REQUEST FOR PROPOSALS NO. NIH-NINDS-02-03

HUMAN GENETICS RESOURCE CENTER: DNA AND CELL LINE REPOSITORY

DATE ISSUED: March 21, 2002
DATE DUE: May 6, 2002

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-02-03.

THIS PROCUREMENT IS FOR FULL AND OPEN COMPETITION. THE AWARD FROM THIS SOLICITATION WILL BE A PERFORMANCE-BASED CONTRACT. DEPENDING UPON YOUR TYPE OF ORGANIZATION, THE CONTRACT WILL BE AWARDED AS EITHER A PERFORMANCE-BASED COST PLUS AWARD FEE TYPE CONTRACT, OR A PERFORMANCE-BASED COST TYPE CONTRACT.

- **IF YOUR ORGANIZATION IS AN EDUCATIONAL INSTITUTION OR A NON-PROFIT ORGANIZATION (NOT ELIGIBLE TO RECEIVE A FEE) THE CONTRACT WILL BE AWARDED AS A PERFORMANCE-BASED COST TYPE CONTRACT, WHICH WILL INCLUDE NON-MONETARY INCENTIVES/DISINCENTIVES**

THE EXAMPLE TERMS INCLUDED IN THIS SOLICITATION ARE BASED ON AN AWARD FEE TYPE SCENARIO. THEREFORE, EDUCATIONAL INSTITUTIONS AND NON-PROFIT ORGANIZATIONS (NOT ELIGIBLE TO RECEIVE A FEE) MUST REFER TO SECTION L ENTITLED: "INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS", FOR FURTHER GUIDANCE. YOUR ORGANIZATION WILL BE REQUIRED TO DEVELOP NON-MONETARY TYPE INCENTIVES, WHICH THE GOVERNMENT WILL CONSIDER DURING NEGOTIATIONS, IF YOUR ORGANIZATION IS IN THE COMPETITIVE RANGE AND SELECTED FOR CONTRACT AWARD.

- **FOR ALL OTHER TYPES OF ORGANIZATIONS WHO ARE ELIGIBLE TO RECEIVE A PROFIT/FEE, THE CONTRACT WILL BE AWARDED AS A PERFORMANCE-BASED COST PLUS AWARD FEE TYPE CONTRACT, WHICH WILL INCLUDE MONETARY INCENTIVES.**

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

The deadline for questions is April 19th, 2002. Questions which, in your opinion, require clarification or correction by the Government, must be furnished in writing to the Contracting Officer. You are requested to submit (preferably via "e-mail") your questions to Patricia S. Denney (pd22n@nih.gov). Your questions must be mailed, e-mailed or faxed in sufficient time to be received in the contracting office on or before April 19th, 2002, at 4:30 P.M. (local time), in order to allow a reply to reach all prospective offerors before submission of their proposals.

If you intend to submit a proposal in response to this solicitation, **you must** inform the Contracting Officer of your intent, by completing the Proposal Intent Response Sheet, Attachment #3, by mailing it to the address below, or by e-mailing it to: pd22n@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 issued under this solicitation.

Your proposal must be received by the Contracting Officer no later than 4:30 P.M. (local time) on May 6, 2002, at the following address:

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

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

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

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

It is your responsibility to ensure that your proposal is delivered by the due date and time, and at the specific location (Room 3287) as required in the solicitation. Please be advised that late proposals will be handled in accordance with the solicitation provisions entitled: "LATE PROPOSALS AND REVISIONS."

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

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, and FAR provisions (52-215-10). Please review these provisions so that you will be fully aware of the time requirements for submitting your proposal.

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

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

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

Requests for any information concerning this RFP should be referred only to Patricia S. Denney, Contract Specialist, who may be reached at pd22n@nih.gov or (301) 496-1813. Discussion with any other individual outside of the Contracts Management Branch may result in the disqualification of a potential offeror's proposal.

Sincerely,

Kirkland L. Davis

Kirkland L. Davis
Chief, Contracting Officer, NINDS

OMB NO. 0990-0115

SOLICITATION

SECTION A – SOLICITATION/CONTRACT FORM

1. **Request For Proposal (RFP) Number:** NIH-NINDS-02-03	2. **Issue Date:** March 21, 2002	3. **Just in Time:** ___ NO _X_ YES See Part IV, Section L.	4. **Set Aside:** X NO ____ YES See Part IV, Section L.

5. TITLE: HUMAN GENETICS RESOURCE CENTER: DNA AND CELL LINE REPOSITORY

6. ISSUED BY:	**7. SUBMIT OFFERORS TO:**
National Institutes of Health National Institute of Neurological Disorders and Stroke Contracts Management Branch, DER NeuroScience Center, MSC 9531 6001 Executive Boulevard, Suite 3287 Bethesda, Maryland 20892-9531	The address noted in Item #6 to the left.

8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the location specified above, and in the number of copies specified in Section L.1., GENERAL INFORMATION, paragraph (a), until **4:30 p.m.** (local time), **May 6, 2002.** 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: Patricia S. Denney, Contract Specialist
PHONE: 301-496-1813
E-MAIL: mailto: pd22n@nih.gov.
COLLECT CALLS WILL NOT BE ACCEPTED.

11. Table of Contents on following page.

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

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PART II - CONTRACT CLAUSES

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PART IV - REPRESENTATIONS AND INSTRUCTIONS

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

PART I - THE SCHEDULE

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The specific objective of this contract is to promote gene discovery through the development and operation of a Genetic Resource Center for Human Neurological Gene Discovery (GRC) for neurological disorders. It is anticipated that the award from this solicitation will be a Performance-based contract.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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

ARTICLE C.2. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR CLA USE 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 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
NeuroScience Center, MSC 9531
6001 Executive Boulevard, Suite 3287
Bethesda, Maryland 20892-9531

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

ARTICLE C.3. REPORTING REQUIREMENTS

a. Technical Progress Reports

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

1. Monthly Public Outreach Progress Report:

By the tenth day of each month, after the inception of the contract, for the entire contract period, the Contractor shall submit to the Contracting Officer and Project Officer, as an electronic Microsoft Word document, a report, describing the use of the public forum and how it was used to educate the lay and scientific communities, and investigators on the use of the Repository.

2. Quarterly Progress Reports:

The Contractor shall deliver this report electronically as a Microsoft Word document to both the Project Officer and the Contracting Officer.

Each quarterly progress report shall include the following:

- The number of samples received by the contractor, and of those, the success rate of transformation.
- The number of cell lines re-grown, number of DNA samples prepared and number of cell lines and DNA samples distributed, per quarter.
- The number of samples requested for each given disease category being collected, and the number of samples rejected from end-users, i.e., investigators, that were unusable, incorrect, etc. The latter serves as a means of monitoring the Contractor's compliance with their internal quality assurance plans and controls.
- Information on activities for the sharing of research resources and intellectual property.
- In accordance with ARTICLE G.4., FEE COLLECTION, the Contractor shall document the fees assessment, total fees collected for each quarter, and total costs.

In addition to the above, each quarterly report shall include an abstract, including a description of work performed during the period reported upon, and the anticipated work plan for the coming quarter.

These reports shall be delivered in accordance with the following schedule for the entire contract period:

Quarterly Reporting Periods	**Delivery Due Dates**
January 1 – March 31	April 15
April 1 - June 30	July 15
July 1 – September 30	October 15
October 1 – December 31	January 15

A progress report is not required for the last six-month period of the contract.

3. Other Reports:

Deliverable	Quantity per Annum	Delivery Date
Future Recommendation Report, which shall include the following: ❑ Data regarding sample size requirement estimates, and, ❑ The diseases which are likely to be amenable to gene discovery through the Repository. Such estimates must be based on current statistical tools and a review of the existing literature.	Deliver this report electronically as a Microsoft Excel document to both the Project Officer and the Contracting Officer	Report will be requested by the Project Officer on an as needed basis. Approximately, two per year. Due within two weeks after request made by Project Officer.
The Contractor shall propose a system for the transfer of all cell lines and other contract resources to a storage facility or successor Contractor.	Deliver this report electronically as a Microsoft Word document to both the Project Officer and the Contracting Officer.	Twelve months prior to the expiration of the contract period of performance.
Annual Summary Report, which shall include the following: activities performed in the preceding yearly period, and data for the fourth quarter.	Deliver this report electronically as a Microsoft Word document **and** as a hard-copy (one original and one copy) to both the Project Officer and the Contracting Officer	Annually

4. Final Reports:

An electronic copy of a brief final report shall be submitted on the last day of this contract. The final report shall summarize what was achieved, what was not achieved and shall include recommendations for future research and development in the area. The summary may refer to quarterly reports and published articles supported by the contract. Copies of all publications, but not quarterly progress reports, should be included in the final report. Any substantive data or other results obtained during the final quarter should be included in the final report.

ARTICLE C.4. SPECIAL REQUIREMENTS

1. Subject Confidentiality:

Traditional personal identifiers that may be utilized to establish the identity of individual subjects (e.g., surname, address, social security number, etc.) shall not be provided to, accepted, or maintained by the Contractor. All data and biological materials received by the Contractor from outside sources shall be untraceable to their original sources. All biological materials generated under this contract (cell lines, DNA samples) shall also remain unlinked to their original source. Neither the investigators receiving data from the Contractor, nor the Contractor him/herself will use information collected under this contract to establish the identity of a given subject or query the databases and retrieve information for an individual subject whose identity is known from some other source. NINDS shall distribute information only for use in scientific research projects and shall prohibit in the Distribution Agreement signed by the Contractor and qualified investigators any efforts to use data or biological materials to establish individual identities.

The Contractor shall assure that all investigators have adequate approval from an Institutional Review Board (IRB), for the collection and use of samples and data submitted or withdrawn from the repository.

2. Number of Subjects and Samples:

Since investigators cannot determine the exact number of subjects over a 12-month period of time, estimates are used for predicting the number of subjects per year. The Contractor will provide statistical support for sample size collection and estimates, based on the available data, contract capacity, and medical literature.

For **estimating** purposes, the Contractor shall anticipate receiving the following minimum – maximum number of subject blood samples: Year 1, 500 –2,750; Year 2, 750 – 3,000; Year 3, 750 – 3,000; Year 4, 2000 – 3000; and Year 5, 2,000 – 3,000.

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: "Human Genetics Resource Center: DNA and Cell Line Repository"
2. Contract Number:
3. Name of Contractor:
4. Name of Principal Investigator:

d. Shipping

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

e. See SECTION F for delivery information.

SECTION E - INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

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

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

c. Inspection and acceptance of contract work/deliverables shall be performed at the National Institute of Neurological Disorders and Stroke (NINDS), NIH, 6001 Executive Boulevard, Suite 2142, MSC 9525, Bethesda, Maryland 20892-9525, (for courier service: Rockville, MD 20852). Inspection and acceptance shall

be performed using quarterly progress reports, other required reports, and the final report. Site visits will also be employed for this purpose. Acceptance of work and/or report deliverables may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within thirty (30) days of receipt.

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

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

ARTICLE F.2. DELIVERIES

Satisfactory performance of the work under this contract shall be deemed to occur upon delivery of the level of effort and reports as specified in ARTICLE C.3. and F.3., 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.___ will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below.

Item	Description	Reporting Period	Delivery Schedule
(1)	Monthly Public Outreach Progress Report	Monthly	Tenth day of each month, after the inception of the contract, for the entire contract period.
(2)	Quarterly Progress Reports (refer to ARTICLE C.3.)	January 1 – March 31 April 1 – June 30 July 1 – September 30 October 1 – December 31	April 15 July 15 October 15 January 15
(3)	Other Reports (refer to ARTICLE C.3.)	(Refer to ARTICLE C.3.)	(Refer to ARTICLE C.3.)
(4)	Final Report (refer to ARTICLE C.3.)	(Refer to ARTICLE C.3.)	(Refer to ARTICLE C.3.)

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

ARTICLE F.3. LEVEL OF EFFORT

a. During the period of performance of this contract, it is estimated that the contractor may provide approximately 74,880 direct labor hours of effort. The labor hours include vacation, sick leave, and holidays. The estimated distribution of labor hours of effort is as follows:

Labor Category	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Totals
Professional	1,040	1,040	1,040	2,080	2,080	7,280
Other Professional	1,040	1,040	1,040	4,160	4,160	11,440
Support	10,400	10,400	14,560	10,400	10,400	56,160
Totals	**12,480**	**12,480**	**16,640**	**16,640**	**16,640**	**74,880**

b. The Contractor shall have satisfied the requirement herein if not less than 90% nor more than 100% of the total direct labor hours specified herein are furnished.

c. In the event fewer hours than the minimum specified number of direct labor hours in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under the clause TERMINATION (Cost-Reimbursement) Federal Acquisition Regulation 52.249-6 incorporated in this contract, these parties agree that the fee (if applicable) will be adjusted based solely upon the quantity of hours by which the number of direct labor hours furnished is less than the number of direct labor hours specified in the ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

ARTICLE F.4. 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.___ 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. 107-116 and ARTICLE H. ___. of the above referenced contract."

ARTICLE G.4. RECIPIENTS REIMBURSEMENT PROCEDURES

a. During the course of this contract, the Contractor will be required to make certain shipments of masked clinical data, cell lines and DNA samples directly to specified U.S. Government Recipients; Contractor/Government Agencies/or other private organizations.

b. The Contractor shall develop and maintain a billing and accounting system in order to assess and collect fees from withdrawing researchers, when indicated, based on their eligibility and fee requirements. Income received from fees charged for access to cell lines and DNA shall be utilized to offset contract costs. Such income shall be reflected on the Contractor's invoice for the month it is received.

c. The Contractor shall establish a system, with the Contracting Officer's approval, separate from other contract costs to account for such fees. The Contractor shall bill withdrawing parties directly for the services provided. The charges for these services shall be determined by the NINDS during the negotiation phase of this contract. Under no circumstances shall the Contractor bill prices other than those approved by the NINDS. Fee amounts are subject to change. Revised fee amounts will be issued by the Government when appropriate without the concurrence of the Contractor.

d. Withdrawers will be charged for sample withdrawal (unless they are submitters of the requested sample and have not yet received the cell line and DNA from that submitted sample). The Contractor shall charge the

withdrawers, whose fees are not waived by virtue of their submitter status, for data and biological materials, and all reasonable shipping charges.

e. The Contractor shall keep an accurate account of all payments received from withdrawing researchers separate from other fiscal aspects of the contract. The Contractor shall record as credits on monthly vouchers to the Government, all fee payments received from the Government Grantees, Contractors, Government Agencies, or other private organizations. The income from recipients must be credited to the Government in the billing period actually received. Thus, the Contractor shall bill the Government directly for payment of contract costs and shall subtract as a credit all payments received from recipients. The actual collections from sales will be offset against the gross billing leaving a net amount due on the invoice.

The NINDS Project Officer may direct from time to time that shipments be made entirely at Government expense.

f. The Contractor shall account for the contract related income separately in accordance with its own double entry accounting system. The Contractor shall submit to the Government a Monthly Summary Sheet of Sales which is listed as an Attachment in Section J of this contract. The Contractor shall submit a copy of Attachment 14 each month, along with the monthly invoice.

The administration of the contract related income shall be subject to the terms of this contract, including specifically and without limitation, the Audit--Negotiation Clause (FAR 52.215-2) of the General Clauses, and the applicable cost principles of the Federal Acquisition Regulation.

g. The Contractor shall use the following procedures for collection of delinquent accounts:

Step 1 - Accounts 30 days past due. A copy of the invoice shall be sent to the recipient with a notation that the account is overdue and request payment.

Step 2 - Accounts 60 days past due. The Contractor shall turn the account over to a collection agency.

h. When the completion (final) invoice is submitted on this contract, a listing of all outstanding recipient invoices shall be provided along with details as to what disposition is expected on each.

ARTICLE G.5. INDIRECT COST RATES

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

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

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

ARTICLE G.6. 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.7. POST AWARD EVALUATION OF PAST PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS (Commercials Only)

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

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

ARTICLE H.2. HUMAN SUBJECTS

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

ARTICLE H.3. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the

Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.4. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHPR) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed Optional Form 310 certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the Optional Form 310.

ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

b.

Public Law and Section No.	**Fiscal Year**	**Period Covered**
P.L. 107-116, Section 510	2002	10/01/2001 – 09/30/2002

ARTICLE H.6. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

   1) The Small Business Subcontracting Plan, dated October 2001, 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) 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. 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 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) The Contractor shall submit one (1) copy of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

The first Report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. This Report shall be mailed to 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) 205-6475 for the correct address if unknown.

ARTICLE H.7. NEEDLE EXCHANGE

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

b. **Public Law and Section No.**	**Fiscal Year**	**Period Covered**
P.L. 107-116, Section 505	2002	10/01/2001 – 09/30/2002

ARTICLE H.8. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an 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 DHHS appropriation acts.

b. **Public Law No.**	**Fiscal Year**	**Dollar Amount of Salary Limitation***
P.L. 107-116	10/01/2001 – 09/30/2002	Executive I

** Currently this amount is $166,700 and will remain at this level until such time as the Executive Level I is increased. See the following web site for Executive Level I rates of pay:*

FOR FY-02 EXECUTIVE LEVEL SALARIES: http://www.opm.gov/oca/02tables/ex

ARTICLE H.9. CONFIDENTIALITY OF INFORMATION

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

- ❑ All data and biological materials received by the Contractor
- ❑ All data and biological materials generated under this contract, to include cell lines and DNA samples

ARTICLE H.10. 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.11. PRESS RELEASES

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

b. **Public Law No. and Section No**	**Fiscal Year**	**Period Covered**
P.L.107-116, Section 507	2002	10/01/2001 – 09/30/2002

ARTICLE H.12. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

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

ARTICLE H.13. 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**
P.L. 107-116, Section 503 (a)	2002	10/01/2001 – 09/30/2002
P.L. 107-116, Section 503 (b)	2002	10/01/2001 – 09/30/2002

ARTICLE H.14. 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.

ARTICLE H.15. 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.16. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

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

OMB A-130 is accessible via web site: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt

DHHS Automated Information Systems Security Program Handbook is accessible via web site: http://irm.cit.nih.gov/policy/aissp.html

ARTICLE H.17. 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/ The standards applicable to this requirement are identified in the Statement of Work listed below:

ARTICLE H. 18. AWARD FEE (THIS ARTICLE DOES NOT APPLY TO EDUCATIONAL INSTITUTIONS OR NON-PROFITS, NOT ELIGIBLE TO RECEIVE A FEE.)

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

a. Purpose and Results Desired

The purpose of this document is to establish a procedure for evaluating a Contractor's performance to receive and process data and biological materials collected from affected subjects, their relatives, and controls, for those diseases approved for inclusion in the repository for the diseases studied by NINDS, and to distribute those materials to qualified investigators. The evaluation will be conducted on a semi-annual basis, (i.e., twice a year) and the Contractor's Award Fee will be based on the quality of services provided, inclusive of deliverables, using a numerical scale from 0 to 100.

The Agency's decision to pay or not to pay Award Fee in no way alters the Contractor's responsibilities to perform any functions or produce any deliverables required by the contract awarded as a result of this solicitation. The Agency's decision to pay or not to pay award fee in no way alters the Department's obligation to pay the Contractor for satisfactory deliverables in accordance with the contract awarded as a result of this solicitation. Award Fee is available for services and products identified in the Quality Assurance Surveillance Plan, noted in Section C. 1., the Statement of Work.

The Contracting Officer and the Project Officer shall determine whether a product/service is delivered on time and within budget. If it is deemed to be on time and within budget, it will be evaluated for quality by an Award Fee Evaluation Group (Group). The Group will consist of the NINDS Project Officer and Contracting Officer, and possibly one other government official or non-government personnel (depending on specific expertise specified by the Project Officer) and approved by the Contracting Officer.

Each member of the Group will evaluate the quality of the deliverable using a numerical rating scale from 0 to 100. The scale will be defined as follows:

ADJECTIVE OF RATING	DEFINITION OF RATING	NUMERIC RATING	AWARD FEE AMOUNT
Superior	Contractor's performance exceeds standards by a substantial margin, and the monitor can cite few, if any, areas for improvement – all of which are minor.	98.0 - 100	Award amount based on points earned. Superior Performance earns 100% of Available Award Fee
Excellent	The Contractor's performance exceeds standard, and although there may be several areas for improvement, these are more than offset by better performance in other areas.	95.0 – 97.9	Award amount based on points earned. Excellent Performance earns 85% of Available Award Fee
Good	The Contractor's performance is standard and areas for improvement are approximately offset by better performance in other areas.	90.0 – 94.9	Award amount based on points earned. Good Performance earns 50% of Available Award Fee
Satisfactory/ Unacceptable	The Contractor's performance is less then standard by a substantial margin, and the monitor can cite many areas for improvement, which are not offset by better performance in other areas.	89.9 – 0.0	Satisfactory/ Unacceptable Performance earns no ($0) Award Fee.

Each member of the Group will give the product a numerical rating and those ratings will be averaged. An Average of 89.9 or less, (Satisfactory/Unacceptable) will result in no Award Fee for that six month rating period.
An averaged score between 90.0 to 94.9 (Good) will result in 50% of Available Award Fee. An average of 95.0 to 97.9 (Excellent) will result in an award of 85% of the Available Award Fee, and an average of 98.0 to 100

(Superior) will result in award of 100% of the Available Award Fee. The Contractor and the Government agree that the award determinations are not subject to the Disputes Clause.

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

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

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

b. Responsibilities of the Award Fee Evaluation Group

The Award Fee Evaluation Group will evaluate the Contractor's technical achievements on a semi-annual basis using the various sources of performance information available.

c. Award Mechanism

The award fee will be made semi-annually. The Contracting Officer will inform the Contractor of the amount of the semi-annual award along with the narrative explanation of the basis for the award. The payment of the award fee will be made by either a unilateral or bilateral modification, (depending on the terms of the contract), prepared and signed by the Contracting Officer and an invoice is received from the Contractor for such award fee.

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 1997	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	Feb 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	Aug 1996	Convict Labor
FAR	52.222-26	Feb 1999	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	Oct 2000	Toxic Chemical Release Reporting
FAR	52.225-1	Feb 2002	Buy American Act - Balance of Payments Program - Supplies
FAR	52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
FAR	52.227-14	Jun 1987	Rights in Data - General
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	Jun 1996	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Feb 2002	Prompt Payment
FAR	52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
FAR	52.233-1	Dec 1998	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	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	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.249-6	Sep 1996	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

Reg	Clause	Date	Clause Title
HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
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. A HUBZone small business concern may elect to waive the evaluation preference, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of this clause do not apply if the offeror has waived the evaluation preference."

- ❑ Offeror elects to waive the evaluation preference.

FAR 52.219-23, Note of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (MAY 2001) Alternate I (OCTOBER 1998)

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

FAR 52.223-3, Hazardous Material Identification and Material Safety Data (JANUARY 1997), Alternate I (JULY 1995).

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).

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

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

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

HHSAR 352.223-70, Safety and Health (JANUARY 2001).

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

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

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

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

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

This contract incorporates the following in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:
FAR Clause 52.244-6, Subcontracts for Commercial Items and Commercial Components (DECEMBER 2001)

(a) **Definition**.

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

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

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

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d) (2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(ii) 52.222-26, Equal Opportunity (FEB 1999) (E.O. 11246).
(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
(v) 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial tiems a minimal number of additional clauses necessary to satisfy its contractual obligations.

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

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

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this RFP:

1. Statement of Work, 19 pages
2. Government Notice for Handling Proposals, 1 page.
3. Proposal Intent Response Sheet, 1 page.

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

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

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

5. NIH-2043, Proposal Summary and Data Record, 2 pages.
6. Summary of Annual Costs (BUSINESS PROPOSAL), 1 page.
7. Summary of Related Activities, 1 page.
8. SF-LLL, Disclosure of Lobbying Activities, 4 pages.
9. Small Business Subcontracting Plan Format, 7 pages.
10. Small Disadvantaged Business (SDB) Participation Plan Outline, 1 page.

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

11. NIH (RC)-7, Procurement of Certain Equipment, (OMB Bulletin 81-16), 1 page.
12. NIH (RC)-4, Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, 5 pages.
13. HHSAR 352.223-70, Safety and Health (JANUARY 2001)
14. Monthly Summary Sheet of Sales, May, 1991, 1 page.

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

PART IV - REPRESENTATIONS AND INSTRUCTIONS

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

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

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

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **PACKAGING AND DELIVERY OF PROPOSAL**

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

Proposals for furnishing the supplies and/or services in the SCHEDULE will be accepted at the location specified in (3) below, and in the number of copies specified in (1) below, **until 4:30 p.m. (local time), May 6, 2002**. Delivery and marking of proposals shall be as indicated below:

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

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

2. External Package Marking

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

   RFP No. NIH-NINDS-02-03

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 postaward debriefings to other offerors:

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

(End of Provision)

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

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

(End of Provision)

c. **"JUST IN TIME"**

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan and

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

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

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

Subcontracting Plan. The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only the apparent successful offeror will be required to submit an acceptable subcontracting plan.

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.

f. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that ONE (1) AWARD may be made from this solicitation and that the award may be made on/about September 30, 2002. Depending upon the type of organization selected for contract award, it is anticipated that the award from this solicitation will be a multiple-year Level of Effort, Performance-based Cost-Plus Award Fee type contract, **OR**, a Level of Effort, Performance-based Cost Type contract.

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

Certain types of organizations are not eligible to receive a fee, i.e., educational institutions and some non-profit organizations. Therefore, those organizations are required to develop and create non-monetary incentives, disincentives. Each incentive/disincentive should be associated with a monetary value, which the Government will consider during negotiations. The Government encourages you to be creative when developing your incentives, disincentives. This information must be submitted along with your technical and business proposal. The monetary value should be itemized and placed under "Other Direct Cost", in your business proposal. Failure to comply with this requirement may result in your proposal being excluded from the competitive range, and not being considered further by the Government.

Depending upon the type of contract awarded as a result of this solicitation, the term will be for five (5) years. See SECTION C.1., for the description of the Performance Standards and Quality Assurance Surveillancee Plan applicable to this requirement. It is also anticipated that incremental funding will be used for this contract (see Section L.2. (c) - Business Proposal Instructions.

g. ESTIMATE OF EFFORT

It is expected that a cost-reimbursement type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the total effort required to complete the RFP objectives to be approximately 74,880 labor hours for the entire contract period. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

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

h. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition. Any other commitment, either explicit or implied, is invalid.

i. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

j. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

k. COMPARATIVE IMPORTANCE OF PROPOSALS

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

l. PREPARATION COSTS

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

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

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

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

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

(End of Provision)

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

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

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

(1) Contract Type and General Clauses

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

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm (120 days minimum) and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) Separation of Technical and Business Proposals

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

(5) Alternate Proposals

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

(6) Evaluation of Proposals

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

(7) Potential Award Without Discussions

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

(8) Use of the Metric System of Measurement

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

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

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

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

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

(9) Privacy Act – 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.

(10) Selection of Offerors

a) The acceptability of the technical portion of each research contract proposal will be evaluated by a technical review panel. The panel will evaluate each technical proposal in strict conformity with the technical evaluation criteria of the RFP, utilizing point scores and written critiques. The panel may suggest that the Contracting Officer request clarifying information from an offeror.

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

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

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

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

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

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

While it is NINDS' policy to conduct discussions with all offerors in the competitive range, NINDS reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, evaluation of cost and past performance.

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

(11) Small Business Subcontracting Plan

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

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

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

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

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

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

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

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

(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, and Veteran-Owned Small Businesses 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, and Veteran-Owned Small Businesses 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.

(12) 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.

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

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation.

*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.

(14) 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 conditions 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.

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

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

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

(16) Salary Rate Limitation in Fiscal Year 2002*

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) 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, patent 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. 107-116 applies only to Fiscal Year 2002 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. 107-116 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."

Information regarding the FY-2002 rate can be found at:
http://www.opm.gov/oca/02tables/ex.pdf

(17) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

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

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

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

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

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

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

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

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

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

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

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

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

Institutional Management of Conflicting Interests

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

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

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

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

(18) ROTC Access and Federal Military Recruiting on Campus

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

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

(19) Past Performance Information

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.

(20) Electronic and Information Technology Accessibility

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

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

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

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

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

The offeror must:

1. Provide and maintain a DNA, and immortalized (lymphoblast) cell line repository.

2. Provide for the safe storage, re-packing, and distribution of such items (termed "samples" hereafter).

3. Maintain a database of the sample characteristics, donating researchers, associated clinical and other data, and perform subject confidentiality assurances.

4. Utilize a databasing system that will allow pedigree and clinical data accompanying samples upon arrival to be tabulated and tracked so that they can be shared without revealing subject identity upon distribution.

5. Utilize clinical diagnostic criteria as designated by the Project Officer.

6. Insure that the system in place for databasing originally can be expanded to include data on other diseases that those originally included.

7. Insure that the system in place for sample collection, storage, distribution, and accompanying information databasing can be expanded to include tissues other than blood and accompanying data including epidemiological in order to dovetail the repository activities with the future goals of the institute.

8. Insure that there is a system in place for determination of sample size appropriateness to guide collection of sample series for a given set of diagnostically defined disorders.

9. Maintain a public forum, including a web site, which shall act as a resource for sample acquisition and request mechanisms, as well as to act as a public educational tool about the repository and its goals,.

10. Provide information regarding quality control, repository utilization,, and scientific advances resulting from repository usage to the Project Officer and Contacting Officer.

(1) Technical Approach

The Government has identified the following key contract performance measures and standards.

- Contractor's potential to achieve and maintain a blood sample and data acceptance rate from 95% to 98% of the submitting investigators (See Section 4.2)
- Contractor's potential to achieve and maintain a cell line transformation rate of no less than 95% of all blood samples processed (See Section 4.3)
- Contractor's potential to achieve and maintain a recipient valid complaint rate of no more than 1% of cell lines and DNA distributed (See Sections 4.4 and 4.5)
- Contractor's ability to ensure that the project management information system and public website are available 23 hours per day, seven days per week (See Sections 4.6 and 4.7)

The Government will evaluate the non-price factors by reviewing each offeror's approach to achieving these performance measures and standards during contract performance. The Government will select the offeror whose proposed approach to achieving these performance measures and standards gives the Government a high degree of confidence that the Contractor is capable of meeting or exceeding the performance measures and standards contained in the contract at a realistic and reasonable cost to the Government.

The offeror's proposal should provide adequate and sufficient information to allow the Government to make a reasonable assessment of the offeror's ability to meet or exceed all of the contract's performance measures and standards.

For each set of performance measures and standards listed above, the offeror shall provide a narrative description of its proposed technical approach, that at a minimum, addresses the following areas:

a. Approach

Use as many subparagraphs as needed, appropriately titled, to clearly outline the general plan of work that you will to implement to meet or exceed the contract performance measure and standard. Describe each work task at the lowest level that you believe is necessary to convey a complete understanding of your proposed approach to the reviewer. If appropriate, include experimental design and possible or probable outcome of approach proposed.

b. Methods

Describe in detail the methodologies you will use in your plan to meet or exceed the contract performance measure and standard. Indicate your level of experience with each methodology**. In the section of your proposal that addresses project management, discuss areas of anticipated difficulties, and any unusual expenses you anticipate**.

c. Personnel

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

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

1. Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and the 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 this project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

2. Other Investigators

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

3. Additional Personnel

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

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.

- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

4. Resumes

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

d. Facilities, Equipment and Information Technology Systems Security

Discuss the availability and adequacy of appropriate facilities and equipment required to successfully meet or exceed the contract performance measure and standard. If the required equipment and resources are not available at the time of award, the Offeror must present a schedule for timely acquisition of the necessary facilities. In this case, the offeror must already have similar equipment currently committed to other projects.

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

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

e. Project Management

Provide a schedule for achievement and maintenance of each performance measure and standard 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 performance measure and standard. 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.

Identify which types of events may occur that will impair your ability to execute your proposed approach in a manner that will result in your meeting the contract performance measures and standards. Describe your strategy to ensure that such events do not occur. Describe the system that you will employ to monitor these types of events so that they can be identified while corrective action is still possible. Describe your system for implementing such corrective actions.

For the event that may occur that will impair your ability to execute your proposed approach in a manner that will result in your meeting the contract performance measures and standards, describe your strategy to mitigate the effects of the undesirable events that may result from these risks. Describe how your mitigation strategies will allow meeting or exceeding the contract performance measure and standard.

Describe your approach to managing the quality of task outputs to ensure that such outputs are of sufficient quality allow you to meet or exceed the contract performance measure and standard.

The Offeror must provide a detailed performance integration plan that will be followed during contract execution. The Offeror's Performance Integration Plan must include the following:

- Proposed line of responsibility, authority, and communication through which the tasks will be managed, and the procedures that will be used to ensure quality control, cost/performance control, and tracking procedures.

- Methods by which the identity of human subjects will be safeguarded during the collection, receipt, processing, storage and dissemination of biological material and data under this contract.
- Proposed organizational structure (including responsibilities and reporting structure) for the project, how personnel will be assigned from task to task throughout the contract period, and how the proposed project team will interface with both the Offeror's organizational structure and with the Contracting Officer and the Project Officer teams.
- Identification of the policies and procedures in place of verifying education and experience to ensure that resumes submitted for key personnel are current, complete and accurate and meet the requirements of those labor categories.
- Policies and procedures for managing and directing the effort for standardization, productivity, quality, cost control and cost management.
- Description of the plan for early identification and resolution of problems, especially problems that affect multiple contract performance measures and standards.
- Comprehensive startup/staffing plan that details the step-by-step phase-in of employees. This plan should address the following:
    - The period from contract award to 60 days after contract award
    - Making changes to the contractor's staff, including assignment, reassignment and training
    - Replacement of personnel without adversely affecting the technical quality or cost of performance under the contract.
- An augmentation plan that demonstrates the offeror's ability to respond to workload fluctuation in a timely manner.
- A Subcontract Management Plan detailing how each subcontractor will be managed to assure cohesive integration into the overall management approach to ensure all contract performance measures and standards are met or exceeded.

f. <u>Other Considerations</u>

Record and discuss specific factors not included elsewhere which support your proposed approach to meeting or exceeding the contract measure and standard. Using specifically titled subparagraphs, items may include:

- Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the contract measure and standard will be accomplished within this working relationship.

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

- Equipment and unusual operating procedures established to protect personnel from hazards associated with this contract measure and standard.

- Other factors you feel are important and support your proposed approach.

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

(2) Technical Evaluation

Proposals will be technically evaluated in accordance with the technical 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.

c. BUSINESS PROPOSAL INSTRUCTIONS

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

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, and, if applicable, possible base fee and award fee. It is anticipated that the award from this solicitation will be a performance-based type contract, with a term of five (5) years. See SECTION C.1.,Statement of Work, paragraph 4, for the description of the Performance-based Evaluation and Quality Assurance Plan applicable to this requirement.

(2) **Proposal Cover Sheet**

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

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

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required with the initial proposal but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

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

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

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

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

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

i) **Direct Labor**

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

ii) **Materials**

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

iii) **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $500,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.806.

iv) **Raw Materials**

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

v) **Purchased Parts**

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

vi) **Fringe Benefits**

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

vii) **Indirect Costs**

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

viii) **Special Equipment**

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

ix) **Travel**

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

x) **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

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

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

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

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

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

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

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

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

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

(End of provision)

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

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

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) **Qualifications of the Offeror**

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

(1) **General Experience**

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

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

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

(3) **Performance History**

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

(4) **Pertinent Contracts**

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

(5) **Pertinent Grants**

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

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process. **Past Performance information (see Section L.2.a.19 of this RFP) must be submitted with the Business Proposal.**

(6) **Other Administrative Data**

a) Property

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

Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

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

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

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

b) Royalties

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

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

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

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

d) Financial Capacity

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

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

(End of provision)

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

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

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

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

(End of Provision)

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

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

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

(7) **Subcontractors**

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

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

(8) **Representations and Certifications**

One copy of the Representations and Certifications located at the following web site: http://amb.nci.gov/forms/rcneg.pdf shall be completed and 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.

(9) **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.a. 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 five factors. The factors in order of importance are: technical, data sharing plan, past performance, cost, and extent of small disadvantaged business participation. The data sharing plan factor will be evaluated as either acceptable or unacceptable. Although technical factors are of paramount consideration in the award of the contract, data sharing plan methodology, past performance, cost and/or price, and extent of small disadvantaged business participation are also important to the overall contract award decision. All evaluation factors other than cost, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

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

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

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

The Government will evaluate the likelihood of success and your ability to meet the performance objectives of the Statement of Work by evaluating the offeror's approach, methods, personnel, facilities, equipment, information security, and project management within and for each of the technical standards cited below.

While the successful offeror will be responsible for meeting all key contract performance measures and standards as outlined in the Statement of Work, the following technical standards represent the criteria considered to be more critical to the success of this Initiative. The relative weights of these standards are as follows:

Technical Standards	Points
Contractor's potential to achieve and maintain a blood sample and data acceptance rate from 95% to 98% of submitting investigators	0 - 25 Points
Contractor's potential to achieve and maintain a cell line transformation rate of no less than 95% of all blood samples processed	0 - 25 Points
Contractor's potential to achieve and maintain a recipient valid complaint rate of no more than 1% of cell lines and DNA distributed	0 - 25 Points
Contractor's ability to ensure that the project management information system and public website are available 23 hours per day, seven days per week.	0 - 25 Points

The technical evaluation group will use the four technical standards noted above for evaluating the technical acceptability/unacceptability of each proposal. The following attributes will be considered and

applied when evaluating and scoring each of the technical standards: approach, methods, personnel, facilities, equipment, information security, and project management.

C. DATA SHARING PLAN

Restricted availability of unique research resources, upon which further studies are dependent, can impede the advancement of research. The NINDS is interested in ensuring that the research resources developed through this solicitation become readily available to the broader research community in a timely manner for further research, development, and application, in the expectation that this will lead to products and knowledge of benefit to the public health. It is expected that resources to be shared will include, among others, cell lines, mutant animals, germplasm, and novel reagents and techniques.

PLANS. To address this interest in assuring research resources are accessible, NIH requires offerors who respond to this solicitation to submit a plan: (1) for sharing the research resources generated through the contract; and (2) addressing how they will exercise intellectual property rights, should any be generated through this contract, while making such research resources available to the broader scientific community.

The sharing of research resources plan and intellectual property plan must make unique research resources readily available for research purposes to qualified individuals within the scientific community in accordance with the NIH Grants Policy Statement (http://grants.nih.gov/grants/policy/nihgps/) and the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999 (http://ott.od.nih.gov/NewPages/RTguide_final.html) and (http://ott.od.nih.gov/NewPages/64FR72090.pdf)].). These documents also define terms, parties, responsibilities, prescribe the order of disposition of rights, prescribe a chronology of reporting requirements, and delineate the basis for and extent of government actions to retain rights. Patent rights clauses may be found at 37 CFR Part 401.14 and are accessible from the Interagency Edison web page, http://www.iedison.gov.

REVIEW. Reviewers will evaluate the adequacy and feasibility of each offeror's data sharing of research resources and intellectual property plans. Although intended as a non-scored factor, the NINDS will consider the adequacy of the plans in the award selection process. Any awardee shall be required to submit reports containing information on activities for the sharing of research resources and intellectual property. Data sharing plans shall be made a part of any resultant contract.

If the information provided about Data Sharing Plan and Intellectual Property Plan is determined to be *"unacceptable"* you may be afforded the opportunity to further discuss and/or clarify your plan. If, after discussions, the plan is still considered *"unacceptable,"* your proposal may not be considered further for award.

D. PAST PERFORMANCE

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be considered further based on the results of the evaluation of factors other than past performance.

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

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

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information. When assessing performance risks, the

Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

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

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

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

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

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

0 None - No past performance history identifiable.

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

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

E. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTOR

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

Evaluation of the SDB Participation Plan will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform. Offerors will be evaluated on the following 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; and

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

Offerors are encouraged to use attachment #10 to this Request for Proposals, entitled: SMALL DISADVANTAGED BUSINESS (SDB) PARTICIPATION PLAN OUTLINE, as the basis for their SDB Participation Plan target and goals.

ARTICLE C.1.
Statement of Work

TABLE OF CONTENTS Page No.

1. Introduction/Background

The National Institute of Neurological Disorders and Stroke (NINDS) has the stated mission to reduce the burden of neurological disease—a burden borne by every age group, by every segment of society, by people all over the world. To support this mission, NINDS:

- Conducts, fosters, coordinates, and guides research on the causes, prevention, diagnosis, and treatment of neurological disorders and stroke, and supports basic research in related scientific areas.
- Provides grants-in-aid to public and private institutions and individuals in fields related to its areas of interest, including research project, program project, and research center grants.
- Operates a program of contracts for the funding of research and research support efforts in selected areas of institute need. Provides individual and institutional fellowships to increase scientific expertise in neurological fields.
- Conducts a diversified program of intramural and collaborative research in its own laboratories, branches, and clinics.
- Collects and disseminates research information related to neurological disorders.

Within this mission falls gene discovery. Gene discovery elucidates the cause of some diseases, and also, the underlying pathogenesis of related disorders. Therefore, this contract, which will build an infrastructure to support and encourage gene discovery, serves the mission of NINDS.

Genetic studies of neurological disorders are increasing in number and complexity. Such studies require a large and diverse sample and accompanying information base. Thus, a repository of DNA samples, immortalized cell lines (from which DNA can be extracted continuously), and accompanying clinical and pedigree data is clearly an invaluable resource for the neuroscience community. This project, which will be referred to herein as "the Repository", is conceptually related to repositories in existence at other institutes at the NIH. To date, no such resource has been available to the investigators studying the genetics of Neurological diseases.

An NINDS repository will allow receipt, storage, maintenance, standardization, quality control, and equitable, ethical distribution of DNA and other resources important to research in Neurological diseases. This will allow sharing of resources, as mandated by NIH policy, and thus will encourage work by junior investigators, investigators with novel approaches, and others not included in current collaborations, without excluding those who are established in their fields. It will ensure that research participants will be making a maximal contribution, and decrease duplicative sampling efforts.

These requirements will be met through a cost reimbursement, performance-based contract (PBC). The overall guiding purpose of the PBC mode of contracting is to provide a strong incentive for the Contractor to achieve superior performance. It allows the Contractor flexibility in performing the work and promotes maximum cooperation between the Contractor and the Government. See Section 4 entitled: Service Areas/Performance Requirements, for the performance objectives, measures and standards applicable to this solicitation.

2. Scope

The objective of this contract is to establish an NINDS DNA sample and cell line repository, with accompanying clinical and phenotypic data management, for human neurological gene discovery.

Independently, and not as an agent of the Government, the Contractor shall receive and process data and biological materials collected from affected subjects, their relatives, and controls, for those diseases approved for inclusion in the repository for the diseases studied by NINDS, and distribute those materials to qualified investigators (as specified by the Project Officer and the Contracting Officer). For estimation purposes only, the number of diseases included in the repository will be approximately 2-4/year; a total of 2000 samples across all diseases are estimated to be received per year, and approximately 500 withdrawn per year. Note also, for estimation purposes, that the diseases to be collected into the repository in the first year may include Parkinson's disease, Stroke, and Epilepsy, and/or subtypes thereof; in subsequent years, additional diseases may be included. Outreach to develop repository resources will also be a part of this process, to ensure repository utilization by the Neurological scientific community. In performing the work called for under this Contract, the Contractor shall:

1. Provide for the receipt, processing, storage, re-packing, and distribution of human blood, cell lines and DNA samples (termed "samples" hereafter).

2. Utilize a data management system that will allow standardized pedigree and clinical data that does not reveal subject identity to allow data to accompany samples upon arrival and distribution.

3. Utilize a fee collection system that allows costs to be offset by charges, the goals of which is not to generate profit, and which does not discourage, but ideally, encourages repository usage.

4. Insure that there is a system in place for determination of sample size appropriateness to guide collection of a sample series.

5. Maintain a public forum, including a web site, which shall act as a resource for sample acquisition and distribution and which will also act as a public educational tool about the repository and its goals.

6. Provide information regarding quality control, fees, repository utilization, and scientific advances resulting from repository usage to the Project Officer and Contracting Officer.

2.1 Contractor Furnished Resources

The Contractor will furnish all necessary labor, services, equipment, materials and supplies required for the performance of services under this contract. All equipment purchased under this contract as well as database platforms developed under this contract will be property of the US Government.

The Contractor shall ensure that staff is trained to receive, store, process, prepare, and distribute human blood, DNA, and cell lines in order to meet the deliverables of the contract and in

keeping with national safety standards for handling and shipping biological materials. (Selected guidelines are available as noted in the section titled "Applicable Documents".)

2.2 Location (s) of Performance

To be determined by the Contractor.

3. Applicable Documents

The below documents were at the given URL at the time of this writing. However, if the documents and guidelines referenced below are not available when accessed subsequently, the Contractor should contact the Contracting Officer or the Contracting Officer's Representative.

3.1. The NIH guidelines regarding distribution of biological materials published at http://ott.od.nih.gov/NewPages/RTguide_final.html shall be followed.

3.2. The guidelines of ethical standards protecting subject confidentiality and rights as described at http://grants.nih.gov/grants/funding/SBIRConf2000/Scharke/ apply and shall be followed in regard to repository activities.

3.3 An overview provided via the documents at http://www.hcfa.gov/hipaa/hipaahm.htm and http://aspe.hhs.gov/admnsimp/Index.htm shall be referenced in order to answer general questions regarding the regulations governing privacy in this contract.

3.4 The safety standards for on the job performance are outlined at http://www.osha.gov/ and must be followed in the performance of the work for this contract.

3.5 Shipping guidelines as outlined at http://www.nih.gov/od/ors/ds/shipping/index.html, for shipping tissue, biological, and other research materials, shall be observed.

3.6 Information regarding Federal Wide Assurance for the protection of Human Subjects can be found at http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasurt.htm and may apply to contract activities.

4. Service Areas/Performance Requirements

Performance Requirements in this contract are expressed in the following manner:

Each performance requirement will contain the following three elements. In each case, when taken together, these elements constitute a performance requirement.

- *Performance Objective - A statement of the outcome or results expected of the contractor.*

- *Performance Measures – The critical few characteristics or aspects of achieving the objective that will be monitored by the Government, those things that the Government will be gathering data about. Each objective may have one or more measures.*

- *Performance Standards – The targeted level or range of levels of performance for each performance measure.*

The following performance objectives measures and standards apply to this Statement of Work (SOW):

Objective	Measure	Standard	Quality Assurance
			Surveillance Plan
Sample receipt and collection (See Section 4.2)	Sample and data acceptance rate for the submitter population	Ninety five percent (95%) sample and data acceptance rate (acceptance per sample) for ninety-eight percent of the submitters each quarter.	Review of contract deliverables by PO and CO
Sample processing and cell line expansion (See Section 4.3)	Cell line transformation success rate	Ninety-five percent (95%) of the samples processed per quarter.	Review of contract deliverables by PO and CO
Sample storage and Sample and Data distribution. (See Sections 4.4 and 4.5)	Valid sample and data recipient complaints to the Government Project Officer about timeliness and quality of samples and accompanying data.	Valid complaint rate of no more than one percent (1%) per total quarterly withdrawals.	Review of contract deliverables by PO and CO
Project Management Information System and Public Outreach (See Sections 4.6 and 4.8)	Availability of project management information systems and public website	Management information system and public website are available 23 hours per day, seven days per week.	Periodic use of the website by PO and CO and input from other users.
Preparation of Reports (See Section 4.7)	Compliance with Deliverables, see ARTICLE F.1.	No more than one ten (10) workday delay per 6-month period.	Review of contract deliverables by PO and CO
Invoice Submission	Accuracy and timeliness of invoices in compliance with Billing Instructions, See ARTICLE G.3.	No more than one (1) invoice per 6-month period requiring suspension or disallowance due to mistakes, incompleteness or unallowable costs.	Review of invoices by PO and CO
Overall Contract Management	Contractor maintains high level of quality assurance responsiveness, and contacts CO/PO immediately with problems, when appropriate.	CO/PO has no more than 3 valid complaints in 6month period, minimal CO intervention required.	Review of contract deliverables by PO and CO

4.1 General Requirements

The Contractor shall maintain a quality assurance program to ensure the integrity of blood samples, cell lines, DNA and data throughout the collection, receipt, processing, storage and distribution of the material and data covered by the scope of this contract. All data pertaining quality control processes that are applied to each sample shall be documented in the electronic data management system required in Section 4.6.1.

4.1.1 Ownership and Property

The contractor shall be responsible for any and all negotiations, interactions and meeting requirements as dictated by law with commercial and academic organizations regarding intellectual and other property concerns. The Contractor retains the right to publish and present research results subject to the following terms:

- All articles and /or presentations that pertain to the work to be performed under this contract shall acknowledge the collaborative efforts of all participants, including contributing members of the Contractor's staff, submitting investigators, and NINDS staff.
- Prior to publication, articles shall be submitted to the NINDS Project Officer for review.
- The contractor will not act as a co-author on publications resulting from repository resources.

Under certain conditions the Contractor may be eligible for filing for patent protection to protect any inventions that they may have made during the course of their contract assignments. Contractor agrees to promptly notify the NINDS and Collaborator in writing of any inventions made by the Contractor's principal investigator or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using samples, clinical, or genetic data, or other data collected under the performance of this contract.

The US government shall own cell lines and all other resources (e.g., DNA, databases, documentation) produced under this contract and stored during and five years after the completion of the course of the contract.

All equipment purchased under this contract will be property of the US government.

The clinical, genetic, and other data to be collected and tabulated, and the sample set collected under this contract are to be regarded as proprietary in nature. Data generated using clinical information will be kept confidential and shared only with the NINDS.

4.2 Sample Collection and Receipt

4.2.1 Collection

The Contractor shall collect blood samples and related data from DHHS–funded grantees and other submitting investigators. Related data shall include as a minimum, the elements listed in section 4.2.2.2 (data) including the clinical data elements (CDEs) and pedigree structure. When a submitting investigator contacts the Contractor about a prospective collection, the Contractor shall determine if the submitter is a DHHS grantee, and if so, shall accept samples. If the submitter is not a DHHS grantee, then the Contractor shall direct the submitter to apply for permission to submit samples by contacting the Project Officer. The Project Officer will review the application, which must include documentation of IRB approval and informed consent of sample sharing plans, and make a determination. If the investigator receives approval to submit samples, the Contractor shall arrange for sample collection. A submitting investigator need only go through the approval process once for a particular project, no matter how many samples are requested for submission under a given disease diagnostic category. Once approved, the submission process will be simplified to be identical to that of DHHS grantees, as described above.

The Contractor shall provide the collecting investigator with sample collection kits that preserve the physical integrity of samples. The Contractor shall also provide data collection instruments such that all data accompanying a sample possess a unique, confidential and standard subject

identifier, and kindred identifier; and that allow clinical diagnosis and pedigree structure to be analyzed without revealing any identifiable private information about the subjects. The Contractor shall provide sample collection kits, data collection instruments and return packaging at no cost to the submitting investigator. The Contractor shall also bear the transportation cost of samples submitted by the investigator.

4.2.2 Receipt

4.2.2.1 Blood Samples

The Contractor shall define for submitting investigators, the standards for an adequate sample in terms of sample quality, and volume. The Contractor shall verify that the submitted sample is of adequate volume and quality within 48 hours of sample receipt.

If the sample is inadequate either in quality or volume, the Contractor shall notify the sample submitter of any inadequacies within 48 hours of sample receipt. The Contractor shall request the submitter to either 1) obtain and send another sample, and provide the Contractor with an estimated time of sample collection and shipment, or 2) inform the Contractor of an inability to collect that particular sample and the reason. The Contractor shall document in the quarterly report, the number of inadequate samples, the submitter, and the outcome (sample resubmitted successfully, sample lost to follow-up, etc.) If the sample is adequate, the Contractor shall notify the submitter that the Repository has received an adequate sample, within two business days of the sample's receipt. The Contractor shall maintain a capability to receive samples on any day of the week, including weekends.

Since investigators cannot determine the exact number of subjects over a 12-month period of time, estimates are used for predicting the number of subjects per year. The Contractor will provide statistical support for sample size collection and estimates, based on the available data, contract capacity, and medical literature.

> For **estimating** purposes, the Contractor shall anticipate receiving the following minimum – maximum number of subject blood samples: Year 1, 500 –2,750; Year 2, 750 – 3,000; Year 3, 750 – 3,000; Year 4, 2000 – 3000; and Year 5, 2,000 – 3,000.

4.2.2.2 Data

The Contractor shall ensure that the data accompanying each sample is adequate for research purposes. As a minimum, the data must document the following sample characteristics:

- Coded Subject Identifier
- Coded Kindred Identifier
- Relationship to other samples in the Repository or other public repositories
- Gender
- Death status
- Ethnicity
- Age of subject at collection
- Best estimate of age of subject at disease onset
- Twin status

- ♦ Diagnosis (or control, or unaffected status)
- ♦ Clinical Data Elements (CDEs)

The Contractor shall contact the submitter, by telephone and in writing, within two business days of receipt of a blood sample if the sample is not accompanied by adequate data. The Contractor shall follow up with the submitter to ensure that the data will be submitted. If, after contacting the submitter monthly for three consecutive months, the submitter has not provided adequate data, the Contractor shall discard the sample and inform the Project Officer and the submitter of this action.

4.3 Sample Processing and Cell Line Expansion

4.3.1 Sample Processing

The Contractor shall provide a capacity to process samples that are shipped by the submitter and received by the Contractor within 48 hours of collection. The Contractor shall process and maintain samples in a manner to ensure that they remain free of contamination by bacteria, fungi, mycoplasma, and other cells and contaminants. The Contractor shall save a back-up aliquot of every sample to be used in case of sample mix-up, loss or contamination.

4.3.2 Cell Line Expansion

The Contractor shall use submitted samples to expand lymphoblastoid cell lines from which DNA can be prepared continuously. If the transformation fails, the Contractor shall document the failure, the cause of the failure, and its plan to ensure that sample will produce successful cell lines and DNA samples. The Contractor shall inform the Project Officer of the failure and the plan to addressing it within two weeks of the failure's occurrence.

The Contractor shall provide the submitter with a growing cell line and at least 50 μg of DNA in accordance with Section 4.5.1. The Contractor shall store the remaining cell line in accordance with Section 4.4, "Storage".

4.4 Storage

The Contractor shall store cell lines and DNA in a manner that the viable cell lines which are produced through cell expansion as set forth in Section 4.3.2, are available to requesting researchers during the contract period of performance and that will allow viable cell lines to be transferred to another repository at the end of the contract period of performance.

The Contractor shall store cryo-preserved aliquots of each sample in a remote location, different physically than the Repository, to provide for disaster recovery, in case the Repository or its contents are damaged or destroyed.

4. 5 Distribution

Samples will not be made available for distribution to investigators other than the submitting investigator, until completion of the grace period (see glossary), unless otherwise advised by the Project Officer. When a withdrawing investigator contacts the Contractor about a prospective

distribution, the Contractor shall determine if the withdrawing investigator is an NINDS grantee, and shall determine the receipt of a signed non-distribution agreement from that investigator, and if both these criteria are met, this investigator is a qualified investigator, and the Contractor shall grant withdrawal and distribute requested samples.

If the investigator requesting a sample is not an NINDS grantee, then the Contractor shall direct the investigator to apply for permission to withdraw samples by contacting the Project Officer. The Project Officer will review the application, which will include a signed non-distribution agreement (see glossary), and make a determination and inform the Contractor. If the investigator receives approval to withdraw samples, then the investigator is a qualified investigator, and the Contractor shall arrange for sample distribution. A withdrawing investigator need only go through the approval process once for a particular project.

The Contractor will keep track of all investigators withdrawing samples and update this information on the website, for Project Officer review, as specified below (section 4.6.1.3).

4.5.1 Distribution to Submitters

The Contractor shall prepare a single viable cell line and at least 50µg of DNA from each sample and provide both to the sample submitter free of charge within three months or earlier, of receiving an adequate sample and complete accompanying data. The Contractor shall ensure the identifier assigned by the Contractor accompanies that sample upon distribution. The Contractor shall provide the submitter with advance notice of shipment of the DNA and cell lines.

The Contractor shall not distribute DNA or cell line samples to submitters that have not submitted adequate accompanying data.

4.5.2 Distribution to Other Qualified Investigators

The Contractor shall make samples, cell lines and data available to researchers other than the submitting researcher at the earliest possible time after the occurrence of one of the following events:

- The submitting investigator has published findings related to his or her submitted sample in any peer-reviewed journal, including those published in peer reviewed electronic media, such as the Internet;

Or

- The period of performance specified in the submitting investigator's research grant has expired plus six months. (Note that this expiration date is not extended upon competitive renewal, and that samples will be released based on the original expiration date plus six months of the original granting period.)

The Contractor shall track the timeframes and events described above and release samples accordingly, unless directed otherwise by the Project Officer.

The Contractor shall distribute viable lymphoblastoid cell lines and at least 50µg of DNA and the associated clinical data for each cell line and DNA sample to qualified investigators who request research material and are approved for such receipt by the Project Officer. Associated clinical

data includes diagnostic criteria (CDEs), pedigrees and sample characteristics (see section 4.2.2.2). The Contractor shall ensure that the investigator receives the materials described above within three weeks of receiving a valid request from a qualified investigator (as defined above, section 4.5).

4.6 Management Information System

The Contractor shall develop and maintain a management information system that permits the Contractor and Government to monitor whether the Contractor is performing in accordance with contract requirements, that provides the Project Officer with critical project management information, and that permits the dissemination of appropriate information to qualified members of the scientific community.

4.6.1 Electronic Data Management System

The Contractor shall create and maintain an electronic data system of clinical, diagnostic data, pedigree structure, and quality control information that meets the general requirements set forth in Section 4.1 and the following requirements:

4.6.1.1 Compartmentalization of Sample Data by Disorder

The Contractor shall maintain separate database views for each disorder. Each database view shall include the CDEs of each subject. The Contractor shall provide those who have been granted secure, password-protected access with web-based, menu-driven ad hoc query capability of data provided in each view. Each database view shall allow for stratification by clinical or pedigree information, e.g., all subjects with a certain diagnosis of a certain age or all subjects and their affected siblings or other family members, so that samples can be rapidly identified for withdrawal by qualified investigators. The electronic data management system shall facilitate downloading of data from database views or ad-hoc queries to the querying workstation, in ASCII flat-file format.

4.6.1.2 Easy Interoperability of Data

The Contractor shall design the electronic data management system to accommodate rapid and efficient data entry using a wide variety of data formats, such as Microsoft excel©, SAS system files, ASCII, and Progeny© and other commercially available systems for data management and pedigree structure files.

4.6.1.3 Project Management Information

The Contractor shall maintain an electronic data management system that provides information to the Project Officer, and the Contracting Officer about investigators, their funding sources and other related data to allow internal review of repository usage. This information shall be available on-line through secure and password protected access to the World Wide Web by the Contracting Officer and the Project Officer or their authorized representatives only, and not repository utilizers. For each Repository transaction, such data shall include as a minimum:

- Name of the principal investigator

- ♦ The submitting/withdrawing investigator's mailing address, phone number, fax number and e-mail address
- ♦ Number of DNA or cell lines received/sent
- ♦ Number of pedigrees on which information was received/sent
- ♦ Title of grant or research project
- ♦ Granting agency
- ♦ Grant identifier (number)
- ♦ Grant administrator
- ♦ Grant administrator's mailing address, phone number, fax number, and e-mail address

The Contractor shall maintain sufficient data query capability for each disorder to answer the following database queries as a minimum:

- ♦ Number of samples distributed
- ♦ Number and identity of submitting researchers
- ♦ Number of research publications resulting from Repository use for a given investigator
- ♦ Sample identifier, Submitter/institution identifier, sample diagnosis for each withdrawal/submission
- ♦ Number of other samples available in the Repository for that pedigree
- ♦ Number of times that the sample has been withdrawn
- ♦ Total number of samples
- ♦ Coded Sample pedigrees
- ♦ The sample distribution availability, including date samples will become available for distribution

4.6.1.4 World Wide Web (WWW) Accessibility

The Contractor shall design all client/server connections traversing public pathways such as the Internet to use encrypted technologies such as Secure Socket Layers and/or Virtual Private Networking. The Contractor shall provide secure, password protected Web access that allows the qualified investigators who are granted Access by the Project Officer to download various types of files rapidly and efficiently. The Contractor shall also provide secure, password protected Web access to a database view that allows sample submitters and qualified withdrawers to review sample characteristics for available as defined in Section 4.2.2.2 of this Statement of Work.

As new information becomes available for a given sample or sample set, the Contractor shall update the data systems. Updates shall include, but not be limited to: changes in diagnostic status; changes in pedigree structure; and updates in phenotypic, genotypic and SNP data. The format of these updates shall permit sample submitters and qualified investigators to easily identify which subjects have an updated or modified diagnosis, and which have newly available DNA samples that may be obtained from the Contractor.

The Contractor shall ensure that sample submitters and qualified researchers have secure, password–protected access at the time a sample is shared either with or by the Repository. The Contractor shall ensure that access to sample characteristic data does not disclose the sample donor's identity.

The Contractor shall provide Web access to the sample collection data as defined in Section 4.2.1 of this Statement of Work. The Contractor shall ensure that the sample characteristic data is available on the Web within one week of receipt of an adequate sample.

The Contractor will receive the guidelines regarding necessary clinical and other phenotype data, including CDEs, which must be included for each sample for a given diagnosis from the Project Officer, or representatives prior to the time samples will be accepted for that disorder. Within one calendar week of receipt, the Contractor will publish those guidelines on the repository web site.

4.6.1.5 Configuration Management

The Contractor shall perform configuration management of the electronic data management system. The Contractor shall thoroughly document all tables, variables, computer software configuration items and any changes, or corrections thereto.

4.7 General Reporting Requirements

The Contractor shall submit to the Government periodic reports detailing status of operations of the Repository. Such reports shall be due quarterly. Submission of periodic reports does not in any way relieve the Contractor from the other notification requirements of this contract, e.g., cell transformation failure. Quarterly reports shall contain the following information:

Sample characteristic summary: The Contractor shall report the characteristics of samples received during the quarter. For each sample, the Contractor shall provide tabulation of all samples received for a given diagnosis and for a given submitting investigator, institution, pedigree/kindred, diagnosis, and age group.

Quality control summary: For each sample received during the quarter, the Contractor shall provide evidence of compliance with its quality assurance program.

Electronic data management system configuration changes: The Contractor shall provide a detailed list of updates, changes or corrections to the configuration status of the electronic data management system.

Accounting including Fees assessed and collected. The Contractor will provide information regarding all costs of repository function, including fee administration, collection, and determination.

4.8 Public Outreach

The Contractor shall develop and maintain a public forum, which as a minimum will include a publicly accessible website that will educate the lay and scientific communities, and provide an information resource to investigators and other who use the Repository.

4.8.1 Public Website

The Contractor shall ensure that the website provides access to the following material 23 hours per day, seven days per week:

- Instructions and applications for submitters
- Instructions and applications for withdrawers
- Diagnostic criteria (CDEs), including downloadable forms for use in sample collection
- Current policy governing the Repository
- Links to government and non–government organizations that are relevant to the NINDS mission
- The quarterly current inventory summary as described in Section 4.6.2.2 with access as specified above.
- A current inventory summary that includes: number of samples; number of samples available by diagnostic category; sample pedigrees; donor ages: donor ethnic description; publications associated by sample; and number of times withdrawn
- Inventory of cell lines and associated characteristics

The Contractor shall provide Web access to an inventory of cell lines and characteristics. The inventory shall not disclose the identity of the sample submitter or sample withdrawers.

4.9 Statistical Planning Support

From time to time, the Project Officer will furnish the Contractor with a list of diseases that NINDS may wish to study. Upon a written request of the Contracting Officer, the Contractor shall assess the potential challenges and benefits of collecting blood samples for specific diseases. The Contractor shall provide a report that documents its assessment of based on prevalence data, and other data regarding diseases studied by NINDS, what reasonable number of samples must be collected. Such estimates must be based on current statistical tools and a review of the existing literature. The estimates shall reference sources.

4.10 Fees

Income received from fees charged for access to cell lines and DNA shall be utilized to offset contract costs. Such income shall be reflected on the contractor's invoice for the month it is received. The contractor shall establish a system, with the CO's approval, separate from other contract costs to account for such fees. Fees will not be utilized to generate profit. Fees shall be reasonable based on costs for similar services provided elsewhere. Fees shall motivate rather than impede repository usage by the scientific community studying Neurological diseases.

If NINDS policy or the Project Officer does not waive the access charge, the contractor shall not distribute materials before payment in full is received.

Requests for exemptions from the fees will require compelling justification and will be fully evaluated through peer review and by the project officer and her representatives.

4.11 Contract Completion and Transition

The Contractor shall develop a plan for transition, resource protection and retention, and data transfer and collation for execution in the event the contract is terminated or expires.

The Contractor shall provide a project summary to the Project Officer three months prior to the end of the contract. The summary must include a full inventory of cell lines, DNA, and plasma; a report of costs incurred and fees collected for each year of the contract; and a list of submitting and withdrawing investigators in hard–copy and electronic formats.

Twelve months prior to the expiration of the contract period of performance, the Contractor shall propose a system for the transfer of all cell lines, other biological material, electronic databases, data management systems, and files to a storage facility or successor Contractor. Upon approval of the Contracting Officer, the Contractor shall transfer all electronic databases, data management systems, and files as directed by the Contracting Officer.

5. Notes/Guidance

5.1 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 "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.

5.2 Notes and Guidance-General

Note that the Repository decisions regarding sample needs and disease inclusion will be overseen by an internal NINDS Steering Committee, who will in turn rely on guidance from a group of external advisors who will comprise an Oversight Committee for this contract.

It is not required, but encouraged, that the system developed by the Contractor for data management system originally can be expanded to include data on other diseases, tissues, or epidemiological data than that specified as originally included. This should be addressed in the original contract proposal. All investigators who collect blood samples under an NINDS funded grant will be strongly encouraged to submit their samples to the repository, whether their study is towards a genetics goal or other purposes. This encouragement will exist in language on the NINDS website, under information for applicants, and under the Neurogenetics link and should also be prominent on the repository website.

5.3 Notes and Guidance-Receipt

Submitters are responsible for verifying the extensive array of clinical information collected.

5.4 Notes and Guidance-Data Management System

Ideally, but not as a requirement of the contract, the Contractor should utilize data management and sample processing systems that will allow expansion of the original repository to include

other samples, such as tissue biopsy or brain specimens, and likewise systematically distribute them to researchers according to a request system.

5.5 Notes and Guidance-Outreach

Outreach will be directed towards multiple users, and thus, a web based outreach program must be designed with this in mind.

Groups who will be targeted via outreach include:

- Submitters
- Withdrawers
- Potential utilizers
- The lay public including Patient Advocacy groups and foundations

5.6 Notes and Guidance-Statistical and Scientific Support

There is no formula for determining sample size of the repository. Size will depend on the genetic complexity of the disease process and the specific research hypothesis being tested. The general statement that "the more samples, the better" is as close to the state of the art as we can get, given that we do not know the number of loci involved in each disease process nor do we know their prevalence in the population.

The more samples that are collected and stored in the repository the more scientific value the repository will have. This is particularly true for research on complex non-Mendelian neurodegenerative diseases. In order to identify the genetic components of the disease process, samples from the disease population need to be obtained, as well as samples from related family members. Within this disease population there will be subpopulations or strata defined by gender, age, race, ethnicity, and potentially other classification variables. The more stratified a population is, the larger the sample size needed.

There are a number of constraints on the repository size, i.e., number of samples. For example, the cost of processing new samples, maintaining the existing samples and preparing research material for distribution must fit within a specified budget. In addition to cost related constraints, there are limits on the laboratory's physical ability to process new samples, maintain the growing repository population, and to prepare research material for distribution. In the early stages of the repository, it is expected that the number of samples received will be within the ability of the repository to manage. However, as the repository grows and researchers provide more and more samples, a point will be reached where the above constraints will limit the ability to incorporate all samples into the repository. Under these conditions, a system will be needed to prioritize sample selection and processing. This system will need to reflect the complex nature of the research and the need for samples for different disease populations and their subpopulations.

6. Glossary

Adequate Sample-a sample of blood which has physical characteristics specified by the Contractor as necessary for performance of the contract including; the correct volume, shipping timing, collection standard, labeling, and other features necessary to allow it to be utilized to

meet the deliverables of the Contractor regarding DNA and cell line sample receipt, processing, storage, and distribution as specified in this contract.

Affected(s), Affected Individual(s)-an individual, or a sample from that subject, in whom the diagnosis of interest has been made, or disease under study, has been diagnosed.

CDE-Clinical Data Element. These are subject data requirements for every dataset, regardless of provider, which will include all of the essential elements that will be needed by users. Some system needs to be in place to audit the data that is provided to ensure that it is of consistently high quality.

Clinical Data Element-**see CDEs.**

Control-**a sample collected from a subject who does not have the diagnosis under study; a "normal" individual or a sample from such an individual.**

Depositor-**an investigator who submits samples for processing, storage, and ultimate distribution to the repository.**

DHHS- **(the United States) Department of Health and Human Services**

Federal Wide Assurance-**a process by which Institutions and other organizations which work with human subjects undergo credentialing for such work under the ethical and legal standards in place under the United States Government.**

Grace Period-**the interval between sample submission to and receipt by the repository and display of sample availability and distribution, release by the repository to investigators other than the submitter.**

Investigator-**As also used in common parlance, a researcher who has funding to study a particular scientific question. The person holding a grant for the study of a certain question is often termed the Principal Investigator.**

Kindred (Pedigree) identifier **– a coded identification number used for sample tracking that does not reveal any identifiable private information about the subjects in the kindred (pedigree).**

NINDS- **National Institute of Neurological Disorders and Stroke**

Non-Distribution Agreement-**an agreement, drafted by the Project Officer, shared with the Contractor, via the website and hard copy, and given to withdrawing investigators, which outlines the terms of sample receipt and in which the signer agrees to not distribute samples received from the repository to a third party without expressed permission of the Project Officer. The Project Officer, generally, will not authorize distribution of samples to investigators who have not signed and submitted such an agreement.**

OHRP-**The Office for Human Research Protections (of the US DHHS), http://ohrp.osophs.dhhs.gov/.**

OSHA-**Occupational Safety and Health Administration (of the United States Department of Labor), http://www.osha.gov/.**

Participants in the repository-**individuals who are either submitters or withdrawers, or both, of the repository. See Utilizers.**

Provider-**investigators who submit one or more samples to the repository. See submitter.**

PI-**Principal Investigator**

Repository-**in the context of this contract, a collection of DNA samples, immortalized cell lines, and accompanying clinical and pedigree data**

Requestor-**an investigator who requests samples and data from the repository**

Samples-**blood, cell lines, DNA from a given subject. May include other tissues and biomaterials.**

SNP-**single nucleotide polymorphism.**

SOW **– Statement of Work**

Subject-**an individual from whom a blood sample has been drawn and submitted to the repository.**

Subject identifier **– a coded identification number used for sample tracking that does not reveal any identifiable private information about the subject.**

Submitter-**an investigator who submits a sample and accompanying data to the repository. Also termed providers**

Valid Complaint-**a complaint generated by a repository Utilizer, subject, or institution judged to be valid by the Project Officer.**

Website-**as used in common parlance, a URL, and in this context, that particular URL and links for the repository as established, maintained, and monitored by the Contractor.**

Withdrawer-**an investigator who requests and receives samples and data from the repository**

Utilizer-**an institution or Principal Investigator who either submits to the repository or withdraws from the repository.**

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

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

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

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

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

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

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

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

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

PROPOSAL INTENT RESPONSE SHEET

RFP No. NINDS-

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

==========

[ ] DO INTEND TO SUBMIT A PROPOSAL

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

COMPANY/INSTITUTION NAME:

AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

==========

RETURN TO:

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

(SUBMIT WITH TECHNICAL PROPOSAL)

SUMMARY OF LABOR AND DIRECT COSTS

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

Specific Instructions:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH **PROPOSAL SUMMARY AND DATA RECORD**	Solicitation/CONTRACT NUMBER

PROJECT TITLE (Title or Solicitation or Contract Proposal)

LEGAL NAME AND ADDRESS OF OFFEROR	PLACE OF PERFORMANCE (Full address including ZIP)

TYPE OF CONTRACT PROPOSED

? COST-REIMBURSEMENT ? FIXED PRICE ? COST-PLUS-FIXED-FEE ? OTHER

ESTIMATED TIME REQUIRED TO COMPLETE PROJECT

ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget	PROPOSED STARTING DATE

DOES THIS PROPOSAL INCLUDE A SUBCONTRACT ? YES ? NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)

NAME AND TITLE OF PRINCIPAL INVESTIGATOR	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary.)			

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS	AREA CODE/TELEPHONE NUMBER
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS	AREA CODE/TELEPHONE NUMBER

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS ? YES ? NO
Institution's General Assurance re: Human Subjects DATE APPROVED _____ ? PENDING
Institution's Review Board's Approval of this Proposal DATE APPROVED _____ ? PENDING
An example of the informed consent for this study is enclosed ? YES ? NO
A Clinical Protocol is enclosed ? YES ? NO

OFFEROR'S ACKNOWLEDGMENT OF AMENDMENTS TO THE Solicitation (Use attachment if necessary)

ERRATA NUMBER	DATE	ERRATA NUMBER	DATE

NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY	NUMBER OF EMPLOYEES CURRENTLY EMPLOYED
	DOLLAR VOLUME OF BUSINESS PER ANNUM
	THIS OFFER EXPIRES _____ DAYS FROM THE DATE OF THIS OFFER (120 days if not specified)

FOR THE INSTITUTION

SIGNATURE OF PRINCIPAL INVESTIGATOR	SIGNATURE OF BUSINESS REPRESENTATIVE
TYPED NAME AND TITLE	TYPED NAME AND TITLE
EMPLOYER IDENTIFICATION NUMBER	DATE OF OFFER

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

(SUBMIT WITH BUSINESS PROPOSAL)

SUMMARY OF ANNUAL COSTS

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

Specific Instructions:

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

SUMMARY OF RELATED ACTIVITIES

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

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

Professional's Name and Title/Position: _____

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

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

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

Professional's Name and Title/Position: _____

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

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

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

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

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

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

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

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

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

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

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

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

DISCLOSURE OF LOBBYING ACTIVITIES

CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity:_____ Page _____ of _____

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

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

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (Solicitation) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "Solicitation-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

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

SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN:

CONTRACTOR: _____

ADDRESS: _____

_____

_____

DUNN & BRADSTREET NUMBER : _____

SOLICITATION OR CONTRACT NUMBER: _____

ITEM/SERVICE (Description): _____

TOTAL CONTRACT AMOUNT (Breakout Options): **$**_____ **$**_____

Total Contract Base-Year, if options	Option #1 (if applicable)	Option #2 (if applicable)	Option #3 (if applicable)	Option #4 (if applicable)
$_____	**$**_____	$_____	**$**_____	**$**_____

TOTAL MODIFICATION AMOUNT (If Applicable): _____

TOTAL TASK ORDER AMOUNT (If Applicable): _____

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

The following is a suggested model for use when developing subcontracting plans as required by P.L. 95-507 and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this model plan has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable; however, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. Further, the use of this model is not intended to waive other requirements that may be applicable under statute or regulation. "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.

Type of Plan (Check One)

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

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

___ Commercial product/service plan (Contractor sells large quantities of off-the-shelf commodities to many Government agencies. Plans/goals negotiated on a company, division, plant or product line basis reflecting projected annual sales for commercial and non-commercial items. Must be renewed annually and Contractor must provide copy of lead agency approval).

2. Goals

State separate dollar and percentage goals for Small Business Concerns (SB), Small Disadvantaged Business Concerns (SDB), Women-Owned Small Business Concerns, (WOSB), Historically Underutilized business Zone (HUBZone), Veteran-Owned Small Business Concerns (VOSB), Service Disabled Veteran-Owned Small Business (SDVOSB), and Other than Small Business Concerns (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 applicable) or project annual subcontracting base and goals under commercial plans.

Total estimated dollar value of **ALL** planned subcontracting, i.e., with ALL types of concerns under this contract, is $.

b. Total estimated dollar value and percent of planned subcontracting with **SMALL BUSINESS CONCERNS** (includes SDB, WOSB, and HUBZone): (% of "a")
$_____ and _____%

c. Total estimated dollar value and percent of planned subcontracting with **SMALL DISADVANTAGED BUSINESS CONCERNS**: (% of "a")
$_____ and _____%

d. Total estimated dollar value and percent of planned subcontracting with **WOMEN-OWNED SMALL BUSINESS CONCERNS**: (% of "a")
$_____ and _____%

e. Total estimated dollar value and percent of planned subcontracting with **HUBZone SMALL BUSINESS CONCERNS**: (% of "a")
$_____ and _____%

f. Total estimated dollar value and percent of planned subcontracting with **VETERAN-OWNED SMALL BUSINESS CONCERNS**: (% of "a")
$_____ and _____%

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

h. Total estimated dollar value and percent of planned subcontracting with **OTHER THAN SMALL BUSINESS CONCERNS**: (% of "a")
$_____ and _____%

i. Provide a description of ALL the products and/or services, to be subcontracted under this contract, and indicate the types of businesses supplying them: [i.e. (OTHER), (SB), (SDB), (WOSB), (HUBZone), (VOSB), (SDVOSB)].

	TYPE OF BUSINESS (Check all that Apply)						
Subcontracted Product/Service	**OTHER**	**SB**	**SDB**	**WOSB**	**HUBZone**	**VOSB**	**SDVOSB**

j. Provide a description of the method used to develop the subcontracting goals for small, small disadvantaged, women-owned, HUBZone, veteran-owned small business concerns, and service-disabled veteran-owned small business concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns. 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 small, small disadvantaged, women-owned, HUBZone, veteran-owned small business concerns, and service-disabled veteran-owned small business concerns were determined and how the capabilities of these concerns were considered for subcontract opportunities. Identify any source lists or other resources used in the determination process.

(Attach additional sheets, if necessary)

k. Indirect costs have been ___ have not been __ included in the dollar and percentage subcontracting goals stated above. (Check one)

If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to small, small disadvantaged, and women-owned, HUBZone, veteran-owned small business concerns, and service-disabled veteran-owned small business concerns.

Program Administrator

Name, title, and position within the corporate structure as well as duties and responsibilities of the employee who will administer the contractor's subcontracting program.

NAME: _____

TITLE: _____

ADDRESS: _____

_____

TELEPHONE/E-MAIL: _____

Duties: Has 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. Other duties include, but are not limited to, the following activities:

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to small, small disadvantaged, and women-owned, HUBZone, veteran-owned small business concerns, and service-disabled veteran-owned small business concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing;

b. Developing and maintaining bidders lists of small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business concerns from all possible sources.

c. Ensuring periodic rotation of potential subcontractors on bidder's lists.

Ensuring that requests for contracts (RFC) are designed to permit the maximum practicable participation of small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business concerns;

e. Using various sources for the identification of small, small disadvantaged, and women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business concerns to include the SBA's PRONET System, the Federal Acquisition Computer Network (FACNET) Contractor Registration Data Base, 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 agencys' Small Business Offices;

f Establishing and maintaining contract and subcontract award records;

g. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc.

h. Ensuring small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company;

i. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Public Law 95-507 on purchasing;

j. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals;

k. Preparing, and submitting timely, required subcontract reports;

l. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies, and;

m. Other duties

4. Equitable Opportunity

Describe efforts the offeror will make to ensure that small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business 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 small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business procurement conferences and trade fairs;

4) Requesting sources from the Small Business Administration's (SBA) PRONET, and, and other SBA resources, and;

5) Conducting market surveys to identify new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1) Presenting workshops, seminars, and training programs;

2) Establishing, maintaining, and using small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business source lists, guides, and other data for soliciting subcontracts, 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 subcontracts that offer 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." (FAR 19.704(a)(4)).

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 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 - Sep 30	SF-294	10/30
Oct 1 - Sep 30	SF-295	10/30

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

ADDRESSES

(a) SF-294 to be submitted to: cognizant Contracting Officer

(b) SF-295 to be submitted to cognizant Contracting Officer and to the following office:

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

(c) Submit "info" copy to SBA Commercial Market Representative (CMR); call SBA at (202) 205-6475 to locate CMR.

7. Recordkeeping

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. Small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business concerns source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business sources;

c. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation (1) whether small business concerns were solicited, and if not, why not; (2) whether small disadvantaged business concerns were solicited, if not, why not; (3) whether women-owned small business concerns were solicited, and if not, why not; (4) whether HUBZone small business concerns were solicited, and if not, why not; (5) whether veteran-owned small business concerns were solicited; (6) whether service-disabled veteran-owned small business concerns were solicited and (7) the reason for the failure of solicited small, small disadvantaged, women-owned, and HUBZone small business concerns to receive the subcontract award;

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 size of each subcontractor. (This item is not required for company or division-wide commercial products plans.)

g. Additional records:

SIGNATURE PAGE

THIS SUBCONTRACTING PLAN WAS SUBMITTED BY:

CONTRACTOR: _____

CONTRACTOR SIGNATURE: _____

TYPED NAME: _____

TITLE: _____

DATE PREPARED: _____

THIS PLAN (Check One): **[ ] INDIVIDUAL** **[ ] MASTER** **[ ] COMMERCIAL**

IS ACCEPTED BY:

FEDERAL AGENCY: _____

FEDERAL CONTRACTING OFFICER SIGNATURE: _____

TYPED NAME: _____

DATE: _____

PLEASE COMPLETE THE PLAN BELOW AND INCLUDE IT IN THE BUSINESS PROPOSAL

SMALL DISADVANTAGED BUSINESS PARTICIPATION PLAN OUTLINE

1. **The extent of an offeror's commitment to use SDB concerns. Commitment should be as specific as possible, i.e., are subcontract arrangements already in place, letters of commitment, etc. Specific SDB concerns must be identified with points of contact and phone numbers. Enforceable commitments will be weighted more heavily than non-enforceable ones. Targets expressed as dollars and percentage of total contract value for each SDB participating will be incorporated into and become part of any resulting contract. The extent of participation of all SDB concerns in terms of the value of the total acquisition must be identified. NOTE: Targets as expressed in dollars and percentages of total contract value will be judged based on findings of technical merit by the Technical Evaluation Committee, and on findings by the Contracting Officer that proposed costs are fair, reasonable, and realistic. Additional points will not be given simply for higher dollars or percentages of work going to SDBs.**

   RESPOND HERE:

2. **The complexity and variety of the work SDB concerns are to perform. Greater weight will be given for arrangements where the SDB shall be performing a greater variety of work, and work of greater complexity.**

   RESPOND HERE:

PROCUREMENT OF CERTAIN EQUIPMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) **Contract Number and Date:** Insert the contract number and the effective date of the contract.

(e) **Payee's Name and Address:** Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) **Total Estimated Cost of Contract:** Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) **Incurred Cost – Current:** Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the current period.

(j) **Incurred Cost – Cumulative:** Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(l) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. For Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(q) **Grand Totals**

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

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

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

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

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

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

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

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

(a) Billing Office Name and Address

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

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

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

(b) Invoice/Financing Request No.
_____

(c) Date Invoice Prepared
_____

(d) Contract No.
_____

Effective Date
_____

(f) Total Estimated Cost
_____

(g) Total Fixed Fee
_____

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

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

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

_____ (Name of Official)

_____ (Title)

* Attach details as specified in the contract

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of Clause)

MONTHLY SUMMARY OF SALES

CONTRACTOR:
CONTRACT NUMBER:
MODIFICATION NUMBER:
ATTACHMENT NUMBER:
MONTHLY SUMMARY OF SALES DATED:
MONTH OF INVOICE:

PAGE ___ OF ___ PAGES

Recipient	Items/ Qty.	Unit Cost	Shipping Cost	Total Billed	Total Collected	Balance Due	Days Late