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**: 260-03-15	3. **Issue Date**: 06/13/03	4. **Just In Time**: **[X]** NO **[ ]** YES See Part IV Section L	5. **Set Aside**: **[ ]** NO **[X]** YES See Part IV Section L

6. TITLE: Representative Sampling for the Healthy Aging in Neighborhoods of Diversity Across the Life Span (HANDLS) Study

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

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1 until 2:00 p.m. local time on August 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. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HER DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE DIVISION OF RESEARCH ACQUISITION, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS AND REVISIONS" LOCATED IN THIS SOLICITATION.

11. Offeror must provide full name, address, TIN, and, if different, the address to which payment should be mailed.

12. FOR INFORMATION CALL: Teresa A. Baughman
PHONE: 301-496-4487
COLLECT CALLS WILL NOT BE ACCEPTED.

13. Table of Contents on following page.

Contracting Officer
Division of Research Acquisition, OLAO
National Institutes of Health

13. DETAILED TABLE OF RFP CONTENTS

ATTACHMENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE 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 contact and recruit a community-based sample for the longitudinal study "*Healthy Aging in Neighborhoods of Diversity across the Life Span* (HANDLS)". The Contractor shall perform household listings, recruit a representative sampling of African Americans and Whites ages 30-64 from Baltimore City, MD and conduct initial interviews.

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

ARTICLE C.1. STATEMENT OF WORK

a. 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 June, 2003, attached hereto and made a part of this Solicitation.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

For proposal preparation purposes only, it is estimated that 2 (two) copies of these reports will be required as follows:

( ) Monthly
(X) Quarterly
( ) Semi-Annually
( ) Annually
(X) Final - Upon final completion of the contract

b. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

c. Other Reports

1. 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 Contractor shall submit the report in accordance with ARTICLE F.1. DELIVERIES of this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies.

If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

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

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

The first report shall be due thirty (30) calendar days after the anniversary date of the contract. Thereafter, the report shall be due thirty (30) calendar days following each reporting period. The final report shall be due on or before the expiration date of the contract.

2. 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 Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.1. DELIVERIES of this contract. 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
Division of Research Acquisition, OLAO
National Institutes of Health
6100 Executive Blvd., Room 6E01, 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.

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 Gerontology Research Center, National Institute on Aging, National Institutes of Health, Baltimore, Maryland 21224.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

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

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

Item	Description	Quantity	Delivery Schedule
(a)	Project Plan	2	Three (3) weeks after contract award
(b)	Draft Listings Operations Guide	2	Four (4) weeks after contract award
©	Final Listings Operations Guide	2	Two (2) weeks after comments on the Draft are received
(d)	Draft Interviewer Operations Guide	2	Four (4) weeks after contract award
(e)	Final Interviewer Operations Guide	2	Two (2) weeks after comments on the Draft are received
(f)	Dress Rehearsal Evaluation	2	Three (3) weeks after end of dress rehearsal
(g)	Electronic Transmission of Raw Data	Electronic	Weekly
(h)	Electronic Transmission of Processed Data	Electronic	Monthly
(i)	Quarterly Progress Report	2	Ten (10) calendar days after each three (3) month period
(j)	Annual Technical Progress Report for Clinical Research Study Populations	1	Thirty (30) calendar days after each anniversary date of the contract
(k)	Annual Invention Utilization Report	1	Thirty (30) calendar days after each anniversary date of the contract
(l)	Final Invention Report	2	On or before the expiration date of the contract
(m)	Final Report	2	On or before the expiration date of the contract

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

Addressee	Deliverable Item No.	Quantity
Project Officer National Institute on Aging Gerontology Research Center (GRC) Baltimore, Maryland 21224	All, except (j) and (k)	1
Contracting Officer Division of Research Acquisition National Institutes of Health 6100 Executive Boulevard, Room 6E01, MSC 7540 Bethesda, Maryland 20892-7540	All, except (g) and (h)	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. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP 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 prior to award]

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

The Contracting Officer is the only person with 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 prior to 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. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

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

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

(1) One (1) copy to the following program official:

Project Officer
National Institute on Aging
Gerontology Research Center (GRC)
Baltimore, Maryland 21224

(3) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-4487.

ARTICLE G.4. INDIRECT COST RATES

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

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Executive Blvd., Room 6B05, MSC 7540
Bethesda, MD 20892-7540

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

ARTICLE G.5. GOVERNMENT PROPERTY

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

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The Contracting Officer will determine the frequency with which interim performance evaluations will be prepared. The final performance evaluation will be prepared at the time of completion of work.

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

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

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:
http://ocm.od.nih.gov/cdmp/cps_contractor.htm

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

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

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

ARTICLE H.2. 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. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

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

[Applicable information to be included at award]

ARTICLE H.4. NEEDLE EXCHANGE

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

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

[Applicable information to be included at award]

ARTICLE H.5. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties. The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as Attachment 12.

ARTICLE H.6. OMB CLEARANCE

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

ARTICLE H.7. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

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

[Applicable information to be included at award]

** Currently this amount is $166,700 and will remain at this level until such time as the Executive Level I is increased. See the following web site for Executive 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.8. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

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

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

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

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

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

(1) Required IT Systems Security Training

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

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

(2) Position Sensitivity Designations

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

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

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

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

(3) Commitment to Protect Sensitive Information

(1) Contractor Agreement

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

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

(2) Contractor-Employee Non-Disclosure Agreements

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

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

ARTICLE H.9. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

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

The standards applicable to this requirement are identified in the Statement of Work.

ARTICLE H.10. CONFIDENTIALITY OF INFORMATION

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

All data relating to the participants

ARTICLE H.11. 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 Aging, the National Institutes of Health, Department of Health and Human Services, under Contract No. .

ARTICLE H.12. 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 award]

ARTICLE H.13. 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.14. YEAR 2000 COMPLIANCE

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

1. Service Involving the Use of Information Technology

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

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

(End of Clause)

ARTICLE H.15. ANTI -LOBBYING

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

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

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

[Applicable information to be included at award]

ARTICLE H.16. 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.17. SHARING RESEARCH DATA

The data sharing plan submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

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

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

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

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

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 1997	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	Aug 1996	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	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	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	Jan 1986	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. 4/2003].

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

FAR Clause 52.215-15, PENSION ADJUSTMENTS AND ASSET REVERSIONS (DECEMBER 1998), FAR Clause 52.215-18, REVERSION OR ADJUSTMENT OF PLANS FOR POST RETIREMENT BENEFITS (PRB) OTHER THAN PENSIONS (OCTOBER 1997) and 52.215-19, NOTIFICATION OF OWNERSHIP CHANGES (OCTOBER 1997), are deleted in their entirety.

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) is added.

FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 20021), and FAR Clause 52.219-16, LIQUIDATED DAMAGES--SUBCONTRACTING PLAN (JANUARY 1999) are deleted in their entirety.

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/Contractor shall be determined during negotiations. 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.

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

(1) FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

(2) FAR 52.219-6, Notice of Total Small Business Set-Aside (JULY 1996).

(3) FAR 52.219-14, Limitations on Subcontracting (DECEMBER 1996).

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

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

(6) 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 52.239-1, Privacy or Security Safeguards (AUGUST 1996).

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

(11) FAR 52.251-1, Government Supply Sources (APRIL 1984).

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

3) CLAUSES:

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

(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).

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** (MAY 2002)

(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 (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

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

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

1. Packaging and Delivery of Proposal, May 1994, 1 page.
2. Statement of Work, June, 2003, 9 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. Annual Technical Progress Report Format for Each Study[1], July, 1994, 1 page.
7. 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.
8. Privacy Act System of Record Number 09-25-0200 [4], 12 pages.
9. Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)[4], April, 1984, 1 page.
10. Disclosure of Lobbying Activities, OMB Form SF-LLL[2], December, 1989, 3 pages.
11. Proposal Summary and Data Record, NIH-2043 (Rev. 6/82)[2], June, 1982, 2 pages.
12. Contact Points[2], July, 1991, 1 page.
13. Technical Proposal Cost Information[1], December, 1988, 1 page.
14. Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours[2], September, 1992, 2 pages.
15. Summary of Related Activities[1], March, 1984, 1 page.
16. Proposal Intent Response Sheet[6], March, 1984, 1 page.
17. Government Notice for Handling Proposals[1], January, 2001, 1 page.
18. Government Furnished Items [4], 1 page.
19. Commitment To Protect Non-Public Information, Located at: http://irm.cit.nih.gov/security/Nondisclosure.pdf

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. N/A
4. These forms will be attached to any contract resulting from this RFP.
5. N/A
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.

PART IV - SECTION K

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

1. REPRESENTATIONS AND CERTIFICATIONS

1.	FAR 52.203-2	Certification of Independent Price Determination
2.	FAR 52.203-11	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (DEVIATION)
3.	FAR 52.204-3	Taxpayer Identification
4.	FAR 52.204-5	Women-Owned Business (Other Than Small Business)
5.	FAR 52.204-6	Data Universal Numbering System (DUNS) Number
6.	FAR 52.209-5	Certification Regarding Debarment, Suspension, Proposed Debarment and Other Responsibility Matters
7.	FAR 52.215-6	Place of Performance
8.	FAR 52.219-1	Small Business Program Representations
9.	FAR 52.219-19	Small Business Concern Representation for the Small Business Competitiveness Demonstration Program
10.	FAR 52.219-21	Small Business Size Representation for Targeted Industry Categories Under the Small Business Competitiveness Demonstration Program
11.	FAR 52.219-22	Small Disadvantaged Business Status
12.	FAR 52.222-18	Certification Regarding Knowledge of Child Labor for Listed End Products
13.	FAR 52.222-21	Certification of Nonsegregated Facilities
14.	FAR 52.222-22	Previous Contracts and Compliance Reports
15.	FAR 52.222-25	Affirmative Action Compliance
16.	FAR 52.222-38	Compliance with Veterans' Employment Reporting Requirements
17.	FAR 52.222-48	Exemption From Application of Service Contract Act Provisions
18.	FAR 52.223-4	Recovered Material Certification
19.	FAR 52.223-13	Certification of Toxic Chemical Release Reporting
20.	FAR 52.225-2	Buy American Act Certificate
21.	FAR 52.225-4	Buy American Act--North American Free Trade Agreement--Israeli Trade Act Certificate
22.	FAR 52.225-6	Trade Agreements Certificate
23.	FAR 52.226-2	Historically Black College or University and Minority Institution Representation
24.	FAR 52.227-6	Royalty Information
25.	FAR 52.230-1	Cost Accounting Standards Notices and Certification
26.	-----	Certification Regarding Environmental Tobacco Smoke
27.	-----	Certification of Institutional Policy on Conflict of Financial Interest
28.	FAR 15.406-2	Certificate of Current Cost or Pricing Data

To Be Completed by the Offeror: **(The Representations and Certifications must be executed by an individual authorized to bind the offeror.)** The offeror makes the following Representations and Certifications as part of its proposal **(check/complete all appropriate boxes or blanks on the following pages)**.

_____ _____

(Name of Offeror) **(RFP No.)**

_____ _____

(Signature of Authorized Individual) **(Date)**

_____

(Typed Name of Authorized Individual)

Note: The penalty for making false statements in offers is prescribed in 18 U.S.C 1001.

1. **52.203-2 CERTIFICATE OF INDEPENDENT PRICE DETERMINATION (APRIL 1985)**

[NOTE: This provision is applicable when a firm-fixed price or fixed-price with economic price adjustment contract is contemplated.]

(a) The offeror certifies that -

(1) The prices in this offer have been arrived at independently, without, for the purpose of restricting competition, any consultation, communication, or agreement with any other offeror or competitor relating to (i) those prices, (ii) the intention to submit an offer, or (iii) the methods or factors used to calculate the prices offered;

(2) The prices in this offer have not been and will not be knowingly disclosed by the offeror, directly or indirectly, to any other offeror or competitor before bid opening (in the case of a sealed bid solicitation) or contract award (in the case of a negotiated solicitation) unless otherwise required by law; and

(3) No attempt has been made or will be made by the offeror to induce any other concern to submit or not to submit an offer for the purpose of restricting competition.

(b) Each signature on the offer is considered to be a certification by the signatory that the signatory--

(1) Is the person in the offeror's organization responsible for determining the prices being offered in this bid or proposal, and that the signatory has not participated and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above; or

(2) (i) Has been authorized in writing, to act as agent for the following principals in certifying that those principals have not participated, and will not participate in any action contrary to subparagraphs (a)(1) through (a)(3) above

.....

.....

[insert full name of person(s) in the offeror's organization responsible for determining the prices offered in this bid or proposal, and the title of his or her position in the offeror's organization];

(ii) As an authorized agent, does certify that the principals named in subdivision (b)(2)(i) above have not participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above; and

(iii) As an agent, has not personally participated, and will not participate, in any action contrary to subparagraphs (a)(1) through (a)(3) above.

(c) If the offeror deletes or modifies subparagraph (a)(2) above, the offeror must furnish with its offer a signed statement setting forth in detail the circumstances of the disclosure.

2. **52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (DEVIATION)**

(a) The definitions and prohibitions contained in the clause, at FAR 52.203-12, Limitations on Payments to Influence Certain Federal Transactions, included in this solicitation, are hereby incorporated by reference in paragraph (b) of this certification.

(b) The offeror, by signing its offer, hereby certifies to the best of his or her knowledge and belief that on or after December 23, 1989 -

(1) No Federal appropriated funds have been paid or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with the awarding of a contract resulting from this solicitation.

(2) If any funds other than Federal appropriated funds (including profit or fee received under a covered Federal transaction) have been paid, or will be paid, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress on his or her behalf in connection with this solicitation, the offeror shall complete and submit with its offer, OMB Standard Form-LLL, "Disclosure of Lobbying Activities", to the Contracting Officer, and

(3) He or she will include the language of this certification in all subcontract awards at any tier and require that all recipients of subcontract awards in excess of $100,000 shall certify and disclose accordingly.

(c) Submission of this certification and disclosure is a prerequisite for making or entering into this contract imposed by section 1352, Title 31, United States Code. Any person who makes an expenditure prohibited under this provision or who fails to file or amend the disclosure form to be filed or amended by this provision, shall be subject to a civil penalty of not less than $10,000, and not more than $100,000, for each such failure.

3. **52.204-3 TAXPAYER IDENTIFICATION (OCTOBER 1998)**

1. Definitions.

Common parent, as used in this provision, means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

Taxpayer Identification Number (TIN), as used in this provision, means the number required by the Internal Revenue Service (IRS) to be used by the offeror in reporting income tax and other returns. The TIN may be either a Social Security Number or an Employer Identification Number.

2. All offerors must submit the information required in paragraphs (d) through (f) of this provision to comply with debt collection requirements of 31 U.S.C. 7701© and 3325(d), reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M, and implementing regulations issued by the IRS. If the resulting contract is subject to the payment reporting requirements described in Federal Acquisition Regulation (FAR) 4.904, the failure or refusal by the offeror to furnish the information may result in a 31 percent reduction of payments otherwise due under the contract.

3. The TIN may be used by the Government to collect and report on any delinquent amounts arising out of the offeror's relationship with the Government (31 U.S.C. 7701(c)(3)). If the resulting contract is subject to the payment reporting requirements described in FAR 4.904, the TIN provided hereunder may be matched with IRS records to verify the accuracy of the offeror's TIN.

4. Taxpayer Identification Number (TIN).
[ ] TIN:_____
[ ] TIN has been applied for.
[ ] TIN is not required because:
[ ] Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;
[ ] Offeror is an agency or instrumentality of a foreign government;
[ ] Offeror is an agency or instrumentality of the Federal Government.

5. Type of organization.
[ ] Sole proprietorship;
[ ] Partnership;
[ ] Corporate entity (not tax-exempt);
[ ] Corporate entity (tax-exempt);
[ ] Government entity (Federal, State, or local);
[ ] Foreign government;
[ ] International organization per 26 CFR 1.6049-4;
[ ] Other _____

6. Common parent.

[ ] Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision.
[ ] Name and TIN of common parent:
Name _____
TIN _____

4. **52.204-5 WOMEN-OWNED BUSINESS (Other Than Small Business) (MAY 1999)**

(a) *Definition*. Women-owned business concern, as used in this provision, means a concern that is at least 51 percent owned by one or more women; or in the case of any publicly owned business, at least 51 percent of its stock is owned by one or more women; and whose management and daily business operations are controlled by one or more women.

(b) *Representation*. [*Complete only if the offeror is a women-owned business concern and has not represented itself as a small business concern in paragraph (b)(1) of FAR 52.219-1, Small Business Program Representations, of this solicitation*.]

The offeror represents that it **[ ]** is a women-owned business concern.

5. **52.204-6 DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER (JUNE 1999)**

(a) The offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "DUNS" followed by the DUNS number that identifies the offeror's name and address exactly as stated in the offer. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services.

(b) If the offeror does not have a DUNS number, it should contact Dun and Bradstreet directly to obtain one. A DUNS number will be provided immediately by telephone at no charge to the offeror. For information on obtaining a DUNS number, if located within the United States, the offeror should call Dun and Bradstreet at 1-800-333-0505. The offeror should be prepared to provide the following information:

(1) Company name.
(2) Company address.
(3) Company telephone number.
(4) Line of business.
(5) Chief executive officer/key manager.
(6) Date the company was started.
(7) Number of people employed by the company.
(8) Company affiliation.

(c) Offerors located outside the United States may obtain the location and phone number of the local Dun and Bradstreet Information Services office from the Internet home page at http://www.customerservice@dnb.com. If an offeror is unable to locate a local service center, it may send an e-mail to Dun and Bradstreet at globalinfo@mail.dnb.com.

6. **52.209-5 CERTIFICATION REGARDING DEBARMENT, SUSPENSION, PROPOSED SUSPENSION, PROPOSED DEBARMENT AND OTHER RESPONSIBILITY MATTERS (DECEMBER 2001)**

(NOTE: Applies to contracts expected to exceed $100,000.)

(a) (1) The Offeror certifies, to the best of its knowledge and belief, that -

(i) The Offeror and/or any of its Principals --

(A) Are **[ ]**, are not **[ ]** presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federal agency;

(B) Have **[ ]**, have not **[ ]**, within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, state or local) contract or subcontract; violation of Federal or state antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, or receiving stolen property; and

(C) Are **[ ]**, are not **[ ]** presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in subdivision (a)(1)(i)(B) of this provision.

(D) If the offeror has responded affirmatively, the offeror shall provide additional information if requested by the Contracting Officer; and

(ii) The Offeror has **[ ]**, has not **[ ]**, within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principals" for the purposes of this certification, means officers; directors; owners; partners; and, persons having primary management or supervisory responsibilities within a business entity (e.g., general manager, plant manager, head of a subsidiary, division, or business segment, and similar positions).

THIS CERTIFICATION CONCERNS A MATTER WITHIN THE JURISDICTION OF AN AGENCY OF THE UNITED STATES AND THE MAKING OF A FALSE, FICTITIOUS, OR FRAUDULENT CERTIFICATION MAY RENDER THE MAKER SUBJECT TO PROSECUTION UNDER SECTION 1001, TITLE 18, UNITED STATES CODE.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror nonresponsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making an award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

7. **52.215-6 PLACE OF PERFORMANCE (OCTOBER 1997)**

(a) The offeror or respondent, in the performance of any contract resulting from this solicitation, **[ ]** intends, **[ ]** does not intend **(check applicable block)** to use one or more plants or facilities located at a different address from the address of the offeror or respondent as indicated in this proposal or response to request for information.

(b) If the offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of Performance (Street Address (City, State, County, Zip Code)	**Name and Address of Owner and Operator of the Plant or Facility if Other than Offeror or Respondent**

8. **52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (APRIL 2002)**

(Note: This provision applies to solicitations exceeding the micro-purchase threshold when the contract is to be performed in the United States, its territories or possessions, Puerto Rico, the Trust Territory of the Pacific Islands, or the District of Columbia.)

(a) (1) The North American Industry Classification System (NAICS) code for this acquisition is [INSERT NAICS CODE] .

(2) The small business size standard is [INSERT SIZE STANDARD] .

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b) **Representations**.

(1) The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a small business concern.

(2) (**Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision**.) The offeror represents, for general statistical purposes, that it **[ ]** is, **[ ]** is not a small disadvantaged business concern as defined in 13 CFR 124.1002.

(3) (**Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision**.) The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a women-owned small business concern.

(4) (**Complete only if the offeror represented itself as a small business concern in paragraph (b)(1) of this provision**.) The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a veteran-owned small business concern.

(5) (**Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (b)(4) of this provision**.) The offeror represents as part of its offer that it **[ ]** is, **[ ]** is not a service-disabled veteran-owned small business concern.

6. (**Complete only if the offeror represented itself a small business concern in paragraph (b)(1) of this provision.)** The offeror represents , as a part of its offeror, that–

1. It **[ ]** is, **[ ]** is not a HUBZone small business concern listed, on the date of this representation, on the List of Qualified HUBZone Small Business Concerns maintained by the Small business Administration, and no material change in ownership and control, principal office, or HUBZone employee percentage has occurred since it was certified by the Small Business Administration in accordance with 13 CFR part 126; and

2. It **[ ]** is, **[ ]** is not a joint venture that complies with the requirements of 13 CFR part 126, and the representation in paragraph (b)(6)(i) of this provision is accurate for the HUBZone small business concern or concerns that are participating in the joint venture. *[The offeror shall enter the name or names of the HUBZone small business concern or concerns that are participating in the joint venture:* _____ _____*.]* Each HUBZone small business concern participating in the joint venture shall submit a separate signed copy of the HUBZone representation.

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

Service-disabled veteran-owned small business concern--

(1) Means a small business concern--

(i) Not less than 51 percent of which is owned by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock or which is owned by one or more service-disabled veterans; and
(ii) The Management and daily business operation of which are controlled by one or more service-disabled veterans or, in the case of a veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran.

(2) Service-disabled veteran means a veteran, as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16).

Small business concern, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (a) of this provision.

Women-owned small business concern, means a small business concern-

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

Veteran-owned small business concern means a small business concern--

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S. C. 101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

(d) **Notice**.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a small, HUBZone small, small disadvantaged, or women-owned small business concern in order to obtain a contract to be awarded under the preference programs established pursuant to section 8(a), 8(d), 9, or 15 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall--

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

9. **52.219-19 SMALL BUSINESS CONCERN REPRESENTATION FOR THE SMALL BUSINESS COMPETITIVENESS DEMONSTRATION PROGRAM (OCTOBER 2000)**

(This representation must be completed if the acquisition is for one of the four designated industry groups of the Small Business Competitiveness Demonstration Program specified in FAR 19.1005(a)[includes Construction Contracts under NAICS codes that comprise Industry Subsectors 233, 234 and 235].)

(a) **Definition**

"Emerging small business" as used in this solicitation, means a small business concern whose size is no greater than 50 percent of the numerical size standard applicable to the North American Industry Classification System (NAICS) code assigned to a contracting opportunity.

(b) **(Complete only if offeror has represented itself under the provision at FAR 52.219-1 as a small business concern under the size standards of this solicitation.)**

The Offeror **[ ]** is, **[ ]** is not an emerging small business.

(c) **(Complete only if the Offeror is a small business or an emerging small business, indicating its size range.)**

Offeror's number of employees for the past twelve months **(check this column if size standard stated in solicitation is expressed in terms of number of employees)** or Offeror's average annual gross revenue for the last 3 fiscal years **(Check this column if size standard stated in solicitation is expressed in terms of annual receipts). (Check one of the following.)**

Number of Employees	Average Annual Gross Revenues
[ ] 50 or fewer	[ ] $1 million or less
[ ] 51 - 100	[ ] $1,000,001 - $2 million
[ ] 101 - 250	[ ] $2,000,001 - $3.5 million
[ ] 251 - 500	[ ] $3,500,001 - $5 million
[ ] 501 - 750	[ ] $5,000,001 - $10 million
[ ] 751 - 1,000	[ ] $10,000,001 - $17 million
[ ] Over 1,000	[ ] Over $17 million

10. **52.219-21 SMALL BUSINESS SIZE REPRESENTATION FOR TARGETED INDUSTRY CATEGORIES UNDER THE SMALL BUSINESS COMPETITIVENESS DEMONSTRATION PROGRAM (MAY 1999)**

(Complete only if the Offeror has represented itself under the provision 52.219-1 as a small business concern under the size standards of this solicitation.)

(NOTE: This representation must be completed if this solicitation covers one of the ten targeted industry categories under the Small Business Competitiveness Demonstration Program and if the offeror has certified itself under the clause at FAR 52.219-1 to be a small business concern under the size standards of this solicitation).

Offeror's number of employees for the past twelve months **(check this column if size standard stated in solicitation is expressed in terms of number of employees)** or Offeror's average annual gross revenue for the last three fiscal years **(check this column if size standard stated in solicitation is expressed in terms of annual receipts). (Check one of the following.)**

No. of Employees	Average Annual Gross Revenues
[ ] 50 or fewer	[ ] $1 million or less
[ ] 51 - 100	[ ] $1,000,001 - $2 million
[ ] 101 -250	[ ] $2,000,001 - $3.5 million
[ ] 251 - 500	[ ] $3,500,001 - $5 million
[ ] 501 - 750	[ ] $5,000,001 - $10 million
[ ] 751 - 1,000	[ ] $10,000,001 - $17 million
[ ] Over 1,000	[ ] Over $17 million

The ten targeted industries are as follows:

Product Service Code	SIC Code	Description
G004	8742	Counseling/Training/Social Rehabilitation Services
J099	7699	Maintenance, Repair and Rebuilding of Equipment (Office Machines, Text Processing Systems & Visible Record Equipment)
K099	7699	Modification of Equipment (misc.)
Q210	8099, 8742	General Health Care Services
R406	8742	Policy Review/Development Services
R497	7299	Personal Services
6505	2833, 2834 2835, 2836	Drugs and Biologics
7045	3572, 3695 5065	ADP Supplies
7110	5021	Office Furniture
7510	5112	Office Supplies

11. **52.219-22 SMALL DISADVANTAGED BUSINESS STATUS (OCTOBER 1999)**

(Note: This applies to competitive solicitations over $100,000 under the SIC Major Groups for which a price evaluation adjustment is applicable.)

(a) **General**. This provision is used to assess an offeror's small disadvantaged business status for the purpose of obtaining a benefit on this solicitation. Status as a small business and status as a small disadvantaged business for general statistical purposes is covered by the provision at FAR 52.219-1, Small Business Program Representation.

(b) **Representations**.

(1) **General**. The offeror represents, as part of its offer, that it is a small business under the size standard applicable to this acquisition; and either--

[ ] (i) It has received certification by the Small Business Administration as a small disadvantaged business concern consistent with 13 CFR 124, Subpart B; and

(A) No material change in disadvantaged ownership and control has occurred since its certification;

(B) Where the concern is owned by one or more disadvantaged individuals, the net worth of each individual upon whom the certification is based does not exceed $750,000 after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(C) It is identified, on the date of its representation, as a certified small disadvantaged business concern in the database maintained by the Small Business Administration (PRO-Net); or

[ ] (ii) It has submitted a completed application to the Small Business Administration or a Private Certifier to be certified as a small disadvantaged business concern in accordance with 13 CFR 124, Subpart B, and a decision on that application is pending, and that no material change in disadvantaged ownership and control has occurred since its application was submitted.

(2) **[ ] For Joint Ventures**. The offeror represents, as part of its offer, that it is a joint venture that complies with the requirements at 13 CFR 124.1002(f) and that the representation in paragraph (b)(1) of this provision is accurate for the small disadvantaged business concern that is participating in the joint venture. *[The offeror shall enter the name of the small disadvantaged business concern that is participating in the joint venture: _____.]*

(c) **Penalties and Remedies**. Anyone who misrepresents any aspects of the disadvantaged status of a concern for the purposes of securing a contract or subcontract shall:

(1) Be punished by imposition of a fine, imprisonment, or both;
(2) Be subject to administrative remedies, including suspension and debarment; and
(3) Be ineligible for participation in programs conducted under the authority of the Small Business Act.

Alternate I (OCTOBER 1998)

(Note: Applies when price evaluation adjustment for small disadvantaged business concerns is authorized on a regional basis. Designated regions by Major SIC Category can be found at http://www.arnet.gov/References/sdbadjustments.htm . Currently, this includes SIC Major Industry Groups 15, 16, 17 which are all construction related groups.)

As prescribed in 19.306(b), add the following paragraph (b)(3) to the basic provision:

(3) Address. The offeror represents that its address_____is, _____is not in a region for which a small disadvantaged business procurement mechanism is authorized and its address has not changed since its certification as a small disadvantaged business concern or submission of its application for certification. The list of authorized small disadvantaged business procurement mechanisms and regions is posted at http://www.arnet.gov/References/sdbadjustments.htm The offeror shall use the list in effect on the date of this solicitation. "Address," as used in this provision, means the address of the offeror as listed on the Small Business Administration's register of small disadvantaged business concerns or the address on the completed application that the concern has submitted to the Small Business Administration or a Private Certifier in accordance with 13 CFR part 124, subpart B. For joint ventures, "address" refers to the address of the small disadvantaged business concern that is participating in the joint venture.

12. **52.222-18 CERTIFICATION REGARDING KNOWLEDGE OF CHILD LABOR FOR LISTED END PRODUCTS (MAY 2001)**

(Applies to all contracts for supplies over $2,500. See FAR 22.1503 for more information)

a. *Definition*.

Forced or indentured child labor means all work or service--

(1) Exacted from any person under the age of 18 under the menace of any penalty for its nonperformance and for which the worker does not offer himself voluntarily; or

(2) Performed by any person under the age of 18 pursuant to a contract the enforcement of which can be accomplished by process or penalties.

b. *Listed end products.* The following end product(s) being acquired under this solicitation is (are) included in the List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, identified by their country of origin. There is a reasonable basis to believe that listed end products from the listed countries of origin may have been mined, produced, or manufactured by forced or indentured child labor.

Listed End Product

_____

_____

Listed Countries of Origin

_____

_____

c. *Certification*. The Government will not make award to an offeror unless the offeror, by checking the appropriate block, certifies to either paragraph (c)(1) or paragraph (c)(2) of this provision.

[ ] (1) The offeror will not supply any end product listed in paragraph (b) of this provision that was mined, produced, or manufactured in a corresponding country as listed for that end product.

[ ] (2) The offeror may supply an end product listed in paragraph (b) of this provision that was mined, produced, or manufactured in the corresponding country as listed for that product. The offeror certifies that it has made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture such end product. On the basis of those efforts, the offeror certifies that it is not aware of any such use of child labor.

13. **52.222-21 CERTIFICATION OF NONSEGREGATED FACILITIES (FEBRUARY 1999)**

(a) *Segregated facilities*, as used in this clause, means any waiting rooms, work areas, rest rooms and wash rooms, restaurants and other eating areas, time clocks, locker rooms and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transportation, and housing facilities provided for employees, that are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, sex, or national origin because of written or oral policies or employee custom. The term does not include separate or single-user rest rooms or necessary dressing or sleeping areas provided to assure privacy between the sexes.

(b) The Contractor agrees that it does not and will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not and will not permit its employees to perform their services at any location under its control where segregated facilities are maintained. The Contractor agrees that a breach of this clause is a violation of the Equal Opportunity clause in this contract.

(c) The Contractor shall include this clause in every subcontract and purchase order that is subject to the Equal Opportunity clause of this contract.

14. **52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS (FEBRUARY 1999)**

The offeror represents that --

(a) It **[ ]** has, **[ ]** has not participated in a previous contract or subcontract subject to the Equal Opportunity clause of this solicitation;

(b) It **[ ]** has, **[ ]** has not, filed all required compliance reports; and

(c) Representations indicating submission of required compliance reports, signed by proposed subcontractors, will be obtained before subcontract awards.

15. **52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APRIL 1984)**

The offeror represents that (a) it **[ ]** has developed and has on file, **[ ]** has not developed and does not have on file, at each establishment, affirmative action programs required by the rules and regulations of the Secretary of Labor (41 CFR 60-1 and 60-2), or (b) it **[ ]** has not previously had contracts subject to the written affirmative action programs requirement of the rules and regulations of the Secretary of Labor.

16. **52.222-38 COMPLIANCE WITH VETERANS' EMPLOYMENT REPORTING REQUIREMENTS (DECEMBER 2001)**

By submission of its offer, the offeror represents that, if it is subject to the reporting requirements of 38 U.S.C. 4212(d) (i.e., if it has any contract containing Federal Acquisition Regulation clause 52.222-37, Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans), it has submitted the most recent VETS-100 Report required by that clause.

17. **52.222-48 EXEMPTION FROM APPLICATION OF SERVICE CONTRACT ACT PROVISIONS FOR CONTRACTS FOR MAINTENANCE, CALIBRATION, AND/OR REPAIR OF CERTAIN INFORMATION TECHNOLOGY, SCIENTIFIC AND MEDICAL AND/OR OFFICE AND BUSINESS EQUIPMENT--CONTRACTOR CERTIFICATION (AUGUST 1996)**

(NOTE: This clause is applicable to all solicitations and resultant contracts calling for maintenance, calibration, and/or repair of information technology, scientific and medical, and office and business equipment if the contracting officer determines that the resultant contract may be exempt from Service Contract Act coverage).

(a) The following certification shall be checked:

CERTIFICATION

The offeror certifies **[ ]**, does not certify **[ ]** that: (1) The items of equipment to be serviced under this contract are commercial items which are used regularly for other than Government purposes, and are sold or traded by the Contractor in substantial quantities to the general public in the course of normal business operations; (2) The contract services are furnished at prices which are, or are based on, established catalog or market prices for the maintenance, calibration, and/or repair of certain information technology, scientific and medical, and/or office and business equipment. An "established catalog price" is a price (including discount price) recorded in a catalog, price list schedule, or other verifiable and established record that is regularly maintained by the manufacturer or the Contractor and is either published or otherwise available for inspection by customers. An "established market price" is a current price, established in the usual course of ordinary and usual trade between buyers and sellers free to bargain, which can be substantiated by data from sources independent of the manufacturer or Contractor; and (3) The Contractor utilizes the same compensation (wage and fringe benefits) plan for all service employees performing work under the contract as the Contractor uses for equivalent employees servicing the same equipment of commercial customers.

(b) If a negative certification is made and a Service Contract Act wage determination is not attached to the solicitation, the Contractor shall notify the Contracting Officer as soon as possible.

(c) Failure to execute the certification in paragraph (a) of this clause or to contact the Contracting Officer as required in paragraph (b) of this clause may render the bid or offer nonresponsive.

18. **52.223-4 RECOVERED MATERIAL CERTIFICATION (OCTOBER 1997)**

(This certification is applicable in solicitations that are for, or specify the use, of recovered materials.)

As required by the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6962(c)(3)(A)(i)), the offeror certifies, by signing this offer, that the percentage of recovered materials to be used in the performance of the contract will be at least the amount required by the applicable contract specifications.

19. **52.223-13 CERTIFICATION OF TOXIC CHEMICAL RELEASE REPORTING (OCTOBER 2000)**

NOTE: This certification is applicable for all solicitations for competitive contracts expected to exceed $100,000 (including all options) and competitive 8(a) contracts. It is not applicable to acquisitions of commercial items, or to contracts where the Contractor's facilities are located outside the United States (the "United States" includes any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, the Northern Mariana Islands, and any other territory or possession over which the United States has jurisdiction)

(a) Submission of this certification is a prerequisite for making or entering into this contract imposed by Executive Order 12969, August 8, 1995.

(b) By signing this offer, the offeror certifies that–

(1) As the owner or operator of facilities that will be used in the performance of this contract that are subject to the filing and reporting requirements described in section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11023) and section 6607 of the Pollution Prevention Act of 1990 (PPA) (42 U.S.C. 13106), the offeror will file and continue to file for such facilities for the life of the contract the Toxic Chemical Release Inventory Form (Form R) as described in sections 313(a) and (g) of EPCRA and section 6607 of PPA; or

(2) None of its owned or operated facilities to be used in the performance of this contract is subject to the Form R filing and reporting requirements because each such facility is exempt for at least one of the following reasons: (Check each block that is applicable.)

[ ] (i) The facility does not manufacture, process, or otherwise use any toxic chemicals listed under section 313© of EPCRA, 42 U.S.C. 11023(c);

[ ] (ii) The facility does not have 10 or more full-time employees as specified in section 313(b)(1)(A) of EPCRA, 42 U.S.C. 11023(b)(1)(A);

[ ] (iii) The facility does not meet the reporting thresholds of toxic chemicals established under section 313(f) of EPCRA, 42 U.S.C. 11023(f) (including the alternate thresholds at 40 CFR 372.27, provided an appropriate certification form has been filed with EPA);

[ ] (iv) The facility does not fall within Standard Industrial Classification Code (SIC) major groups 20 through 39 or their corresponding North American Industry Classification System (NAICS) sectors 31 through 33; or

[ ] (v) The facility is not located within any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, the Northern Mariana Islands, or any other territory or possession over which the United States has jurisdiction.

20. **52.225-2 BUY AMERICAN ACT CERTIFICATE (MAY 2002)**

[Note: This provision is applicable for all requirements EXCEPT for 1) foreign contracts or 2) when one of the following two provisions (52.225-4, Buy American Act--North American Free Trade Agreement--Israeli Trade Act Certificate, or 52.225-6, Trade Agreements Certificate) apply.

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a domestic end product as defined in the clause of this solicitation entitled "Buy American Act--Supplies" and that the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States. The offeror shall list as foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

(b) Foreign End Products:

Line Item No.:_____
Country of Origin:_____
(List as necessary)

(c) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation.

21. **52.225-4 BUY AMERICAN ACT NORTH AMERICAN FREE TRADE AGREEMENT--ISRAELI TRADE ACT CERTIFICATE (MAY 2002)**

[Note: This provision is applicable for requirements with a value of $25,000 or more but less than $169,000 EXCEPT for 1) foreign acquisitions or 2) acquisitions that are exempt from NAFTA and the Israeli Trade Act. (See FAR 25.401).]

(a) The offeror certifies that each end product, except those listed in paragraph (b) or © of this provision, is a domestic end product (as defined in the clause of this solicitation entitled, "Buy American Act--North American Free Trade Agreement--Israeli Trade Act") and that the offeror has considered components of unknown origin to have been mined, produced, or manufactured outside the United States.

(b) The offeror certifies that the following supplies are NAFTA country end products or Israeli end products as defined in the clause of this solicitation entitled, "Buy American Act--North American Free Trade Agreement--Israeli Trade Act":

NAFTA Country or Israeli End Products:
Line Item No.:_____
Country of Origin:_____
(List as necessary)

(c) The offeror shall list those supplies that are foreign end products (other than those listed in paragraph (b) of this provision) as defined in the clause of this solicitation entitled, "Buy American Act--North American Free Trade Agreement--Israeli Trade Act." The offeror shall list as other foreign end products those end products manufactured in the United States that do not qualify as domestic end products.

Other Foreign End Products
Line Item No.:_____
Country of Origin:_____
(List as necessary)

(d) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation.

ALTERNATE I (MAY 2002) As prescribed in 25.1101(b)(2)(ii), substitute the following paragraph (b) for paragraph (b) of the basic provision:

[Note: Applies when the acquisition value is $25,000 or more but is less than $50,000.]

(b) The offeror certifies that the following supplies are Canadian end products as defined in the clause of this solicitation entitled "Buy American Act--North American Free Trade Agreement--Israeli Trade Act":

Canadian End Products:
Line Item No.:_____
(List as necessary)

ALTERNATE II (MAY 2002) As prescribed in 25.1101(b)(2)(iii), substitute the following paragraph (b) for paragraph (b) of the basic provision:
[Note: Applies when the acquisition value is $50,000 or more, but is less than $56,190.]

(b) The offeror certifies that the following supplies are Canadian end products or Israeli end products as defined in the clause of this solicitation entitled "Buy American Act--North American Free Trade Agreement--Israeli Trade Act":

Canadian or Israeli End Products
Line Item No.:_____
Country of Origin:_____
(List as necessary)

22. **52.225-6 TRADE AGREEMENTS CERTIFICATE - (MAY 2002)**

[Note: This provision is applicable for acquisitions valued at $169,000 or more, if the Trade Agreement Act applies. (See FAR 25.401 and 25.403).]

(a) The offeror certifies that each end product, except those listed in paragraph (b) of this provision, is a U.S.-made, designated country, Caribbean Basin country, or NAFTA country end product, as defined in the clause of this solicitation entitled "Trade Agreements."

(b) The offeror shall list as other end products those supplies that are not U.S.-made, designated country, Caribbean Basin country, or NAFTA country end products.

Other End Products
Line Item No.:_____
Country of Origin:_____
(List as necessary)

(c) The Government will evaluate offers in accordance with the policies and procedures of Part 25 of the Federal Acquisition Regulation. For line items subject to the Trade Agreements Act, the Government will evaluate offers of U.S.-made, designated country, Caribbean Basin country, or NAFTA country end products without regard to the restrictions of the Buy American Act. The Government will consider for award only offers of U.S.-made, designated country, Caribbean Basin country, or NAFTA country end products unless the Contracting Officer determines that there are no offers for those products or that the offers for those products are insufficient to fulfill the requirements of this solicitation.

23. **52.226-2 HISTORICALLY BLACK COLLEGE OR UNIVERSITY AND MINORITY INSTITUTION REPRESENTATION - (MAY 2001)**

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

Historically Black College or University means an institution determined by the Secretary of Education to meet the requirements of 34 CFR 608.2. For the Department of Defense, the National Aeronautics and Space Administration, and the Coast Guard, the term also includes any nonprofit research institution that was an integral part of such a college or university before November 14, 1986.

Minority Institution means an institution of higher education meeting the requirements of Section 1046(3) of the Higher Education Act of 1965 (20 U.S.C. 1067k, including a Hispanic-serving institution of higher education, as defined in Section 316(b)(1) of the Act (20 U.S.C. 1101a.)).

(b) *Representation*. The offeror represents that it--

[ ] is **[ ]** is not a Historically Black College or University;
[ ] is **[ ]** is not a Minority Institution.

24. **52.227-6 ROYALTY INFORMATION - (APRIL 1984)**

(a) **Cost or charges for royalties.** When the response to this solicitation contains costs or charges for royalties totaling more than $250, the following information shall be included in the response relating to each separate item of royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers, patent application serial numbers or other basis on which the royalty is payable.
(4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable.
(5) Percentage or dollar rate of royalty per unit.
(6) Unit price of contract item.

(7) Number of units.
(8) Total dollar amount of royalties.

(b) **Copies of current licenses**. In addition, if specifically requested by the Contracting Officer before execution of the contract, the offeror shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents.

(**NOTE: Alternate I, below, is applicable for communication services and facilities by a common carrier.**)

ALTERNATE I (APRIL 1984), 52.227-6 ROYALTY INFORMATION (APRIL 1984)

Substitute the following for the introductory portion of paragraph (a) of the basic clause:

When the response to this solicitation covers charges for special construction or special assembly that contain costs or charges for royalties totaling more than $250, the following information shall be included in the response relating to each separate item of royalty or license fee:

25. **52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (JUNE 2000)**

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS-coverage pursuant to 48 CFR 9903.201-2(C)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement -- Cost Accounting Practices and Certification

(a) Any contract in excess of $500,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph © of Part I of this provision.

CAUTION: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

[ ] (1) Certificate of Concurrent Submission of Disclosure Statement.

The offeror hereby certifies that, as part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) original and one copy to the cognizant Administrative Contracting Officer (ACO), or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable, and;
(ii) one copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable.. Forms may be obtained from the cognizant ACO or Federal official and/or from the looseleaf version of the Federal Acquisition Regulation).

Date of Disclosure Statement: _____
Name and Address of Cognizant ACO or Federal Official Where Filed: _____
_____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

[ ] (2) Certificate of Previously Submitted Disclosure Statement.

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: _____
Name and Address of Cognizant ACO or Federal Official Where Filed: _____
_____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

[ ] (3) Certificate of Monetary Exemption.

The offeror hereby certifies that the offeror together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than $50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

[ ] (4) Certificate of Interim Exemption.

The offeror hereby certifies that:

(i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted, and

(ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

CAUTION: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of $50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

[ ] (5) Certificate of Disclosure Statement Due Date by Educational Institution. (ALTERNATE I - APRIL 1996)

If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903-202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that (***check one and complete***):

[ ] (i) A Disclosure Statement filing Due Date of _____ has been established with the cognizant Federal agency.

[ ](ii) The Disclosure Statement will be submitted within the 6-month period ending _____ months after receipt of this award.

Name and Address of Cognizant ACO or Federal Official Where Disclosure Statement is to be Filed: _____

_____

II. Cost Accounting Standards -- Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

[ ] The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than $50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

CAUTION: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of $50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of $50 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards Clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

[ ] YES **[ ]** NO

26. **CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE (DECEMBER 1994)**

(Note: This certification applies only to those contract which contain provisions for children's services. The offeror's signature on the face page of these Representations and Certifications constitutes certification by the submitting organization of its compliance with the Act.)

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract,

loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By signing this certification, the Contractor certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

27. **CERTIFICATION OF INSTITUTIONAL POLICY ON CONFLICT OF FINANCIAL INTEREST (OCTOBER 1995)**

(Note: This certification is applicable to Research and Development (R&D) Contracts. However, this certification does not apply to SBIR-Phase I Contractors.)

By submission of its offer, the offeror certifies that:

(1) A written and enforced administrative process to identify and manage, reduce or eliminate conflicting financial interest with respect to all research projects for which funding is sought from the NIH is **[ ]**, is not **[ ]** currently in effect.

(2) Should a process not be in effect at the time of the submission of its offer, the offeror certifies that it will, no later than 30 days subsequent to submission of its offer or prior to award, whichever is earlier, notify the Contracting Officer of the establishment of a written and enforced financial conflict of interest policy.

28. **15.406-2 CERTIFICATE OF CURRENT COST OR PRICING DATA**

(When cost or pricing data are required in accordance with FAR 15.406-2, the Contracting Officer will request that the offeror complete, execute, and submit to the Contracting Officer a certification in the format shown in the following Certificate of Current Cost or Pricing Data. The certification shall be submitted only at the time negotiations are concluded. Offerors should complete the certificate and return it when requested by the Contracting Officer.)

This is to certify that, to the best of my knowledge and belief, the cost or pricing data (as defined in section 15.401 of the Federal Acquisition Regulation (FAR) and required under FAR subsection 15.403-4) submitted, either actually or by specific identification in writing, to the Contracting Officer or to the Contracting Officer's representative in support of _____* are accurate, complete, and current as of_____**.

This certification includes the cost or pricing data supporting any advance agreements and forward pricing rate agreements between the offeror and the Government that are part of the proposal.

Firm _____

Signature _____

Name _____

Title _____

Date of execution*** _____

* Identify the proposal, request for price adjustment, or other submission involved, giving the appropriate identifying number (e.g., RFP No.)

** Insert the day, month, and year when price negotiations were concluded and price agreement was reached, or, if applicable, an earlier date agreed upon between the parties that is as close as practicable to the date of agreement on price.

*** Insert the day, month, and year of signing, which should be as close as practicable to the date when the price negotiations were concluded and the contract price was agreed to.

(End of Certificate)

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

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

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

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

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

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

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

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

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

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

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

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

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

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

(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. **NOTICE OF SMALL BUSINESS SET-ASIDE**

(1) **General**. Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

(2) **Definitions**. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.

c. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

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

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

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that one (1) award will be made from this solicitation and that the award(s) will be made on/about December 15, 2003.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type contract, completion with a period of performance of three years, 6 months, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 85,576 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

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 procurement. 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 Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

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

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

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

k. **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
Division of Research Acquisition
National Institutes of Health
6100 Executive Blvd., Room 6E01, MSC 7540
Bethesda, MD 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)

l. **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. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

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

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

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

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm 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) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all 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.

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

(9) **Human Subjects**

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

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

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

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

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

d) Inappropriate designations of the noninvolvement of human subjects 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.*

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

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

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

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

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

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

Sources of Materials:

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

Potential Risks:

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

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

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

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

Protection Against Risk:

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

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

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

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

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe 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.

(11) **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.

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

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion 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, © 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, 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 RFP for more information about evaluation factors for award.)

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

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

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

---

[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.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

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

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

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

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.

(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 RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

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

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

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

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

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

-to the cognizant audit agency and the General Accounting Office for auditing.

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

-to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(17) **Selection of Offerors**

a) The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

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

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

d) If the Government determines that discussions are necessary, the Contracting Officer will determine the competitive range. The oral or written discussions will be conducted with all offerors in the competitive range. Pursuant to FAR 15.306(c)(2), the competitive range may be limited for purposes of efficiency. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror in the competitive range shall 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 price offeror or other than the highest technically rated offeror. The process will take into consideration the results of the technical evaluation, cost realism analysis, past performance evaluation, and ability to complete the work within the Government's required schedule. The Government reserves the right to make an award to the offeror who's proposal provides the best value to the Government, technical merit, cost, and other factors considered.

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

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

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

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

(19) **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.

(20) **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.

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

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

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

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

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

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

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

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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

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

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

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

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

(21) **Past Performance Information**

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

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

Include the following information for each contract or subcontract:

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

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

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

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

(22) **Electronic and Information Technology Accessibility**

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

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

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

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

(1) **Technical Discussions**

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

a) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

(4) Resumes

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

(2) **Technical Evaluation**

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

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

(5) **Qualifications of the Offeror**

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

a) **General Experience**

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

b) **Organizational Experience Related to the RFP**

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

c) **Performance History**

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

d) **Pertinent Contracts**

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

e) **Pertinent Grants**

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

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could

have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(6) **Information Technology Systems Security**

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

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

(1) Category of Safeguarded Information

The category of safeguarded agency information that the successful offeror will develop or access shall be NonSensitive Information.

(2) Security Level Designations

The information that the successful offeror will develop or access shall be as follows:

-The **Sensitivity** of the data - Level 1
-The **Operational Criticality** of the data - Level 1
-The **Overall Security** for the requirement - Level 1

(3) Position Sensitivity Designations

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

[ ] Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).
Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI). Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

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

The offeror's proposal must:

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

(2) Demonstrate that it complies with the AISSP security requirements, the ComputerSecurity Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook. At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards that correspond with the Overall Security Level identified herein.

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

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

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

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

(d) **References**

The following documents are electronically accessible:

(1) OMB Circular A-130, Appendix III: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt
(2) DHHS AISSP Handbook: http://irm.cit.nih.gov/policy/aissp.html
(3) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(4) NIH Applications/Systems Security Template: http://cit.nih.gov/security/secplantemp.html
(5) NIST Special Publication 800-16, "Information Technology Security Training Requirements:" http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
(6) NIH CIT-Policies, Guidelines and Regulations:
Table 1 - Categories of Safeguarded Agency Information: http://irm.cit.nih.gov/security/table1.htm
Table 2 - Security Level Designations for Agency Information: http://irm.cit.nih.gov/security/table2.htm
Table 3 - Positions Sensitivity Designations for Individuals Accessing Agency Information: http://irm.cit.nih.gov/security/table3.htm

c. BUSINESS PROPOSAL INSTRUCTIONS

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

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) **Proposal Cover Sheet**

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

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

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

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

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

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

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

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

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

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 (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

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

5. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

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

10. **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

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

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

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

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

(End of provision)

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

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

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

(5) **Other Administrative Data**

a) **Property**

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

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

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

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

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

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

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

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.

(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **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.

d) **Incremental Funding**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

(End of provision)

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

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

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

(End of Provision)

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

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

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

(6) **Subcontractors**

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

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

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

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

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(8) **Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(9) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

a. **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, and past performance. Although technical factors are of paramount consideration in the award of the contract, cost/price and past performance 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 RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

b. **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 in the proposed research plan, or provide sufficient information on the research subjects to allow a determination by NIH 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".

The Government intends to make award without discussions; however, if the Government decides to hold discussions, then you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

(b) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. 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.

The Government intends to make award without discussions; however, if the Government decides to hold discussions, then you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

c. **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.

d. **TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

A. Technical Approach (40 points)

The offeror's overall understanding of the objectives and requirements of the RFP, ability to identify problems and suggest solutions, and the ability to enhance the achievement of the scientific goals of the overall program will be evaluated for the following elements.

1) Evidence of a clear understanding of the purpose, scope, requirements, and project objectives. Demonstrated understanding of the study design, specific study design issues as they relate to longitudinal studies.

2) Feasibility and adequacy of the proposed technical approach, as demonstrated by the practicality, feasibility and logical sequence of the proposed plans to accomplish the tasks in the Statement of Work. Adequacy of the discussion of problems likely to occur in performance of this work including plans to address and correct any problems that may occur.

3) Adequacy of methods proposed for meeting minimum response rates for screenings and household interviews.

4) Adequacy of proposed quality assurance programs for each stage of data collection.

5) Acceptability of data collection techniques, informed consent procedures, human subject protection and cultural awareness concerns.

6) Acceptability of the approach for collecting the 24-hour dietary recall and the manner in which training for performing the dietary recall interview is integrated into the overall interviewer training program

7) Suitability of the organizational structure of the proposed project team with clearly identified roles and responsibilities, and clear lines of authority.

B. Personnel Qualifications (40 points)

1) Expertise, experience, and demonstrated availability of all proposed staff in successfully conducting projects similar in size and scope to the one described in this RFP, including longitudinal studies, work with census tracts, cross-cultural communications, survey methodologies, participant recruitment and retention, participant interviews, and study design outcome analysis.

2) Documented experience and qualifications of the proposed Project Manager and all key personnel in supervising/managing projects involving field staff, household listings, participant recruitment and interviews.

3) Qualifications of proposed staff in longitudinal study evaluations and data analysis.

C. Organizational Experience (10 points)

Evidence of corporate experience in timely and successful performance on projects of similar size and scope, including the ability to recruit participants and conduct interviews.

D. Facilities and Equipment (10 points)

Documented availability and accessibility of space and major equipment needed to conduct the studies in this Statement of Work in a timely and effective manner.

e. **PAST PERFORMANCE FACTOR**

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

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

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

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

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

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

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

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

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

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

0 **None** - No past performance history identifiable.

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

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

PACKAGING AND DELIVERY OF THE PROPOSAL

Your proposal shall be organized as specified in Section L.2., "Instructions to Offerors" - General Instructions. 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. 260-03-15 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY:

NUMBER OF COPIES

TECHNICAL PROPOSAL:	ORIGINAL* AND 12 COPIES TO:
BUSINESS PROPOSAL:	ORIGINAL* AND 6 COPIES TO:

If hand-delivered or delivery service	If using U.S. Postal Service
Teresa Baughman Contracting Officer Division of Research Acquisition, OLAO National Institutes of Health 6100 Executive Boulevard, Room 6E01 Rockville, Maryland 20852	Teresa Baughman Contracting Officer Division of Research Acquisition, OLAO National Institutes of Health 6100 Executive Blvd., Room 6E01, MSC 7540 Bethesda, MD 20892-7540

*THE **ORIGINALS** MUST BE READILY ACCESSIBLE FOR DATE STAMPING PURPOSES

NOTE:

The U.S. Postal Service's "Express Mail" does not deliver to the Rockville, Maryland address. Any package sent to the Rockville address via this service will be held at a local post office for pick-up. The Government is not responsible for picking up any mail at a local post office. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal."

STATEMENT OF WORK FOR SOLICITATION PURPOSES

Representative Sampling for the Healthy Aging in Neighborhoods of Diversity Across the Life Span (HANDLS) Study

BACKGROUND

The need to understand the sources of persistent health disparities in overall longevity, cardiovascular disease, and cerebrovascular disease has led to the development of the *Healthy Aging in Neighborhoods of Diversity across the Life Span* (HANDLS) study. By posing fundamental questions about differences in rates and risks for pathological conditions associated with aging, the National Institute on Aging (NIA), Intramural Research Program (IRP) hopes to disentangle the relationship between race, socioeconomic status, and health outcomes. Among the questions the NIA IRP will address are: What are the independent influences of socioeconomic status and race on normal age-related changes in function? What are the independent influences of socioeconomic status and race on the incidence of age-related diseases? What are the influences on the natural history of common age-related diseases? How does socioeconomic status and race contribute to health disparities? Are there early biomarkers of age-related health disparities that may enhance our ability to prevent or ameliorate the severity of these diseases? In order to address these questions in the appropriate populations, the NIA IRP has established a new paradigm by using mobile medical research vehicles (MRV). These vehicles serve as community-based platforms for clinical research. The MRVs are tools for creating effective methods for recruiting and retaining non-traditional research participants into age-related clinical research.

Before embarking on the full-fledged neighborhood study, the NIA IRP performed a pilot study to test the feasibility of this style of research and to test the logistics of using the mobile research vehicles. The pilot study recruited a sample of convenience from a low socioeconomic neighborhood in West Baltimore. Although the NIA IRP anticipated a sample of about 100 volunteers, participants were so enthusiastic that the pilot ended with 442 volunteers. The sample was comprised largely of African-Americans, nearly 40% men. The NIA IRP's experience with the pilot study has revised our previously held beliefs about barriers to participation through our efforts to connect with community groups and our presence in the neighborhood in our mobile research vehicle. Although the goal of the pilot was to assess the feasibility of the study, the NIA IRP also succeeded in collecting data on some aspects of health disparities. Preliminary analyses of psychophysiological data suggest important differences in blood pressure responses to certain stimuli among African American subjects that may be tied to differences in control of mechanisms of blood pressure. These analyses support the notion that there is a delay in cardiovascular recovery among African Americans that may be a potential factor in the cardiovascular health disparity between Blacks and Whites. In addition, there was a significant association between symptoms of depression and cardiovascular reactivity, and in women, a significant association between loneliness and peripheral resistance. These results serve to highlight the multiple levels of system functioning that may contribute to health disparities in cardiovascular disease, especially hypertension. The HANDLS pilot sample had much higher levels of depressive symptomatology as measured by the Center for Epidemiological Studies Depression Inventory suggesting greater rates of depression or that this widely used instrument is less accurate for screening in low socioeconomic status and minority cohorts. Preliminary results indicate that there are significant age differences in depressive symptoms in women but not in men, a surprising result because there is no evidence for age differences in depressive symptoms in nationally representative data. In addition, there were no mean differences between women and men, particularly surprising because nationally representative data unanimously show that women self-report more depressive symptoms than men.

The NIA IRP is presently performing a second pilot study in which we are investigating the rate of follow-up for re-contact and participants' willingness to volunteer for re-examinations.

Study design

The baseline HANDLS sample will consist of approximately 4,000 community-dwelling African American and White adults aged 30-64. Participants will be drawn from 12 pre-determined census tracts in Baltimore City so as to sample representatively across a wide range of socioeconomic and income circumstances. The heuristic study design is a factorial cross of four (4) factors: age, sex, race, and socioeconomic status with approximately equal numbers of subjects per "cell" (Figure 1 below). HANDLS is planned as a 20-year longitudinal study. Using the NIA IRP's mobile research vehicles, HANDLS will visit each census tract for three (3) months and re-visit every census tract in a three-year cycle.

The twelve (12) census tracts identified by the NIA IRP, plus the one (1) census tract for the dress rehearsal, were selected because they are likely to yield representative distributions of individuals between 30 and 64 years old who are African Americans and Whites, men and women, and lower and higher socioeconomic status. Individuals calling themselves multi-ethnic shall be included amongst the group with which they most strongly identify, but their multi-ethnic identification shall be recorded for subsequent statistical analyses. Multi-ethnic individuals who identify strongly with neither African Americans nor Whites shall be excluded from the present study.

Initial estimates based on 2000 census data suggest that the sample recruiters will need to visit approximately 35% of the households in each census tract to collect the required 333 individuals per census tract. The initial sample of 4,000 participants is based on power analyses and assumptions about attrition over twenty years. For a power of 80% (the likelihood of finding an effect if it is really present), NIA IRP can identify moderate effects (magnitude of the differences between groups) for various outcomes with as few as 30 participants per group at the end of the study. Working backwards by assuming 20% attrition after the baseline assessment and 15% attrition between subsequent assessments, the NIA IRP will need approximately 4,000 participants at baseline to yield 1,680 after twenty years (30 per cell with 56 cells shown in Figure 1 below).

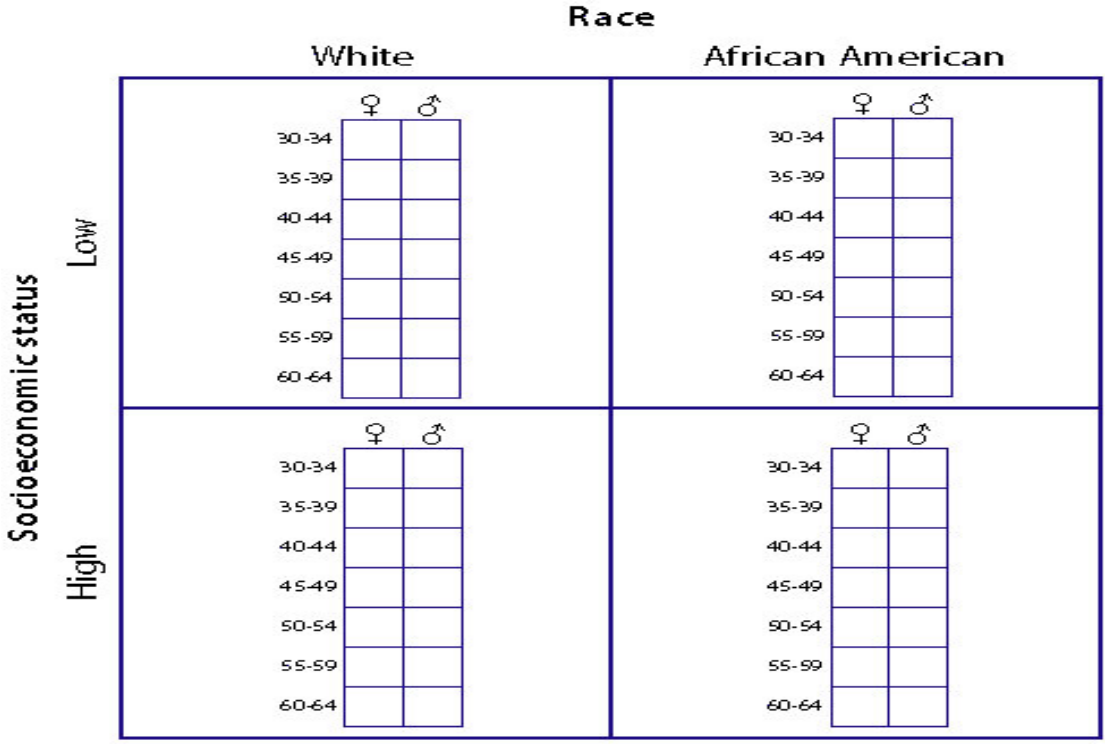

Figure 1. HANDLS sampling design

The NIA IRP will remunerate study participants for their time and inconvenience as part of the participant examinations on the MRV.

The NIA IRP will perform the necessary community outreach. The NIA IRP does not anticipate the need to provide multilingual materials in this phase of HANDLS because there are relatively few households in which English is not the primary language. Subsequent phases of this study beyond the scope of the present contract may focus on multilingual families, particularly those in which Spanish is spoken in the home.

Overall survey plan

For the purposes of this contract, the NIA IRP will identify thirteen (13) baseline census tracts, designating one (1) tract for a dress rehearsal and twelve (12) tracts for the longitudinal HANDLS study. After completion of this contract, the NIA IRP shall perform follow-up in the twelve (12) census tracts designated for longitudinal research. The NIA IRP has no plans for follow-up in the dress rehearsal tract.

OBJECTIVES

This contract shall acquire the services of a Contractor to perform household listings, recruit a representative sample of African Americans and Whites aged 30-64 from Baltimore City, and conduct initial household interviews for the *Healthy Aging in Neighborhoods of Diversity across the Life Span* (HANDLS) study. This contract shall supply the NIA IRP with expertise in contacting and recruiting a community-based representative sample that will comprise the foundation for the NIA IRP's longitudinal study.

WORK TO BE PERFORMED

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material equipment and facilities, not otherwise provided by the Government, and as needed to perform the Statement of Work below.

A. <u>General Requirements</u>

Work performed by the Contractor shall proceed in two (2) phases. Phase 1 is Household Listings. In Phase 1, the Contractor shall produce household listings for identifying the residential dwellings in each census tract. Phase 2 is Participant Recruitment/Household Interviews. In Phase 2, the Contractor shall perform doorstep interviews by identifying eligible persons in each household, selecting one eligible person per household for an invitation to participate in HANDLS, and, if the invitation is accepted, complete a Government-supplied, two-hour household interview in which half-an-hour is devoted to a 24-hour dietary recall. The household interview will conclude with an appointment for testing on the MRV. Successfully recruited participants are individuals who fit the eligibility criteria provided by the NIA IRP, complete the household interview, and complete the examination protocols on the MRV. The Contractor shall recruit equal sized samples of African Americans and Whites. The Contractor shall prepare their field staff for circumstances in which they must insure approximately equal-sized samples by (in some instances) selecting no eligible person in a household with eligible persons.

The Contractor shall first perform both phases in one (1) census tract that will serve as a dress-rehearsal site and then perform both phases again in twelve (12) other census tracts.

The NIA IRP shall identify a total of thirteen (13) census tracts in Baltimore City (one for the dress rehearsal and twelve for the study). These tracts will be based on demographic characteristics suitable for the objectives and design of the HANDLS study that meet the logistics requirements of the MRVs. The Contractor shall recruit 333 individuals per census tract who complete examinations on the MRV.

For each census tract visited, the NIA IRP shall send advance letters to all of the listed dwellings two weeks before initiating examinations on the MRV. The week before the NIA IRP initiates examinations on the MRV, the Contractor shall begin door-to-door recruitment based on the residential listing data. The Contractor shall survey each residential listing, inviting an eligible household resident to participate in HANDLS. The Contractor shall recruit one and only one resident from each household. When an eligible resident volunteers to participate, the Contractor shall administer a Government-supplied household interview and 24-hour dietary recall in the selected residence. Before ending the household interview, the

Contractor shall make a follow-up appointment for the participant's examination on the MRV.

The NIA IRP will provide outreach materials to the Contractor, and the Contractor shall be responsible for introducing these materials to their interviewers and for distributing the materials to potential participants.

B. Response Rate Requirements

The Contractor shall develop and implement methods for meeting minimum response rates. The Contractor shall develop and implement methods for achieving at least a 98 percent screening response rate. The screening response rate is defined as the number of housing units screened divided by the number of occupied housing units from those listed. The Contractor shall develop and implement methods for conducting household interviews to obtain an examination rate of 85 percent or better. The examination rate is defined as the number of sample persons with completed household interviews who complete their appointments for examination on the MRV divided by the total number of sample persons identified. A completed household survey is defined as one in which the participant responds to all of the questions in the interview. Partially completed surveys are insufficient to qualify a participant for an examination appointment. Individuals who decline to complete the entire household survey are ineligible for subsequent participation in the study.

C. Quality Control

The Contractor shall design a quality assurance program for each component, at every stage of data collection, that is reliable and valid, easily understood and implemented, easily documented and surveyed, precise and accurate, and monitored as specified by the Project Officer. Minimal monitoring shall include but not be limited to quantification and qualification of all "missingness" of data, audit trails of all data edited during data collection, statistical evaluations of observer variability, and periodic observation of data collection resulting in documented feedback to field staff on data quality that deploys retraining if necessary. The Contractor shall provide continued assurance that all Contractor personnel understand the principles of each component they are performing, are thoroughly trained, apply and maintain high standards for courtesy and unbiased contact with the public, and apply and maintain standard and consistent procedures in administering that component.

D. Training

The Contractor shall conduct any training and retraining of Contractor personnel necessary to meet the standards of data quality required. All Contractor personnel shall be available for evening and weekend work, and for overtime work if necessary. Once each year during the survey, the Contractor shall hold a two-day retraining session for all Contractor field staff.

The Contractor shall conduct annual cultural proficiency training for all Contractor personnel involved in this project. At a minimum, training shall promote techniques for cross-cultural communications and assist Contractor personnel in avoiding cultural generalizations. The training shall address topics related to the culture of poverty, the nuances of membership in under-represented groups, and personal biases about under-represented groups. Contractor personnel in the training shall receive information about the relationship of research participation to the dynamics of healthcare delivery in medically underserved, minority, and socio-economically disadvantaged communities. In particular, Contractor personnel shall be trained to avoid any coercion of potential participants or any appearance of bias or prejudice toward participants, other Contractor personnel, or Government personnel. The NIA IRP provides similar training for its personnel.

Note: The NIA IRP may consider proposals from the Offerors to conduct joint training sessions with the Government and the Contractor, sharing proportionate payment to an appropriate third-party training enterprise.

E. Dress Rehearsal

The Contractor shall participate with the NIA IRP in performing a full-fledged dress rehearsal in a census tract to be determined. The dress rehearsal shall consist of both Phase 1 and Phase 2. The purpose of the dress rehearsal is to field-test the Contractor's listing and interview procedures, to field-test the NIA IRP's examination procedures on the MRV, and to field-test the interface between the Contractor and the NIA IRP.

The dress rehearsal shall be conducted over a two (2) month period. The Contractor shall have six (6) weeks post-award to prepare for the dress rehearsal, and six (6) weeks after the dress rehearsal to examine the results of the dress rehearsal, refine operational procedures and revise procedures, and deploy staff for the neighborhood listing of the first longitudinal census tract. After completing the dress rehearsal, the NIA IRP plans to visit each longitudinal census tract for three (3) months. The Contractor shall perform their household listings and door-to-door interviews in concert with the NIA IRP such that the household listings are completed before beginning door-to-door recruiting and door-to-door recruiting begins when the NIA IRP installs the MRV in the census tract. The NIA IRP and the Contractor shall coordinate project management during weekly progress meetings.

The Contractor and the NIA IRP shall analyze jointly the results of the dress rehearsal by methods that include an evaluation of the outreach materials distributed by HANDLS, examination procedures and times, examination center staffing needs, the computer-assisted interview system, and all aspects of Contractor's survey methodology. The Contractor shall report to the Project Officer on the completeness, range, and consistency of questionnaires done in the household, and relevant observations made by interviewers' supervisors. The Contractor shall conduct debriefings with the Project Officer and other NIA IRP staff to make recommendations for modifying its listing and interview procedures, the computer-assisted household interview, outreach methods and materials, manuals, questionnaires, examination staff composition, interview materials, and examination procedures.

The work listed for each phase below shall be carried out in the dress rehearsal, as well as in the study itself.

F. Phase 1 - Household Listings

The Contractor shall create a listing operations guide which shall consist of a listings operation manual and a lister training guide. The listing operations guide shall include instructions and materials for training Contractor personnel to list residential dwellings. The Contractor shall use these materials in training neighborhood listers and as the standards for evaluating the listers' adherence to study policies and procedures. The Contractor shall submit a draft listing operations guide to the Project Officer within four (4) weeks of contract award. The Project Officer shall provide the Contractor with comments within one (1) week after receipt of the draft. The Contractor shall incorporate those comments and submit a final listing operations guide two (2) weeks after comments are received.

One month before HANDLS initiates examinations on the MRV, the Contractor shall select a sample of blocks in each of the Government-provided census tracts. The Contractor shall list each selected block in the census tract by systematically recording the address of every residential dwelling within the block. The Contractor need not list commercial buildings and other nonresidential buildings, but if it chooses to do so then it must clearly distinguish between residential and non-residential locations. The Contractor shall note the location of each dwelling so that a geographic information system (GIS) generated map can be drawn based on the recorded data. The Contractor shall provide the Government with electronic copies of the listing data and maps using mutually agreed upon standard formats.

G. Phase 2 - Participant Recruitment/Household Interviews

The Contractor shall create an interviewer operations guide which shall consist of an interviewer operations manual and an interviewer training guide that includes all instructions and materials for training Contractor personnel to do the sample selection procedures and interview procedures. The Contractor shall use these materials in training interviewers and as the standards for evaluating the interviewers' adherence to study policies and procedures. The Contractor shall submit a draft interviewer operations guide to the Project Officer within four (4) weeks of contract award. The Project Officer shall provide the Contractor with comments within one (1) week after receipt of the draft. The Contractor shall incorporate those comments and submit a final interviewer operations guide two (2) weeks after comments are received.

The Contractor shall train interviewers to administer the doorstep screening questions and the household interview in a consistent fashion. The Contractor shall design their procedures so that quality control checks can be performed. The Contractor shall propose a plan for performing routine quality control checks and the Contractor shall demonstrate that interviewers are adhering to the standards in the interviewer operations guide. In particular, the Contractor shall develop and place in force verification procedures that will make it easy to clearly recognize attempts to falsify household information and manipulate sample selection.

The Government will supply the content of household interview in the format of a web site that operates on a portable computer. The Contractor shall supply portable computers to their field interviewers if they are required.

NOTE: The Government will consider reasonable alternative methods for collecting the household interview if an Offeror proposes them.

NOTE: The Contractor's proposal should demonstrate the stability of their systems through their successful application in one or more large studies.

1) The Contractor shall perform doorstep interviews, inviting eligible candidates to participate in HANDLS and performing NIA IRP-supplied, two-hour household interviews concluding with an appointment for testing on the MRV.

2) The NIA IRP will collaborate with the Department of Agriculture to perform a 24-hour dietary recall. The dietary recall uses 30 minutes of the 2 hours set aside for the household interview. The procedures for dietary recall require using the Blaise computer-assisting interview system. If the Contractor doesn't already have licenses to use Blaise, then the Contractor shall license the system for its use in this survey. The Department of Agriculture shall supply the contents of the dietary recall using their previously validated methodology. The Government will train contract interviewers to perform the dietary recall using Government-supplied measuring guides. The Contractor shall coordinate its training schedule with the Government to integrate instruction for the 24-hour dietary recall with training for remainder of the household interview.

3) The Contractor shall implement a residential screening interview to classify the household as eligible according to the HANDLS sample design. The screening interview is complete when the household can be classified as eligible or ineligible. The instrument shall include information about the income or poverty status of the household and the age, sex, and race of household occupants. If one or more occupant is eligible for HANDLS, then the interviewer may invite him or her to participate in the study. The Contractor shall select one and only one occupant from each household. The Contractor shall include the doorstep screening data among the data delivered to the Government for all of the households visited by interviewers. The denominator of the completion rate is the number of occupied households in the segments selected. Information about sample households may be obtained from residents occupying other households in the immediate neighborhood after the Contractor makes three tries at sample households. However, the design of the baseline HANDLS recruitment has no provision for proxy data and therefore proxy data shall not be used in lieu of in-person interviews.

4) The Contractor shall use a global positioning system (GPS) to establish the longitude and latitude of each participant's place of residence. The interviewers shall record these data electronically. If new technology allows this information to be entered directly into the computer then this should be instituted at the earliest possible date. The Contractor shall purchase and maintain the GPS units used in the field.

5) Successfully recruited participants are individuals who fit the eligibility criteria of the sample design, complete the household interview, and complete the examination protocols on the mobile medical research vehicle. The Contractor shall recruit equal sized samples of African Americans and Whites. Without overt coercion or the appearance of coercion, the Contractor shall determine and apply the best strategies for persuading sample persons who have refused or broken their examination appointments to come for the examination.

6) When making the appointments for examinations, the Contractor shall give participants NIA IRP-supplied information booklets, appointment cards, and directions with a map showing the location of the MRV in their census tract. The card shall be a business-card-sized clinic appointment slip to remind participants about the date of their examination appointment. The directions shall show the location of the MRV in the present stand. The booklet will inform participants of the examination procedures that the NIA IRP will perform on the MRV, and it will explain the necessity for a 12-hour fast prior to their examination. The NIA IRP will make reminder phone calls to all participants prior to their appointment on the MRV, and in particular, the NIA IRP will remind participants about the necessity for a 12-hour fast prior to their appointment. The NIA IRP will also remind participants that breakfast is served after their blood is drawn and before they begin any other examination procedures.

7) The Contractor shall record and transmit to the Government data on their progress in recruiting as the work is performed. The Contractor shall transmit these data electronically and in a format approved by the Project Officer. The Contractor shall track the progress toward initial contacts by recording the numbers and types of attempts at different times on different days, the total time allocated to making initial contact, and the ultimate success or failure to contact. Contact failures are designated nonrespondent households.

H. Required Reports and Deliverables

1) Project Plan

Within three (3) weeks of award, the Contractor shall submit two (2) copies of a project plan, one to the Project Officer and one to the Contracting Officer. This document shall include a plan and schedule for household listings, the deployment plan for sample recruitment, the logistics and training schedule for staff training, data confidentiality and security plan, and an outline agenda for issues requiring further discussion or coordination. The Contractor shall hold a meeting with the NIA IRP Project Officer to review the plan and remaining issues within one (1) week of the submission of the project plan.

2) Draft and Final Listings Operations Guide

The Contractor shall create a listing operations guide which shall consist of a listings operation manual and a lister training guide. The listing operations guide shall include instructions and materials for training Contractor personnel to list residential dwellings. The Contractor shall use these materials in training neighborhood listers and as the standards for evaluating the listers' adherence to study policies and procedures. The Contractor shall submit a draft listing operations guide to the Project Officer within four (4) weeks of contract award. The Project Officer shall provide the Contractor with comments within one (1) week after receipt of the draft. The Contractor shall incorporate those comments and submit a final listing operations guide two (2) weeks after comments are received.

3) Draft and Final Interviewer Operations Guide

The Contractor shall create an interviewer operations guide which shall consist of an interviewer operations manual and an interviewer training guide that includes all instructions and materials for training Contractor personnel to do the sample selection procedures and interview procedures. The Contractor shall use these materials in training interviewers and as the standards for evaluating the interviewers' adherence to study policies and procedures. The Contractor shall submit a draft interviewer operations guide to the Project Officer within four (4) weeks of contract award. The Project Officer shall provide the Contractor with comments within one (1) week after receipt of the draft. The Contractor shall incorporate those comments and submit a final interviewer operations guide two (2) weeks after comments are received.

4) Weekly Progress Updates

The Contractor shall conduct weekly in-person or telephone conferences to provide the Project Officer with up-to-date information about progress and changes, if any, in recruitment rates, refusal rates, or completion rates. The Contractor shall present up-to-date information on quality control checks on the neighborhood listings and on the household interviewers. In addition, the Contractor and the Project Officer shall discuss the coordination of project management and timing. The Contractor and the Project Officer shall arrange a mutually convenient standing meeting time for these conferences.

5) Quarterly Progress Reports

The Contractor shall submit two (2) copies (one to the Project Officer and one to the Contracting Officer) of a progress report within ten (10) calendar days after each reporting period. The initial report shall be submitted for the first full three (3) months of the contract performance, including any fractional part of the initial month. Thereafter, the reporting period shall consist of three (3) calendar months. A quarterly progress report will not be required for the period when the final report is due. This report shall include the following:

1) A cover page containing:

   a) Contract number and title;
   b) Period of performance being reported;
   c) Contractor's name and address;
   d) Author(s); and
   e) Date of Submission.

2) The numbers and locations of neighborhoods for which household listing were performed, recruitment yield summary data including the numbers of households visited, the number of households visited but never screened because participation was refused, the number of households providing an initial response, the number of households with a member apparently eligible for the study, the number of household interviews performed on eligible members upon immediate identification, the number of interviews scheduled for a later date but not completed, the number of interviews scheduled for a later date that were completed, and the number of successfully scheduled volunteers for study on the mobile research vehicles.

3) Cumulative summaries of the items in (B) after the first 6 months.

4) Proposed hardware or software changes.

5) The report shall also include an indication of any current problems encountered that may impede progress and proposed corrective action.

6) Dress Rehearsal Evaluation

The Contractor shall provide written comments and recommendations for procedural revisions no later than three weeks after the end of the dress rehearsal. The Government shall base evaluations of the dress rehearsal on this document, at least in part, and discussions of policy and procedure shall take into account the Contractor's recommendations.

7) Final Report

The Contractor shall submit two (2) copies (one to the Project Officer and one to the Contracting Officer) of a final progress report on or before the last day of the contract performance period. The Contractor shall submit a draft file report 60 days before the end of the contract on which the Government will provide comments within 30 days. This report shall include a summation of the results of the entire contract work for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the numbers and types of evaluations performed as a result of the Work Statement.

8) Electronic Transmission of Data

All data generated shall be transmitted electronically to the Project Officer, at least weekly for raw data and at least every month for processed data. These data include but may not be limited to maps drawn with geographic information systems (GIS), listing data, recruitment yield itemizations and summaries, recruitment eligibility data, and household interview responses.

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.

© **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.

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

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

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

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

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

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

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

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

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

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

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

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

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

- The item number for the specific piece of equipment listed in the Property Schedule.
- The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule.
- Be preceded by an asterisk (*) if the equipment is below the approval level.

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

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

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

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

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

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

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

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

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

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

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

(q) **Grand Totals**

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

FINANCIAL REPORTING INSTRUCTIONS:

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

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

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

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

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

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

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

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

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

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

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

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

(a) Billing Office Name and Address Division of Research Acquisition, OLAO NATIONAL INSTITUTES OF HEALTH 6100 EXECUTIVE BLVD, RM 6E01 MSC 7540 Bethesda, MD 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._____ © 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				

ANNUAL TECHNICAL PROGRESS REPORT FORMAT FOR EACH STUDY

Study Title:
Date:

Provide the number of subject enrolled in the study to date according to the following categories:

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
TOTAL							

Subpopulations of the minority groups should also be reported, using a similar format.

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 th 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

Authorized for local Reproduction — Sponsored by HHS

Public reporting burden for this collection of information is estimated to average less than an hour per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 503 200 Independence Avenue, SW., Washington, DC 20201. *Do not return the completed form to this address.*

PRIVACY ACT SYSTEM OF RECORDS NUMBER 09-25-0200

System name: Clinical, Epidemiologic, and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

Security classification: None.

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

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

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

Authority for maintenance of the system: "Research and Investigation," "Appointment and Authority of the Directors of the National Research Institutes," "National Cancer Institute," "National Eye Institute," "National Heart, Lung and Blood Institute," "National Institute on Aging," "National Institute on Alcohol Abuse and Alcoholism," "National Institute on Allergy and Infectious Diseases," "National Institute of Arthritis and Musculoskeletal and Skin Diseases," "National Institute of Child Health and Human Development," "National Institute on Deafness and Other Communication Disorders," "National Institute of Dental and Craniofacial Research," "National Institute of Diabetes, and Digestive and Kidney Diseases," "National Institute of Drug Abuse," "National Institute of Environmental Health Sciences," "National Institute of Mental Health," "National Institute of Neurological Disorders and Stroke," and the "National Human Genome Research Institute" of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

Purpose(s): To document, track, monitor and evaluate NIH clinical, epidemiologic, and biometric research activities. Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

1. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; © has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, © for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or © the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is, therefore, deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency Contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences, and to locate individuals for follow-up studies. Social security numbers, date of birth and other identifiers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital

status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in epidemiologic studies.

7. (a). PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or Contractors; (2) The PHS employee or Contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or Contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices. (b.) PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

11. Disclosure may be made for the purpose of reporting child, elder, or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

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

Retrievability:

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

Safeguards:

1. Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including Contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.

2. Physical Safeguards: Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

3. Procedural Safeguards: Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or Contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

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

Retention and disposal:

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

System manager(s) and address:

See Appendix I for a listing of current system managers. This system is for use by all NIH Institutes and Centers. The following system notices have been subsumed under this umbrella system notice.

09-25-0001, Clinical Research: Patient Records, HHS/NIH/NHLBI.

09-25-0010, Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI.

09-25-0015, Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS.

09-25-0016, Clinical Research: Collaborative Perinatal Project, HHS/NIH/NINDS.

09-25-0026, Clinical Research: Nervous System Studies, HHS/NIH/NINDS.

09-25-0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.

09-25-0031, Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS.

09-25-0037, Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA.

09-25-0038, Clinical Research: Patient Data, HHS/NIH/NIDDK.

09-25-0039, Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK.

09-25-0040, Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK.

09-25-0042, Clinical Research: National Institute of Dental and Craniofacial Research Patient Records, HHS/NIH/NIDCR.

09-25-0044, Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDCR.

09-25-0046, Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID.

09-25-0053, Clinical Research: Vision Studies, HHS/NIH/NEI.

09-25-0057, Clinical Research: Burkitt's Lymphoma Registry, HHS/NIH/NCI.

09-25-0060, Clinical Research: Division of Clinical Sciences Clinical Investigations, HHS/NIH/NCI.

09-25-0067, Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI.

09-25-0069, NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI.

09-25-0074, Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI.

09-25-0077, Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI.

09-25-0126, Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI.

09-25-0128, Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS.

09-25-0129, Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD.

09-25-0130, Clinical Research: Epidemiologic Studies in the Division of Cancer Epidemiology and Genetics, HHS/NIH/NCI.

09-25-0134, Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS.

09-25-0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.

09-25-0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID.

09-25-0145, Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/NEI.

09-25-0148, Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD.

09-25-0152, Biomedical Research: Records of Subjects in National Institute of Dental and Craniofacial Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDCR.

09-25-0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD.

09-25-0154, Biomedical Research: Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

09-25-0170, Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK.

09-25-0172, Clinical Research: National Human Genome Research Institute, HHS/NIH/NHGRI.

09-25-0201, Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH.

09-25-0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH.

09-25-0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

Notification procedure:

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

NIH Privacy Act Coordinators

Office of the Director, (OD), NIH, Associate Director for Disease Prevention, OD, NIH, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

National Cancer Institute (NCI), Privacy Act Coordinator, NCI, NIH, Building 31, Room 10A34, 31 Center Drive, Bethesda, MD 20892.

National Eye Institute (NEI), Privacy Act Coordinator, NEI, NIH, Building 31, Room 6A32, 31 Center Drive, MSC 2510, Bethesda, MD 20892-2510.

National Heart, Lung and Blood Institute (NHLBI), Privacy Act Coordinator, NHLBI, NIH Building 31, Room 5A08, 31 Center Drive, Bethesda, MD 20892.

National Institute on Aging (NIA), Privacy Act Coordinator, NIA, NIH, Building 31, Room 2C12, 31 Center Drive, Bethesda, MD 20892.

National Institute on Alcohol Abuse and Alcoholism (NIAAA), Privacy Act Coordinator, NIAAA, NIH, Willco Building, Suite, 6000 Executive Blvd., MSC 7003, Bethesda, MD 20892-7003.

National Institute of Allergy and Infectious Diseases (NIAID), Privacy Act Coordinator, NIAID, NIH, Solar Building, Room 3C-23, 6003 Executive Blvd., Bethesda, MD 20892.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Privacy Act Coordinator, NIAMS, NIH, Natcher Building, Room 5AS49, 45 Center Drive, Bethesda, MD 20892.

National Institute of Child Health and Human Development (NICHD), Privacy Act Coordinator, NICHD, NIH, 6100 Executive Blvd., Room 5D01, Bethesda, MD 20892.

National Institute on Deafness and Other Communication Disorders (NIDCD), Privacy Act Coordinator, NIDCD, NIH, Building 31, Room 3C02, 9000 Rockville Pike, Bethesda, MD 20892.

National Institute of Dental and Craniofacial Research (NIDCR), Privacy Act Coordinator, NIDCR, NIH, Natcher Building, Room 4AS-43A, 45 Center Drive, MSC 6401, Bethesda, MD 20892-6401.

National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Privacy Act Coordinator, NIDDK, NIH, Building 31, Room 9A47, 31 Center Drive, Bethesda, MD 20892.

National Institute on Drug Abuse (NIDA), Privacy Act Coordinator, NIDA, NIH, Parklawn Building, Room 10A-42, 5600 Fishers Lane, Rockville, MD 20857.

National Institute of Environmental Health Sciences (NIEHS), Privacy Act Coordinator, NIEHS, NIH, PO Box 12233, Research Triangle Park, NC 27709.

National Institute of Mental Health (NIMH), Privacy Act Coordinator, NIMH, NIH, Parklawn Building, Room 7C-22, 5600 Fishers Lane, Rockville, MD 20857.

National Institute of Neurological Disorders and Stroke (NINDS), Privacy Act Coordinator, NINDS, NIH Federal Building, Room 816, 7550 Wisconsin Avenue, Bethesda, MD 20892.

National Human Genome Research Institute (NHGRI), Office of Policy Coordination, Bldg. 31, Room 4B09, Bethesda, MD 20892.

Record access procedure:

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

Contesting record procedure:

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

Record source categories:

The system contains information obtained directly from the subject individual by interview (face-to-face

or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: Referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

Systems exempted from certain provisions of the act: None.

Appendix I: System Manager(s) and Address(es)

Office of the Director, NIH, Associate Director for Disease Prevention, OD, NIH, Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

National Cancer Institute, Computer Systems Analyst, DCBD, NCI, NIH, Executive Plaza North, Room 344, Bethesda, MD 20892.

American Burkitt's Lymphoma Registry, Division of Cancer Etiology, NCI, NIH, Executive Plaza North, Suite 434, 6130 Executive Blvd., Bethesda, MD 20892.

Chief, Genetic Epidemiology Branch, DCEG, NCI, NIH, Executive Plaza South, Rm 7122, MSC 7236, 6120 Executive Blvd, Bethesda, MD 20892-7236.

Program Director, Research Resources, Biological Carcinogenesis Branch, DCE, NCI, NIH Executive Plaza North, Room 540, 6130 Executive Blvd., Bethesda, MD 20892.

Chief, Environmental Epidemiology Branch, DCE, NCI, NIH, Executive Plaza North, Room 443, 6130 Executive Blvd., Bethesda, MD 20892.

Associate Director, Surveillance Program, DCPC, NCI, NIH, Executive Plaza North, Room 343K, 6130 Executive Blvd., Bethesda, MD 20892.

Head, Biostatistics and Data Management Section, DCS, NCI, NIH, 6116 Executive Blvd., Room 702, Bethesda, MD 20892.

Chief, Clinical Research Branch, Biological Response Modifiers Program, Frederick Cancer Research and Development Center, DCT, NCI, NIH, 501 W. 7th Street, Suite #3, Frederick, MD 21701.

Deputy Branch Chief, Navy Hospital, NCI--Naval Medical Oncology Branch, DCT, NCI, NIH Building 8, Room 5101, Bethesda, MD 20814.

Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, DCT, NCI, NIH, Executive Plaza North, Suite 804, Bethesda, MD 20892.

Director, Extramural Clinical Studies, BRB, BRMP, DCT, NCI, NIH, Frederick Cancer Research and Development Center, Fort Detrick, Frederick, MD 21701.

National Eye Institute, Clinical Director, NEI, NIH, Building 10, Room 10N-202, 10 Center Drive, Bethesda, MD 20892.

Director, Division of Biometry and Epidemiology, NEI, NIH, Building 31, Room 6A-52, 31 Center Drive, Bethesda, MD 20892.

National Heart Lung and Blood Institute, Administrative Officer, Division of Intramural Research, NHLBI, NIH, Building 10 Room 7N220, 10 Center Drive, MSC 1670, Bethesda, MD 20892-1670.

Senior Scientific Advisor, OD, Division of Epidemiology and Clinical Applications, NHLBI, NIH, Federal Building, 220, 7550 Wisconsin Avenue, Bethesda, MD 20892.

National Institute on Aging, Computer Scientist, Longitudinal Studies Branch, IRP, NIH Gerontology Research Center, GRC, 4940 Eastern Avenue, Baltimore, MD 21224.

Associate Director, Epidemiology, Demography and Biometry Program, NIA, NIH, Gateway Building, Suite 3C309, 7201 Wisconsin Avenue, Bethesda, MD 20892.

National Institute on Alcohol Abuse and Alcoholism, Deputy Director, Division of Biometry and Epidemiology, NIAAA, NIH, Willco Building, Suite 514, 6000 Executive Blvd., MSC 7003, Bethesda, MD 20892-7003.

Deputy Director, Div. of Clinical and Prevention Res., NIAAA, NIH, Willco Building, Suite 505, 6000 Executive Blvd., MSC 7003, Bethesda, MD 20892-7003.

National Institute of Allergy and Infectious Diseases, Chief, Respiratory Viruses Section, LID, NIAID, NIH, Building 7, Room 106, 9000 Rockville Pike, Bethesda, MD 20892.

Chief, Hepatitis Virus Section, LID, NIAID, NIH, Building 7, Room 202, 9000 Rockville Pike, Bethesda, MD 20892.

Chief, Epidemiology and Biometry Branch, DMID, NIAID, NIH, Solar Building, Room 3A24, Bethesda, MD 20892.

Special Assistant, Clinical Research Program, DAIDS, NIAID, NIH, Solar Building, Room 2C-20, 6003 Executive Blvd., Bethesda, MD 20892.

National Institute of Arthritis and Musculoskeletal and Skin Diseases, Clinical Director, NIAMS, NIH, Building 10, Room 9S205, 10 Center Drive, Bethesda, MD 20892.

National Institute of Child Health and Human Development, Chief, Contracts Management Branch, NICHD, NIH, Executive Plaza North, Room 7A07, 6100 Executive Blvd., North Bethesda, MD 20892.

National Institute on Deafness and Other Communication Disorders, Acting Director of Intramural Research, NIDCD, NIH, Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.

Director, Division of Human Communication, NIDCD, NIH, Executive Plaza South, Room 400C, 6120 Executive Blvd, MSC 7180, Bethesda, MD 20892-7180.

National Institute of Dental and Craniofacial Research, Deputy Clinical Director, NIDCR, NIH Building 10, Room 1N-113, 10 Center Drive, MSC 1190, Bethesda, MD 20892-1190.

Research Psychologist, Gene Therapy and Therapeutics Branch, NIDCR, NIH, Building 10, Room 1N114, 10 Center Drive, MSC 1190, Bethesda, MD 20892-1190.

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

Chief, Phoenix Clinical Research Section, NIDDK, NIH, Phoenix Area Indian Hospital, Room 541, 4212 North 16th Street, Phoenix, AZ 85016.

Chief, Diabetes Research Section, DPB, DDEMD, NIDDK, NIH, Natcher Building, Room 5AN-18G, 45 Center Drive, MSC 6600, Bethesda, MD 20892.

National Institute on Drug Abuse, Privacy Act Coordinator, NIDA, NIH, Parklawn Building, Room 10A-42, 5600 Fishers Lane, Rockville, MD 20857.

National Institute of Environmental Health Sciences, Chief, Epidemiology Branch, NIEHS, NIH, PO Box 12233, Research Triangle Park, NC 27709.

National Institute of Mental Health, Director, Intramural Research Program, NIMH, NIH Building 10, Room 4N-224, 9000 Rockville Pike, Bethesda, MD 20892.

Privacy Act Coordinator, NIMH, NIH, 6001 Executive Blvd., Room 6112, Bethesda, MD 20982.

National Institute of Neurological Disorders and Stroke, Privacy Act Coordinator, NINDS, NIH, Neuroscience Center, 6001 Executive Blvd., Suite 3305, MSC 9531, Bethesda, MD 20892-9531.

Chief, Epilepsy Branch, NINDS, NIH, Neuroscience Center, 6001 Executive Blvd., Suite 2110, MSC 9523, Bethesda, MD 20892-9523.

Assistant Director, CNP, DIR, NINDS, NIH, Building 10, Room 5N226, 10 Center Drive, Bethesda, MD 20892.

Deputy Chief, Laboratory of Central Nervous Systems Studies, Intramural Research Program, NINDS, NIH, Building 36, Room 5B21, 9000 Rockville Pike, Bethesda, MD 20892.

Director, Division of Fundamental Neuroscience and Developmental Disorders, NINDS, NIH, Neuroscience Center, 6001 Executive Blvd., Suite 2136, MSC 9527, Bethesda, MD 20892-9527.

Director, Division of Convulsive, Infectious and Immune Disorders, NINDS, NIH, Neuroscience Center, 6001 Executive Blvd., Suite 2110, MSC 9521, Bethesda, MD 20892-9521.

Director, Division of Stroke, Trauma, and Neurodegenerative Disorders, NINDS, NIH Neuroscience Center, 6001 Executive Blvd, Suite 2209, MSC 9525, Bethesda, MD 20892-9525.

Division of Experimental Therapeutics and Clinical Trials, NINDS, NIH, Neuroscience Center, 6001 Executive Blvd., Suite 2213, MSC 9520, Bethesda, MD 20892-9520.

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

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.

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	13. Type of Payment (check all that apply): ☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____
12. Form of Payment (check all that apply): ☐ a. cash ☐ b. in-kind; specify: nature_____ value_____	

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

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

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

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

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity:_____ Page _____ of _____

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 ma

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 o 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

DIRECT LABOR:

Labor Category (Title and Name-- use additional pages as necessary)	Year 1 (Hours)	Year 2 (Hours)	Year 3 (Hours)	Year 4 (Hours)	Total
_____					
_____					
_____					
_____					
_____					
Total Hours	___	___	___	___	____
DIRECT LABOR COST:	$ ___	$ ___	$ ___	$ ___	$ ___
MATERIAL COST:	$ ___	$ ___	$ ___	$ ___	$ ___
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 portion 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 cost/price data which must be adhered to.

2. This format has been prepared as a universal guideline for all solicitations issued by the National Institutes of Health. It may require amending to meet the specific requirements of this solicitation. For example, this solicitation may require the submission of cost/price data for three years listed on this form. (See Section L.1., General Information for the estimated duration of this project.) If this solicitation is phased, identify each phase in addition to each year. Total each year, phase, and sub-element.

3. This format must be used to submit the breakdown of all proposed estimated cost elements. List each cost element and sub-element for direct costs, indirect costs and fee, if applicable. In addition, provide detailed calculations for all items. For example:

   a. For all personnel, list the name, title, rate per hour and number of hours proposed. If a pool of personnel is proposed, list the composition of the pool and how the cost proposed was calculated. List the factor used for prorating Year One and the escalation rate applied between years.

      Offeror's proposal should be stated in the same terms as will be used to account for and record direct labor under a contract (i.e. percentage of effort is used for most faculty and professional employees at educational institutions). If percentages of effort are used, the basis to which such percentages are applied must also be submitted by the offeror. The attached format should be revised to accommodate direct labor proposed as a percentage of effort.

   b. For all materials, supplies, and other direct costs, list all unit prices, etc., to detail how the calculations were made.

   c. For all indirect costs, list the rates applied and the base the rate is applied to.

   d. For all travel, list the specifics for each trip.

   e. For any subcontract proposed, submit a separate breakdown format.

   f. Justification for the need of some cost elements may be listed as an attachment, i.e., special equipment, above average consultant fees, etc.

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

5. **It is requested that you use the ELECTRONIC SPREADSHEET (provided below) to prepare your business proposal in lieu of the hardcopy contained in this Attachment. It is in EXCEL format and has instructions for use and submission. It is anticipated that use of this form will help expedite the review and award process. This electronic cost and price spreadsheet can be accessed at the following URL:**

   http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls

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

   For security purposes, please include a hard copy of the completed spreadsheet and submit the electronic file on a diskette with your proposal. The Division of Research Acquisition is currently not capable of decoding encrypted files.

RFP Number: _____
Organization: _____
Date: _____

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

COST ELEMENT		Year 1	Year 2	Year 3	Year 4	Total
DIRECT LABOR:						
Labor Category (Title and Name-- use additional pages as necessary)	Rate	Hours Amt	Hours Amt	Hours Amt	Hours Amt	Hours Amt
_____						
_____						
_____						
_____						
_____						
DIRECT LABOR COST:		$____	$____	$____	$____	$____
MATERIAL COST:		$____	$____	$____	$____	$____
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		$____	$____	$____	$____	$____
GRAND TOTAL ESTIMATED COST (PLUS FIXED FEE)		$____	$____	$____	$____	$____

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.		

PROPOSAL INTENT RESPONSE SHEET

RFP No. 260-03-15

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

==========

[ ] DO INTEND TO SUBMIT A PROPOSAL

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

_____

_____

COMPANY/INSTITUTION NAME:

AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

==========

RETURN TO:

Teresa A. Baughman
Contracting Officer
National Institutes of Health
Division of Research Acquisition, OLAO
6100 Executive Blvd., Room 6E01, MSC 7540
Bethesda, MD 20892-7540

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. 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.)

GOVERNMENT FURNISHED ITEMS

1) HANDLS outreach materials

2) Content and materials for 24-hour dietary recall

3) NIA Intramural Research Program materials for examination appointments and directions to the Mobile Medical Research Vehicle