OMB NO. 0990-0115

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

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

2. **Request For Proposal (RFP) Number**:	3. **Issue Date**:	4. **Just In Time**:	5. **Set Aside**:
260-03-19	07/16/03	**[x]** NO **[ ]** YES See Part IV, Section L	**[x]** NO **[ ]** YES See Part IV, Section L

6. TITLE: The Natural History of CMV-related Hearing Loss and the Feasibility of CMV Screening as Adjunct to Hearing Screening in the Newborn

7. ISSUED BY:	8. SUBMIT OFFERS TO:
National Institutes of Health Division of Research Acquisition, OLAO/OA/OD Room 6E01 6100 Executive Boulevard, MSC 7540 Bethesda, Maryland 20892-7540	See Part III, Section J, Attachment 1, Packaging and Delivery of the Proposal.

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place designated and quantity specified in Part III, Section J, Attachment 1, until **3:00 p.m.**, local time, **November 13, 2003**. Offers will be valid for 120 days unless a different period is specified by the offeror on the attachment entitled, "Proposal Summary and Data Record, NIH 2043."

10. **This solicitation requires delivery of proposals to two different locations. The official point of receipt for determining a timely proposal is the Division of Research Acquisition, OLAO/OA/OD (see Part III, Section J, Attachment 1). If your proposal is not received by the Contracting Officer or his/her designee at the place and time specified for receipt, it will be considered late and handled in accordance with HHSAR Clause 352.215-70, Late Proposals and Revisions, located on page 27 of this solicitation.**

11. Offeror must provide its full name, complete address (including street, city, county, state, and zip code), electronic address, and facsimile number.

12. FOR INFORMATION CALL: John P. DeCenzo, Contracting Officer
PHONE: (301) 496-4487
E-MAIL: jd93o@nih.gov
COLLECT CALLS WILL NOT BE ACCEPTED.

13. Table of Contents on following page.

NOTE TO OFFERORS: The Government intends to evaluate proposals and award a contract without discussions with offerors. Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. See Section L, paragraph 1.a. of this solicitation, "Instructions to Offerors--Competitive Acquisition."

13. DETAILED TABLE OF CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR [I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE (E.G., NONPROFIT, COMMERCIAL) AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL] WILL BE DETERMINED BEFORE AWARD AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this contract is to 1) address the relationship between the presence of congenital CMV and long-term audiologic/otologic outcome, and 2) address the clinical validity and utility of CMV screening in the detection of permanent hearing impairment in the newborn, as well as the prediction of hearing impairment with onset during infancy or in the early years of life. The goals are to correlate CMV status at birth with the presence of permanent and/or progressive sensorineural hearing loss; to acquire information on the incidence, time course and audiologic outcomes of CMV related hearing loss; and to determine the extent to which CMV screening can improve detection and predictions of either existing or progressive hearing loss if combined with physiological metrics already in use for newborn hearing screening.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This Article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer for (1) acquisition, by purchase or lease, of any interest in real property; (2) special rearrangement or alteration of facilities; (3)purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; (4) travel costs; (5) consultant costs; (6) subcontract costs; (7) patient care costs; (8) accountable Government property; and (9) research funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

Independently and not as an agent of the Government, the Contractor shall be required to 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 2, dated July 2003, attached hereto and made a part of this solicitation.

SECTION D - PACKAGING, MARKING, AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this Section, the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the following location:

National Institutes of Health
National Institute on Deafness and Other Communication Disorders
Bethesda, Maryland 20892

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. FAR clauses are also available on the Internet at http://www.arnet.gov/far/.

FAR Clause No. 52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM) (APRIL 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

a. Satisfactory performance of this contract shall occur upon performance of the work described in SECTION C and acceptance by the Contracting Officer, or duly authorized representative, of the items specified below. The items 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)	Semiannual Progress Report	2	Quarterly. Reports shall be due on or before the 30th calendar day following the close of the reporting period. A quarterly report is not due for the final quarterly period of the contract.
(2)	Phase 1 Summary Report	2	Upon completion of Phase 1.
(3)	Phase 2 Final Protocol/Methodology Report	2	Upon completion of Phase 2.
(4)	Annual Technical Progress Report for Clinical Research Study Populations	2	Annually. Reports shall be due on or before the 30th calendar day following the close of the reporting period. The report for the final period of the contract shall be submitted with the Final Report.
(5)	Final Report	2	On or before the contract expiration date.

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

Addressee	Deliverable Item No.	Quantity
Project Officer National Institutes of Health National Institute on Deafness and Other Communication Disorders Bethesda, Maryland 20892	(1), (2), (3), (4), and (5)	1
Contracting Officer National Institutes of Health Division of Research Acquisition, OLAO/OA/OD Room 6E01 6100 Executive Boulevard, MSC 7540 Bethesda, Maryland 20892-7540	(1), (2), (3), (4), and (5)	1

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

This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. FAR clauses are also available on the Internet at 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

Any contract awarded from this solicitation will contain the following:

ARTICLE G.1. PROJECT OFFICER

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

[to be specified at time of 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 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 to the contractor 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.2. 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:

NAME	TITLE

[to be specified at time of award]

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

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

b. The combined Invoice/Financing Request and Contract Financial Report shall be submitted concurrently as follows:

(1) An original and one copy to the following approving official:

Contracting Officer
National Institutes of Health
Division of Research Acquisition, OLAO/OA/OD
Room 6E01
6100 Executive Boulevard, MSC 7540
Bethesda, Maryland 20892-7540

(2) One copy to the following program official:

Project Officer
National Institutes of Health
National Institute on Deafness and Other Communication Disorders
Bethesda, Maryland 20892

c. Inquiries regarding payments shall be directed to the Contracting Officer at (301) 496-4487.

ARTICLE G.4. GOVERNMENT PROPERTY

If this solicitation results in the acquisition or use of Government Property, this Article will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled Contractor's Guide for Control of Government Property (1990), which is available on the Internet at http://knownet.hhs.gov/log/contractorsguide.htm.

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Interim and final evaluations of contractor performance will be prepared for this contract in accordance with FAR Subpart 42.15. The Contracting Officer will determine the frequency with which interim evaluations will be prepared. The final evaluation will be prepared when all work under the contract is completed.

An evaluation report will be provided to the contractor as soon as practicable after completion of each evaluation. The contractor will have thirty days to review the report and submit to the Contracting Officer any comments, rebutting statements, or additional information. Any disagreements 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.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

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

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

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

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

(NOTE: This contract is designated as NIH-defined clinical research and is not considered a clinical trial. However, a Data and Safety Monitoring Plan must be provided and will be evaluated as part of the proposal.)

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

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

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

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

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

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

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

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

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[applicable information to be included at time of award]

ARTICLE H.5. NEEDLE EXCHANGE

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

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[applicable information to be included at time of award]

ARTICLE H.6. PRIVACY ACT

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

The Privacy Act System of Records applicable to this project is number 09-25-0200, which is incorporated into this contract by reference. A copy of the of the System Notice is available at http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm.

ARTICLE H.7. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

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

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

April 30
October 30

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

Contracting Officer
National Institutes of Health
Division of Research Acquisition, OLAO/OA/OD
Room 6E01
6100 Executive Boulevard, MSC 7540
Bethesda, Maryland 20892-7540

(2) **Summary Subcontract Report, SF-295**

The contractor shall submit two copies of Summary Subcontract Report, SF-295, in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30

One copy of this report shall be sent to the Contracting Officer at the address above and one copy shall be sent to the Office of Small and Disadvantaged Business Utilization, DHHS at the address below:

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

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

ARTICLE H.8. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

b.	**Public Law No.**	**Fiscal Year**	**Dollar Amount of Salary Limitation***

[applicable information to be included at time of award]

** Currently this amount is $171,900 and will remain at this level until such time as the Executive Level I is increased. See the following web site for Executive Schedule rates of pay:*

LINK to EXECUTIVE SCHEDULE SALARIES: *http://www.opm.gov/oca/PAYRATES/index.htm*
(Click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years.)

ARTICLE H.9. 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 on Deafness and Other Communication Disorders, National Institutes of Health, Department of Health and Human Services, under Contract No. ___."

ARTICLE H.10. PRESS RELEASES

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

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[applicable information to be included at time of award]

ARTICLE H.11. REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE

Anyone who becomes aware of the existence or apparent existence of 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.12. ANTI-LOBBYING

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

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

c. **Public Law and Section No.** **Fiscal Year** **Period Covered**

[applicable information to be included at time of award]

ARTICLE H.13. 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 interchangeably and have the same meaning.

ARTICLE H.14. SHARING RESEARCH DATA

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

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

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

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

ARTICLE H.15. INVENTION REPORTING REQUIREMENT

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

Contracting Officer
National Institutes of Health
Division of Research Acquisition, OLAO/OA/OD
Room 6E01
6100 Executive Boulevard, MSC 7540
Bethesda, Maryland 20892-7540

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

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.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS SOLICITATION. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES TO BE INCLUDED IN THE CONTRACT(S) AWARDED FROM THIS SOLICITATION.

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. FAR clauses are also available on the Internet at http://www.arnet.gov/far/.

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes

52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Jun 2003	Toxic Chemical Release Reporting
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Jun 2003	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
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.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment, Alternate I (Feb 2002)
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)

52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
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.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jun 2003	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 6/2003].

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications to the General Clauses, which are based on the type of contract and contractor, will be determined before award. It is expected that the following changes will be made a part of the resultant contract.

a. The following clauses are deleted in their entirety:

(1) FAR Clause 52.215-10, Price Reduction for Defective Cost or Pricing Data (OCTOBER 1997).

(2) FAR Clause 52.215-12, Subcontractor Cost or Pricing Data (OCTOBER 1997).

(3) FAR 52.215-14, Integrity of Unit Prices (OCTOBER 1997).

(4) FAR Clause 52.215-15, Pension Adjustments and Asset Reversions (DECEMBER 1998).

(5) FAR Clause 52.215-18, Reversion or Adjustment of Plans for Post Retirement Benefits (PRB) Other Than Pensions (OCTOBER 1997).

(6) FAR Clause 52.215-19, Notification of Ownership Changes (OCTOBER 1997).

b. The following clauses are added:

(1) Alternate IV (OCTOBER 1997) of FAR Clause 52.215-21, Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data--Modifications (OCTOBER 1997).

(2) Alternate II (OCTOBER 2001) of FAR Clause 52.219-9, Small Business Subcontracting Plan (JANUARY 2002).

c. FAR Clause 52.232-20, Limitation of Cost, is deleted in its entirety and FAR Clause 52.232-22, Limitation of Funds (APRIL 1984) is substituted therefor. Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

This contract incorporates the following clauses by reference, unless otherwise noted, 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. FAR clauses are also available on the Internet at http://www.arnet.gov/far/.

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

(1) 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."

(2) FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (JUNE 2003).

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

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

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

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

(6) Alternate I (JUNE 1987), FAR 52.227-14, Rights in Data--General (JUNE 1987).

(7) 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.

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

(9) FAR 52.230-2 through 52.230-6, Cost Accounting Standards (CAS) clauses. The appropriate clause(s) for a CAS-covered contract will be determined at the time of award.

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

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

(12) FAR 52.246-23, Limitation of Liability (FEBRUARY 1997).

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

(1) HHSAR 352.223-70, Safety and Health (JANUARY 2001). [This clause is provided in full text in SECTION J - ATTACHMENTS.]

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

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

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

The following clauses are attached and made a part of this contract:

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

(2) NIH(RC)-11, Research Patient Care Costs (4/1/84).

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 clauses in full text.

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

a. FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS AND COMMERCIAL COMPONENTS (APRIL 2003)

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

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

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

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

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

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
(v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (APR 2003) (46 U.S.C. Appx 1241 and 10 U.S.C. 2631) (flow down required in accordance with paragraph (d) of FAR clause 52.247-64).

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

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

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

1. Packaging and Delivery of Proposal, September 1997, 2 pages.
2. Statement of Work, July 2003, 5 pages.
3. Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4[4], May 1997, 5 pages.
4. Targeted/Planned Enrollment Table[1], October 2001, 1 page.
5. Inclusion Enrollment Report[4], October 2001, 1 page.
6. Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, Form OMB No. 0990-0263(formerly Optional Form 310)[7], January 2003, 1 page.
7. Small Business Subcontracting Plan Format[2] or [3], March 2003, 8 pages.
8. Safety and Health , HHSAR Clause 352.223-70[4], January 2001, 1 page.
9. Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)[4], April 1984, 1 page.
10. Research Patient Care Costs, NIH(RC)-11, April 1984, 1 page.
11. Disclosure of Lobbying Activities, OMB Form SF-LLL[2], December 1989, 3 pages.
12. Proposal Summary and Data Record, NIH-2043 (Rev. 6/82)[2], June 1982, 2 pages.
13. Contact Points[2], July 1991, 1 page.
14. Technical Proposal Cost Information[1], December 1988, 1 page.
15. Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours[2], September 1992, 2 pages.
16. Summary of Related Activities[1], March 1984, 1 page.
17. Government Notice for Handling Proposals[1], January 2001, 1 page.

Footnotes:

1. These forms must be completed (where applicable) and submitted with the Technical Proposal.
2. These forms must be completed (where applicable) and submitted with the Business Proposal.
3. These forms are for informational purposes only.
4. These forms will be attached to any contract resulting from this solicitation.
5. Submission instructions are contained on the form.
6. Complete this form as soon as possible and return as indicated on the form.
7. If applicable, this form is to be completed and submitted with the Technical Proposal. ALL INSTITUTIONS MUST HAVE THE FORM REVIEWED AND APPROVED BY THEIR INSTITUTIONAL REVIEW COMMITTEE.
8. Submission Instructions are contained in Section L.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications and Other Statements of Offerors or Quoters (Negotiated)

The Representations and Certifications required by this acquisition can be accessed through the Internet at the following address: http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf.

If you are unable to access this document, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM WITH YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (May 2001)], with **ALTERNATE II** (October 1997).

(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.

(9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the stated requirements, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

(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 paragraph (e) of 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.

b. **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 solicitation), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500 employees.

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

c. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

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

offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

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

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that one award will be made from this solicitation and that the award will be made on/about September 30, 2004.

It is anticipated that the award from this solicitation will be a multiple-year, completion type, cost reimbursement contract with a period of performance of seven years. It is also anticipated that the contract will be incremental funded.

e. ESTIMATE OF EFFORT

To assist you in the preparation of your proposal, the Government considers the total effort necessary to perform this contract to be approximately 96,200 labor hours (based on a work-year equaling 2,080 hours) or 46.25 FTEs (full-time equivalent employment). Although not to be considered restrictive for proposal purposes, the Government's estimate of labor hours/level of effort is broken down as follows:

Labor Hours/Level of Effort

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Total
Professional	11,960/5.75	11,960/5.75	11,960/5.75	6,240/3.00	6,240/3.00	6,240/3.00	6,240/3.00	60,840/29.25
Technical	6,240/3.00	6,240/3.00	6,240/3.00	4,160/2.00	4,160/2.00	4,160/2.00	4,160/2.00	35,360/17.00
Total	18,200/8.75	18,200/8.75	18,200/8.75	10,400/5.00	10,400/5.00	10,400/5.00	10,400/5.00	96,200/46.25

f. 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.

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

h. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with the regulations applicable to this acquisition. The Contracting Officer will notify offerors promptly in writing when their proposals are eliminated from competition or are not selected for award.

i. **PREPARATION COSTS**

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

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

(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
National Institutes of Health
Division of Research Acquisition, OLAO/OA/OD
Room 6E01
6100 Executive Boulevard, MSC 7540
Bethesda, Maryland 20892-7540

(b) 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)

k. **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. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals.

(1) **Contract Type and General Clauses**

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

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this solicitation. The proposal shall be marked, addressed, and submitted in the number of copies specified in the attachment entitled PACKAGING AND DELIVERY OF THE PROPOSAL, Part III, Section J, hereof. Proposals must be typewritten, paginated, reproduced on letter size paper and must be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the solicitation should be placed in the following order:

I. COVER PAGE

Include solicitation 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 SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, table of contents, and the information requested in the Business Proposal Instructions and 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 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 categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (see attachment entitled TECHNICAL PROPOSAL COST INFORMATION/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) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M, of this solicitation.

(6) **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 procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

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

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

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

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

IMPORTANT NOTE TO OFFERORS: The following six paragraphs [(7) through (12)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled "HUMAN SUBJECTS."

(7) **Human Subjects**

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

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

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

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

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

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

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

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

(End of Provision)

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

(8) **Instructions to Offerors Regarding Protection of Human Subjects**

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

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

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

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

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

Sources of Materials:

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

Potential Risks:

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

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

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

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

Protection Against Risk:

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

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

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

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

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

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

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

Collaborating Site(s)

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

(9) **Required Education in the Protection of Human Research Participants**

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

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

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

(10) **Inclusion of Women and Minorities in Research Involving Human Subjects**

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

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

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

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

Information Required for ALL Clinical Research Proposals

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

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

The proposal must include the following information:

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

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

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

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

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

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

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

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

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

(11) **Inclusion of Children in Research Involving Human Subjects**

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

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

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998, and is available at the following URL address: http://www.nih.gov/grants/guide/notice-files/not98-024.html.

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

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

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

Justifications for Exclusion of Children

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

- The objective of the solicitation is not relevant to children.
    - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
    - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
    - A separate, age-specific study in children is warranted and preferable. Examples include:
        - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
        - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
        - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or

- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

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

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

(12) **Data and Safety Monitoring in Clinical Trials**

(NOTE: This contract is designated as NIH-defined clinical research and is <u>not</u> considered a clinical trial. However, a Data and Safety Monitoring Plan must be provided and will be evaluated as part of the proposal.)

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

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

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

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

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

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

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

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

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

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

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

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

(13) **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003, with the exception of small health plans, which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

(14) **Obtaining and Disseminating Biomedical Research Resources**

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

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

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.

(15) **Sharing Research Data**

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html.

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

(16) **Privacy Act - Treatment of Proposal Information**

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

The NIH is requesting the information called for in this solicitation 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.

(17) **Selection of Offerors**

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

(b) The business portion of each contract proposal will be subjected to a cost or price evaluation and business analysis.

(c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal or to resolve minor or clerical errors.

(d) If the Government determines that discussions are necessary, the Contracting Officer will establish a competitive range comprised of all of the most highly rated proposals, unless the range is further reduced for purposes of efficiency. [Note: Communications with offerors before establishment of the competitive range may be necessary for reasons specified in FAR 15.306(b).] Oral or written discussions will be conducted with all offerors in the competitive range. All aspects of the proposal are subject to discussions, including cost, technical approach, past performance (if applicable), SDB participation, and contractual terms and conditions. At the conclusion of discussions, each offeror in the competitive range will be given an opportunity to submit a final proposal revision.

(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 priced offeror or other than the highest technically rated offeror.

(18) **Small Business Subcontracting Plan**

******* This document must be submitted with the initial proposal.*******

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, offerors shall submit a subcontracting plan in accordance with the terms of FAR Clause 52.219-9, Small Business Subcontracting Plan (January 2002), with Alternate II (October 2001).

(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:

i) No contract will be awarded unless an acceptable subcontracting plan is negotiated with the Contracting Officer. The plan will be incorporated into the resultant contract.

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

iii) 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.

iv) 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.

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

vi) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions therein, 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:

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

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

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

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

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

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

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

viii) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

ix) 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.

x) 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.

xi) 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, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan (January 2002), with Alternate II (October 2001), and the Sample Subcontracting Plan, which is provided as an attachment in SECTION J of this solicitation.

HHS expects each procuring activity to establish minimum subcontracting goals for all acquisitions. The anticipated minimum goals for this solicitation are as follows:

36.6% for Small Business; 6.8% for Small Disadvantaged Business; 5.1% for Women-Owned Small Business; 3.0% for HUBZone Small Business; and 1.5% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(19) **HUBZone Small Business Concerns**

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

(20) **Extent of Small Disadvantaged Business Participation**

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

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

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

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

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

(21) **Salary Rate Limitation in Fiscal Year 2003**

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

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

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

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

Note: If this award is made in Fiscal Year 2004, the current Fiscal Year 2003 Salary Rate Limitations should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate Limitations.

(22) **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:

i) 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;

ii) 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;

iii) 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

iv) 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.

(23) **ROTC Access and Federal Military Recruiting on Campus**

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

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

(24) **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. Solicitation provisions are also available on the Internet at http://www.arnet.gov/far/. 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.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

(d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical proposal should be in as much detail as you consider necessary to fully explain your technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken, and it 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:

(b) **Statement of Work**

i) Objectives

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

ii) Approach

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

iii) Methods

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

iv) Schedule

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

(c) **Personnel**

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

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

i) Principal Investigator/Project Director

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

ii) Other Investigators

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

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 will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

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 of this solicitation.

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

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 to determine price reasonableness or cost realism. This information shall include the basic elements of the proposed cost or price, such as direct labor, fringe benefits, materials/supplies, travel, other costs, subcontracted items, equipment, indirect costs, and profit or fee.

(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; profit or fee (as applicable); and total;
(g) The following statement: *By submitting this proposal, we grant the Contracting Officer or authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price.*
(h) Date of submission; and
(i) Name, title and signature of authorized representative.

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

(a) The offeror shall submit a detailed breakdown of estimated costs by phase, segment, or year in the format prescribed in Section J, attachment entitled Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(b) The information submitted shall be at the level of detail described below, as applicable:

i) **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by individual, and furnish bases for estimates.

ii) **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.

iii) **Materials/Supplies**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing.

iv) **Travel**

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

v) **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.

vi) **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.

vii) **Equipment**

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

viii) **Indirect Costs**

Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show budgetary data to provide a basis for evaluating the reasonableness of proposed rate(s), or where a rate agreement exists, provide a copy.

(4) **Qualifications of the Offeror**

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

(a) **General Experience**

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

(b) **Organizational Experience Related to the Solicitation**

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 solicitation. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this solicitation.

(c) **Performance History**

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

(d) **Pertinent Contracts**

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

(e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this solicitation. Include the grant number, involved agency, names of the Grant Specialist and the Health Scientist Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important solicitation 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.

(5) **Other Administrative Data**

(a) **Property**

i) 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 solicitation, 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 this 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.

ii) 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.

iii) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686, entitled Contractor's Guide for Control of Government Property (1990), which is available on the Internet at http://knownet.hhs.gov/log/contractorsguide.htm.

(b) **Royalties**

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

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

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

i) The solicitation number (or other procurement identification number).
ii) The offeror's name and remittance address, as stated in the offer.
iii) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
iv) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
v) The offeror's account number and the type of account (checking, savings, or lockbox).
vi) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
vii) 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 contract award. If this requirement is specified elsewhere in this solicitation, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

(End of provision)

(6) **Subcontractors**

If subcontractors are proposed, 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 subcontracts with educational institutions should refer to the following Web Site for a listing of clauses that are required to be incorporated into cost-reimbursement type Research and Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm.

(7) **Annual Financial Report**

One copy of the offeror's most recent annual financial report must be submitted with the business proposal.

(8) **Representations and Certifications**

One copy of the Representations and Certifications (Section K of this solicitation) shall be completed and signed by an official authorized to bind your organization.

(9) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). 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

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost/price, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

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

2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

a. Protection of Human Subjects from Research Risks

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

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

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

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable," you may be given an opportunity to clarify and/or discuss your position. If your proposed plan for the protection of human subjects from research risks is still considered unacceptable after these exchanges, your proposal will not be considered for award.

b. Data and Safety Monitoring

(NOTE: This contract is designated as NIH-defined clinical research and is <u>not</u> considered a clinical trial. However, a Data and Safety Monitoring Plan must be provided and will be evaluated as part of the proposal.)

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

evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring.

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

If the information provided regarding Data and Safety Monitoring is rated "unacceptable," you may be given an opportunity to clarify and/or discuss your plan. If your proposed Data and Safety Monitoring Plan is still found unacceptable after these exchanges, your proposal will not be considered for award.

c. **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

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

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

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health,;or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

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

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

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable," you may be given an opportunity to clarify and/or discuss your plan. If your plan for inclusion/exclusion of women/minorities is still considered "unacceptable" after these exchanges, your proposal will not be considered for award.

d. **Children**

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

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

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

If the information provided in your proposal about the inclusion of children is rated "unacceptable," you may be given an opportunity to clarify and/or discuss your plan. If your plan for inclusion of children is still considered "unacceptable" after these exchanges, your proposal will not be considered for award.

3. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

4. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria listed below will be used by the technical evaluation panel when reviewing technical proposals.

a. **Understanding of the Field** **20 points**

The offeror's understanding and analysis of the proposed project: Evidence of understanding of the current status of the field and the need for the specific items requested in the Statement of Work.

b. **Technical Approach** **40 points**

Quality of the study design, including recognition and discussion of anticipated problems, together with suggested solutions; originality of ideas presented; soundness and feasibility of the procedures proposed. Adequacy of addressing all items in the Statement of Work.

c. **Personnel Qualifications** **30 points**

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

d. **Facilities and Equipment** **10 points**

Facilities and equipment of the organization deemed to be of value to the project. Availability of same to accomplish the objectives of the Statement of Work.

5. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

The extent of participation of small disadvantaged business (SDB) concerns in the performance of this acquisition will not be scored. However, the Government's conclusions about the overall commitment and realism of the offeror's targets for SDB participation 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 SDB participation will be based on the following subfactors:

a. The extent of commitment to use SDB concerns in performance of the contract (in terms of dollars and percentages of total contract value).

b. The complexity and variety of work to be performed by SDB concerns (in terms of NAICS Industry Subsectors identified).

PACKAGING AND DELIVERY OF THE PROPOSAL

Your proposal shall be organized as specified in Section L.2., "Instructions to Offerors." Shipment and marking shall be as indicated below.

EXTERNAL PACKAGE MARKING

In addition to the address cited below, mark each package as follows:

"RFP NO. 260-03-19

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

NUMBER OF COPIES

PLEASE NOTE - THE TECHNICAL PROPOSAL SHALL BE SENT TO TWO DIFFERENT LOCATIONS. PLEASE READ THE FOLLOWING INFORMATION CAREFULLY.

A. TECHNICAL PROPOSAL ONLY

ORIGINAL* AND 4 COPIES TO:

If hand-delivered or delivery service

Contracting Officer
Division of Research Acquisition, OLAO/OA/OD
National Institutes of Health
Room 6E01
6100 Executive Boulevard
Rockville, Maryland 20852

If using U.S. Postal Service

Contracting Officer
Division of Research Acquisition, OLAO/OA/OD
National Institutes of Health
Room 6E01
6100 Executive Boulevard, MSC 7540
Bethesda, Maryland 20892-7540

8 COPIES TO:

If hand-delivered or delivery service

Chief
Scientific Review Branch, DER, NIDCD
National Institutes of Health
Room 400C, Executive Plaza South
6120 Executive Boulevard
Rockville, Maryland 20852

If using U.S. Postal Service

Chief
Scientific Review Branch, DER, NIDCD
National Institutes of Health
Room 400C, Executive Plaza South
6120 Executive Boulevard, MSC 7180
Bethesda, Maryland 20892-7180

B. BUSINESS PROPOSAL

ORIGINAL* AND 4 COPIES TO:

If hand-delivered or delivery service

Contracting Officer
Division of Research Acquisition, OLAO/OA/OD
National Institutes of Health
Room 6E01
6100 Executive Boulevard
Rockville, Maryland 20852

If using U.S. Postal Service

Contracting Officer
Division of Research Acquisition, OLAO/OA/OD
National Institutes of Health
Room 6E01
6100 Executive Boulevard, MSC 7540
Bethesda, Maryland 20892-7540

*THE ORIGINALS MUST BE READILY ACCESSIBLE FOR DATE STAMPING.

NOTE: The U.S. Postal Service's "Express Mail Next Day Service" does not deliver to the Rockville, Maryland addresses. Any package sent to those addresses via the U.S. Postal Service will be delivered to the NIH central mail-handling facility for processing. If your proposal is received at the place designated in the solicitation after the exact date and time specified for receipt, it will be considered a "late proposal."

STATEMENT OF WORK

The Natural History of CMV-related Hearing Loss and the Feasibility of CMV Screening as Adjunct to Hearing Screening in the Newborn

1. BACKGROUND

Approximately 1 in 1000 newborns will have hearing impairment serious enough to cause delays in the development of speech and language. Using high risk registries alone misses approximately 50% of newborns with hearing loss. Beginning in the mid 1990s, screening of all newborns for hearing impairment was initiated across much of the nation on a state by state basis. At present, thirty-three states have legislation that requires universal hearing screening for newborns; it is estimated that 80% of infants born in the United States are screened for hearing impairment prior to hospital discharge. Current newborn hearing screening protocols utilize otoacoustic emissions, auditory brainstem response measures, or a combination of the two tests. Infants who fail screening are referred for further audiometric testing to determine hearing status. The goal is to identify all infants with hearing loss as soon as possible after birth so that intervention can begin prior to the age of six months.

Newborn hearing screening prior to hospital discharge cannot detect delayed-onset hearing loss (hearing loss occurring in early infancy after the newborn hearing screening). The incidence of delayed onset hearing loss and the origin of such losses are unknown, but it is thought that congenital cytomegalovirus (CMV) infection accounts for a significant portion of late-onset childhood hearing loss. Recent reports suggest a wider role for CMV infection in sensorineural hearing loss than previously thought, indicating that 20% to 30% of childhood hearing loss is caused by CMV.

The incidence of CMV infection in newborns varies widely throughout the world. It is estimated to occur in 0.5 to 1.5% of live births in the United States. The public health impact of congenital CMV infection is largely due to its ability to damage the central nervous system, including the auditory system. Intrauterine CMV infection from a primary maternal infection (a 40% vertical transplacental transmission rate) or a recurrent maternal infection (reactivation of a latent virus) is associated with fetal damage. The standard diagnostic test for congenital CMV is virus culture from urine or saliva before 3 weeks of age as virus isolation from infants over 3 weeks of age may reflect an acquired infection, making retrospective etiologic diagnosis difficult. Viral DNA can be detected by polymerase chain reaction (PCR) in serum, urine or saliva samples. Further, studies are evaluating the ability to detect CMV DNA in bloodspots collected for metabolic newborn screening.

Approximately 90 - 95% of children with congenital CMV are clinically silent (asymptomatic) at birth. Of the asymptomatic children, 5-15% are at risk for developing hearing loss, chorioretinitis, or mental retardation, with hearing loss being the most common outcome. The remaining 5-10% (symptomatic) has a variety of central nervous system and systemic manifestations. Approximately 90% of infants who are symptomatic at birth have long-term sequelae, including hearing loss, retardation, seizures, visual defects, and/or cerebral palsy. Due to the severity of their symptoms, these children are usually entered into a medical surveillance system quickly.

Although there are few population-based studies of the etiology of hearing loss in infants, when such studies have included assays for congenital CMV infection, they strongly suggested that congenital CMV infection is a leading cause of sensorineural hearing loss in children. Although the majority (approximately 90%) of congenitally infected infants are asymptomatic at birth, a subset (approximately 5-10%) of such infants eventually develop hearing loss of variable severity. Limited data from two United States populations in Alabama and Texas indicates that 30-65% of symptomatic CMV infants will develop hearing loss, and that 8-15% of asymptomatic CMV infants will develop hearing loss. The hearing loss presents in children of ages from 6 months to 6 years, may be moderate to profound in degree, may be unilateral or bilateral, and may be fluctuating or progressive in nature.

In March 2002, the NIDCD convened a workshop of experts in related fields of congenital CMV infection and hearing loss, intrauterine CMV transmission, treatment of CMV-positive neonates, neonatal hearing and metabolic screening, and CMV diagnostics. The goal of the workshop was to develop a set of recommendations for future research in the area of congenital CMV infection and hearing loss (minutes may be found at http://www.nidcd.nih.gov/funding/programs/hb/cmvwrkshop.asp). This contract addresses one of the research recommendations from that workshop.

Additional information about the natural history of hearing loss, including the severity, the age of onset and the rate of the progression of the hearing loss, is needed in infants with congenital CMV infection. Evaluating the accuracy of available

diagnostic assays, and ascertaining the role and added value of CMV screening together with existing auditory physiological methods of newborn hearing screening is also needed. This information will be of significant value as the possibility of augmenting hearing screening protocols with CMV information is considered.

2. OBJECTIVE

The purpose of this contract is to 1) address the relationship between the presence of congenital CMV and long-term audiologic/otologic outcome, and 2) address the clinical validity and utility of CMV screening in the detection of permanent hearing impairment in the newborn, as well as the prediction of hearing impairment with onset during infancy or in the early years of life. The goals are to correlate CMV status at birth with the presence of permanent and/or progressive sensorineural hearing loss; to acquire information on the incidence, time course and audiologic outcomes of CMV related hearing loss; and to determine the extent to which CMV screening can improve detection and predictions of either existing or progressive hearing loss if combined with physiological metrics already in use for newborn hearing screening.

3. PROJECT DESIGN

This project shall utilize a population-based prospective study design, including a nested case-control design for follow-up. The control sample must be matched on key variables to the case infants and followed-up using the same protocol.

Newborns shall be screened for CMV infection. All asymptomatic CMV positives shall be enrolled in an audiometric follow-up arm as part of this contract. Symptomatic CMV positives shall be followed through standard clinical care. A control sample must also be included. The accuracy of two diagnostic methodologies for CMV screening will be compared.

4. WORK TO BE PERFORMED

Phase I: Startup and Methodology

1. Identify an appropriate and adequate population(s) of infants who are currently undergoing newborn hearing screening, in which to study CMV related hearing loss. (A minimum of 150,000 infants shall be screened for CMV.) Newborns shall be screened for CMV infection. All asymptomatic CMV positives shall be enrolled in an audiometric follow-up arm as part of this contract. Symptomatic CMV positives shall be followed through standard clinical care. A control sample must also be included. Matching variables for the cases and control infants must be stipulated.

2. Ensure access to newborn hearing screening results. Required information includes pass/fail rates, referral rates, follow-up rates, dropout rates, hearing screening program methodology, oversight, and coordination. Ensure access to associated infant medical information, such as family history and any medical conditions identified or treated in the perinatal period. This shall include hyperbilirubinemia, hypoxia, ototoxicity, sepsis, and any prolonged perinatal hospitalization.

3. Develop a manual of procedures (MOP), data forms, data safety and monitoring plan, informed consent forms, and any other documents needed for collaborative arrangements and collection of CMV and audiometric screening and follow-up data. Ensure that safeguards for maintaining confidentiality are in place and effective. Special attention must be given to the potential for increased anxiety in the families of CMV-positive infants who are unaffected at birth.

4. Finalize and confirm interactions (including any remaining documentary verification) with the state health departments or other participating agencies. It is necessary that cooperation and access to the population and associated medical birth information is assured and that parents may be contacted for specimen collection for CMV screening.

5. Upon consultation with the Project Officer, prepare documentation for obtaining approval from the Office of Management and Budget (OMB) for the collection of information from the public. (The Contractor should allow for a minimum of 6 months in its planning schedule for obtaining OMB clearance or NIH clinical exemption).

6. Upon completion of the aforementioned tasks, provide the Government with a summary report regarding the status of those requirements, including one set of all test forms, protocols, procedures, informed consents, and any other documentation needed for the collection of project data.

Phase II: Collection of Pilot Data

Commencement of Phase II is contingent upon the successful completion of Phase I, OMB approval or notification of NIH clinical exemption, and certification of Institutional Review Board (IRB) review and approval of all protocols. The Contractor shall not begin Phase II without the written approval of the Contracting Officer.

1. Pilot all aspects of this Phase in selected locations that are included and representative of the facilities targeted for the main study. Piloting must include the coordination and transfer of information among all study personnel, as well as parental counseling. The pilot must also include demonstration of the feasibility of biological (congenital CMV) assays.

2. In response to piloting and upon consultation with the Project Officer, make final modifications in methodology, criteria, testing protocols, and other appropriate issues. Provide a report to the Government documenting these final modifications, including the final versions of all protocols with certification of IRB review and approval.

Phase III: Full Project Initiation

Commencement of Phase III is contingent upon the successful completion of Phase II. The Contractor shall not begin Phase III without the written approval of the Contracting Officer.

1. Initiate CMV screening of the study population. Perform CMV screening, comparing the accuracy of two diagnostic methodologies, using samples acquired under the auspices of this contract. One method shall involve assaying DNA from dried blood spots collected for routine metabolic screening. Typically, in a PCR based strategy only a portion of each spot is utilized per reaction. Thus, the remaining spots shall be retained for future experiments. DNA extracted from whole blood specimens must be stored for future research purposes for the life of this contract. CMV results must be stored in a manner that will allow for linkage with newborn hearing screening results. Infants with symptomatic CMV will be followed under the clinical standard of care; thus, their medical services shall not be provided through this contract.

2. Obtain information from ongoing newborn hearing screening and audiometric follow-up programs. Ensure access to audiometric information obtained from follow-up and diagnostic testing of infants who fail the newborn hearing screening (i.e., 'fails'). Ensure access to associated infant medical information, including family history of hearing impairment. It is expected that follow-up testing for infants referred as 'fails' from the hearing screening is covered under the clinical standard of care, thus those expenses should not be recoverable under this contract. If that is not the case, adequate justification for expenses must be provided.

3. Initiate audiometric follow-up studies for CMV screening positives and selected sample populations. Perform audiometric follow-up and diagnostics for CMV screening positives and controls. These diagnostic tests shall be similar to the diagnostics provided for hearing screening referrals, and shall include emittance, otoacoustic emissions, auditory brainstem response, and play/visual-reinforced/behavioral audiometry, as appropriate for the age of the child. Audiometric testing must be performed at least four times over a 4 year period, with at least one test performed between ages 36 and 48 months.

   When late-onset hearing loss is detected, medical follow-up services (beyond audiometry as noted above) and intervention provisions shall be covered under the clinical standard of care, thus those expenses should not be recoverable under this contract. If that is not the case, adequate justification for expenses must be provided. Services to be provided during the contract performance period shall be clearly stated in the informed consent document.

4. Ensure access to information regarding early intervention enrollment and management of children with hearing impairment.

5. Analyze data regarding correlation of hearing status and CMV status, and determine the extent to which CMV screening can improve detection and prediction of permanent hearing loss in children if combined with current physiological methods of hearing screening and produce a document for publication in scientific journal.

5. ADDITIONAL CONSIDERATIONS

Offerors should address the following in their proposals:

a. A minimum of 150,000 infants shall be screened for CMV. Population characteristics must be included. The project design must allow for an estimation of the magnitude of the CMV-related hearing loss in terms of percentage of infants and children affected, should describe the time course and audiologic outcomes of CMV related hearing loss, and should describe the prevalence for a variety of degrees of hearing loss severity and configurations, thus the large sample population required.

b. Statistical/biostatistical information regarding sample size, power analyses, and data analysis must be included.

c. If additional audiometric testing beyond that normally provided under the clinical standard of care is proposed for hearing screening 'fails', justification and information on those additional tests must be included, will only be provided during the contract period, and should be clearly stated in the informed document.

d. A definition of audiometric outcome to be used for data analysis purposes must be provided. Issues to be considered include better/worse ear, unilateral hearing loss, and definition of progressive hearing loss. The possibility of the presence of otitis media/middle ear effusion must be considered in the audiologic outcome.

e. Recommended timelines/intervals for audiometric testing must be clearly stated and justified, for infants with hearing loss at birth as well as for CMV positive infants/young children with late-onset hearing loss.

f. Justification for proposed diagnostic methodologies and sample types (virus culture from saliva, CMV DNA from serum, viral DNA from saliva, CMV DNA from bloodspots, etc.) must be provided. Additional molecular studies providing additional information on clinical isolates/genetic strains may be proposed. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the stated requirements, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

g. Demonstrate the feasibility of biological (congenital CMV) assays. Provide information on analytic validity, as well as precision within and between laboratories. If appropriate, describe how confirmatory testing will be performed to resolve false positives.

h. The administrative structure must be clearly stated and outlined. Issues to be addressed include, but are not limited to, administrative management, database design and structure, data transfer, data entry and accuracy, database management, subject tracking, record keeping and tracking, and center compliance. Management of audiologic data across data collection sites must be specified. Information detailing the process for transmitting CMV screening and audiometric testing results to appropriate medical personnel and medical records, as well as to parents, must be included.

i. Distinctions must be clear between activities considered research and those which are the clinical standard of care during the contract performance period as well as in the informed consent forms.

6. REQUIRED REPORTS/DELIVERABLES

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit to the Government the following reports/deliverables in the manner and number specified below:

a. Semiannual Progress Report

The Semiannual Progress Report shall consist of a description of the work performed during the prior six months and the anticipated work plan for the coming six months. The first reporting period consists of the first full six months of performance, including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months. The report shall be submitted within 30 calendar days following the close of the reporting period. A Semiannual Progress Report is not due for the final six month period of the contract. One copy of each Semiannual Progress Report shall be submitted to the Project Officer and one copy to the Contracting Officer by e-mail in PDF document format (addresses will be provided at the time of award).

b. Phase I Summary Report

The Phase I Summary Report shall consist of the status of those requirements performed in Phase I, including one set of all test forms, protocols, procedures, informed consents and any other documentation needed for the collection of project data. The report is due upon completion of Phase I. One copy shall be submitted to the Project Officer and one copy to the Contracting Officer by e-mail in PDF document format.

c. Phase II Summary Report

The Phase II Final Protocol/Methodology Report shall document the final modifications in methodology, criteria, testing protocols, etc., including the final versions of all protocols. The report is due upon completion of Phase II. One copy shall be submitted to the Project Officer and one copy to the Contracting Officer by e-mail in PDF document format.

d. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the Final Report. The reporting period shall consist of the first full twelve months of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of twelve full calendar months. The report shall be due on or before the 30th calendar day following the close of the reporting period. One copy shall be submitted to the Project Officer and one copy to the Contracting Officer by e-mail in PDF document format. The report for the final period of the contract shall be submitted with the Final Report.

e. Final Report

The Final Report shall be a 'publication ready' document, delivered electronically in PDF document format. It shall summarize the findings of the studies performed under the contract, and should include both positive and negative results. It shall also include recommendations for future research and development in the area. Copies of all published articles supported by the contract, but not copies of Semiannual Progress Reports, shall be included, along with the final study populations report. One copy of the Final Report shall be submitted to the Project Officer and one copy to the Contracting Officer, on or before the expiration date of the contract.

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR NIH COST-REIMBURSEMENT CONTRACTS, NIH(RC)-4

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(q) **Grand Totals**

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

Column B--Cumulative Percentage of Effort/Hrs.-Negotiated - Enter the percentage of effort or number of hours agreed to 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 for all expenditure categories listed in Column A.

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Billing Office Name and Address NATIONAL INSTITUTES OF HEALTH Division of Research Acquisition, OLAO/OA/OD Room 6E01 6100 Executive Boulevard, MSC 7540 Bethesda, Maryland 20892-7540 (e) Payee's Name and Address ABC CORPORATION 100 Main Street Anywhere, USA zip code Attn: Name, Title, & Phone Number of Official to Whom Payment is Sent	(b) Invoice/Financing Request No._____ (c) Date Invoice Prepared_____ (d) Contract No._____ Effective Date_____ (f) Total Estimated Cost _____ (g) Total Fixed Fee_____

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

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

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

_____ _____
(Name of Official) (Title)

* Attach details as specified in the contract

TARGETED/PLANNED ENROLLMENT TABLE

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

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

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

INCLUSION ENROLLMENT REPORT

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

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

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

	Sex/Gender			
Ethnic Category	**Females**	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				
*These totals must agree **These totals must agree				

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

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

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

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ]FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:_____	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

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

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

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

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

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

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

[ ] his activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting)_____ or [ ] Expedited Review on (date) _____
[ ] If less than one year approval, provide expiration date _____
[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

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

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SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN:_____

CONTRACTOR: _____

ADDRESS: _____

_____

DUNN & BRADSTREET NUMBER : _____

SOLICITATION OR CONTRACT NUMBER: _____

ITEM/SERVICE (Description): _____

_____

TOTAL CONTRACT AMOUNT: **$**_____

Total Contract or
Base-Year, if options

$_____ $_____ **$**_____ **$**_____

Option #1 (if applicable) | Option #2 (if applicable) | Option #3 (if applicable) | Option #4 (if applicable)

TOTAL MODIFICATION AMOUNT (if applicable): _____

TOTAL TASK ORDER AMOUNT (if applicable): _____

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

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

If assistance is needed to locate small business sources, contact the Office of Small and Disadvantage Business Utilization (OSDBU) at (202)690-7300 or the NIH Small Business Office at (301) 496-9639. Sources may also be obtained from SBA's PRONET website (http://pro-net.sba.gov/).

HHS expects each procuring activity to establish minimum subcontracting goals for all acquisitions. The minimum goals for each small business category will be identified in every applicable solicitation (see Section L.2., Instructions to Offerors). These goals are expressed as percentages of the total estimated subcontracting dollars.

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

1. Type of Plan (Check One)

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

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

2. Goals

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Women-Owned Small Business (WOSB), Historically Underutilized Business Zone Small Business (HUBZone), Veteran-Owned Small Business (VOSB), Service Disabled Veteran-Owned Small Business (SDVOSB), and "Other Than Small Business" (OTHER) as subcontractors, as specified in FAR 19.704. (For contracts containing options, separate base year from option years.) **Provide an explanation for any category that has a zero dollar goal.**

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

$ _____ (1^{st} Option) $ _____ (2^{nd} Option) $ _____ (3^{rd} Option) $ _____ (4^{th} Option)

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

$ _____ (1^{st} Option) $ _____ (2^{nd} Option) $ _____ (3^{rd} Option) $ _____ (4^{th} Option)

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

$ _____ (1^{st} Option) $ _____ (2^{nd} Option) $ _____ (3^{rd} Option) $ _____ (4^{th} Option)

d. Total estimated dollar value and percent of planned subcontracting with WOMEN-OWNED SMALL BUSINESSES: (% of "a") $_____ and _____% (Total Contract or Base Year, if Options)

$ _____ (1^{st} Option) $ _____ (2^{nd} Option) $ _____ (3^{rd} Option) $ _____ (4^{th} Option)

e. Total estimated dollar value and percent of planned subcontracting with HUBZONE SMALL BUSINESSES: (% of "a") $_____ and _____% (Total Contract or Base Year, if Options)

$ _____ (1^{st} Option) $ _____ (2^{nd} Option) $ _____ (3^{rd} Option) $ _____ (4^{th} Option)

f. Total estimated dollar value and percent of planned subcontracting with VETERAN-OWNED SMALL BUSINESSES: (% of "a") $_____ and _____% (Total Contract or Base Year, if Options)

$ _____ (1^{st} Option) $ _____ (2^{nd} Option) $ _____ (3^{rd} Option) $ _____ (4^{th} Option)

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

$ _____ (1st Option) $ _____ (2nd Option) $ _____ (3rd Option) $ _____ (4th Option)

h. Total estimated dollar value and percent of planned subcontracting with OTHER THAN SMALL BUSINESS CONCERNS: (% of "a") $_____ and _____% (Total Contract or Base Year, if Options)

$ _____ (1st Option) $ _____ (2nd Option) $ _____ (3rd Option) $ _____ (4th Option)

Notes:
1. Federal prime contract goals are as follows:
SB equals 23%; SDB equals 5%; HUBZone equals 3%; WOSB equals 5%; VOSB equals 3%; SDVOSB equals 3% and can serve as objectives for subcontracting goal development.
2. SDB, WOSB, HUBZone, VOSB, and SDVOSB goals are subsets of SB and should be counted and reported in multiple categories, as appropriate.

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

Subcontracted Product/Service	Other	SB	SDB	WOSB	HUBZONE	VOSB	SDVOSB

j. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns were determined, how the capabilities of these concerns were considered for 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.)

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

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

_____

_____

_____

_____

3. Program Administrator

NAME/TITLE: _____

ADDRESS: _____

TELEPHONE/E-MAIL: _____

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

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

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

b. Develops and maintains bidders lists of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns from all possible sources: [ ] yes [ ] no.

c. Ensures periodic rotation of potential subcontractors on bidder's lists: [ ] yes [ ]no.

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

e. Ensures that solicitations are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB participation: [ ] yes [ ] no.

f Reviews subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB participation: [ ] yes [ ] no.

g. Accesses various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns to include the SBA's PRO-Net and SUB-Net Systems (http://www.sba.gov), the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce, and Federal agencies' Small Business Offices:
[ ] yes [ ] no.

h. Establishes and maintains contract and subcontract award records: [ ] yes [ ] no.

i. Participates in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc.: [ ] yes [ ] no.

j. Ensures that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company: [ ] yes [ ] no.

k. Conducts or arranges for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended: [ ] yes [ ] no.

l. Monitors the organization's/institution's subcontracting program performance and makes any adjustments necessary to achieve the subcontract plan goals: [ ] yes [ ] no.

m. Prepares and submits timely, required subcontract reports: [ ] yes [ ] no.

n. Coordinates the organization's/institution's activities during the conduct of compliance reviews by Federal agencies: [ ] yes [ ] no.

o. Other duties _____.

4. Equitable Opportunity

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

a. Outreach efforts to obtain sources:

1. Contacting minority and small business trade associations;

2. Contacting business development organizations and local chambers of commerce;

3. Attending SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB procurement conferences and trade fairs;

4. Requesting sources from the Small Business Administration's (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/. The NIH e-Portals in Commerce is not a mandatory source and may be used at the offeror's discretion.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conducting workshops, seminars, and training programs;

2. Establishing, maintaining, and using SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB source lists, guides, and other data for soliciting subcontracts, and;

3. Monitoring activities to evaluate compliance with the subcontracting plan.

c. Additional efforts:

_____

_____

_____

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offer further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $500,000 ($1,000,000 for construction) must adopt and

comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (Flow down is not applicable for commercial items/services as described in 52.212-5(e) and 52.244-6(c)).

6. Reporting and Cooperation

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

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	SF 294	4/30
Apr 1 - Sep 30	SF 294	10/30
Oct 1 - Sep 30	SF 295	10/30
Contract Completion	OF 312	30 days after completion

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

a. Submit SF 294 to cognizant Awarding Contracting Officer

b. Submit Optional Form 312 (OF 312), if applicable, to the cognizant Awarding Contracting Officer.

c. Submit SF 295 to the cognizant Awarding Contracting Officer and to the following office:

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

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

7. Record Keeping

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

a. SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB sources;

c. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation whether SB, SDB, WOSB, HUBZone, VOSB, and/or SDVOSB concerns were solicited, if not, why not, and the reasons solicited concerns did not receive subcontract awards;

d. Records to support other outreach efforts, e.g. contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;

e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements, and;

f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This item is not required on a *contract-by-contract basis* for company or division-wide commercial products plans.)

g. Other records to support compliance with the subcontracting plan: (please describe).

_____

_____

_____

8. Timely Payments to Subcontractors

FAR 19.702 requires your organization/institution to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with small business concerns, small disadvantaged business concerns, women-owned small business concerns, HUBZone small business concerns, veteran-owned small business concerns, and service-disabled veteran-owned small business concerns.

Your organization/institution has established and used such procedures: [ ] yes [ ] no.

9. Description of Good Faith Effort

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

_____

_____

_____

SIGNATURE PAGE

Signatures Required:

Plan submitted by :

Signature: _____

Typed name: _____

Title: _____

Date: _____

Plan approved by:

Signature: _____

Typed Name: _____

Title: _____

Date: _____

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

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

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

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

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

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

(End of clause)

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 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.

RESEARCH PATIENT CARE COSTS

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary of HHS or his duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB 0348-0046

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

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

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

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

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

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

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

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity:_____ Page _____ of _____

Authorized for Local Reproduction
Standard Form--LLL-A

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 (RFP) 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., "RFP-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.

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

PROJECT TITLE (Title or RFP or Contract Proposal)

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

TYPE OF CONTRACT PROPOSED

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

ESTIMATED TIME REQUIRED TO COMPLETE PROJECT

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

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

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

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

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS ☐ YES ☐ NO

Institution's General Assurance re: Human Subjects DATE APPROVED _____ ☐ PENDING

Institution's Review Board's Approval of this Proposal DATE APPROVED _____ ☐ PENDING

An example of the informed consent for this study is enclosed ☐ YES ☐ NO

A Clinical Protocol is enclosed ☐ YES ☐ NO

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

ERRATA NUMBER	DATE	ERRATA NUMBER	DATE

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

FOR THE INSTITUTION

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

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

CONTACT POINTS

Complete the following and return with the BUSINESS PROPOSAL.

Name, Title and Address* of Business Representative with whom daily contact is required.

_____ _____
Name Telephone Number

_____ _____
Institutional Title FAX Number

_____ _____
Institutional Office E-Mail Address

_____
Institution Name

_____
**Street Address

_____
City, State Zip Code

Name, Institutional Title and Address of Proposed Principal Investigator

_____ _____
Name Telephone Number

_____ _____
Institutional Title FAX Number

_____ _____
Institutional Division, etc. E-Mail Address

_____
**Street Address

_____
City, State Zip Code

These exact addresses are necessary to ensure that contact can be made with the proper individual(s) in the most expeditious manner.

* May not necessarily be same as legal address of offeror.
**Please use actual street address, not P.O. Box.

TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS

COST ELEMENT	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Total
DIRECT LABOR:								
Labor Category (Title and Name-- use additional pages as necessary)	Hrs/%	Hrs/%	Hrs/%	Hrs/%	Hrs/%	Hrs/%	Hrs/%	Hrs/%
_____								
_____								
_____								
_____								
_____								
Total Hours/% Effort	_____	_____	_____	_____	_____	_____	_____	_____
DIRECT LABOR COST:	$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
MATERIALS/SUPPLIES:	$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
TRAVEL COST:	$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
OTHER (Specify):	$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
OTHER (Specify):	$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
TOTAL DIRECT COST:	$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____

Specific Instructions:

1. Do not include any individual salary information.
2. Do not include any indirect cost or fee.
3. Do not submit the total amount of proposal.
4. Submit this information as a part of the Technical Proposal.

BREAKDOWN OF PROPOSED ESTIMATED COST (PLUS FEE) AND LABOR HOURS

INSTRUCTIONS FOR USE OF THE FORMAT

1. Refer to Business Proposal Instructions, Section L of this solicitation. The instructions contain the requirements for proper submission of pricing information.

2. This format has been prepared as a universal guideline for solicitations. It may require modification to meet the specific requirements of this solicitation or the offeror's accounting system. If the statement of work is broken down into discrete phases, identify each phase in addition to each year. Total each year, phase, and sub-element.

3. If the Government has provided "uniform pricing assumptions" for this solicitation, the offeror must comply with and identify each item.

RFP Number: _____
Organization: _____
Date: _____

BREAKDOWN OF PROPOSED ESTIMATED COST (PLUS FEE) AND LABOR HOURS

COST ELEMENT		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Total
DIRECT LABOR:									
Labor Category (Title and Name-- use additional pages as necessary)	Rate	Hrs/% Amt	Hrs/% Amt	Hrs/% Amt	Hrs/% Amt	Hrs/% Amt	Hrs/% Amt	Hrs/% Amt	Hrs/% Amt
_____									
_____									
_____									
_____									
_____									
DIRECT LABOR COST:		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
MATERIALS/SUPPLIES:		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
TRAVEL COST:		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
OTHER (Specify):		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
OTHER (Specify):		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
TOTAL DIRECT COST:		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
FRINGE BENEFIT COST: (if applicable) ___% of Direct Labor Cost		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
INDIRECT COST: ___% of Total Direct Cost		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
TOTAL COST:		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
FEE: (if applicable) ___% of Total Est. Cost		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____
TOTAL ESTIMATED COST (plus fixed fee, if applicable)		$_____	$_____	$_____	$_____	$_____	$_____	$_____	$_____

SUMMARY OF RELATED ACTIVITIES

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

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

Professional's Name and Title/Position: _____

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

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

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

Professional's Name and Title/Position: _____

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

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

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

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

NOTE: This Notice is for the Technical Evaluation Panel who will be reviewing the proposals submitted in response to this solicitation. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

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 352.215-1.

(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.)