

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

COLLABORATIVE PROGRAM TO ACCELERATE THERAPEUTICS DEVELOPMENT FOR
SPINAL MUSCULAR ATROPHY (SMA)

DATE ISSUED: April 22, 2003
DATE DUE: June 5, 2003

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-03-03.

THIS PROCUREMENT IS FOR FULL AND OPEN COMPETITION. WE ANTICIPATE THAT ANY RESULTANT AWARD 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.

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.

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

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

Your proposal must be received by the Contracting Officer at the following address, no later than 4:30 P.M. (local time) on June 5, 2003, at:

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

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

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

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

Your attention is directed to the solicitation provision entitled "LATE PROPOSALS AND REVISIONS" set forth in Section L, paragraph n, of this RFP, implemented by HHSAR 352.215-70. Please review these provisions so that you

will be fully aware of the time requirements for submitting your proposal. It is your responsibility to ensure that your proposal is delivered by the due date and time, and at the specific location (Room 3287) as required in the solicitation.

If you deliver your proposal in person, you will be required to provide photo identification and provide a name and telephone number of the individual being visited, (in this case, 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 proposal must be prepared in accordance with **Section L** entitled “Instructions, Conditions, and Notices to Offerors”, **Section C** entitled “Description/Specification/Work Statement”, and will be evaluated pursuant to **Section M** entitled “Evaluation Factors for Award”. Please be aware that in addition to hard copies, **Section L 1.a.** also requires you to submit a yearly and cumulative summary of your business proposal on a 3.5" diskette in Microsoft Excel[®] format.

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

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

Requests for any information concerning this RFP, and all questions should be referred only to Patricia S. Denney, Contracting Officer, 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

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

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1. Request For Proposal (RFP) Number: NIH-NINDS-03-03	2. Issue Date: April 22, 2003	3. Just in Time: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES See Part IV, Section L.	4. Set Aside: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES See Part IV, Section L.
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5. TITLE: COLLABORATIVE PROGRAM TO ACCELERATE THERAPEUTICS DEVELOPMENT FOR SPINAL MUSCULAR ATROPHY (SMA)
6. ISSUED BY:

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

7. SUBMIT OFFERORS TO:

The address noted in Item #6 to the left.

- 8.** Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the location specified above, and in the number of copies specified in Section L.1., GENERAL INFORMATION, paragraph (a), until **4:30 p.m.** (local time), **June 5, 2003**. 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: 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/currentfops.htm>. Individual notifications will not be provided.

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

PART I - THE SCHEDULE

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The specific objective of this contract is to establish an innovative translational research program to accelerate the development of a treatment for Spinal Muscular Atrophy (SMA). It is anticipated that the award from this solicitation will be a Performance-based contract.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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

ARTICLE C.2. REPORTING REQUIREMENTS

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

1. Monthly Progress Reports

The contractor shall describe the activities during the reporting period, and the activities planned for the ensuing reporting period. This report shall include a summary and schedules of solicitations released, proposals received, proposals reviewed, and subcontract awards in progress and completed. In addition, for each current subcontract project, the report shall include the following: (1) a description of overall progress within each current subcontract, how that progress corresponds to planned milestones, and measures taken to correct any lack of milestone achievement, (2) an indication of any current problems that may impede performance, and proposed corrective action, (3) justification for discontinuation of any subcontract, if appropriate, (4) a discussion of the work to be performed during the next reporting period and (5) any recommendations. Monthly reports are not due in the final month of the quarter. As with the Quarterly and Annual Progress Reports, these reports will be submitted electronically to the Contracting Officer and Project Officer.

2. Quarterly Progress Reports

This report shall include a summation of the monthly progress reports, including the final month of the quarter, and a full report for the final month of the quarter in the format of the monthly progress reports. This report shall be in sufficient detail to comprehensively describe the results achieved.

3. Other Reports:

Annual Progress Reports

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

Receipt of Proposal Reports

Within 1 week of the receipt date for proposals for any solicitation for research proposals released under the contract, a report of proposals received will be submitted electronically. This report may be in spreadsheet form and shall include for each proposal:

- a. Name of Organization
- b. Proposal Identification Number
- c. Principal Investigator Name
- d. Proposal Title
- e. Dollar Amount of Funds Requested
- f. Proposal Receipt Date

Reports of Upcoming Reviews

For the scientific review of proposals, reports of upcoming reviews shall identify the reviewer assignments for each proposal and the date, time and venue for the review meeting. These reports shall be submitted within 2 weeks of the receipt of proposals.

Reports of Proposal Review Results

Reports of the proposal review proceedings shall be submitted within 1 week of the review meeting. For each proposal, this report shall include a summary of strengths and weaknesses, a statement of relatedness to the strategic plan for SMA therapeutics development, and any recommendations for revision or withdrawal from further consideration. This report will include a list of proposals that is considered appropriate for subcontract award, pending negotiation and discussion with the Steering Committee and the Project Officer, and will indicate any deficiencies of the proposed subcontract(s) with respect to achieving the goals of the original solicitation.

Subcontract Award Notification

Immediately upon the award of a subcontract, the Contractor shall electronically notify the Contracting Officer of the award. In this notification, the subcontract will be identified by Project Identification Number, Principal Investigator Name, Name of Organization who Received Subcontract Award, and Project Title.

Individual Subcontract Reports

Upon the completion of each subcontract, a report of the results of that project will be submitted. These reports shall be submitted within 1 week after completion of the subcontract. In addition to the complete reporting of the data developed under the subcontract, this report shall include the following: (1) the goal of the project and milestones for achieving this goal, (2) planned schedule of achievement of project milestones, and (3) actual schedule of achievement of project milestones.

4. **Final Report**

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

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

The contractor shall provide the Contracting Officer with copies of the final report in draft form 60 CALENDAR days prior to the delivery date for the final version of the final report. The Project Officer shall review the draft report and provide the Contracting Officer with comments within 30 CALENDAR days after receipt. The final report shall be corrected by the contractor, if necessary, and the final version delivered in accordance with Section F, Deliveries or Performance, of the contract.

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

<u>Reports</u>	<u>Period Covered</u>	<u>Due Date</u>
(1) Monthly Report	1/1-1/31	2/10
	2/1-2/29	3/10
	4/1-4/30	5/10
	5/1-5/31	6/10
	7/1-7/31	8/10
	8/1-8/31	9/10
	10/1-10/31	11/10
	11/1-11/30	12/10
(2) Quarterly Report	1/1-3/31	4/10
	4/1-6/30	7/10
	7/1-9/30	10/10
	10/1-12/31	1/10
(3) Other Reports:		
Annual Report	1/1-12/31	1/31
Report of Proposals Received	to be determined	1 week after receipt deadline
Review Schedule Report	to be determined	2 weeks after receipt deadline
Proposal review results	to be determined	1 week after review
Subcontract award notification	to be determined	upon award
Individual Subcontract Reports	to be determined	1 week post completion
(4) Final Report:		
Draft Final Report	duration of contract	60 days before last day of contract
Final Report	duration of contract	last day of contract

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR CLAUSE 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301/435-1986). In addition, one copy of 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 on the expiration date of the contract to the Contracting Officer, whose address will be identified in the resultant contract

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

SECTION D - PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. PACKAGING, MARKING, AND SHIPPING

- a. All deliverables required under this contract shall be packaged, marked, and shipped in accordance with the Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.
- b. Packaging
 1. For the purpose of reports, "immediately usable and acceptable condition" includes securing the pages together in a suitable and reasonable manner to be agreed upon by the Contractor and the NINDS Project Officer.
 2. Boxes and/or other types of outer packaging, i.e., containers, wraps, etc., shall be suitable to the type of items being transmitted; and the mode of transportation utilized shall assure that such materials be received in an acceptable condition.
- c. Marking

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

 1. Project Title: "Collaborative Program to Accelerate Therapeutics Development for Spinal Muscular Atrophy (SMA)"
 2. Contract Number:
 3. Name of Contractor:
 4. Name of Principal Investigator:
- d. Shipping

Shipping shall be accomplished by reasonable and suitable means to be mutually agreed upon by the Contractor and the NINDS Project Officer.
- e. See SECTION F for delivery information.

SECTION E - INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or a duly authorized representative shall perform inspection and acceptance of all deliverables and services to be provided.
- b. For the purpose of this SECTION, the NINDS Project Officer designated in ARTICLE G.2. is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance of contract work/deliverables shall be performed at the National Institute of Neurological Disorders and Stroke (NINDS), NIH, 6001 Executive Boulevard, Suite 2229, MSC 9527, Bethesda, Maryland 20892-9527, (for courier service: Rockville, MD 20852). Inspection and acceptance shall be performed using quarterly progress reports, other required reports, and the final report. Site visits will also be employed for this purpose. Acceptance of work and/or report deliverables may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within thirty (30) days of receipt.
- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. TERM OF CONTRACT

The contract term is from _____ through _____.

ARTICLE F.2. DELIVERIES

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

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

<u>Item</u>	<u>Description</u>	<u>Reporting Period</u>	<u>Delivery Schedule</u>
(1)	Monthly Progress Report (refer to ARTICLE C.2.)	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.2.)	January 1 – March 31 April 1 – June 30 July 1 – September 30 October 1 – December 31	April 10 July 10 October 10 January 10
(3)	Other Reports: (refer to ARTICLE C.2.) Annual Report Report of Proposals Received Review Schedule Report Proposal Review Results Subcontract Award Notification Individual Subcontract Reports	01/01 – 12/31 To be determined To be determined To be determined To be determined	01/31 One week after receipt deadline Two weeks after receipt deadline One week after review Upon Award One week post completion
(4)	Draft Final Report and Final Report (refer to ARTICLE C.2.)	Duration of contract and Duration of contract	Sixty (60) days before last day of contract. Last day of contract.

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

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

This contract incorporates the following clause by reference with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.amet.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.7 of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. 108-7 and ARTICLE H.7. of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

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

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

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

ARTICLE G.5. GOVERNMENT PROPERTY

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

ARTICLE G.6. POST AWARD EVALUATION OF PAST PERFORMANCE

a. Contractor Performance Evaluations

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

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at <http://grants1.nih.gov/grants/olaw/references/phso1.htm>

ARTICLE H.4. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

- | | | | |
|----|--|---------------------------|------------------------------|
| b. | <u>Public Law and Section No.</u> | <u>Fiscal Year</u> | <u>Period Covered</u> |
| | 108-7, Division G, Title V-
General Provisions, Section 510 | 2003 | 10/01/2002 – 09/30/2003 |

ARTICLE H.5. SUBCONTRACTING PROVISIONS

- a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

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

The Contractor shall submit the original and one (1) copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

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

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

(2) Summary Subcontract Report, SF-295

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

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

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 517-D
200 Independence Avenue, S.W.
Washington, D.C. 20201

- (3) The Contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 606-4000, x234 for the correct address if unknown.

ARTICLE H.6. NEEDLE EXCHANGE

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

b.	<u>Public Law and Section No.</u> 108-7, Division G, Title V- General Provisions, Section 505	<u>Fiscal Year</u> 2003	<u>Period Covered</u> 10/01/2002 – 09/30/2003
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ARTICLE H.7. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

b.	<u>Public Law No.</u> 108-7, Division G, Title II - General Provisions, Section 204	<u>Fiscal Year</u> 2003	<u>Dollar Amount of Salary Limitation*</u> Executive Level I
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* For contract expenditures using FY-03 funds, the period 10/1/02 – 12/31/02 the Executive Level I rate is \$166,700. Effective 1/1/03, for contract expenditures using FY-03 funds, the Executive Level I rate is increased to \$171,900 and will remain at the level until such time as it is determined to raise the Executive Schedule annual rates. See the web site listed below for Executive Schedule rates of pay.

LINK to EXECUTIVE LEVEL SALARIES: <http://www.opm.gov/oca/PAYRATES/indix.htm>
(Click on “Executive Schedule” for the current Fiscal Year’s salary rate or scroll down to the “General Schedule Salary Tables from Previous Years” to locate the Executive Level salary rates from previous years.)

ARTICLE H.8. PUBLICATION AND PUBLICITY

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

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

ARTICLE H.9. PRESS RELEASES

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

b.	<u>Public Law No. and Section No</u> 108-7, Division G, Title V - General Provisions, Section 507	<u>Fiscal Year</u> 2003	<u>Period Covered</u> 10/01/2002 – 09/30/2003
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ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.11. ANTI -LOBBYING

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall 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.	<u>Public Law and Section No.</u>	<u>Fiscal Year</u>	<u>Period Covered</u>
	108-7, Section 503 (a) Division G, Title V- General Provisions	2003	10/01/2002 – 09/30/2003
	108-7, Section 503 (b) Division G, Title V- General Provisions	2003	10/01/2002 – 09/30/2003

ARTICLE H.12. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

ARTICLE H.13. YEAR 2000 COMPLIANCE

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

- a. Service Involving the Use of Information Technology

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

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

ARTICLE H.14. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

The Contractor agrees to comply with the Information Technology (IT) systems security and/or privacy specifications set forth in the Statement of Work (SOW); the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS Automated Information Systems Security Program (AISSP) Handbook. The Contractor further agrees to include this provision in any subcontract awarded pursuant to this prime contract. Failure to comply with these requirements shall constitute cause for termination.

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

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

Contractor Certification of IT Systems Security Training

- a. The Contractor shall certify in writing to the Project Officer that each Contractor employee shall, at a minimum, complete the following NIH Computer Security Awareness Training course prior to performing work under the contract: <http://irtsectraining.nih.gov/>

Additional security training commensurate with the position may be required as defined in OMB Circular A-130, Appendix III B., 2, b., or in NIST Special Publication 800-16, "Information Technology Security Training Requirements."

- b. Position Sensitivity Designations

The Project Officer and the Information Systems Security Officer have determined that the following position sensitivity designation applies under this contract:

Level 1C: Non-Sensitive (Suitability Determination with an NACI)

Contractor employees in AIS-related positions shall comply with the DHHS criteria for assigning position sensitivity designations.

Contractor employees assigned to a Level 6C (High Risk) position are subject to a Background Investigation (BI). Contractor employees assigned to a Level 5C (Moderate Risk) position, with no previous investigation and approval, shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI). Contractor employees assigned to a Level 1C position (Non-sensitive, i.e. Low Risk) shall be subject to a National Agency Check and Inquiry Investigation (NACI).

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

The following table summarizes investigation requirements by position risk level.

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

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

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

c. Contractor Agreement -- Commitment to Protect Privileged Information

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

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

d. Contractor Employee Non-Disclosure Agreement (**To be completed prior to award**).

Each Contractor employee who may be involved in the performance of this contact shall be required, as a condition of award, to complete the Non-Disclosure Agreement and submit it to the Project Officer. **See Section J, Attachment #5.**

Note that the following documents are electronically accessible:

- (1) OMB A-130, Appendix III:
<http://csrc.ncsl.nist.gov/secplcy/a130app3.txt>
- (2) DHHS AISSP Handbook:
<http://irm.cit.nih.gov/policy/aissp.html>

ARTICLE H.15. 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.

ARTICLE H.16. SHARING RESEARCH DATA

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

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

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

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

ARTICLE H.17. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

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.amet.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	Dec 2002	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.219-8	Oct 2000	Utilization of Small Business Concerns
FAR	52.219-9	Jan 2002	Small Business Subcontracting Plan
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	Apr 2002	Equal Opportunity
FAR	52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-14	Oct 2000	Toxic Chemical Release Reporting
FAR	52.225-1	May 2002	Buy American Act - 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.

Reg	Clause	Date	Clause Title
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	Jul 2002	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2001	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
FAR	52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.245-5	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
HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.216-72	Oct 1990	Additional Cost Principles
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS AND MODIFICATIONS OF CLAUSES

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

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

FAR 52.204-2, Security Requirements (AUGUST 1996), Alternate I (APRIL 1984)

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

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

- Offeror elects to waive the evaluation preference.

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

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

FAR 52.227-14, Rights in Data – General (JUNE 1987).

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

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

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

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

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

HHSAR 352.270-9 Care of Laboratory Animals (SEPTEMBER 1985).

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 Commercial Components (APRIL 2003)

(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 items 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, 15 pages.
2. Government Notice for Handling Proposals, 1 page.
3. Proposal Intent Response Sheet, 1 page.
4. NIH Form 1688-1, Project Objectives, 1 page.
5. Contractor Employee Non-Disclosure Agreement, 1 page.
6. National Institutes of Health Customer Survey of Contractor Performance, 5 pages.
7. Example, Request for Past Performance Information, 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).

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

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

9. NIH-2043, Proposal Summary and Data Record, 2 pages.
10. Summary of Annual Costs (BUSINESS PROPOSAL), 1 page.
11. Summary of Related Activities, 1 page.
12. SF-LLL, Disclosure of Lobbying Activities, 3 pages.
13. Small Business Subcontracting Plan Format, 8 pages.
14. Small Disadvantaged Business (SDB) Participation Factor, 1 page.

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

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

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

PART IV - REPRESENTATIONS AND INSTRUCTIONS

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

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

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

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. PACKAGING AND DELIVERY OF PROPOSAL

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

Proposals for furnishing the supplies and/or services in the SCHEDULE will be accepted at the location specified in (3) below, and in the number of copies specified in (1) below, **until 4:30 p.m. (local time), June 5, 2003**. 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-03-03

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 offeror's travel policy, total compensation plan and small business

subcontracting plan 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 management 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, 2003. Depending upon the type of organization selected for contract award, it is anticipated that the award from this solicitation will be a multiple-year Performance-based Cost-Plus Award Fee type contract, **OR**, a Performance-based Cost Type contract.

The overall purpose of Performance Based Contracts is to provide a strong incentive and maximum flexibility for the Contractor to achieve superior performance, allowing the Contractor flexibility in performing the work, and encouraging cooperation with the Government. 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 four (4) years. See SECTION C.1., for the description of the Performance Standards and Quality Assurance Surveillance Plan applicable to this requirement. It is also anticipated that incremental funding will be used for this contract (see Section L.2. (c) - Business Proposal Instructions).

g. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 15,392 labor hours. This information is furnished for the offeror’s information only and is not to be considered restrictive for proposal purposes.

Labor Category	Yr 1	Yr 2	Yr 3	Yr 4	Totals
Professional	1,664	1,664	1,664	1,664	6,656
Other Professional	1,040	1,040	1,040	1,040	4,160
Support	1,144	1,144	1,144	1,144	4,576
Totals	3,848	3,848	3,848	3,848	15,392

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.

I. 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, 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. **The “technical discussion” portion of your proposal should not exceed 50 pages. This 50 page limit applies to the technical discussion portion of your proposal, i.e., proposed information in response to Sections (1)(a), Project Objectives; (b) Statement of Work; (c) Personnel; (2) Additional**

Technical Proposal Information; (3) Other Considerations; and (4) Information Technology Systems Security; excluding resumes themselves.

To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

(4) Separation of Technical and Business Proposals

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

(5) Alternate Proposals

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

(6) Evaluation of Proposals

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

(7) Potential Award Without Discussions

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

(8) Use of the Metric System of Measurement

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

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

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

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

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

(9) Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects – (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Human Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I – Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies of the PHS Policy are available at (301) 402-2803. This policy is also available on the Internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

b. The following information must be included in the offerors technical proposal:

- identification of the species and approximate number of animals to be used;
- rationale for involving animals, and for the appropriateness of the species and numbers used;
- a complete description of the proposed use of the animals;

- a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- a description of any euthanasia method to be used.

c. If an Animal Assurance is already in place, the offeror's proposal shall include:

- The Animal Welfare Assurance number.
- The date last certified by OLAW. (i.e. assurance letter from OLAW)
- Evidence of recent AAALAC Accreditation.

(End of provision)

(10) 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.

(11) 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.

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

(12) Selection of Offerors

- a) The acceptability of the technical portion of each research contract proposal will be evaluated by a technical review panel. The panel will evaluate each technical proposal in strict conformity with the technical evaluation criteria of the RFP, utilizing point scores and written critiques. The panel may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost realism and/or a cost analysis.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-
 - (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

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

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

While it is NINDS' policy to conduct discussions with all offerors in the competitive range, NINDS reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the

conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This 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 on the FedBizOpps web stie.

(13) Small Business Subcontracting Plan

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

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

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

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c) The offeror understands that:
 - (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 - (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, 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.

(14) HUBZone Small Business Concerns

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

(15) Extent of Small Disadvantaged Business Participation

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

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

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

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

Offerors shall include with their offers, SDB 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.

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

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. 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.

(17) Salary Rate Limitation in Fiscal Year 2003

Offerors are advised that pursuant to P.L. 108-7, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-7 applies only to Fiscal Year 2003 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-7 states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES:

<http://www.opm.gov/oca/PAYRATES/index.htm>

Note to Offerors: If this award is made in Fiscal Year 2004, the current Fiscal Year 2003 Salary Rate Limitations should be adhered to in the preparation of your proposal. All costs associated

with any resultant contract award will be required to be in compliance with the current Fiscal Year 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate Limitations.

(18) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
 - (1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
 - (2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
 - (3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

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

Institutional Management of Conflicting Interests

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

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

- i) public disclosure of significant financial interests;
 - ii) monitoring of research by independent reviewers;
 - iii) modification of the research plan;
 - iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
 - v) divestiture of significant financial interests; or
 - vi) severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(19) ROTC Access and Federal Military Recruiting on Campus

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

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

(20) Past Performance Information

Offerors shall mail the Past Performance Information Survey to at least five previous clients (see Section J, Attachment 6) using the criterion below for selection of clients. In addition, offeror's shall submit the following information in their proposal (for both the offeror and proposed major subcontractors). Attachment 7 may be used to request past performance information from previous clients.

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

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

Include the following information for each contract or subcontract:

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

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

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

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

(21) Electronic and Information Technology Accessibility

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

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

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

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

(22) 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)
- (e) Preaward On-Site Equal Opportunity Compliance Evaluation, FAR Clause 52.222-24, (February 1999)

(23) Sharing Research Data

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

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

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 “technical discussion” portion of your proposal should not exceed 50 pages. This 50 page limit applies to the technical discussions portion of your proposal, i.e., proposed information in response to Sections (1)(a), Project Objectives; (b) Statement of Work; (c) Personnel; (2) Additional Technical Proposal Information; (3) Other Considerations; and (4) Information Technology Systems Security; excluding resumes themselves.**

The offeror must:

- Implement the SMA therapeutics development research plan through the solicitation and scientific evaluation of research proposals and award of research subcontracts.
- Monitor and manage the scientific progress of the subcontracted research projects to insure the timely completion of milestones.
- Coordinate and integrate the results of subcontracted projects to assure efficient execution of the overall strategic plan.

1. Technical Discussions

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

(a) Project Objectives, NIH-1688-1

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

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

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

(b) Statement of Work

i) Objectives

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

ii) Approach

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

iii) Methods

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

iv) Schedule

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

c) Personnel

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

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

i) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be

spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

ii) Other Investigators

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

iii) Additional Personnel

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

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

iv) Resumes

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

2. 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.

3. Other Considerations

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

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.

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

4. Information Technology Systems Security

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

(1) Category of Safeguarded Information

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

(2) Security Level Designations

Level 2 applies to the sensitivity of the data contained in the AIS and **Level 2** applies to the operational criticality of the data processing capabilities of the AIS. The overall security level designation is **Level 2**.

(3) Position Sensitivity Designations

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

Level 1C: Non-Sensitive (Suitability Determination with an NACI)

Contractor employees assigned to a Level 6C (High Risk) position are subject to a Background Investigation (BI). Contractor employees assigned to a Level 5C (Moderate Risk) position, with no previous investigation and approval, shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI). Contractor employees assigned to a Level 1C position (Non-sensitive, i.e. Low Risk) shall be subject to a National Agency Check and Inquiry Investigation (NACI).

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

The following table summarizes investigation requirements by position risk level.

<u>Required Investigation by Position Risk Level</u>		
<u>Level</u>	<u>Description</u>	<u>Required Investigation</u>
6C	Public Trust (High Risk)	BI
5C	Public Trust (Moderate Risk)	NACIC (or LBI)

4C/3C	Special Access/Top Secret	SSBI
2C	Secret/Confidential Access	LBI
1C	Non-sensitive (Low Risk)	NACI

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

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

- b) The offeror's proposal must include:
- (1) A detailed outline (commensurate with the size and complexity of the requirements of the SOW) of its present and proposed Information Technology systems security program and demonstrate that it complies with the AISSP security requirements of the SOW, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook. At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements of a **Security Level Designation 2** identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards.
 - (2) An acknowledgement of its understanding of the security requirements in the SOW.
 - (3) Similar information for any proposed subcontractor having access to an AIS.

5. 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).

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 four (4) years. See SECTION C.1., Statement of Work, section 3, for the description of the Performance-based Evaluation and Quality Assurance Plan applicable to this requirement.

(2) Proposal Cover Sheet

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

- (a) Solicitation, contract, and/or modification number;
- (b) Name and address of Offeror;
- (c) Name and telephone number of point of contact;
- (d) Name, address, and telephone number of Contract Administration Office, (if available);
- (e) Name, address, and telephone number of Audit Office (if available);
- (f) Proposed cost and/or price; profit or fee (as applicable); and total;

- (g) The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
- (h) Date of submission; and
- (i) Name, title and signature of authorized representative.

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

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

(3) Information Other than Cost or Pricing Data

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

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

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

- 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**

- Research subcontracts are those subcontracts awarded under any resultant contract that are directly related to the NINDS' research goal for Spinal Muscular Atrophy, i.e., to efficiently translate a mechanistic understanding of SMA into a testable therapy suitable for clinical trials. Management subcontracts are all other subcontracts issued under any resultant contract. The Government intends to fund research subcontracts at a level of \$4.5 million per year. The Government anticipates that this amount will support approximately ten (10) research subcontracts. The offeror shall use the Government's estimate in preparing its proposal for research subcontracts. For management subcontracts the offeror shall include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each management subcontract over \$550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price,

as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

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(1), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

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

The format specified in paragraph L.2.c.(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.

(6) **Other Administrative Data**

a) **Property**

- (1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:
 - (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
 - (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) Royalties

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

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

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

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

d) Financial Capacity

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

e) Incremental Funding

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

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.

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

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

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

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

(9) **Representations and Certifications**

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

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

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

B. TECHNICAL EVALUATION CRITERIA

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

1. Understanding the Requirement

35 points

The proposal must demonstrate a thorough understanding of the specific tasks and deliverables described in the Statement of Work and describe an approach that will achieve timely and acceptable performance. The offerors' understanding of the RFP objectives and their ability to achieve these is demonstrated by the presentation of a comprehensive statement of the scope and purpose of the project and the quality of the proposed plan to achieve the project goals. Critical factors include:

- Quality and efficiency of the proposed plan to establish the SMA Research Program through the identification and award of research subcontracts combining high technical merit and responsiveness to the strategic plan.
- Quality of the proposed plan to manage the SMA Research Program through the aggressive monitoring, evaluation and facilitation of research progress within subcontracts.
- Quality of the proposed plan to correct any problems that may arise in the course of the subcontracted research projects, including a scientific plan to identify the need to add, replace, or remove scientific subcontractor(s), dependent on progress or changes in scientific direction.
- Quality of the proposed plan to maximize the overall efficiency of identifying a therapy for SMA, including integrating the results of individual subcontracts and by the anticipation and timely initiation of projects that are further along in the path to therapeutics development.

2. Qualifications and Availability of Proposed Personnel

35 points

The proposal must demonstrate the training, experience and availability of the proposed professional, technical and administrative staff. This includes documentation of their ability to perform their roles in the proposed program,

their expertise in similar projects and the availability of the staff to commit time to this project. The evaluation of the qualifications and availability of the proposed personnel will have the following point weights:

- a. Scientific Staff (20 points). This includes the project manager, the scientist responsible for peer review of proposals and the additional PhD level staff. In addition to broad and sophisticated scientific capabilities, the project manager should be a high level member of the organization with demonstrated ability in pre-clinical research management. The scientist coordinating the peer review of proposals must have extensive experience conducting peer review and demonstrate a high level of scientific maturity and judgment. Sufficient additional PhD level staff must be available to provide expertise in defined areas of therapeutics development for subcontract management throughout the course of the program. Factors for evaluation of ability to achieve performance requirements include *curriculum vitae*, statements of reference, prior experience in pre-clinical research direction and management, and availability.
- b. Technical Staff (10 points). This includes individuals such as the scientific analyst, information systems analyst, science writer and subcontract manager. These individuals may be evaluated on the basis of *curriculum vitae*, prior experience in assigned area of work, and availability.
- c. Administrative Staff (5 points). This includes the staff providing office and conference support services.

3. Managerial Capability

20 points

The proposal must demonstrate the ability to achieve the performance requirements as demonstrated by the proposed use of management and other personnel resources. The proposal should demonstrate the ability to successfully manage the project, including subcontractor and/or consultant efforts, as evidenced by the management plan and demonstrated by previous experience.

4. Offeror Facilities and Resources

10 points

The proposal must demonstrate the availability and adequacy of facilities, equipment and resources necessary to carry out all phases of the proposed projects.

C. PAST PERFORMANCE

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

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken. The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

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

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

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

D. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTOR

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

Evaluation of the SDB Participation Factor will be assessed based on consideration of the information presented in the offeror's proposal. We request that offeror's provide the "Participation Factor" information on the attached form "Small Disadvantaged Business (SDB) Participation Plan", see Attachment Number 14 to the RFP. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

The offeror's overall SDB Participation Factor will be evaluated by the following two sub-factors:

- 1) Extent of commitment to use SDB concerns in performance of the contract (in terms of dollars and percentage of total contract value (maximum 3 points); and
- 2) The complexity and variety of work to be performed by SDB concerns (maximum 2 points).

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

OTHER NON-SCORED FACTOR

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

STATEMENT OF WORK

Collaborative Program to Accelerate Therapeutics Development for Spinal Muscular Atrophy (SMA)

1. Introduction

1.1 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. Provides individual and institutional fellowships to increase scientific expertise in neurological fields.
- Operates a program of contracts for the funding of research and research support efforts in selected areas of institute need.
- 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.

NINDS has targeted Spinal Muscular Atrophy (SMA) for a pilot program in accelerated therapeutics development. SMA is a devastating neurological disease of childhood for which no effective treatment is currently available. SMA causes degeneration of motor neurons in the spinal cord and brainstem, leading to muscle weakness and, in severe forms of the disease, death. It is the most severe of the common genetic neurological diseases and is the leading heritable cause of infant death. SMA is an ideal candidate for targeted therapeutics development. It is caused by the loss of function of a known gene, SMN1. Thus, there are tractable strategies for developing treatments based on replacement of the lost function. Multiple therapeutic avenues are available, including drug development, gene therapy and stem cell therapy.

1.2 Objectives

NINDS' research goal for Spinal Muscular Atrophy is to efficiently translate a mechanistic understanding of SMA into a testable therapy suitable for clinical trials. The NINDS strategy for achieving its research goal is to fund parallel therapeutic pathways in a rapid milestone-driven process that will identify a promising therapeutic candidate.

The overall objective of this contract is to conduct an innovative translational research program to achieve the NINDS goal of identifying a treatment for SMA. This research program will be guided by a strategic plan that will be developed by the NINDS with input from a NINDS-appointed Steering Committee. The contractor shall creatively implement the strategic plan through the establishment and management of a collaborative research program. As a first step in this process, specific topics for research project solicitations consistent with the strategic plan will be identified by NINDS with input from the Steering Committee and the Contractor selected for award. Through the development and issuance of solicitations in these areas, the Contractor will identify the researchers most capable of carrying out the goals of the solicitation. The contractor shall solicit research proposals, conduct scientific peer review of the proposals received, and recommend to NINDS the award of specific proposals as subcontract awards.

In addition to establishing the research program, the Contractor will foster the efficient implementation of the strategic plan by closely monitoring the course of the subcontracted research projects and assuring their timely completion. Further, the contractor will integrate the results of research projects focused on individual elements of the strategic plan such that the overall course of research flows smoothly. Through the activities of the contractor, with ongoing advice of the Steering Committee, parallel research avenues

for therapeutics development will be pursued in a rapid, coordinated, milestone-driven process to identify a therapy suitable for clinical trials. The result will be a fast and focused research program targeted to the rapid identification of a treatment for SMA. To be successful in identifying a treatment for SMA, the Contractor must be actively engaged in and committed to the evolution of the strategic plan, and this project will require a high level of scientific expertise and experience on the part of the Contractor. Furthermore, efficient progress will involve an unusual degree of acceleration and integration of multiple research projects, and thus success will also require that the Contractor use creativity and flexibility in applying that scientific expertise.

2. Scope

Independently and not as an agent of the Government, the Contractor shall provide scientific, administrative, and other resources and expertise as required to implement and accelerate therapeutics development for Spinal Muscular Atrophy (SMA) by performing the following tasks:

- The contractor shall implement the SMA therapeutics development research plan through the solicitation and scientific evaluation of research proposals and award of research subcontracts.
- The contractor will monitor and manage the scientific progress of the subcontracted research projects to insure the timely completion of milestones.
- The contractor will coordinate and integrate the results of subcontracted projects to assure efficient execution of the overall strategic plan.

Clinical testing of potential therapies that may be identified under this program are outside the scope of this contract and will be undertaken through other means, including the NINDS clinical trials program.

2.1. Contractor Furnished Resources

The Contractor shall furnish all necessary labor, services, equipment, materials and supplies required for the performance of work under this contract.

3. Performance Standards

The following chart reflects the major performance requirements and standards applicable to any subsequent award. These requirements and standards will serve as the basis for all award fee/incentive determinations under any resultant contract.

PERFORMANCE STANDARDS

<u>Required Performance</u>	<u>Performance Standards</u>	<u>Method of Surveillance</u>	<u>Rating Scale</u>
<p>Contractor's management effort results in the efficient execution and implementation of the overall strategic plan to identify testable SMA therapies.</p> <p>Contractor's ability to avoid undue delays in execution of the strategic plan in moving from one research initiative to the next.</p> <p>(see section 3.2 below)</p>	<p>Contractor advertises research initiatives for sequential areas of the strategic plan as identified without undue delays.</p> <p>Contractor issues Requests for Proposals within 30 days of receiving technical direction from the Project Officer or the Contracting Officer, after the specific research initiative is identified and approved.</p>	<p>Review of contract deliverables by Project Officer and Contracting Officer, including reports specified in sections 3.4.1, 3.4.2, 3.4.3 and 3.4.9 below.</p> <p>Date of issuance of solicitation will be the date of posting in FedBizOpps.</p>	<p>Excellent = Contractor issues Requests for Proposals in less than 30 days.</p> <p>Satisfactory = Contractor issues Requests for Proposals in 30 days.</p> <p>Unacceptable = Contractor issues Requests for Proposals in more than 30 days.</p>
<p>Contractor's management effort results in the timely achievement of research milestones that support the NINDS goal of efficiently translating a mechanistic understanding of SMA into testable therapies.</p> <p>(see section 3.2 below)</p>	<p>Contractor's ability to obtain subcontractor's compliance with the terms and conditions of the research subcontracts, with specific emphasis to include, but not limited to timely achievement of research objectives, performance/delivery schedules and cost.</p>	<p>Review of subcontract progress and contract deliverables by Project Officer and Contracting Officer, including reports specified in sections 3.4.1, 3.4.2, 3.4.3 and 3.4.8 below.</p>	<p>Excellent = All subcontracts are compliant with terms and conditions of the subcontract award.</p> <p>Satisfactory = At least one half of the subcontracts are compliant with terms and conditions of the subcontract award.</p> <p>Unacceptable = Less than one half of subcontracts are compliant with terms and conditions of the subcontract award.</p>
<p>Recommended subcontractor proposals demonstrate high potential to support the NINDS goal of efficiently translating a mechanistic understanding of SMA into testable therapies.</p> <p>(see section 3.1 below)</p>	<p>Contractor provides the Project Officer with source selection documentation that allows the Project Officer to identify proposals that are most relevant to the goals of the solicitation and the strategic plan.</p>	<p>Review of source selection and consent documentation by Project Officer and Contracting Officer. Compliance with requirements as stipulated by FAR, Part 44. Documentation shall be provided in the reports specified in sections 3.4.1 and 3.4.6 below.</p>	<p>Excellent = Quality and scientific appropriateness of proposal evaluation documentation for all cases are fully compliant.</p> <p>Unacceptable = Documentation that is less than fully compliant earns no award fee.</p>
<p>Timely award of research subcontracts.</p> <p>(see section 3.1 below)</p>	<p>Contractor awards subcontracts in four (4) months or less from the time proposals are received.</p> <p>The 4-month time period will exclude any Government review, approval, consent time.</p>	<p>Review of contract report deliverables by Project Officer and Contracting Officer. Date of subcontract award will be determined by receipt of the report specified in sections 3.4.1 and 3.4.7</p>	<p>Excellent = Awards made in less than 4 months.</p> <p>Satisfactory = Awards made in 4 months.</p> <p>Unacceptable = Awards made longer than 4 months.</p>

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3.1. Implementation of a Research Plan

The contractor shall establish the SMA therapeutics development research program through the award of research sub-contracts for work in research areas identified by the Project Officer. The required elements of this aspect of the contract are described in this section. Additional ideas and information that may assist the offeror in preparing a proposal can be found in Section 7, Notes and Guidance.

A Steering Committee with expertise in therapeutics development will be appointed by NINDS and its activities will be coordinated and supported by the contractor. This committee will assist in devising a strategic plan with critical paths for SMA therapeutics development. These critical paths may be in such areas as drug development, gene therapy or stem cell therapy. Pursuing multiple pathways simultaneously will allow the application of innovative strategies while accommodating the risk that any individual strategy is unsuccessful. The Steering Committee and the Contractor will assist the Project Officer in identifying areas in which to solicit research that are responsive to the strategic plan. It is likely that the strategic plan for SMA therapeutics development will have been devised at the time this contract is awarded. However, the solicitations for research to implement the plan will be developed and issued under the contract.

The NINDS Project Officer, with input from the Steering Committee and the Contractor, shall identify scientific areas of the strategic plan for which to solicit research proposals. The Contractor shall develop solicitations for research proposals within these areas that include a description of research goals and evaluation criteria for scientific peer review. The Contractor shall broadly advertise these solicitations to the commercial, academic and not-for-profit research communities. The Contractor shall arrange and conduct the scientific peer review of these proposals. In addition to scientific merit, cost, and schedules, the programmatic relevance, creativity and originality of proposals are significant factors to the NINDS. The Contractor shall include evaluation criteria appropriate to these factors in proposal solicitations and document its assessment of these proposal qualities in all award selection recommendations. Performance milestones shall be identified in all proposals and research subcontracts. These milestones will be proposed by offerors in their proposals and will be subject to technical evaluation, pre-award negotiation, and, at the time of subcontract award, consent of the NINDS Project Officer. Based on the peer review and on the scientific judgment of the Contractor, the Contractor shall make initial subcontract award recommendations. These initial recommendations will include an evaluation of all proposals that are considered competitive for award based on the evaluation criteria and relevance to the strategic plan. These recommendations shall be presented to the Steering Committee and the NINDS Project Officer for input prior to the final selection by the Contractor of a specific source for subcontract recommendation. The NINDS shall be responsible for reviewing all proposed subcontract award recommendations and shall issue approval pursuant to the applicable consent requirements of the Federal Acquisition Regulations, Part 44.

Should the Contractor, with advice from the Steering Committee, determine that it is necessary to negotiate subcontractor proposals prior to making a recommendation for award to the Project Officer, the Contractor shall identify competitive proposals and conduct negotiation among competing subcontractors. After solicitation, evaluation and negotiations, if any, of subcontractor proposals, the Contractor shall make an award recommendation to the Project Officer.

At the direction of the NINDS Contracting Officer, the Contractor shall make subcontract awards to those sources for which the NINDS has granted consent to subcontract. To achieve the most efficient and responsive subcontract award process possible, the Contractor will be expected to complete this process within a maximum four (4) month period. This four-month period will begin with issuance of the solicitation of research proposals and end with the award of the subcontract(s).

The role of the Steering Committee in assisting the Contractor to implement the strategic plan will involve the following activities:

- Assist the Contractor in identifying areas of the strategic plan in which to issue solicitations for research proposals.

- Recommend critical elements of the solicitations, including specific research requested and evaluation criteria.
- Advise the Contractor on the selection of offerors for subcontract award.
- Advise the Contractor on areas of negotiation among competing subcontractors.

3.2. Management of a Research Program

The Contractor shall monitor and manage the scientific progress of the subcontracted research projects to insure the timely completion of milestones. The required elements of this aspect of the contract are described in this section. Additional ideas and information that may assist the offeror in preparing a proposal can be found in Section 7, Notes and Guidance.

The Contractor shall coordinate the progress of the overall program to assure efficient progress toward the identification of a therapy for SMA. The Contractor shall monitor the various research projects in the context of the strategic plan to insure that individual required elements of a therapeutics development strategy are available in a timely fashion and that overall progress is not interrupted unnecessarily in the transition from one research project to the next.

The Contractor, with input from the Steering Committee, will refine the strategic plan in response to the results of the subcontracted research projects and new developments in the field. To inform the Steering Committee of progress, the Contractor shall convene biannual oversight meetings at which the subcontracted investigators shall present their research progress to the Steering Committee for their review. In addition, the Contractor shall discuss proposed strategic refinements with the Steering Committee.

The role of the Steering Committee in assisting the Contractor in the management of the SMA research program will involve the following activities:

- Review progress at biannual oversight meetings at which subcontractors will report research progress.
- Advise the Contractor in assessment of research milestones.
- Advise the Contractor in strategies for overcoming difficulties in research progress.
- Assist the Contractor in identifying upcoming areas for proposal solicitation.
- Propose refinements to the strategic plan with input from the Contractor and the Project Officer.

3.3. Scientific Oversight and Expertise

The following scientific oversight and expertise is required of the Contractor:

- a. Peer Review of Scientific Proposals. The contractor shall evaluate research proposals by an objective, thorough and fair peer review process. An integrated member of the contractor's PhD-level scientific staff shall coordinate the review of proposals. S/he shall identify reviewers with appropriate expertise who are free from conflicts of interest. At least two expert reviewers will be assigned primary responsibility for evaluation of each proposal reviewed. The review will be conducted so as to ensure adherence of peer reviewers to the review criteria for scientific merit and other required elements established in the solicitation for proposals. Confidentiality of proprietary information will be maintained throughout the process. In addition, the scientist who conducts the review of proposals is required to have a thorough understanding of the strategic plan and its progress, and will serve as an *ex officio* member of the Steering Committee to insure continuity between the goals of the strategic plan and the review of proposals. S/he shall interpret the results of the review for the steering committee in the context of the strategic plan.
- b. Project Manager. The scientific expertise of the Project Manager plays a critical role in the success of this program throughout all stages. The Project Manager will be required to exercise high level scientific judgment in making subcontract award recommendations to NINDS: the choice of subcontracted research projects is critical to the success of this program and will require weighing the results of peer review and the needs of the strategic plan. Once subcontracted research begins, the Project Manager shall monitor the progress of the subcontracts and, most importantly, assist subcontractors in the resolution of technical problems that may be encountered during

performance. The contractor will also require mature scientific judgment in order to efficiently integrate the results of separate subcontracted projects to avoid unnecessary delays that can arise in transitioning from one phase of the program to the next.

- c. Additional PhD-level staff. The Contractor's staff will be required to encompass a broad range of scientific expertise. This program will be multidisciplinary, approaching an SMA therapy through many avenues such as gene therapy, stem cell therapy and drug discovery. This range will necessitate a sophisticated level of scientific knowledge across many disciplines, such as chemistry, cell biology, and virology. This broad expertise will possibly involve 3-5 separate individuals, and will be important in the identification and management of research subcontracts.

3.4. Technical Reporting Requirements

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.

3.4.1. Monthly Progress Reports

The contractor shall describe the activities during the reporting period, and the activities planned for the ensuing reporting period. This report shall include a summary and schedules of solicitations released, proposals received, proposals reviewed, and subcontract awards in progress and completed. In addition, for each current subcontract project, the report shall include the following: (1) a description of overall progress within each current subcontract, how that progress corresponds to planned milestones, and measures taken to correct any lack of milestone achievement, (2) an indication of any current problems that may impede performance, and proposed corrective action, (3) justification for discontinuation of any subcontract, if appropriate, (4) a discussion of the work to be performed during the next reporting period and (5) any recommendations. Monthly reports are not due in the final month of the quarter. As with the Quarterly and Annual Progress Reports, these reports will be submitted electronically to the Contracting Officer and Project Officer.

3.4.2. Quarterly Progress Reports

This report shall include a summation of the monthly progress reports, including the final month of the quarter, and a full report for the final month of the quarter in the format of the monthly progress reports. This report shall be in sufficient detail to comprehensively describe the results achieved.

3.4.3. Annual Progress Reports

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

3.4.4. Receipt of Proposal Reports

Within 1 week of the receipt date for proposals for any solicitation for research proposals released under the contract, a report of proposals received will be submitted electronically. This report may be in spreadsheet form and shall include for each proposal:

- a. Name of Organization
- b. Proposal Identification Number
- c. Principal Investigator Name
- d. Proposal Title
- e. Dollar Amount of Funds Requested
- f. Proposal Receipt date

3.4.5. Reports of Upcoming Reviews

For the scientific review of proposals, reports of upcoming reviews shall identify the reviewer assignments for each proposal and the date, time and venue for the review meeting. These reports shall be submitted within 2 weeks of the receipt of proposals.

3.4.6. Reports of Proposal Review Results

Reports of the proposal review proceedings shall be submitted within 1 week of the review meeting. For each proposal, this report shall include a summary of strengths and weaknesses, a statement of relatedness to the strategic plan for SMA therapeutics development, and any recommendations for revision or withdrawal from further consideration. This report will include a list of proposals that is considered appropriate for subcontract award, pending negotiation and discussion with the Steering Committee and the Project Officer, and will indicate any deficiencies of the proposed subcontract(s) with respect to achieving the goals of the original solicitation.

3.4.7. Subcontract Award Notification

Immediately upon the award of a subcontract, the Contractor shall electronically notify the Contracting Officer of the award. In this notification, the subcontract will be identified by Project Identification Number, Principal Investigator Name, Name of Organization who Received Subcontract Award, and Project Title.

3.4.8. Individual Subcontract Reports

Upon the completion of each subcontract, a report of the results of that project will be submitted. These reports shall be submitted within 1 week after completion of the subcontract. In addition to the complete reporting of the data developed under the subcontract, this report shall include the following: (1) the goal of the project and milestones for achieving this goal, (2) planned schedule of achievement of project milestones, and (3) actual schedule of achievement of project milestones.

3.4.9. Final Report

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

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

The contractor shall provide the Contracting Officer with copies of the final report in draft form 60 CALENDAR days prior to the delivery date for the final version of the final report. The Project Officer shall review the draft report and provide the Contracting Officer with comments within 30 CALENDAR days after receipt. The final report shall be corrected by the contractor, if necessary, and the final version delivered in accordance with Section F, Deliveries or Performance, of the contract.

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

<u>Reports</u>	<u>Period Covered</u>	<u>Due Date</u>
(1) Monthly Report	1/1-1/31	2/10
	2/1-2/29	3/10
	4/1-4/30	5/10
	5/1-5/31	6/10
	7/1-7/31	8/10
	8/1-8/31	9/10
	10/1-10/31	11/10

	11/1-11/30	12/10
(2) Quarterly Report	1/1-3/31	4/10
	4/1-6/30	7/10
	7/1-9/30	10/10
	10/1-12/31	1/10
(3) Annual Report	1/1-12/31	1/31
(4) Report of Proposals Received	to be determined	1 week after receipt deadline
(5) Review Schedule Report	to be determined	2 weeks after receipt deadline
(6) Proposal review results	to be determined	1 week after review
(7) Subcontract award notification	to be determined	upon award
(8) Individual Subcontract Reports	to be determined	1 week post completion
(9) Draft Final Report	duration of contract	60 days before last day of contract
(10) Final Report	duration of contract	last day of contract

4. Intellectual Property Considerations

Data will be generated under subcontract awards to satisfy the components of the strategic plan. The Contractor shall obtain this data from subcontractors and maintain it for use in other subcontracted projects as necessary. The Contractor shall make these data available to NINDS through monthly reports and upon request from the Project Officer.

Patent rights for any invention conceived and/or first actually reduced to practice under the contract will reside with the subcontractor who made the invention in accordance with Bayh-Dole.

The Contractor shall notify the NINDS in writing of any inventions made by the Contractor or any other employees, agents or subcontractors of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of these studies, pursuant to ARTICLE C.3. and FAR clause 52.227-11.

Results of the research conducted by subcontractors will be considered proprietary to the subcontractors. The subcontractor retains the right to publish and present research results subject to the following terms. Under no circumstances are results of the subcontracted projects to be released or divulged without prior notification of the Contracting Officer and the Project Officer. All articles and/or presentations that pertain to the work to be performed under this contract, including subcontracts, shall acknowledge the collaborative efforts of all participants, including contributing members of the Contractor's staff, collaborating investigators, and NINDS staff as may be applicable. At least 30 days prior to publication, articles shall be submitted to the NINDS project officer for review. The contractor and all subcontractors shall be required to acknowledge support of the NINDS SMA Therapeutics Development Program whenever publicizing work under the contract or subcontracts in any media. NINDS will use the data generated under the contract and subcontracts to implement and modify the NINDS strategic plan for SMA therapeutics development and to coordinate the overall research of the SMA Therapeutics Development Program with the goal of rapidly identifying an SMA treatment. Under confidentiality, NINDS will share this data with members of the SMA Therapeutics Development Steering Committee and other researchers as necessary to facilitate the most efficient use of the data in the identification of an SMA treatment.

5. Minimum Information Systems Security Safeguards

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

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

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

2. Require use of current passwords and log-on codes to protect sensitive AIS (Automated Information System) data from unauthorized access.
3. Establish procedures to register and protect secrecy of passwords and log-on codes, including the use of a nonprint, nondisplay feature.
4. Limit the number of unsuccessful attempts to access an AIS or database.
5. Develop means whereby the user's authorization can be determined. (This may include answer back capability.)
6. Ensure that the operating system contains controls to prevent unauthorized access to the executive or control software system.
7. Ensure that the operating system contains controls that separate user and master modes of operations.
8. Install software feature(s) that will automatically lock out the terminal if it is not used for a predetermined period of lapsed inactive time, and/or if a password is not entered correctly after a specified number of attempts.
9. Establish controls over the handling of sensitive data, including labeling materials and controlling the availability and flow of data.
10. Require that all sensitive material be stored in a secure location when not in use.
11. Dispose of unneeded sensitive hard copy documents and erase sensitive data from storage media in a manner which will prevent unauthorized use.
12. Prepare and maintain lists of persons authorized to access facilities and AISs processing sensitive data.
13. Establish procedures for controlling access to facilities and AISs processing sensitive data.
14. Furnish locks and other protective measures on doors and windows to prevent unauthorized access to computer and support areas.
15. Install emergency (panic) hardware on "Emergency Exit Only" doors. Ensure that emergency exits are appropriately marked.
16. Install fire suppression equipment in the computer facility, which may include area sprinkler systems with protected control valves and/or fire extinguishers.
17. Provide emergency power shutdown controls to shut down AIS equipment and air conditioning systems in the event of fire or other emergencies.
18. Establish a fire emergency preparedness plan to include training of fire emergency response teams, development and testing of an evacuation plan, and on-site orientation visits for the local fire department.
19. Secure communication lines.
20. Establish detailed risk management program.
21. Establish Computer Systems Security Plans for sensitive systems.
22. Conduct formal risk analyses.

23. Establish employee security awareness and training programs.
24. Maintain accurate inventory of all hardware and software.
25. Establish security review and certification programs.
26. Establish contingency plan.
27. Establish emergency power program.
28. Ensure that all personnel positions have been assigned security level designations.
29. Conduct periodic security level designation reviews.
30. Ensure that all personnel, including contractors, have received appropriate background investigations.
31. Establish an automated audit trail capability to record user activity.

6. Performance Based Award Fee/Incentive Guidelines

Introduction

The following establishes procedures for evaluating the Contractor's performance in establishing an innovative translational research program to accelerate the development of a treatment for Spinal Muscular Atrophy (SMA). This Performance Based Cost-Plus Award-Fee (PBCPAF) type of contracting is utilized to provide a strong incentive for the Contractor to achieve excellent performance. It allows the Contractor flexibility in performing the work and promotes maximum cooperation between the Contractor and the Government.

The objective of a PBC type contract is to: (1) motivate the Contractor to improve performance in the rated areas, but not at the expense of minimally acceptable performance in all other areas and, (2) emphasize to the Contractor key areas of management focus/performance.

The Performance Standard chart in Section C.1. Statement of Work, outlines the required performance standards, method of surveillance, and rating scale that will be used to determine any award fee/incentive which may be earned under the contract.

Organization Responsibilities

The award fee organization consists of the Fee Determining Official and the NINDS Project Officer.

A. Fee Determining Official

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

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

B. NINDS Project Officer, (PO)

The PO will monitor performance under the resultant contract. The PO shall evaluate the Contractor's performance and recommend earned award fee amount to the CO. He/she may also recommend changes to this plan. The PO is responsible for:

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

Performance Evaluation Process

A. Award Fee Allocation

The base fee included in the award will be determined during negotiations with the successful offeror. The maximum award fee that the contractor may earn will be determined during negotiations with the successful offeror.

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

B. Source of Data for Evaluations

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

C. Award Fee Determination

The amount of award fee earned will be based on the Contractor’s performance as evaluated against the Performance Standards by the PO and accepted by the CO. The PO will monitor the Contractor’s performance and evaluate performance monthly by the Performance Standards. The PO will notify the Contractor of any weaknesses as soon as they are identified. The PO will promptly document significant accomplishments, any weaknesses, or areas of concern on monthly Performance Evaluation Reports and forward them to the CO by the 10th calendar day of the following month.

Semi-annually, the PO will evaluate the Contractor’s performance and recommend their award fee earned to the CO. He/she will use results of the Monthly Performance Evaluation Reports as source data for determining the end-of-period award fee evaluation ratings. Using the following rating scale, the PO will rate Contractor performance in each Performance Standard.

Four (4) Excellent Ratings	Earns 100% of available award fee for the evaluation period.
Three (3) Excellent Ratings	Earns 75% of available award fee for the evaluation period.
Two (2) Excellent Ratings	Earns 50% of available award fee for the evaluation period.
One (1) or less Excellent Rating	Contractor not eligible to receive award fee.

The PO will use Evaluation Report forms for recording the results of the evaluations. The PO will provide award fee recommendations to the CO within twenty (20) days after the end of an

evaluation period. The CO may accept or modify the recommendations of the PO. The CO is the final authority to determine the overall rating and amount of the award fee.

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

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

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

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

D. Revision to the Plan

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

E. Contract Termination

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

7. Notes and Guidance

7.1 Disclaimer

The sole purpose of "Notes and Guidance" is to provide prospective offerors with guidance and additional information that may be useful in developing a performance work plan and proposal in response to this requirement. 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.

7.2 NINDS Prototype for Targeted Translational Research

NINDS has attempted to design a rapid and responsive process for funding targeted translational research. The resulting prototype for strategic planning, rapid funding and research management, outlined below, is intended to be applied to diseases for which late stage therapeutics development is appropriate. The goal of the process is to focus funding on parallel therapeutic pathways in a rapid, milestone-driven process to identify a treatment. This strategy is intended to efficiently translate mechanistic understanding of a disease

into a testable therapy suitable for clinical trials. The following is a description of the NINDS accelerated funding and research prototype. The offeror may adapt this prototype in developing their proposal for identifying and managing research subcontracts.

7.2.1. Subcontract Award

To achieve an efficient process for proposal receipt and review, the proposal process may be in two stages: 1) brief pre-proposals can be solicited and subjected to a rapid first round of review by the Steering Committee to identify those that are most responsive to the strategic plan, and 2) full-length proposals can subsequently be requested from those pre-selected sources. This two-stage process would allow the Contractor to identify a select set of proposals for evaluation by the scientific peer review committee before the proposals are submitted. Reviewers can be identified and the review meeting arranged during the time that the offerors are preparing full-length proposals, which would result in a significant time savings.

For each element of the strategic plan, the contractor would conduct the activities listed in the following schedule to identify research projects and ultimately lead to the award of subcontracts within a 4-month period:

Schedule of Events for Implementing SMA Research Plan

- a. Contractor solicits research proposals
- b. Contractor receives 2 page pre-proposals and submits them to Steering Committee for review of responsiveness to solicitation
- c. Contractor recommends, to Steering Committee and NINDS, a subset of proposals for further consideration via full-length proposals
- d. Contractor schedules scientific peer review of full-length proposals
- e. Contractor receives and conducts scientific peer review of full-length proposals
- f. Contractor submits initial source recommendations to the Steering Committee and Project Officer for input
- g. Contractor completes analysis, clearances and negotiations with those sources recommended for subcontract award
- h. Contractor submits award recommendations to NINDS
- i. NINDS consents to final award recommendation of Contractor
- j. Contractor awards subcontract(s)

The following tasks would be required to accomplish this schedule:

- Convene and maintain the Steering Committee. The Steering Committee is composed of expert scientists and clinicians, and consumer advocates. The membership of this committee will be identified by NINDS. This committee will determine the strategic plan for the program and will assist the Contractor in evaluating research progress. The Contractor shall convene committee meetings 4 times per year, two meetings for 2 days each and two meetings for 5 days each in the Washington, DC area. Intermittent teleconferences will be required to discuss matters arising between meetings.
- Design, prepare and advertise solicitations for research proposals based on the strategic plan. Areas of the strategic plan for which to solicit proposals will be defined through discussions with the Contractor, the Steering Committee and the NINDS. The NINDS

will retain final approval authority of areas of research for initiatives. The Contractor shall design and prepare solicitations that would describe the required research projects, suggest milestones to be used to evaluate progress and specify the review criteria to be used in the evaluation of proposals. The contractor would advertise these solicitations broadly to academic and private research communities. In addition to publication in FedBizOpps, the announcements would be advertised at high profile scientific meetings and in journals as well as on a contractor web site dedicated to the project. For the purposes of preparing the contract proposal, offerors can assume that there would be three parallel therapeutics development areas defined in the strategic plan, for example, drug development, gene therapy and stem cell therapy. Six solicitations in the first year should be anticipated, approximately 2 for each research area. Research projects are expected to be short term, approximately 6 to 12 months in length, and 4 solicitations should be anticipated in years 2 through 4 of the contract.

- Receipt and scientific review of 2 page pre-proposals. For each solicitation, 5 to 20 pre-proposals can be anticipated. The Contractor would convene the Steering Committee to review these proposals for responsiveness to the strategic plan. This committee would identify the most appropriate 5 to 10 proposals for submission of full-length proposals. The Contractor would prepare the results of this review as a recommendation to NINDS. The Contractor would invite full-length proposals from investigators identified by NINDS.
- Based on the list of full-length proposals to be solicited, the Contractor would immediately arrange a scientific review meeting. This meeting would be held within 6 weeks of the request for full-length proposals. The review committee would have sufficient expertise to fully evaluate the proposals, and be free from conflict as defined by NIH guidelines. The scientist who conducts the reviews would be an employee of the contractor and would conduct the review according to NIH standards and procedures. Investigators who submit proposals would be available by phone during the review meeting to answer questions that may arise in the course of review. Members of the Steering Committee would also be present, in a non-voting capacity, to determine whether the goals of the review are in line with the strategic plan. Based on the review and discussions with the Steering Committee and Project Officer, the Contractor would make funding recommendations to NINDS in line with the strategic plan. The Steering Committee will refine the strategic plan and suggest modified calls for proposals as necessary.
- Based on the final consent to subcontract from NINDS, the Contractor would make subcontract awards. It can be anticipated that there will be 1-5 awards per solicitation. The contractor shall evaluate the appropriateness of the budget requested and negotiate accordingly. The contractor shall make these awards within 4 months of the issuance of the solicitation.

7.2.2. Subcontract Management

The contractor would conduct the following activities to monitor research progress and insure the timely completion of milestones:

- a. Investigator meetings: The contractor would arrange investigator meetings to facilitate interactions among the funded investigators. The initial meeting would take place within 30 days of any awards to inform new investigators about the scope of the project and the strategic plan. Quarterly meetings would follow to keep the research groups informed of relevant progress and to solve problems that may arise. The contractor would produce reports of the progress presented at these meetings for review by the Steering Committee and the Project Officer.
- b. Investigator/Steering Committee Meetings: The contractor would arrange biannual meetings to include the investigators and the Steering Committee. At these meetings,

investigators would present their progress relative to project milestones. The Steering Committee would provide recommendations to investigators for overcoming any difficulties that may arise. The Steering Committee would make recommendations to the Contractor for continued funding based on the progress reported. This would be a stringent process that will allow unsuccessful projects to be weeded out or replaced as appropriate. It should be noted that discontinuation of a particular project may not reflect poor performance but rather that a line of research did not prove as fruitful as expected in meeting the goals of the strategic plan.

c. Steering Committee Evaluation Meetings: These meetings would immediately follow the Investigator/Steering Committee meetings. The purpose of these meetings is to allow the Steering Committee to revise the strategic plan according to recent progress and to propose new research solicitations as necessary to maintain the momentum of the strategic plan.

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

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

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

PROPOSAL INTENT RESPONSE SHEET

RFP No. NINDS-

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

DO INTEND TO SUBMIT A PROPOSAL

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

COMPANY/INSTITUTION NAME:

AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

RETURN TO:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

PROJECT OBJECTIVES

SOLICITATION NUMBER: _____

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

OFFEROR NAME AND ADDRESS:

OFFEROR PHONE NUMBER (WITH AREA CODE) _____

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

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

RFP TITLE: _____

PRINCIPAL INVESTIGATOR: _____

SUMMARY OF OBJECTIVES:

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

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

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

Contractor Employee Non-Disclosure Agreement

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

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

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

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

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

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

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

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

_____ by (Date) _____
(Name)

(Address)

(Fax Number)

This survey pertains to: _____

Department/Component: _____

Contract Number: _____ Date of Survey: _____

Name of Person Completing Survey: _____

Signature of Person Completing Survey: _____

Your Company/Agency: _____

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

Contract Value (including options) : \$ _____

Period of Performance (including option periods) : _____

Type of Contract: _____

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

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

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

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

General description of products / services required under the contract:

RATINGS

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

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

QUALITY OF SERVICE

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

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

COST CONTROL

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

TIMELINESS OF PERFORMANCE

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

BUSINESS RELATIONS

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

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

SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS GOALS

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

Comments: (optional) _____

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

Comments: (optional) _____

CUSTOMER SATISFACTION

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

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

ADDITIONAL COMMENTS

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

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

EXAMPLE, REQUEST FOR PAST PERFORMANCE INFORMATION

Date:

Dear Client:

We are currently responding to the DHHS/NIH/NINDS RFP-03-03 entitled: Collaborative Program to Accelerate Therapeutics Development for Spinal Muscular Atrophy (SMA). The Government is placing increased emphasis in their procurements on past performance as a source selection factor and is requiring that clients of firms responding to NINDS solicitations be identified and their participation in the evaluation process be requested.

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

We thank you for your prompt response in this matter.

Sincerely,

(To be signed by offeror)

Attachment

(SUBMIT WITH TECHNICAL PROPOSAL)

SUMMARY OF LABOR AND DIRECT COSTS

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

Specific Instructions:

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

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			
<input type="checkbox"/> COST-REIMBURSEMENT <input type="checkbox"/> FIXED PRICE <input type="checkbox"/> COST-PLUS-FIXED-FEE <input type="checkbox"/> OTHER			
ESTIMATED TIME REQUIRED TO COMPLETE PROJECT			
ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget)	PROPOSED STARTING DATE		
DOES THIS PROPOSAL INCLUDE A SUBCONTRACT <input type="checkbox"/> YES <input type="checkbox"/> NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)			
NAME AND TITLE OF PRINCIPAL INVESTIGATOR	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary.)			
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS	AREA CODE/TELEPHONE NUMBER		
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS	AREA CODE/TELEPHONE NUMBER		
DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS Institution's General Assurance re: Human Subjects Institution's Review Board's Approval of this Proposal An example of the informed consent for this study is enclosed A Clinical Protocol is enclosed		<input type="checkbox"/> YES <input type="checkbox"/> NO DATE APPROVED _____ <input type="checkbox"/> PENDING DATE APPROVED _____ <input type="checkbox"/> PENDING <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> 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.

SUMMARY OF ANNUAL COSTS

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

Specific Instructions:

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

SUMMARY OF RELATED ACTIVITIES

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

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

Professional's Name and Title/Position: _____

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

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

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

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

Professional's Name and Title/Position: _____

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

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

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

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

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

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

DISCLOSURE OF LOBBYING ACTIVITIES

**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.)

<p>1. Type of Federal Action:</p> <ul style="list-style-type: none"> a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance 	<p>2. Status of Federal Action:</p> <ul style="list-style-type: none"> a. bid/offer/application b. Initial award c. post-award 	<p>3. Report Type:</p> <ul style="list-style-type: none"> a. initial filing b. material change <p>For Material Change Only: year _____ quarter _____ date of last report _____</p>
<p>4. Name and Address of Reporting Entity:</p> <p><input type="checkbox"/> Prime <input type="checkbox"/> Subawardee Tier _____, if known:</p> <p>Congressional District, if known: _____</p>		<p>5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime</p> <p>Congressional District, if known: _____</p>
<p>6. Federal Department/Agency:</p>	<p>7. Federal Program Name/Description</p> <p>CFDA Number, if applicable: _____</p>	
<p>8. Federal Action Number, if known:</p>	<p>9. Award Amount, if known: \$ _____</p>	
<p>10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI):</p> <p style="text-align: center;">(attach Continuation Sheet(s))</p>	<p>a. Individual Performing Services (including address if different from No. 10a) (last name, first name, MI)</p> <p style="text-align: center;">SF-LLL-A, if necessary)</p>	
<p>11. Amount of Payment (check all that apply):</p> <p>\$ _____ <input type="checkbox"/> actual <input type="checkbox"/> planned</p>	<p>13. Type of Payment (check all that apply):</p> <ul style="list-style-type: none"> <input type="checkbox"/> a. retainer <input type="checkbox"/> b. one-time fee <input type="checkbox"/> c. commission <input type="checkbox"/> d. contingent fee <input type="checkbox"/> e. deferred <input type="checkbox"/> f. other; specify: _____ 	
<p>12. Form of Payment (check all that apply):</p> <ul style="list-style-type: none"> <input type="checkbox"/> a. cash <input type="checkbox"/> b. in-kind; specify: nature _____ value _____ 		
<p>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:</p> <p style="text-align: center;">(attach Continuation Sheet(s) SF-LLL-A, if necessary)</p>		
<p>15. Continuation Sheet(s) SF-LLL-A attached:</p> <p style="text-align: center;">Yes No</p>		
<p>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.</p>		<p>Signature: _____</p> <p>Print Name: _____</p> <p>Title: _____</p> <p>Telephone No.: _____ Date: _____</p>
<p>Federal Use Only</p>		<p>Authorized for Local Reproduction Standard Form--LLL</p>

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity: _____ Page _____ of _____

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

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

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

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

SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN: _____

CONTRACTOR: _____

ADDRESS: _____

DUNN & BRADSTREET NUMBER: _____

SOLICITATION OR CONTRACT NUMBER: _____

ITEM/SERVICE (Description): _____

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

\$ _____	\$ _____	\$ _____	\$ _____
Option #1 (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 outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this outline has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable. It is not intended to replace any existing corporate plan that is more extensive. Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the Office of Small and Disadvantaged Business Utilization (OSDBU) at (202) 690-7300 or the OPDIV Small Business Specialist at _____ . Sources may also be obtained from SBA's PRONET website.

Please note that for fiscal year 2003, the Department of Health and Human Services (HHS) has subcontracting goals as follows: Total Subcontract Dollars (in Thousands): \$450,000; 36.6% (\$164,700) for Small Business (SB); 6.8% (30,600) for Small Disadvantaged Business (SDB); 5.1% (\$22,950) for Women-Owned Small Business (WOSB); 3.0% (\$13,500) for HUBZone Small Business (HUBZone); and 1.5% (\$6750) for Veteran-Owned Small Business (VOSB), and Service Disabled Veteran-Owned Small Business (SDVOSB) concerns.

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

5. Type of Plan (check one)

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

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

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

2. Goals

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

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

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

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

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

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)

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

d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)

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

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)

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

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

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

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

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

2. SDB, WOSB, HUBZone, SDVOSB and VOSB goals are subsets of SB and should be counted and reported in multiple categories, as appropriate.

3. If any contract has more than four options, please attach additional sheets showing dollar amounts and percentages.

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

Product/Service	Other	SB	SDB	WOSB	HUBZone	VOSB	SDVOSB

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

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

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

3. Program Administrator:

NAME/TITLE:

ADDRESS:

TELEPHONE/E-MAIL:

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties?
 yes no _____

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

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

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

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

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

- e. Ensures that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns; yes no
- f. Reviews subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB participation; yes no
- g. Accesses various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns to include the SBA's PRO-Net and SUB-Net Systems, (<http://www.sba.gov>), the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce and Federal agencies' Small Business Offices; yes no
- h. Establishes and maintains contract and subcontract award records; yes no
- i. Participates in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; yes no
- j. Ensures that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; yes no
- k. Conducts or arranges for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; yes no
- l. Monitors the company's subcontracting program performance and makes any adjustments necessary to achieve the subcontract plan goals; yes no
- m. Prepares and submits timely, required subcontract reports; yes no
- n. Coordinates the company's activities during the conduct of compliance reviews by Federal agencies; yes no; and
- o. Other duties: _____

4. Equitable Opportunity

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

- a. Outreach efforts to obtain sources:
 - 1. Contacting minority and small business trade associations; 2) contacting business development organizations and local chambers of commerce; 3) attending SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB procurement conferences and trade fairs; 4) requesting sources from the Small Business Administrations (SBA) PRO-Net and SUB-Net Systems, (<http://www.sba.gov/>) and other SBA and Federal agency resources. Contractors may also conduct market surveys to identify new sources, to include, accessing the NIH e-Portals in Commerce, (e-PIC), (<http://epic.od.nih.gov/>). The NIH e-Portals in Commerce is not a mandatory source and may be used at the offeror's discretion.
- b. Internal efforts to guide and encourage purchasing personnel:
 - 1. Conducting workshops, seminars, and training programs;
 - 2. Establishing, maintaining, and utilizing SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB source lists, guides, and other data for soliciting subcontractors; and
 - 3. Monitoring activities to evaluate compliance with the subcontracting plan.

c. Additional efforts:

5. Flow Down Clause

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

6. Reporting and Cooperation

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

Reporting Period Report Due Due Date

- Oct 1 - Mar 31 SF 294 4/30
- Apr 1 - Sept 30 SF 294 10/30
- Oct 1 - Sept 30 SF 295 10/30
- Contract Completion OF 312 30 days after completion

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

- a. Submit SF 294 to cognizant Awarding Contracting Officer.
- b. Submit Optional Form 312, (OF-312), if applicable, to cognizant Awarding Contracting Officer.
- c. Submit SF 295 to cognizant Awarding Contracting Officer and to the:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
200 Independence Avenue, SW
Humphrey H. Building, Room 517-D
Washington, D.C. 20201

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

7. Record keeping

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

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

Timely Payments to Subcontractors

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

9. Description of Good Faith Effort

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

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: _____
Typed Name: _____
Title: _____
Date: _____

This plan was reviewed by:

Signature: _____
Typed Name: _____
Title: _____ **Contracting Officer** _____
Date: _____

This plan was reviewed by:

Signature: _____
Typed Name: _____
Title: _____ **Small Business Specialist** _____
Date: _____

This plan was reviewed by:

Signature: _____
Typed Name: _____
Title: _____ **SBA Procurement Center Representative** _____
Date: _____

And Is Accepted By:

Signature: _____
Typed Name: _____
Title: _____
Date: _____

SMALL DISADVANTAGED BUSINESS (SDB) PARTICIPATION FACTOR

1A. OFFEROR'S NAME	2. REQUEST FOR PROPOSAL (RFP) NUMBER	
1B. OFFEROR'S ADDRESS	3. TOTAL SDB PARTICIPATION AT PRIME CONTRACT LEVEL	
	A. NAICS CODE	B. DOLLARS
	C. PERCENT	
	4. TOTAL SDB PARTICIPATION AT SUBCONTRACT LEVEL	
A. DOLLARS	B. PERCENT	
5. SDB PARTICIPATION AT SUBCONTRACT LEVEL BY NAICS SUBSECTOR GROUP		
A. NAICS SUBSECTOR GROUP	B. DOLLARS	C. PERCENT

INSTRUCTIONS

- Item 3.** Identify participation, if any, by SDB concerns at the prime contract level by dollar amount and percentage of total contract value. All prime contract dollars must be identified under the NAICS code assigned to the acquisition (see Section L2(a)(15) of the solicitation).
- Item 4.** Identify participation, if any, by SDB concerns at the subcontract level by dollar amount and percentage of total contract value.
- Item 5.** Identify, by NAICS Subsector Group, participation of SDB concerns at the subcontract level by dollar amount, and percentage of total contract value. (SDB concerns need not be identified by name.) See <http://www.sba.gov/size/NAICS-cover-page.htm> for descriptions of the NAICS Subsector Groups.

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

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

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

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

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

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

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

- (a) **Designated Billing Office Name and Address:** Enter the designated billing office and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.
- (b) **Invoice/Financing Request Number:** Insert the appropriate serial number of the invoice/financing request.
- (c) **Date Invoice/Financing Request Prepared:** Insert the date the invoice/financing request is prepared.
- (d) **Contract Number 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.
 - (1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. For Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.
 - (2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.
 - (3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of \$1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:
 - List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

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

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

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

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

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

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

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

<p>(a) Billing Office Name and Address</p> <p>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</p> <p>(e) Payee's Name and Address</p> <p>ABC CORPORATION 100 Main Street Anywhere, USA zip code</p> <p>Attn: Name, Title, & Phone Number of Official to Whom Payment is Sent</p>	<p>(b) Invoice/Financing Request No. _____</p> <p>(c) Date Invoice Prepared _____</p> <p>(d) Contract No. _____</p> <p>Effective Date _____</p> <p>(f) Total Estimated Cost _____</p> <p>(g) Total Fixed Fee _____</p>
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(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