SOLICITATION

SECTION A – SOLICITATION/CONTRACT FORM

Page 1 of 81 pages

1. Purchase Authority: Public Law 92-218 as amended

2. Request For Proposal	3. Issue Date:	4. Just in Time:	5. Set Aside:
(RFP) Number:		NO	X NO
	December 27, 2001	X YES See Part IV,	YES
NIH-NINDS-02-02		Section L.	

6. TITLE: INSULATING BIOMATERIALS

7. 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

8. SUBMIT OFFERORS TO:

The address noted in Item #7 to the left (Also see instructions under Packaging and Delivery of Proposals, page 21).

- 9. 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), February 27, 2002. Offers must be valid for 120 days. Please specify this period on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043." If your proposal is not received by the Contracting Officer or his/her designee at the place and by the time specified above, then it will be considered late and handled in accordance with HHSAR Clause 352.215-70, entitled "LATE PROPOSALS AND REVISIONS," located in SECTION L.1., paragraph (n) of this solicitation.
- **10.** 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.
- 11. FOR INFORMATION CALL: Laurie A. Leonard, Contract Specialist

PHONE: 301-496-1813

E-MAIL: mail to: <u>LL44S@nih.gov</u>

COLLECT CALLS WILL NOT BE ACCEPTED.

12. Table of Contents on following page.

NOTE: Offerors are responsible for routinely checking both the FedBizOpps website and the NINDS Contracts Management Branch's website. Solicitation amendments, if any, will be posted at the FedBizOpps website (http://www.fedbizopps.gov) and the NINDS Contracts Management Branch's web site (http://www.ninds.nih.gov/funding/currentrfps.htm). Individual notifications will not be provided.

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PART I - THE SCHEDULE

THE CONTRACT SCHEDULE AS SET FORTH IN SECTIONS B THROUGH H HEREIN CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS <u>NOT</u> 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 develop and evaluate insulating biomaterials that function reliably over the lifetime of an implant recipient. Testing of these materials shall be done both *in-vitro* (under physiologic and accelerated test conditions) and *in-vivo*. These biomaterials shall be suitable for insulating silicon-based, micromachined microelectrode arrays and connecting wire microcables that are placed in the central nervous system. The contractor shall develop and validate evaluation methods to test the long-term survival and biocompatibility of implanted devices protected using the developed insulating biomaterials.

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 <u>any</u> 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

a. PERFORMANCE AND TECHNICAL PROGRESS REPORTS

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

1. Quarterly Progress Reports:

The contractor shall deliver these reports electronically as hypertext or as Microsoft Word documents to both the Project Officer and the Contracting Officer.

The quarterly progress report shall include an abstract, including a description of work performed during the period reported upon, and the anticipated work plan for the coming quarter. These reports shall be delivered in accordance with the following schedule for the entire contract period:

Quarterly Reporting Periods Delivery Due Dates

January 1 – March 31	April 30
April 1 – June 30	July 31
July 1 – September 30	October 31
October 1 – December 31	January 31

2. Final Report:

Three (3) copies of a brief final report shall be submitted on or before the completion and/or termination date of this contract. The final report shall summarize what was achieved, what was not achieved and shall include recommendations for future research and development in the area. The summary may refer to quarterly reports and published articles supported by the contract. Copies of all publications, but not quarterly progress reports, should be included in the final report. Any substantive data or other results obtained during the final quarter should be included as an addendum in the final report.

3. Other Reports:

Annual reports evidencing continuing and ongoing IACUC review and approval of project activities involving live vertebrate animals.

4. Contract Financial Reports:

Financial reports to include line item costs and effort expenditure reporting shall be required. If the contract is awarded to an organization that has an approved Letter of Credit, financial reports on Form NIH 2706 shall be submitted by the Contractor on a quarterly basis.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR CLAUSE 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301/435-1986). In addition, one copy of the annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer at the address listed below. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted within 90 days after contract expiration to the following address:

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

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

ARTICLE C.4. SPECIAL REQUIREMENTS

The Contractor will be required to come to Bethesda, MD yearly to present results at the Neural Prosthesis Workshop. Funds to cover this three-day meeting should be included in the budget.

SECTION D - PACKAGING, MARKING AND SHIPPING

a. All report deliverables required under this contract shall be packaged, marked, and delivered in accordance with the contract. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

b. Packaging

- 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: "Insulating Biomaterials"
- 2. Contract Number:
- 3. Name of Contractor:
- 4. Name of Principal Investigator:

d. Shipping

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

e. See SECTION F for delivery information.

SECTION E - INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or a duly authorized representative shall perform inspection and acceptance of all deliverables and services to be provided.
- b. For the purpose of this ARTICLE, the NINDS Project Officer designated in ARTICLE G.2. is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance of contract work/deliverables shall be performed at the National Institute of Neurological Disorders and Stroke (NINDS), NIH, 6001 Executive Boulevard, Suite 2207 MSC 9525, Bethesda, Maryland 20892-9525 (for courier service: Rockville, MD 20852). Inspection and acceptance shall be performed using progress reports, other required reports, and the final report. Site visits will also be employed for this purpose. Acceptance of work and/or report deliverables may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within thirty (30) days of receipt.
- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF CONTRACT

The period of this contract is	to	All work under this contract shall be
completed by		

ARTICLE F.2. DELIVERIES

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

Item	Description	Quantity	Delivery Schedule
1.	Quarterly Progress Report	1 – P.O. 1 – C.O.	Schedule will be included in the resultant contract.
2.	Final Report	2 – P.O. 1 – C.O.	On or before the last day of the contract.

b. The above reports shall be addressed and delivered to:

[The specific information will be included in the resultant contract]

ARTICLE F.3. STOP WORK ORDER

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

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. KEY PERSONNEL

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

[To be specified prior to award]

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

ARTICLE G.2. PROJECT OFFICER

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

[To be specified prior to award]

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

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

The Government may unilaterally change its Project Officer designation.

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

- a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH (RC)-4, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper payment" request, pursuant to FAR 32.9. These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.
 - 1. Invoice/financing requests shall be submitted as follows:

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

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

- 2. Inquiries regarding payment of invoices/financing requests should be directed to the designated billing office, (301) 496-1813.
- 3. The Contractor agrees to provide with each invoice/financing request a detailed breakdown of the direct labor/personnel costs which shall include: (1) a list of the individuals by name; (2) their title/position under the contract; (3) the number of hours/percent of effort worked during the current period and the cumulative over the life of the contract; and (4) amount claimed for each individual for the current period as well as the cumulative since the inception of the contract.
- 4. The Contractor shall include the following certification on every invoice/contract financing request for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.7. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

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

OR

ARTICLE G.3. ADVANCE PAYMENT INFORMATION

a. Advance payments will be provided under Letter of Credit Number _______, in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments. This clause is provided in full text in Article I.4. of this contract.

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

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

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

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

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

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

ARTICLE G.4. CONTRACT FINANCIAL REPORT (will be included in any contract with organizations paid under the Payment Management System)

- a. Financial reports on the attached Form NIH-2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the instructions which accompany the form, in an original and two copies, not later than the thirtieth (30) working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph (e) below. Subsequent changes and/or additions in the line entries shall be made in writing.
- b. Unless otherwise stated in that part of the Instructions for Completing Form NIH-2706 instructions entitled "**Preparation Instructions**," all columns A through J shall be completed for each report submitted.
- c. The first financial report shall cover the period consisting of the *FIRST FULL THREE CALENDAR MONTHS* following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports shall be submitted on a quarterly basis.
- d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

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

Expenditure Category Percentage of Effort/Hours

- 1. Direct Labor (List individuals by name, title/position, level of effort and amount claimed)
- 2. Fringe Benefits (Cite rate, base and amount)
- 3. Consultants (Identify individuals and amounts)
- 4. Subcontracts (Identify subcontractor by name and attach subcontractor invoices)
- 5. Materials and Supplies
- 6. Accountable Personal Property/Equipment (*Identify equipment purchased on form HHS 565 and submit with the invoice*)
- 7. Other Direct Costs
- 8. Total Direct Costs
- 9. Indirect Costs/Overhead (Cite rate, base and amount)
- 10. General and Administrative Costs (if applicable, cite rate, base and amount)
- 11. Total Costs
- 12. Fixed Fee (*If applicable*)
- 13. Total Costs [Plus Fixed Fee]
- f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.5. INDIRECT COST RATES (will be included in any contract if the successful offeror is a profit making organization)

In accordance with Federal Acquisition Regulation (FAR)(48 CFR Chapter 1) Clause 52.216-7(d)(2), "Allowable Cost and Payment" incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer 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 Boulevard, MSC 7540 Bethesda, MD 20892-7540

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

ARTICLE G.6. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, Contractor's Guide for Control of Government Property, (1990).

ARTICLE G.7. POST AWARD EVALUATION OF PAST PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

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

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

ARTICLE H.2. HUMAN SUBJECTS

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

ARTICLE H.3. ANIMAL WELFARE ASSURANCE

The Contractor shall obtain, prior to the start of any work under this contract, an approved Animal Welfare Assurance from the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractor performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

(NOTE TO OFFERORS: PRIOR APPROVAL FROM OER, OLAW MUST BE OBTAINED BEFORE AWARDING TO A CONTRACTOR NOT COVERED BY AN APPROPRIATE ASSURANCE OF COMPLIANCE. THE FOLLOWING MUST BE INCLUDED IN ANY CONTRACT RECEIVING THIS PREAWARD APPROVAL FROM OLAW.)

ARTICLE H.4. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

Under governing policy, federal funds administered by the Public Health Service (PHS) shall not be expended for research involving live vertebrate animals without prior approval of the Office of Laboratory Animal Welfare (OLAW), of an assurance to comply with the PHS policy on humane care and use of laboratory animals. This restriction applies to all performance sites (e.g., collaborating institutions, subcontractors, subgrantees) without OLAW-approved assurances, whether domestic or foreign.

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

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

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

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

ARTICLE H.6. NEEDLE EXCHANGE

- a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
- b. Public Law and Section No. Fiscal Year Period Covered [Applicable information to be included at award]

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 applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.
- b. Public Law No. Fiscal Year Salary Limitation*

 [Applicable information to be included at award]

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

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

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 that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.
- b. **Public Law No. and Section No Fiscal Year** Period Covered [Applicable information to be included at award]

ARTICLE H.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. 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.12. SUBCONTRACTING PROVISIONS

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

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 with the
attached SUBCONTRACTING PLAN will be a material breach of such contract or subcontract and subject
to the remedies reserved to the Government under FAR Clause 52.219-16, entitled "LIQUIDATED
DAMAGES - SUBCONTRACTING PLAN".

b. Subcontracting Reports

1. The Contractor shall submit the original and one (1) copy of the 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, this report shall be submitted on the following dates for the entire life of this contract:

April 30th October 30th

This report shall be sent to the following address:

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

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

October 30th

The first report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective. This report shall be mailed to the following address:

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

3. The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 205-6475 for the correct address if unknown.

ARTICLE H.13. ANTI-LOBBYING

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.
- c. <u>Public Law No. and Section No</u> <u>Fiscal Year</u> <u>Period Covered</u>
 [Applicable information to be included at award]

ARTICLE H.14. 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/news/508-final.htm. The standards applicable to this requirement will be determined during negotiations.

ARTICLE H.15. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

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

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

Reg	Clause	Date	Clause Title	
FAR	52.202-1	May 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	Mar 2000	Allowable Cost and Payment	
FAR	52.216-8	Mar 1997	Fixed Fee	

Reg	Clause	Date	Clause Title	
FAR	52.219-8	Oct 2000	Utilization of Small Business Concerns	
FAR	52.219-9	Oct 2000	Small Business Subcontracting Plan	
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan	
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)	
FAR	52.222-3	Aug 1996	Convict Labor	
FAR	52.222-26	Feb 1999	Equal Opportunity	
FAR	52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era	
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities	
FAR	52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era	
FAR	52.223-6		Drug-Free Workplace	
FAR	52.223-14	Oct 2000	Toxic Chemical Release Reporting	
FAR	52.225-1		Buy American Act - Balance of Payments Program - Supplies	
FAR	52.225-13		Restrictions on Certain Foreign Purchases	
	52.227-1		Authorization and Consent, Alternate I (Apr 1984)	
	52.227-2		Notice and Assistance Regarding Patent and Copyright Infringement	
FAR	52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.	
FAR	52.227-14	Jun 1987	Rights in Data - General	
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments	
FAR	52.232-17	Jun 1996	Interest	
	52.232-20	Apr 1984	Limitation of Cost	
FAR	52.232-23	Jan 1986	Assignment of Claims	
FAR	52.232-25		Prompt Payment, Alternate 1 (Oct 2001)	
FAR	52.232-34	May 1999	Payment by Electronic Funds TransferOther Than Central Contractor Registration	
FAR	52.233-1	Dec 1998	Disputes	
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)	
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs	
FAR	52.242-3	May 2001	Penalties for Unallowable Costs	
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs	
	52.242-13	Jul 1995	Bankruptcy	
FAR	52.243-2		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	Sept 1996	Termination (Cost-Reimbursement)	
FAR	52.249-14	Apr 1984	Excusable Delays	
FAR	52.253-1	Jan 1991	Computer Generated Forms	

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGRULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS AND MODIFICATIONS OF CLAUSES

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

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

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

- "(c) Waiver of evaluation preference.....
 - [] Offeror elects to waive the evaluation preference."

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

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

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

FAR 52.227-14, Rights in Data - General (JUNE 1987) ALTERNATE V (JUNE 1987), FAR 52.227-14, Rights in Data - General (JUNE 1987). Specific data items that are not subject to paragraph (j) include: NONE FAR 52.227-16, Additional Data Requirements (JUNE 1987)

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

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

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

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

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

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

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

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

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

*** (USE BELOW IN NEGOTIATED CONTRACTS THAT CONTAIN EITHER THE FORMER FAR CLAUSE 52.230-2, 52,30-3, OR 52.230-5.) ***

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

FAR 52.243-2, Changes - Cost Reimbursement (AUGUST 1987), Alternate V (APRIL 1984)

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

HHSAR 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001)

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

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

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

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

This contract incorporates the following in full text.

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

FAR Clause 52.244-6, Subcontracts for Commercial Items and Commercial Components (MAY 2001)

a. **Definition**.

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

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

- b. To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.
- c. Notwithstanding any other clause of this contract, the Contractor is not required to include any FAR provision or clause, other than those listed below to the extent they are applicable and as may be required to establish the reasonableness of prices under Part 15, in a subcontract at any tier for commercial items or commercial components:
 - 1. 52.219-8, Utilization of Small Business (15 U.S.C. 637(d)(2) and (3
 - 2. 52.222-26, Equal Opportunity (E.O. 11246);
 - 3. 52.222-35, Affirmative Action for Special Disabled and Vietnam Era Veterans (38 U.S.C. 4212(a));
 - 4. 52.222-36, Affirmative Action for Handicapped Workers (29 U.S.C. 793); and
 - 5. 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (46 U.S.C. 1241)
- d. The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

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

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this RFP:

1. Statement of Work, 3 pages.

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).

- 2. Government Notice for Handling Proposals, 1 page.
- 3. Summary of Labor & Direct Costs (TECHNICAL PROPOSAL), 1 page.

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

- 4. NIH-2043, Proposal Summary and Data Record, 2 pages.
- 5. Summary of Annual Costs (BUSINESS PROPOSAL), 1 page.
- 6. Summary of Related Activities, 1 page.
- 7. SF-LLL, Disclosure of Lobbying Activities, 3 pages.
- 8. Small Business Subcontracting Plan Format, 7 pages.
- 9. Small Disadvantaged Business (SDB) Participation Plan, 1 page.

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

- 10. NIH (RC)-7, Procurement of Certain Equipment, (OMB Bulletin 81-16), 1 page.
- 11. NIH (RC)-4, Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, 5 pages.
- 12. NIH 2706, Financial Report of Individual Project/Contract, with instructions, May 1997, 3 pages.

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

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 <u>MUST</u> 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), February 27, 2002. Delivery and marking of proposals shall be as indicated below:

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

Technical Proposal: Original plus 10 copies Business Proposal: Original plus 4 copies

2. External Package Marking

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

RFP No. NIH-NINDS-02-02

3. Address

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

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

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

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

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

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

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

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

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

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

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

- (b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).
- (c) Submission, modification, revision, and withdrawal of proposals. (1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.
 - (2) The first page of the proposal must show--
 - (i) The solicitation number;
 - (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
 - (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
 - (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
 - (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.
 - (3) Submission, modification, revision, and withdrawal of proposals. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.
 - (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
- (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
- (3) It is the only proposal received.
- (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
- (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
- (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
- (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
- (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

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

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

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

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

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

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

- (3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.
- (f) Contract award. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
 - (2) The Government may reject any or all proposals if such action is in the Government's interest.
 - (3) The Government may waive informalities and minor irregularities in proposals received.
 - (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive

- range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in postaward debriefings to other offerors:
 - (i) The overall evaluated cost or price and technical rating of the successful offeror;
 - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
 - (iii) A summary of the rationale for award; and
 - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

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

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

(End of Provision)

c. "JUST IN TIME"

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

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

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

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

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

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 <u>541710</u>.
- (2) The small business size standard is \$5 million.

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 <u>September 2002</u>.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement type completion contract, with a term of four (4) years, and that incremental funding will be used for this contract (see Section L.2. (c) - Business Proposal Instructions.

g. ESTIMATE OF EFFORT

It is expected that a cost-reimbursement type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the total effort required to complete the RFP objectives to be approximately 20,000 labor hours for the entire contract period. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

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

h. COMMITMENT OF PUBLIC FUNDS

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

i. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

i. 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.

1. PREPARATION COSTS

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

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

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

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

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

(End of Provision)

n. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

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

(End of provision)

2. <u>INSTRUCTIONS TO OFFERORS</u>

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

(1) Contract Type and General Clauses

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

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Section L1.a. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

(4) Separation of Technical and Business Proposals

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

(5) Alternate Proposals

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

(6) Evaluation of Proposals

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

(7) Potential Award Without Discussions

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

(8) Use of the Metric System of Measurement

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

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

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

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

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

(9) Privacy Act

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

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

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

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

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

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

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

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

(10) Care of Live Vertebrate Animals

THE FOLLOWING NOTICE IS APPLICABLE WHEN CONTRACT PERFORMANCE IS EXPECTED TO INVOLVE CARE OF LIVE VERTEBRATE ANIMALS:

Notice to Offerors of Requirement For Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Humane 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), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane 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, Maryland 20817, (301) 496-7163, ext. 234.MSC 7507, Rockville, MD 20892-7507, (301) 496-7163, ext 234. FAX copies of the PHS Policy are available at (301) 402-2803. The policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm

Proposals submitted in response to this RFP and that involve the care and use of animals shall contain the following information:

- (a) identification of the species and approximate number of animals to be used;
- (b) rationale for involving animals, and for the appropriateness of the species and numbers to be used;
- (c) a complete description of the proposed use of animals;
- (d) 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;
- (e) a description of any euthanasia method to be used; and
- (f) a declaration that the institution does or does not have an Animal Welfare Assurance must be submitted with the proposal.

(11) Selection of Offerors

- a) The acceptability of the scientific and 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 proposal will be subjected to a cost realism and/or cost/price analysis.
- c) If award is 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 has communication and/or conducts 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 any and all other award selection factors specified in Section M.
- 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 website.

(12) 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 8 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 business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons 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 business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and 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, and HUBZone 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, and HUBZone 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, and/or HUBZone 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, and HUBZone small business concerns.
- (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, and HUBZone small business concerns 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 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, and HUBZone small business concerns and award subcontracts to them.

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

(13) 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.

(14) Extent of Small Disadvantaged Business Participation

In accordance with FAR part 15.304(c)4, the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract 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 Section M shall be used for evaluating SDB participation under this RFP. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. Waiver of the price evaluation adjustment must clearly stated in your proposal.

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

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

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

*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.

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

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

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

(16) Salary Rate Limitation in Fiscal Year 2002*

Offerors are advised that pursuant to P.L. **___, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses), 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 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. **_ applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's 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. ** states in pertinent part:

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

*FY-2002 information is pending passage of legislation. Information regarding the FY-2001 rate can be found at: http://www.opm.gov/oca/01tables/execses/html/01execsc.htm.

(17) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

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

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

Institutional Management of Conflicting Interests

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

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

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

(18) ROTC Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) the 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 the 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 toe students (who are 17 years of age or older) enrolled at the covered educational entity.

(19) 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 produce development. Intellectual property restrictions can stifle the broad dissemination of the 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 p [public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH0funded 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.

(20) Electronic and Information Technology Accessibility

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

- 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
- 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.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- (a) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991)
- (b) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- (c) Facilities Capital Cost of Money, FAR Clause 52.215-16 (October 1997)
- (d) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8 (October 1997)

b. <u>TECHNICAL PROPOSAL INSTRUCTIONS</u>

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

(1) Technical Discussions

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

a) Statement of Work

i) Objectives

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

ii) Approach

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

iii) Methods

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

iv) Schedule

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

b) Personnel

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

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

i) Principal Investigator/Project Director

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

ii) Other Investigators

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

iii) Additional Personnel

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

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

iv) Resumes

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

(2) Technical Evaluation

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

(3) Additional Technical Proposal Information

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) Other Considerations

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

- a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- 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.

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, fee and profit.

(2) Proposal Cover Sheet

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

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

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

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

(3) Information Other than Cost or Pricing Data

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

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

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

i) Direct Labor

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

ii) Materials

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

iii) Subcontracted Items

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

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

ix) Travel

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

x) Other Costs

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

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

- (a) Exceptions from cost or pricing data.
 - (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.
 - (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
 - (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include—
 - (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
 - (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
 - (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.
 - (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.
- (b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:
 - (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
 - (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

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

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

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

(5) Total Compensation Plan - Instructions

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

- a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors INCLUDED IN THE COMPETITIVE RANGE WILL BE REQUIRED TO SUBMIT a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
- b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
- Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(6) Total Compensation Plan - Evaluation

a) Total Compensation Plan (Professional Employees)

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

b) Cost (Professional Compensation)

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

c) Other (Labor Relations)

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

d) Federal Acquisition Regulation Clauses incorporated by Reference

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

(7) Qualifications of the Offeror

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

(1) General Experience

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

(2) Organizational Experience Related to the RFP

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

(3) Performance History

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

(4) **Pertinent Contracts**

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

(5) Pertinent Grants

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

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process. Past Performance information (see Section L.2.a.18 of this RFP) must be submitted with the Business Proposal.

(8) Other Administrative Data

a) **Property**

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

b) Royalties

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

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

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

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

d) Financial Capacity

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

e) Incremental Funding

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

HHSAR 352.232-75, Incremental Funding (January 2001)

- a. It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled "Limitation of Funds." Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.
- b. The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

(End of Provision)

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

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

- (a) Facilities capital cost of money [(see FAR 15.408(h))] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(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.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

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

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

(9) Subcontractors

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

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

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

(10) 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.

(11) Representations and Certifications

One copy of the Representations and Certifications shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor. The Representations and Certifications are available at the following URL: http://amb.nci.nih.gov/forms/rcneg.pdf

(12) Travel Costs/Travel Policy

a) Travel Costs - Commercial

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

b) Travel Policy

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

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

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

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

The evaluation of cost and the extent of SDB participation will not be conducted on any proposal determined to be "technically unacceptable," or on any proposal not deemed to be one of the most highly rated technical proposals based on the initial technical review. In addition, evaluation of SDB Participation Plan factor will not be conducted on any proposal not included in the competitive range on the basis of the evaluation of factors other than the SDB Participation Plan factor.

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.

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

B. TECHNICAL EVALUATION CRITERIA

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

The offeror's analysis of the proposed project: Evidence of understanding of the conceptual problems. **0-20 Points.**

Quality of experimental design, including recognition and discussion of anticipated major experimental problems together with suggested solutions; originality of ideas presented; and soundness and feasibility of the procedures proposed; the proposed animal model, and plans for the care, use and protection of vertebrate animals from research risks. **0-40 Points**.

Experience, qualifications, competence and availability of offeror's investigative team including evidence of significant collaboration among personnel proposed. **0-30 Points**.

Adequacy and availability of resources and facilities of the organization deemed to be of value to the project. **0-10 Points**.

C. SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTOR

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

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

Offers will be evaluated on the following sub-factors:

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

D. OTHER NON-SCORED CONSIDERATIONS

<u>Use of Live Vertebrate Animals</u> – The TEG will also evaluate, but not score, the adequacy of the protection of vertebrate animals in the proposed work.

SECTION C

DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

A. Background:

Packaging is a critical issue in all implantable biomedical applications and particularly for implanted neural prostheses. Yet despite its importance, a hermetic package in the form of a metal, ceramic or glass can has been and remains essentially the only means available for packaging implanted electronic devices for long-term human applications. While the hermetic can has served well in the pacemaker industry, the requirements for increased numbers of electrodes and increased miniaturation leads to the requirement for new packaging methods for microsize neural implants. The central nervous system (CNS) presents a special environment for implants. Devices and insulating biomaterials placed here benefit from the mechanical protection that is afforded to CNS tissue by the skull and spinal canal. However, the extracellular fluid (ECF) environment is also a harsh one for microelectronic devices and microwires and cables. Ions from the salts in the ECF as well as a variety of proteins and lipids can degrade or change the properties of an insulating coating. Insulating biomaterials intended for implants into the central nervous system need to protect devices from this hostile ionic environment of extracellular fluids for the lifetime of an implant recipient. In the case of materials used for devices implanted in young children, this might extend to 100 years.

Studies in the Neural Prosthesis Program have demonstrated reliable operation in *in-vitro* soak tests of polymer insulated silicon chips and wires for periods of over ten years. Accelerated life testing of these same materials suggests that they will function reliably for a lifetime as required. These promising results must be balanced with the observation that the results have been difficult to transfer to other investigators because of stringent requirements for properly cleaned substrates. Also, major failures such as lead wire fracture following encapsulation in connective tissue and breakdown of insulation on pacemaker lead wires were discovered in *in vivo* studies or clinical applications. *In-vivo* evaluation in a good model of the target application remains the gold standard for evaluation of insulating biomaterials. However, it is not realistic to test materials in this setting for 100 years. Some methods are needed to accelerate the test.

The polymers that have been successful in *in-vitro* tests are in the classes of the fluropolymers and silicones. Silicones are particularly promising as insulating materials because they both insulate wires and insulate the surface of implanted silicon microelectrode arrays by chemical bonding. Fluropolymers have so far failed to adhere to silicon microdevices during saline soak testing. A new class of materials, liquid-crystal polymers, also appears promising in pilot studies. These materials may be particularly valuable for use in electronic implants because they are dimensionally stable permitting them to be patterned with conductive leads.

In-vivo studies of the silicone, fluropolymer, and liquid-crystal insulating materials are essential. In order to estimate the long-term, *in-vivo* survival of insulating systems in reasonable time periods it is desirable to develop and validate an accelerated *in-vivo* testing system. It is not possible to increase temperature to accelerate *in-vivo* tests but it is feasible to use a combination of more sensitive measurements and other accelerators to detect early signs of decreased performance that may be predictive of failure. This research and development work will develop an implantable test system to evaluate the long-term stability of insulating biomaterials. Consideration will be given to increasing electrical stress, increasing sensitivity of measurements, increasing sensitivity of test devices, and increasing mechanical stress as means to accelerate the *in-vivo* testing of insulating biomaterials. In addition, ongoing *in-vitro* testing of promising materials will continue.

This requested research is a competitive extension of work currently underway at InnerSea Technology, which will expire in September 2002. Quarterly reports from this research and a bibliography listing publications from this and other related studies is available on the Neural Prosthesis Program home page at: NPP.NINDS.NIH.GOV.

B. Objectives:

The goals of this research are to develop biomaterials for the long-term electrical insulation of implanted neural prostheses and to validate material preparation and processing technology for consistent reliable application of these materials. *In-vivo* and *in-vitro* studies shall be conducted with a significant emphasis on chronic *in-vivo* evaluation. *In-vitro* evaluation will focus on already identified promising materials such as liquid-crystal polymers, silicones, and fluropolymers and other materials that show significant potential for this application. Methods for accelerated as well as non-accelerated *in-vivo* testing of insulating biomaterials will be developed and validated. These *in-vivo* test systems then will be used to test the most promising materials identified by *in vitro* soak testing.

C. Technical Specifications:

Independently, and not as an agent of the Government, the contractor shall develop and evaluate insulating biomaterials that function reliably over the lifetime of an implant recipient. Testing of these materials shall be done both *in-vitro* (under physiologic and accelerated test conditions) and *in-vivo*. These biomaterials shall be suitable for insulating silicon-based, micromachined microelectrode arrays and connecting wire microcables that are placed in the central nervous system. The contractor shall develop and validate evaluation methods to test the long-term survival and biocompatibility of implanted devices protected using the developed insulating biomaterials.

Specifically, the Contractor shall:

- 1. Conduct *in-vitro* testing of new insulating biomaterials materials as they become available and continue testing fluorocarbon, silicone and LCP polymers presently under test. At the beginning of the contract the Project Officer will deliver to the contractor up to 300 microwires and microdevices presently under soak testing in 0.9% saline.
 - (a) Insulated conductors shall be tested at potentials of plus and minus 5 volts with respect to a 0.9% saline soak bath. Samples shall be maintained at 37 degrees C. (or for devices under accelerated testing at 90 degrees C.) for the duration of the contract or until they fail. Leakage current from the conductor to the bath shall be monitored at least monthly.
 - (b) If insulators fail, as indicated by DC leakage currents of greater than 5 picoampres, the failure mechanism(s) of the insulators shall be determined and this information shall be used to improve the insulation system and to select new insulators if appropriate.
 - (c) Insulated microassemblies consisting of a cable of at least 2 microwires terminated on a silicon micromachined structure shall also be used for evaluating the insulating materials. Design rules for the silicon microstructures shall follow those defined by the University of Michigan Center for Neural Communication Technology. (Design rules and a description of available microelectrodes can be found at www.engin.umich.edu/center/cnct).
- 2. Accelerated *in-vitro* testing shall be used to identify insulating materials expected to function for a lifetime under normal physiological conditions.
- 3. The Contractor shall investigate the factors related to material preparation and coating deposition, such as surface preparation, that are associated with successful and unsuccessful insulating coatings of the most promising insulating materials. The contractor shall develop protocols for material preparation and deposition based on these studies that will lead to reproducible, reliable insulation of implanted devices and wires.
- 4. The contractor shall develop an *in-vivo* test system for testing insulating biomaterials implanted in the central nervous system.
 - (a) The test system shall be designed to permit testing of microdevices for periods exceeding 20 years.

- (b) The test system shall be capable of measuring DC leakage currents in the picoamp range in implanted microwires.
- (c) The test system shall permit daily recording of leakage current through insulation as well as measuring critical device parameters of implanted solid state and thin-film components integrated into micro electronic devices.
- (d) The test system shall permit in-vivo testing of the microcables, microelectrodes, and microassemblies described in section 1.
- 5. The contractor shall design an *in-vivo* test system for accelerated testing of biomaterials implanted in the CNS that shall be capable of testing components as described in section 4. Consideration shall be given to developing a validation procedure for the acceleration rate(s) of the accelerated test system.
- 6. Insulating biomaterials that by *in-vitro* testing appear functional shall be tested *in-vivo* using the test system developed in section 4.
 - (a) Select a suitable animal model (excluding chimpanzees) for implantation of microcables and microdevices. The test devices shall be implanted within the central nervous system.
 - (b) Monitor leakage currents at least weekly for periods of at least 2 years.
 - (1) If insulators fail to maintain their insulating properties, determine the failure mechanism and determine ways to prevent the failure.
 - (2) At the conclusion of animal experiments, analyze the implanted conductors and insulators to determine any changes in their composition and structure.
- 7. Based on the results obtained with the silicone and fluorocarbon polymers that have been studied, develop new materials for this application. Synthesize these candidate insulating materials and evaluate them *invitro*.
- 8. Cooperate with other investigators in the Neural Prosthesis Program by supplying samples of insulating biomaterials for biocompatibility testing and by *in-vitro* testing of up to thirty samples of up to three new insulating materials supplied from other contractors during the period of this contract as directed by the Project Officer.
- 9. Upon completion of the tasks specified above prepare and deliver to the government a comprehensive final report that shall summarize what was achieved, what was not achieved, and shall include recommendations for future research and development in this research area.

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.)

SUMMARY OF LABOR AND DIRECT COSTS

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

Specific Instructions:

- 1. Enter dollar totals for each person/labor category under Direct Labor. Hours or other effort estimates must be indicated.
- 2. <u>DO NOT</u> include salary rates under Direct Labor.
- 3. Total Labor Costs should include fringe benefit cost estimates in this total.
- 4. <u>DO NOT</u> include any Indirect Costs or Fixed-Fee.
- 5. <u>DO NOT</u> 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			tion/CONTRA	CT NUMBER		
PROJECT TITLE (Title or Solicitation	on or Contract Proposal)					
LEGAL NAME AND ADDRESS OF	FOFFEROR	PLACE	OF PERFOR	MANCE (Full ε	nddress inclu	iding ZIP)
TYPE OF CONTRACT PROPOSED						
COST-REIMBURSEMENT	FIXED PRICE	COST-PI	US-FIXED-FI	EE	OTHE	R
ESTIMATED TIME REQUIRED TO					-	
ESTIMATED DIRECT COSTS IN P	ROPOSED YEAR (From Budget	PROPO	OSED STARTI	NG DATE		
DOES THIS PROPOSAL INCLUDE services, basis for selection, responsil		NO (If yes	, please furnish	name and loca	ntion of orga	nization, description of
NAME AND TITLE OF PRINCIPAL	INVESTIGATOR	SOCIAL SE NO.	CURITY	EST. HOUR WEEKLY	S.S	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVEST necessary.)	TIGATOR (Use attachment if					
NAME AND TITLE OF INDIVIDUA CONTRACTS	AL(S) AUTHORIZED TO NEGOT	TATE	AREA COD	DE/TELEPHON	E NUMBEI	₹
NAME AND TITLE OF INDIVIDUA CONTRACTS	AL(S) AUTHORIZED TO EXECU	TE	AREA COD	E/TELEPHON	E NUMBEI	₹
DOES THIS PROPOSAL INVOLVE Institution's General Assurance re: H Institution's Review Board's Approve An example of the informed consent A Clinical Protocol is enclosed	uman Subjects al of this Proposal for this study is enclosed		DATE A YES YES	NO PPROVED PPROVED NO NO		PENDING PENDING
OFFEROR'S ACKNOWLEDGMEN	T OF AMENDMENTS TO THE S	Solicitation (Us	se attachment i	f necessary)		
ERRATA NUMBER	DATE	ERRAT	ΓA NUMBER		DATE	
NAME, ADDRESS, AND PHONE N GOVERNMENT AUDIT AGENCY	IUMBER OF COGNIZANT	NUMB	ER OF EMPLO	OYEES CURR	ENTLY EM	IPLOYED
		DOLLA	AR VOLUME	OF BUSINESS	PER ANNU	JM
		THIS C	OFFER EXPIRE OFFER (120 da	ES _ ys if not specifi		ROM THE DATE OF
CICNATUDE OF PRINCIPAL PARE	FOR THE INS		TUDE OF DAY	CIMIECO DEPRI	ECENTE A TEX	A.E.
SIGNATURE OF PRINCIPAL INVE	SHGATUK	SIGNA	TUKE OF BU	SINESS REPRI	ESENTATI	VE.
TYPED NAME AND TITLE		TYPED	NAME AND	TITLE		
EMPLOYER IDENTIFICATION NU	MBER	DATE	OF OFFER			

NIH-2043 – June 1982 ATTACHMENT # 4

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

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

Specific Instructions:

- 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. For * specify applicable base.
- 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 f agreements citing the committed levels of effort proposal.		
	Professional's Name and Title/Position:		
	<u>Identifying Number</u>	Agency	Total Effort Committed
	1. 2. 3.		
	4.		
	*If an individual has no obligation	(s), so state.	
b.	Provide the total number of outstanding proposa your organization, not presently accepted but in proposed professional individuals*.		
	Professional's Name and Title/Position:		-
	<u>Identifying Number</u>	Agency	Total Effort Committed
	 2. 3. *If no commitment of effort is interesting. 	nded, so state.	
c.	Provide a statement of the level of effort to be do for those individuals designated and cited in this		arded to your organization
	Name	Title/Position	Total Proposed Effort
	1. 2. 3. 4.		

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB 0348-0046

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

1. Type of Federal Action:	2. Status of Federal Ac			3. Report Type:
a. contract	a. bid/offer/applic	cation		a. initial filing
b. grant	 b. Initial award 			b. material change
c. cooperative agreement	c. post-award			For Material Change Only:
d. loan				year quarter
e. loan guarantee				date of last report
f. loan insurance				
4. Name and Address of Reporting Entity:		5. If Report Address of		No. 4 is Subawardee, Enter Name and
Prime Subawarde	ee			
Tier				
Congressional District, if known:			ional District,	
6. Federal Department/Agency:		7. Federal F	Program Nam	e/Description
		CFDA N	umber, if app	licable:
8. Federal Action Number, if known:		9. Award	Amount, if k	nown: \$
10. a. Name and Address of Lobbying Entity				ing Services (including address if different
(if individual, last name, first name, MI):			No. 10a)	
		(last	name, first na	me, MI)
(attach Continuation Sheet(s)		SF-LLL-A, if necessary)		
11. Amount of Payment (check all that apply):		13. Type of Payment (check all that apply):		
\$ actual planned	a. retainer			
•		b. one-time fee		
12.7	c. commission			
12. Form of Payment (check all that apply):	d. contingent fee			
	e. deferred			
a. cash		f othe	r: specify:	
b. in-kind; specify: nature	1. Othe	i, specify		
value				
14. Brief Description of Services Performed or to contacted, for payment indicated in Item 11:	be Performed and Date	(s) of Service.	, including of	ficer(s), employee(s), or Member(s)
contacted, for payment indicated in item 11.				
(atta	ach Continuation Sheet(s) SF-LLL-A	, if necessary)	
15. Continuation Sheet(s) SF-LLL-A attached:				
	Yes	No		
16. Information requested through this form is authorized by title 31 U.S.C			Signature:	
1352. This disclosure of lobbying activities is a material representation of fact upon w				
reliance was placed by the tier above when this transaction was made or entered i			Print Name	·
disclosure is required pursuant to 31 U.S.C. 1352. This information will be report Congress semi-annually and will be available for public inspection. Any person who				
the required disclosure shall be subject to a civil penalty of not less than \$10,000 an			Title:	
than \$100,000 for each failure.				
			Telephone l	No.:Date:
Federal Use Only			Authorized	for Local Reproduction
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DISCLOSURE OF LOBBYING ACTIVITIES

CONTINUATION SHEET

Approved by OMB 0348-0046

Reporting Entity:	_ Page of

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

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

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

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

SMALL BUSINESS SUBCONTRACTING PLAN DATE OF PLAN:

CONTRACTOR			
ADDRESS:			
DUNN & BRADSTREET	NUMBER:		
SOLICITATION OR CON	TRACT NUMBER:		
ITEM/SERVICE (Descript	ion):		
	OUNT: \$ Total contract or Base-Year, if options	Option #1 (if applicable)	
\$. \$		
Option #2 (if applicable)	Option #3	Option #4 (if applicable)	
	AMOUNT, IF APPLICABLE MOUNT, IF APPLICABLE	\$ \$	
PERIOD OF CONTRACT	PERFORMANCE (Month, Day	& Year):	_

The following is a suggested model for use when developing subcontracting plans as required by Section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this model plan has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable; however, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. Further, the use of this model is not intended to waive other requirements that may be applicable under statute or regulation. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

Subcontracting Plan (Rev. October 2001)

1. Type of Plan (check one)
Individual plan (all elements developed specifically for this contract and applicable for the full term of this contract).
Master plan (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.
Commercial products/service plan, including goals, covers the offerer's fiscal year and applies to the entire production of commercial items or delivery of services sold by either the entire company or a portion thereof (e.g., division, plant, or product line); this includes planned subcontracting for both commercial and Government business.
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, (VOSB)Service-Disabled Veteran 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 + g = a)
b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOB, HUBZone, and VOSB): (% of "a") \$ and%
c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") \$ and % Federal Subcontract Goal 5%
d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") \$ and % Federal Subcontract Goal 5%
e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: (% of "a") \$ and%
f. Total estimated dollar and percent of planned subcontracting with VETERAN SMALL BUSINESSES* (% of "a") \$ and Federal Subcontracting Goal 3%
g. Total estimated dollar and percent of planned subcontracting with AOTHER@THAN SMALL BUSINESSES: (% of "a")
(% of "a") \$ and%
Notes: *Service-disaled veteran goal should be included as part of veteran small business goal. 1. Federal prime contract goals are: SB equals 23%; SDB equals 5%; HUBZone equals 2.5%; WOSB equals 5% and VOSB equals 3% and can serve as objectives for subcontracting goal development.

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

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	HUBZoneSB	VOSB

i. 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 for subcontract 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.)

j.	Indirect costs have	_ have not	been included in the dollar	and percentage subcontr	racting goals
	above (check one).				

k.	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, and VOSB concerns.

3. Program Administrator:

NAME/TITLE: ADDRESS: TELEPHONE/E-MAIL:

Duties: Has general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans. Other duties include, but are not limited to, the following activities:

- a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, and VOSB concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing.
- b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone, and VOSB concerns from all possible sources;
- c. Ensuring periodic rotation of potential subcontractors on bidder's lists;

ATTACHMENT #8

- d. Ensuring that requests for contracts (RFC) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone and VOSB concerns;
- e. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone, and VOSB concerns to include the SBA's PRO-Net System, (http://www.sba.gov) the Federal Acquisition Computer Network (FACNET) Contractor Registration Database, the NIH E-Portals in Commerce (e-PIC), (http://epic.od.nih.gov/), 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;
- f. Establishing and maintaining contract and subcontract award records;
- g. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc;
- h. Ensuring that SB, SDB, WOSB, HUBZone, and VOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company;
- i. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended;
- j. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals;
- k. Preparing, and submitting timely, required subcontract reports;
- k. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and

m.	Other duties:		

4. Equitable Opportunity

Describe efforts the offeror will make to ensure that SB, SDB, WOSB, HUBZone, and VOSB 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:
 - 2) Contacting minority and small business trade associations; 2) contacting business development organizations and local chambers of commerce; 3) attending SB, SDB, WOSB, HUBZone, and VOSB 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; and 5) Conducting market surveys to identify new sources, to include, accessing the NIH E-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/).

- 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, and VOSB source lists, guides, and other data for soliciting subcontractors; and
 - 3) Monitoring activities to evaluate compliance with the subcontracting plan.

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/of 312	4/30	
Apr 1 - Sept 30	SF-294/of 312	10/30	
Oct 1 - Sept 30	SF-295	10/30	

Special instructions for commercial products plan: SF295 Report is due on 10/30 each year for the previous fiscal year ending 9/30.

Report forms are posted at http://sbo.od.nih.gov under "Forms."

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

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, and VOSB source lists, guides and other data identifying such vendors;
- b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, and VOSB 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, and/or VOSB 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 for *contract by contract basis* for company or division-wide commercial products plans.)

g.	Additional records:	
0		

SIGNATURE PAGE

(applies to Master or Commercial type plans)

This master or commercial type subcontracting plan is submitted by:
Contractor:
Contractor Signature:
Typed Name:
Title:
Date Prepared:
And Is Accepted By:
Agency:
Contracting Officer Signature:
Typed Name:
Date:

SMALL DISADVANTAGED BUSINESS (SDB) PARTICIPATION PLAN							
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				
		 NTRACT LEVEL BY NAIC	S 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 letterhead 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.
 - (l) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. For Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.
 - (2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.
 - (3) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of \$1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:

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

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

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

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

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

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

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

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

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT									
(a) Billing Office Name and Ad	(b) Invoice/Financing Request No.								
National Institute of Neurologic Contracts Management Branch, 6001 Executive Blvd., Suite 328	(c) Date Invoice Prepared								
Bethesda, MD 20892-9531	(d) Contract N	(d) Contract No.							
(e) Payee's Name and Address ABC CORPORATION 100 Main Street Anywhere, USA zip code	Effective Date								
Attn: Name, Title, & Phone Nur	mber of Official to	o Whom	(f) Total Estimated Cost						
Payment is Sent			(g) Total Fixed Fee						
(h) This invoice/financing reque	est represents rein	nbursable costs t	for the period fro	om to					
Expenditure Category* A	Cumulative Effort	Percentage of /Hrs.	Inci	Incurred Cost		Contract Amount	Variance H		
	Negotiated B	Actual C	(i) Current D	(j) Cumulative E	F	G			
(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)			(Ti	tle)	-				
* Attach details as specified in the contract									

National Institutes of Health				Project Task:		Contract No.:		Date of Report:	0990-0134 0990-0131
FINANCIAL REP PROJECT/CONTR									
Note: Complete thi Accompan	is Form in Accor nying Instruction.		Reporting	g Period:		Contractor Name an	d Address:		
Expenditure Category	Percen Effort <i>i</i>	tage of /Hours	Cumulative Incurred Cost at End of Prior Period	Incurred CostCurrent Period	Cumulative Cost to Date (D + E)		Estimated Cost a Completion (F + G)	Negotiated Contract Amount	Variance (Over or Under) (I - H)
	Negotiated	Actual							
Α	В	С	D	E	F	G	Н	ı	J

INSTRUCTIONS FOR COMPLETING FORM NIH 2706 "FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. Form NIH 2706 is designed to: (1) provide a management tool for use by be NIH in monitoring the application of financial and personnel resources to the NIH contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the project officer.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Form NIH 2706, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form NIH 2706. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

- (1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.
- (2) **Personnel--Other.** List as one amount unless otherwise required by the contract.
- (3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.
- (4) Accountable Personal Property. Include nonexpendable personal property with an acquisition cost of \$1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."
- (5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.
- (6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.
- (7) Outpatient Care. Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.
- (8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.
- (9) Consultant Fee. Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.
- (10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.
- (11) **Subcontracts.** List each subcontract by name and amount billed.

- (12) Other Costs. Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.
- (13) Overhead/Indirect Costs. Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.
- (14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.
- (15) **Fee.** Cite the fee earned, if any.
- (16) Total Costs to the Government.

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on Form NIH 2706.

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

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

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

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

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

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

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