedite recruitment (achieving goals in months rather than years).
2. to involve a wide spectrum of investigators, especially practicing physicians.
3. to recruit a broad range of participants, particularly minorities.
4. to minimize the cost of the infrastructure, so that overall cost/participant are not increased.
5. to make participation in NINDS clinical research more accessible to patients.
6. to facilitate the transfer of research results to clinical practice, especially to community settings.
7. to encourage large, streamlined trial designs, particularly relevant for studies of primary prevention of neurological diseases.
8. to maintain quality by peer-review of competitive investigator-initiated studies.
9. to make study of "small neurological diseases" economically feasible.
10. to engender a tradition of participation in clinical research and of evidence-based therapeutics among neurologists.

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

Background

The Need for a New Approach

Recent progress in neuroscience has led to an explosion in neurological treatments that require testing in randomized clinical trials to determine their efficacy and safety. Conventional approaches to recruitment and follow-up of participants employed in recent NINDS-sponsored trials are slow and inefficient: a recruitment/follow-up infrastructure is

developed *de novo* for individual trials, typically involving a limited number of academically-based neurologists, with recruitment lasting several years.

In other areas of medicine (e.g. cancer, heart disease), the formation of different models of clinical trial networks have facilitated rapid recruitment and efficient execution of clinical trials that involve broader participation of physicians, both academic and practice-based. Over 10% of U.S. patients with cancer are involved in clinical trials aimed at advancing the treatment of their disease; in neurology, the comparable figure is far less than 1%. About 9000 of the 15,000 (60%) oncologists practicing in the U.S. participate in NCI/NIH-sponsored clinical research. Further, as effective treatments have become available for many neurological disorders, novel therapies must increasingly be compared to standard care (rather than to placebo), generally requiring larger clinical trials. Clinical trials sponsored by NHLBI frequently involve 5,000-40,000 participants recruited over 12-24 months; NINDS-sponsored trials typically involve a few hundred to a maximum of two to three thousand participants recruited over several years and are frequently plagued by recruitment delays. Neurological trials that should be completed in a few years often take a decade or more. In short, more clinical trials are urgently needed in neurological disease, but they must be made more efficient, relevant to practicing neurologists, and economical.

The volume of ongoing NINDS-sponsored clinical research justifies a CRC Facility. Currently funded studies testing treatment interventions, if completed, will include 27,000 participants in over 100 studies (including 28 phase III trials) with a total combined annual budget over $90 million in FY 2002.

The NINDS CRC Facility will also permit the study less common, but still important, neurological illnesses. Currently, *de novo* creation of expensive trial infrastructures make competitive funding for "small" diseases unlikely because research costs are out-of-proportion to their public health importance. During the past 20 years, little evidence-based progress in treatment has occurred in many "small" neurological disorders (e.g. pseudotumor cerebri, progressive supranuclear palsy, carotid dissections, CNS lupus, periodic paralyses, neurosarcoidosis are but a few), and this is unlikely to change without the potential for more efficient trials through the CRC Facility.

Design Considerations

From the outset, novel approaches to structuring the NINDS CRC Facility have been encouraged and considered. To this end, the *NINDS CRC Workshop: Exploring the Options* (October 7-8, 2002) involved participants representing a broad range of expertise in clinical trial design, in clinical trial networks and consortia, in minority issues, in human subject protection, in medical ethics, in web-based continuing medical education, in data management and in web-based applications. In addition, input was sought from advocacy groups and medical subspecialty groups, including internal medicine, family medicine, adult neurology and child neurology. A brief synopsis of the workshop highlights follows.

The need for a research infrastructure involving hundreds of practicing physicians was broadly endorsed by the workshop participants as good for neurological research, for patients with neurological disorders, and for neurology as a specialty. The NINDS was perceived as the natural leader of such an effort. Key ideas that emerged that influenced the current CRC Facility structure included:

1. The need to focus on long range planning and to strive to design a CRC Facility that will be relevant and effective in 5-10 years, in addition to addressing immediate needs.

2. Participation by hundreds of academic-based and practiced-based neurologists to achieve recruitment goals in months rather than years and to access a broad range of participants.

3. Adaptability/flexibility to the needs of individual clinical research projects.

4. There should *not* be a core group of CRC Facility investigators that would propose the research. In order to ensure quality and wide input, all NINDS-sponsored clinical research studies undertaken by the CRC Facility would be developed initially as independent investigator-initiated proposals that undergo the usual peer-review.

5. Careful attention must be given to defining types of projects that will and will not benefit from collaboration with the CRC Facility infrastructure.

6. The specific needs driving the creation of a CRC Facility should be defined and prioritized as clearly as possible. Is it primarily aimed at more rapid patient recruitment? More effective recruitment of minority participants? Testing of interventions in "real-life" practice settings? The capacity to disseminate results through the CRC Facility? Raising the general appreciation of level of clinical evidence? While several important objectives may be embedded the CRC Facility, a clear idea of the priorities will importantly influence CRC Facility structure in the face of several design options and economic limitations.

7. Focus group data from patients with neurological diseases, particularly including minority patients, would be helpful to define interest, motivation and barriers to participation the NINDS CRC Facility. Similarly, more information about motivations and barriers to physician investigator participation is important to obtain during the design phase.

8. Develop common instruments/nomenclature (e.g. participant features, functional outcome measures) and standardize the use of common data systems for all CRC Facility-related research projects, making things easier for physician participants, more efficient, and offering potential research advantages.

9. Build-in multiple pathways for participation by patients and physicians. For example, some could be web-based, but others not. For physicians, perhaps separate "tracks" for academic-based and practice-based physicians, who may well have different motivations

and barriers for participation. There could be tiered levels of physician participation: some physicians may screen and refer patients, while others would additionally enter and follow patients.

10. A consistent deficiency in NCI, NHBLI and NINDS clinical research, widely acknowledged by the workshop participants, was the lack of adequate mechanisms to disseminate results to practicing physicians, to modify practice guidelines, and consequently to change clinical practice.

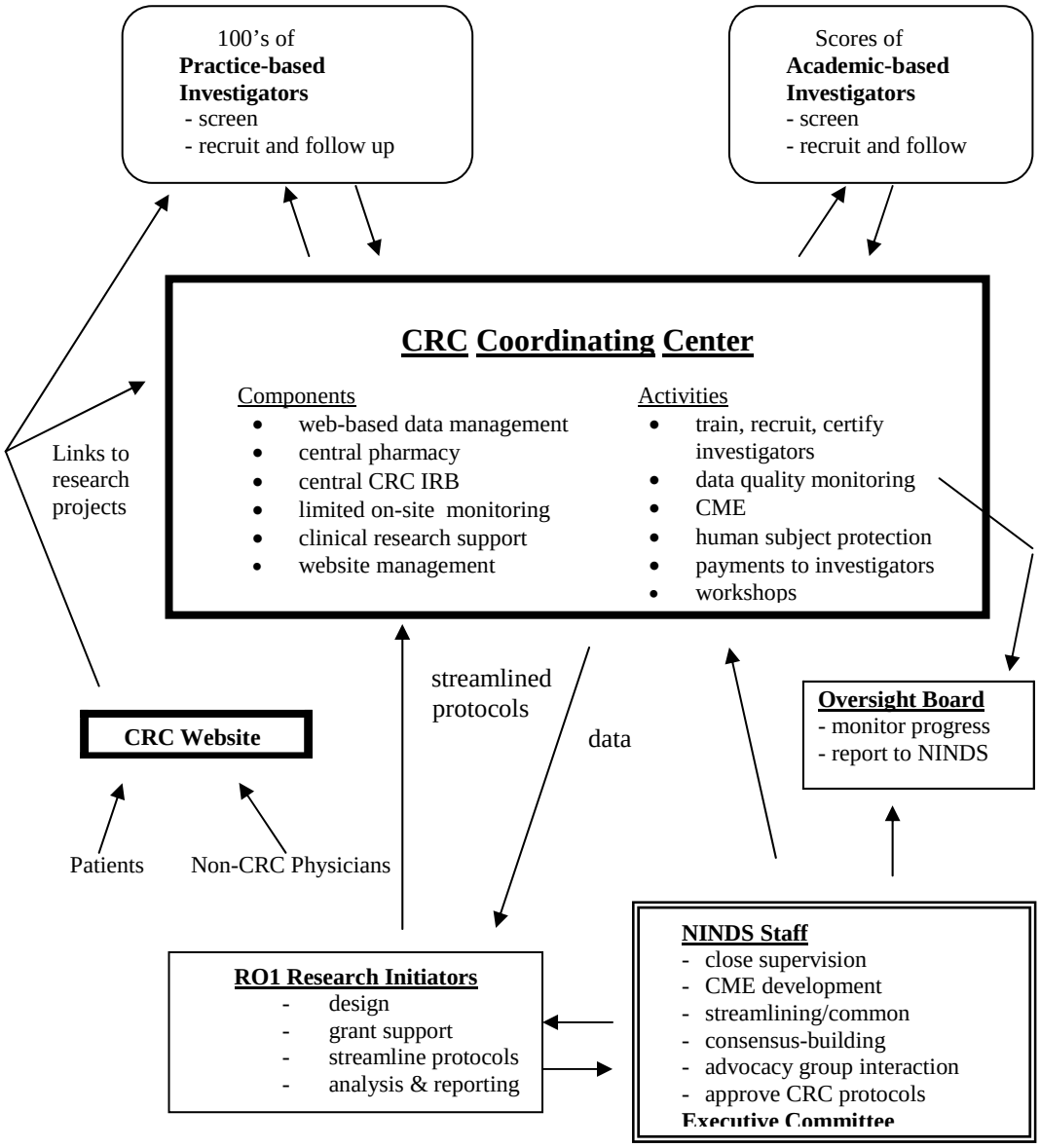
11. The importance of training aspects for physician participants was emphasized as important for the quality of the research, for human subject protection, and for physician motivation. Training courses, including on-line training, and CME should be a key feature of the CRC Facility.

12. To justify the expense of the CRC Facility, the ancillary benefits beyond enrolling patients into research studies (i.e. physician education, patient satisfaction, rapid dissemination of new neurological treatments) should be emphasize and measured. Points of reference: the cost per participant in recent clinical NCI oncology trials averaged $6500; for the NHLBI asthma network, the figures range from $8000-$12,000 per participant. For ongoing RO1 NINDS-funded phase III trials in stroke (n=14), the cost averages nearly $15,000 per participant (by dividing the total cost, direct and indirect, by the number of participants) and the median cost per trial is about $15 million.

13. An immediate need is to put into place effective, user-friendly mechanisms (website, hot-line, etc) allowing patients and physicians to access currently recruiting NINDS-sponsored clinical research. The support and advice of clinical trial investigators and advocacy groups should be sought.

14. Implementation of a CRC Facility that will be efficient and relevant in 5-10 years will be complex. Stepwise implementation was advocated: Envision the ideal CRC Facility, and then move toward it in carefully planned steps. Some important aspects can be initiated immediately.

Structure and Key Components



Description of an Envisioned CRC

The core of the web-based CRC Facility is a clinical investigator network consisting of hundreds of practice-based and academic-based neurologists linked through the CRC Facility. The CRC Facility functions as the switchboard for protocols, data, CME, and questions, monitors data quality and human subject protections, and provides research support. A score or more clinical research projects (clinical trials, epidemiological studies, genetic case series, etc.) are simultaneously enrolling and/or following participants. CRC Facility investigators choose protocols in which they would participate and are certified as investigators for individual projects (including human subject protections) before enrolling patients. CRC Facility investigators elect to participate on different levels, depending on the specific protocol, ranging from screening and referring potential patients to other CRC Facility investigators to enrolling and following patients. CRC Facility investigators register their patients (with the patient's consent) including neurological diagnosis, basic demographic information, and other data relevant to eligibility for subsequent matching with clinical research studies. Patient organizations and patient advocacy groups could additionally participate in a modified system of patient registration, with patients who are potentially eligible for CRC Facility research studies referred to CRC Facility-affiliated investigators.

Payments to CRC Facility investigators are based on patient screening, registration, and enrollment. CME, certification as a CRC Facility investigator, and esprit-de-corps (from being a member of an important, prestigious collaboration spearheading the advances in neurological treatments) are incentives for physician participation. The streamlined research protocols are developed and funded by independent RO1-based investigators; data are transferred to the RO1 study investigators for analysis and reporting. Patients with neurological disease can directly gain access to CRC Facility participation through a widely advertised, user-friendly website linking them to appropriate research protocols and to local CRC Facility investigators. Funding for the CRC Facility infrastructure is largely derived from the research protocols (included as part of the budgetary proposal of the RO1 grant applications).

*CRC Facility Key Components**

1. CRC Facility (the switchboard, including training, data management, contracts, clinical research support, and CME)
2. CRC Facility Investigators (several hundred)
   - practice-based (different optional levels of participation)
   -academic-based (different optional levels of participation)
3. CRC Facility website
4. CRC Facility R01 investigators
5. CRC Facility central IRB

6. CRC Facility drug distribution center
7. NINDS CRC Facility staff (day-to-day oversight, CME materials, liaise with professional organizations and advocacy groups, conduct annual meetings, interact with R01 investigators)
8. CRC Facility Executive Committee (approves new research protocols)
9. NINDS Oversight Committee (reviews progress/policy changes, reports to NINDS/NIH)

* How specifically to package these components is being considered; the central IRB, website and drug distribution center and site monitoring activities may be managed by the CRC Facility.

CRC Facility

The CRC Facility functions as the switchboard for the multifaceted project. Which specific components of the CRC Facility project will be gathered under the CRC Facility contract are currently being considered, but major functions include:

- Identifying, training and certifying the hundreds CRC Facility investigators.
- Establishing contracts with and supervising payments to the CRC Facility investigators.
- Collecting and monitoring human subject assurances / IRB approval.
- Developing web-based data forms and operations manuals / data management / randomization systems.
- Matching eligible patients with clinical research studies.
- Quality control monitoring for each CRC Facility research protocol.
- Transfer of data to R01 investigators for analysis and reporting.
- Limited on-site data verification.
- CRC Facility hotline (email and telephone) to handle or triage protocol questions and address any issues arising
- Clinical research support: identifying problems and intervening with investigators.*
- Implementation of web-based CME programs developed by NINDS staff and RO1 investigators.
- Planning and coordinating CRC Facility meetings (two per year; agenda prepared by NINDS staff).
-Planning and coordinating meetings of the CRC Facility DSMB and Oversight Board; assistance with timely preparation of reports from these meetings.
- Oversee and coordinate interactions between CRC Facility investigators and the drug distribution center(s) and central IRB.

In addition, the CRC Facility may have responsibility for:
- Creating and maintaining the NINDS CRC Facility website.
- Establishing a central IRB mechanism.
- Coordinating the drug distribution activities.

*Examples include:
1. For an individual CRC Facility investigator, participants miss scheduled follow-up appointments, have poor adherence or drop-out are more than expected. These problems must be identified early, further enrollment suspended until retraining was completed. Regular contact and advice until performance improved (or the investigator was withdrawn from CRC Facility participation) would follow.

2. An investigator elects to quit CRC Facility participation (disgruntled, relocates, etc). Follow-up for the dozen CRC Facility participants currently enrolled must be arranged (and agreed to contractually at the time of CRC Facility enrollment by the participant and the CRC Facility investigator).

While the NINDS CRC Facility staff take an active role in creating a milieu within the neurology community that fosters general interest in the CRC Facility, the CRC Facility will be responsible for recruiting, training, and monitoring investigators, creating the research data network, matching patients with research studies, and handling the many day-to-day issues arising. Measures of performance of the CRC Facility could include the timely initiation of protocols, participant accrual (including adequate minority recruitment), adequate research execution parameters, adequate supervision of human subject safeguards, and maintenance of quality CRC Facility website. Satisfaction of the RO1 investigators, Oversight Board, and NINDS staff with performance will also considered.

CRC Facility Website

This is intended for use by patients, non-CRC Facility-affiliated physicians, and CRC Facility investigators.

For patients with neurological diseases (or their families), the purpose is to inform them about available NINDS-sponsored clinical research studies, to their encourage participation, to solicit information to be forwarded to ongoing trialists (who could then contact the patient directly), to provide information about advocacy/support groups, to inform them about the nearest certified CRC Facility investigator, and to respond expeditiously to inquiries.

For non-CRC Facility-affiliated physicians, the intent is to inform them about available clinical research studies, to encourage them to refer their patients for participation, to learn about becoming a CRC Facility-affiliated physician, to provide information about advocacy/support groups, and to offer CME about the neurological disorder in question.

For CRC Facility investigators, the website would announce new protocols, policies, meetings and CRC Facility activities, provide access to the clinical trial protocols, consent forms and data forms, serve as a question/answer forum (response within one working day), present results of NINDS trials, provide access to CME programs. NINDS CRC Facility "certification" (and perhaps re-certification every two years) will be available through the website.

CRC Facility Investigators

Practice-based neurologists will form an important core of CRC Facility investigators, expanding access to the broadest range of patients managed in "real life" settings. Practicing neurologists are barraged with industry-based opportunities that are financially lucrative and increasing financial pressure to see more patients. Why would a practicing

neurologist choose to become involved with the NINDS CRC Facility and what are the impediments to participating? Additional, reliable information is needed to answer these questions and are required to optimally plan and execute the CRC Facility. These data should be developed through focus group in the early phase of CRC Facility development. Based on input received at the CRC Workshop, which included practicing physicians, the following factors appear relevant:

1. The primary motivation is likely to be altruistic: to work toward better care of their patients, if it can be done with a modicum of hassle and no financial sacrifice. The CRC Facility offers to practicing neurologists the opportunity to contribute to advancing neurological treatments: we can promise can promise investigators that they will make a difference. Of course, many neurologists will not be motivated to participate, but of the 9000 practicing U.S. neurologists, several hundred of the best and the brightest should respond to opportunities and challenges offered by the CRC Facility. A lack of tradition for participation in high-quality clinical research by practicing neurologists must be initially overcome.

2. Payments to CRC Facility investigators for CRC Facility activities will cover study costs and will recompense fairly for physician time. The time required for specific CRC Facility activities will be carefully estimated, and the investigator paid at a standard hourly rate plus 20% for facilities and administration overhead. Payments will include time spent on training/certification for specific protocols into which patients are entered within the following year and obtaining IRB approval. No specific funding for research nurse participation will be included (although the CRC Facility payments may be used as elected by the CRC Facility physician investigator).

3. Continuing Medical Education (CME) will be offered without charge to CRC Facility participants, primarily on-line but in other forms as well. High-quality CME will include research training, research ethics and human subject protections, and state-of-the-art reviews relevant to CRC Facility research. Ongoing CME and training activities will be an attractive aspect to encourage CRC Facility participation.

4. Esprit-de-corps as motivation for CRC Facility participation is difficult to quantify, but is nevertheless important. CRC Facility investigators will be certified as trained in basic research principles and ethics (and dated certificates awarded). Posters announcing participation in the CRC Facility will be available for physician offices (and to encourage patients to ask about the CRC). Attendance at CRC Facility workshops and collegial interaction with experts will be encouraged. Visible support for the CRC Facility by major professional organizations and advocacy groups are important.

In summary, while the major underlying motivation of neurologists to participate in the CRC Facility is likely to be altruistic, this will be facilitated by internet-based efficiency, appropriate remuneration to cover costs, high-quality continuing medical education, participation in CRC Facility workshops at national neurology meetings, and collegial interaction with experts in the field.

The lack of research experience of many practicing neurologists (clinical research training is not routinely offered during neurology residency training in most programs) must be addressed through substantial investments in education, careful monitoring, and support services to ensure the quality of CRC Facility studies and the highest ethical standards for conducting research.

Specific issues regarding CRC Facility participation peculiar to practicing neurologists serving minority patients and medically-indigent populations need to be identified and addressed in order to ensure the broadest possible participation in CRC Facility research.

Academic-based neurologists will be crucial to involve as CRC Facility investigators, serving as research mentors to practice-based colleagues and often adding their extensive research experience into the CRC Facility mix. The motivations to participate includes those discussed for practicing neurologists, but special issues for academic-based neurologists merit note. For the increasing number academic neurologists whose primary efforts involve teaching, administration and patient care, the CRC Facility offers the opportunity to contribute to research and to generate modest external funding to broaden their academic activities (and which may be useful for promotion/tenure). For young academicians, the CRC Facility may be an initial contact outside of their institutions with like-minded researchers and NINDS RO1 trialists. Academic-based CRC Facility investigators will be encouraged to develop peer-reviewed CME programs for the CRC Facility. On the other hand, individual fame and glory and large indirect (F&A) costs prized in academia will not be forthcoming from CRC Facility participation.

Potential levels of participation
a. registering patients (with their consent)
b. active screening and referral
c. screening, entry and follow-up

Operating Principles and Procedures

CME and Training

Extensive CME and training programs are essential to the integrity of the CRC Facility. A virtual "NINDS University of Clinical Research and Neurological Therapeutics" was advocated by one CRC Workshop participant.

Areas of CME:
1. clinical research training (basic principals, practical issues)
2. research ethics (required yearly)
3. background for specific protocols
4. results of CRC Facility research
5. updates in neurological therapeutics (general)
6. evidence-based therapy/critical appraisal/controversies

Major sources of CME programs:
1. NINDS CRC Facility staff (including collaboration with OHRP)
2. RO1 investigators (for their studies)
3. CRC Facility investigators (esp. academic-based, peer-reviewed on-line programs)

Human Subjects Protection / Research Ethics

Quality assurance mechanisms will be developed and assessed for the CRC Facility, particularly for verifying eligibility, compliance with the trial interventions, and endpoints. Human subject protection and patient confidentiality issue mandate careful scrutiny. Central institutional review boards have been used successfully for trials sponsored by the National Cancer Institute *(N Engl J Med 2002; 346: 1405-8).*

Control of data

Data generated by the CRC Facility will be transferred to RO1 investigators who initiated the research for analysis and publication. These investigators will have responsibility for eventual archiving of the data with NINDS, in-line with current policies. RO1 investigators have an ethical responsibility for the timely reporting of CRC Facility-generated data.

Operational Issues

I. Consensus Building

The NINDS CRC Facility can potentially go forward at several different levels of complexity and expense, as yet to be settled. The most ambitious option includes design of an innovative structure relevant to clinical research execution in 5-10 years and involving considerable training and CME investment aimed at changing the culture of clinical research in neurology. This will be expensive, and returns on the investment will not be immediately apparent. Support for the NINDS CRC Facility must be broad-based to sustain it through these initial phases. Hence, involvement of all who are invested in neurological clinical research during the planning phase is important, both to explore all available options and to encourage buy-in by the neurology research community.

II. Streamlining Clinical Research Protocols for the CRC Facility

A guideline will be prepared by the CRC Facility Working Group for RO1 clinical investigators regarding how the NINDS CRC Facility can assist with the execution their trials. It would serve as an invitation to adapt protocols for the CRC Facility at the time of initial design. This document will include:
- The advantages of collaboration with the CRC Facility.
- What types of research are appropriate for the CRC Facility.
- How to streamline research protocols: the use of widely applicable functional outcomes, clinically relevant hypotheses, easily understood aims, etc.
- “Streamlined clinical protocols – Guidelines for NINDS Reviewers”

III. Common data elements

Working with RO1 investigators from different areas of neurological research, NINDS CRC Facility staff will develop common data elements involving participant demographic features and functional outcomes. After an initial survey, wide input will be solicited before generating a position/policy report that will eventually be incorporated into CRC Facility procedures.

Additional Ideas and Issues

I. Focus groups: What are the key motivations and barriers to CRC Facility participation?

More information is needed from practicing neurologists, neurological patients, and RO1 clinical investigators regarding incentives and barriers to participation in the CRC Facility. While input from the experts who participated in the October 2002 Workshop and from disease-oriented research groups is invaluable, it likely represents selected viewpoints of those with a special interest in a CRC Facility. The purpose of the focus is to obtain information less biased by self-selection in order that the CRC Facility can be planned with knowledge of the attitudes of most practicing neurologists and patients with neurological disorders (particularly minorities).

Neurology practitioners focus groups:
To consider solo/small group and large group practices, small city and large city, minority and women practitioners. While the emphasis will be on practicing neurologists, some sample of academically-based junior faculty and academically-affiliated neurologists should be included. Issues to be explored include interest in participating, barriers, incentives, budget and monetary concerns, level of internet sophistication, willingness to undergo research training, estimated numbers of patients in specific disease categories, the importance of regional academic leadership.

Neurology patients focus group:
To select participants with neurological disorders currently being studied in ongoing trials and well as "small diseases," patients in small cities without a neurologist, patients followed by a local neurology specialist vs. not, and particularly minorities. Issues to be explored include attitudes about clinical trial participation, barriers, and need for incentives.

II. Novel quality assurance mechanisms to assess and verify eligibility, compliance with interventions and outcomes.

III. Human subject protection and patient confidentiality.

IV. Can practicing neurologists without research experience carry out CRC Facility research to high scientific and ethical standards?

The most frequent model for NINDS-sponsored clinical research to date has been academic-based neurologists assisted by trained research nurses. The NINDS CRC Facility proposal is a different paradigm, and concerns by RO1 investigators about the quality of study execution merit consideration.

Three aspects of the CRC Facility are crucial in this regard:
1. Training (and retraining) of CRC Facility investigators in basic research principles and human subject protections. Principles of randomization, completeness of follow-up, maintaining masking, intention-to-treat analysis, informed consent, participant's rights and safety must be mastered by all CRC Facility investigators (and documented by CME testing).
2. Streamlining of research protocols to bring them into line with the flow of clinical practice.
3. Monitoring of performance of individual CRC Facility investigators by the CRC Facility to identify performance deficiencies early, to assess the source of the problem, and to take remedial action (e.g. retraining, curtailing participation of individual investigators). This will be particularly important for new CRC Facility investigators who do not have a track record of research success.

Pharmaceutical-sponsored clinical research studies have successfully collaborated with practicing physicians for many years to carry out clinical research, albeit with large financial incentives and substantial central monitoring/research support services. Publicly-funded stroke clinical trials in Europe with no financial incentives have been successfully executed largely by practicing physicians (e.g. International Stroke Trial, European Atrial Fibrillation Trial, Dutch TIA Trial), adhering to streamlined protocols coupled with visible, effective trial leadership. Leadership of the RO1 investigators originating the CRC Facility research projects (e.g. personal contact with investigators who enter participants, newsletters, presentations at the CRC Workshops) will continue to be important.

Finally, neurologists, as a group, are smart, resourceful people, and those self-selected to participate in the NINDS CRC Facility will bring these traits in abundance coupled the motivation to advance the treatment of neurological diseases. Key research principles can be readily mastered by smart, motivated people given appropriate training materials. For reassurance, there is no substitute for the experience of actually entering and following patients in research protocols, but the resourcefulness that is required to survive in medical practice is more than enough to solve the day-to-day issues arising from CRC Facility participation. If the motivation is there, and adequate training and research support services are available, practicing neurologists can do it.

Preliminary Budgetary Considerations and Issues

The general CRC Facility budgetary policy is not to add NIH-negotiated F&A (i.e. indirect) costs paid to institutions with which CRC Facility investigators are associated. Budget is based on careful estimates of the incremental time required to carry out the research, reimbursed at Medicare rates plus 20%.

The CRC Facility intended to "pay for itself" after five years, based on savings garnered from more efficient execution of NINDS-sponsored clinical research. Cost accountability will be justified based on estimated savings for completing the research with vs. without the CRC Facility infrastructure, which should shorten the duration of the project as well as result in lower per-participant expenditures.

The total cost per participant (from dividing the total cost of the trial, direct and indirect, by the number of patients) in ongoing NINDS-sponsored stroke trials averages $15,000. By encouraging streamlined design of phase III trials coupled with the CRC Facility infrastructure, this figure can be substantially reduced.

We seek to change the culture of neurological research in the U.S., an ambitious undertaking requiring a massive educational effort and substantial funding. Cost accountability for the substantial training/educational components will be more difficult; for example, funds spent on neurology resident education cannot be easily linked to savings on individual research projects in the short run. These training/education costs may be substantial, and innovative ways to justify their expenditure based on intermediate outcomes must be developed.