

PART I - THE SCHEDULE
SECTION A - SOLICITATION FORM

1. REQUEST FOR PROPOSAL(S) (RFP) NO.

RFP NICHD-2003-03

2. ISSUE DATE

December 10, 2002

3. SET-ASIDE:

NO

YES

4. TITLE:

Designing New Models for Explaining
Family Change and Variation

5. ISSUED BY:

Contracts Management Branch, OAM, NICHD
National Institutes of Health, DHHS
Executive Building, Suite 7A07
6100 EXECUTIVE BLVD MSC 7510
BETHESDA MD 20892-7510

6. SUBMIT OFFERS TO:

See Section L

7. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in Section L until:

Local time 4:00 PM
Date April 14, 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".

(Applicable if Checked) Your attention is directed to the provision in Section L entitled "Late Submissions, Modifications, and Withdrawals of Proposals".

8. Offerors must provide full name, address, telephone number, TIN, and, if different, the address to which payment should be mailed.

9. FOR INFORMATION CALL:

Virginia A. DeSeau

TELEPHONE NUMBER:

301-435-6947; E-mail: vd9t@nih.gov

10. Table of Contents - See the pages immediately following this form.

CONTRACTING OFFICER

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PART I - THE SCHEDULE**SECTION B - SUPPLIES OR SERVICES AND PRICE/COSTS****B.1 BRIEF DESCRIPTION OF SERVICES**

The overall goal of this project is the development and execution of a substantive, interdisciplinary research-based planning process to develop innovative models for research and data collection that will address the question: what drives family change and variation in the United States? Based on a thorough interdisciplinary analysis and assessment of relevant research, theory, and scientific methods, NICHD seeks to develop a model (or models) for a coordinated research and data collection program reflecting a multidisciplinary approach to the study of family change and variation. The model research and data collection program will address previously disparate streams within family research, including research on fertility, marriage and cohabitation, sexual behavior, and parenting, and will have the potential to significantly advance understanding of the factors and processes that drive family change at both the individual and societal levels. The model(s) may have several components which together comprise a coordinated program of research capable of testing specific, theoretically driven hypotheses while also serving as a resource for researchers addressing a broad set of policy-relevant and scientific questions. The model programs should have the ability to expand and contract to respond to varying funding levels, and they should complement existing data and research resources related to family and fertility.

B.2 PRICES/COSTS

The final contract will contain the price/cost clauses agreed upon during negotiations.

B.3 CLAUSES APPLICABLE TO DIRECT COSTS

This clause 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) Patient Care Costs; 6) Accountable Government Property; and 7) Research Funding.

B.4 ADVANCE UNDERSTANDING

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 clause if the Contracting Officer has granted his/her approval in the pre-award negotiation process.

SECTION C - DESCRIPTION/SPECIFICATIONS/STATEMENT OF WORK**C.1 WORK STATEMENT/SPECIFICATIONS (NIH 1040) (JUL 1986)**

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

SCOPE:

Based on a thorough interdisciplinary analysis and assessment of relevant research, theory, and scientific methods, NICHD seeks to develop a model (or models) for a coordinated research and data collection program reflecting an integrated approach to the study of family change and variation.

GOALS

The purpose of the contract is to develop a model for a coordinated program of research and data collection for the study of family that would, if implemented:

1. Advance scientific understanding of at least the following two research questions:
 - a) What factors and processes produce family change in populations over time?
 - b) What factors and processes influence variation in family change and behavior among racial, ethnic, socioeconomic, regional, and cultural groups, and among men and women?
2. To the extent possible, also advance scientific understanding of complementary research questions. Examples of additional questions that might be considered include:
 - a) What is the relationship between family forms, family behaviors, and health and well being within and across generations?
 - b) How does biology influence individual differences in family behaviors and the ways in which family patterns in human populations respond to changes in the environment?
 - c) What meanings are associated with various family forms and fertility strategies across different population groups and how do these change over time (e.g., do marriage and cohabitation mean the same things for men and women; whites, blacks, Mexican Americans, Puerto Ricans, Chinese, etc.)
 - d) How are meanings, norms, and behaviors relating to fertility interrelated with those relating to cohabitation, marriage, parenting, and intergenerational relations?
 - e) How can researchers best capture the contributions of men and women, and the effects of gender in models of family behavior, change, and variation?
 - f) What drives individual and couple decision-making on family choices and how do these processes relate to macro-level change in family patterns?
 - g) How do changing social and economic institutions (e.g., religion, education, workplace, etc.) influence family change and variation?
 - h) How do families' strategies for allocating time and financial resources interrelate with family behaviors, and how are these influenced by norms, values, constraints, and opportunities?
 - i) Is there a limit to low fertility? If so, what is that level and what are the consequences for society?
 - j) What are the relationship between assisted reproductive technologies and the timing of fertility across socioeconomic groups?

3. Achieve the following goals:

- a) Serve as a resource for family and fertility researchers;
- b) Reflect a multidisciplinary theoretical approach or set of approaches to family research;
- c) Permit the testing of hypotheses related to family change and variation drawn from a broad set of theories and disciplines;
- d) Reflect methodological approaches drawn from a variety of disciplines and suitable for answering core questions about family change and variation;
- e) Address the appropriate inclusion of research participants by gender, race, and ethnicity;
- f) Address policy issues related to family change and variation;
- g) Allow for flexibility in responding to variations in available funding;
- h) Coordinate with and complement other ongoing data collection efforts related to family.

Specifically, the Contractor shall:

1. With the consultation and approval of the Project Officer, establish a core working group with 6 to 8 members to manage the development and design of the research and data collection program. The working group will meet in-person four times annually and be comprised of active scholars who are:

- a) Willing and able to commit substantial time to the project;
- b) Willing and able to work cooperatively toward completing the project, taking a broad perspective on the needs of the field;
- c) Diverse in terms of:
 - (1) Disciplines.
 - (2) Institutions.
 - (3) Seniority.
 - (4) Substantive focus.
 - (5) Race, ethnicity, and gender.
- d) Willing to assume responsibility for the completion of the project.

2. With consultation and approval of the NICHD Project Officer, establish and oversee the completion of the core working group responsibilities to:

- a) Devise and implement strategies to seek input from population scholars in conducting reviews, conducting original research, and shaping and refining the design for the research and data collection program. Input may be sought through workshops, consultants, commissioned papers, the formation of committees and subcommittees and other means as appropriate. A wide variety of experts must be consulted in these activities, representing, at a minimum, the fields of anthropology, biology, demography, economics, family studies, policy, psychology, and sociology. Committees and subcommittees should include junior researchers. Prepare a preliminary plan for conducting reviews and original research and, if any research protocol involving more than 9 research subjects is planned, prepare necessary documentation for securing approval for such research from the Office of Management and Budget.
- b) Identify key individuals at policy and research agencies and private foundations with interests relevant to this initiative. Include these individuals in major meetings, seek their input as appropriate, and develop strategies to keep them apprised of the working group's progress.
- c) Conduct a review of existing research on the determinants of family change and variability, identifying questions that have been definitively answered and remaining gaps in and challenges to scientific knowledge on these topics.
- d) Develop a preliminary statement of the questions to be addressed by the proposed research and data collection program (hereafter referred to as "Key Questions"). This may involve restatement of the questions in Paragraph A under "Scope" and the addition of complementary questions such as those listed under Paragraph B. It may also contain elements of the proposal submitted in response to the RFP.

- e) Conduct a review of the major existing sources of data that provide descriptive or explanatory research on issues related to family and fertility, identifying for each source the scope, purposes, and methods of data collection and its potential contributions to answering the Key Questions.
- f) Conduct a review of policy-related issues related to U.S. fertility and family patterns and identify key unanswered questions of importance for informing policy decisions.
- g) Conduct a review of theories informing research on family and fertility drawn from a broad range of disciplines. Use this review as a basis for conducting original research to develop an integrated body of theory or set of theories to guide development of the research and data collection design. These activities will:
 - i. Identify major theories in family and fertility research from appropriate fields.
 - ii. Assess and formalize the contributions of each of the theories to answering the Key Questions.
 - iii. Articulate compatibilities and contradictions.
 - iv. Conduct research, as needed, to address gaps, inconsistencies, and conflicts among theories.
 - v. Develop over-arching theoretical models.
- h) Conduct a study of the scientific approaches used to study causal processes and to test causal hypotheses as well as the methodological issues associated with various approaches. Consider methodologies from a broad range of sciences, including comparative research designs, observational studies using qualitative and quantitative approaches, instrumental variables and other econometric and multivariate approaches, experimental and “natural experiment” approaches, and methods for testing “systems” models. Assess the implications of this study for strategies to address the Key Questions.
- i) Develop a report finalizing the Key Questions to be addressed by the model research and data collection program. This report should address:
 - i. Issues raised by the reviews and studies undertaken above.
 - ii. What is known and not known based on existing studies.
 - iii. Policy-related information needs.
- j) Develop a model or alternative models for a coordinated program of research and data collection to address the Key Questions. These models may have several component parts. The program design should take into account the competing needs to protect human subjects (including the confidentiality of data) and the need to provide access to research data. It may encompass strategies such as, but not limited to:
 - i. Combinations of data collection modes, including qualitative and quantitative approaches.
 - ii. Comparative designs.
 - iii. Experimental designs
 - iv. Longitudinal data collection.
 - v. Links to administrative records.
 - vi. Multi-level designs.
 - vii. National, sub-national, and/or community-centered data collections, but the overall program should be designed to optimize relevance to the national context and to represent the diversity of cultural experiences in the United States.
- k) Refine models, alternative models, and component parts using workshops, consultation, methodological studies and other research as necessary and prioritize study components to accommodate fluctuations in funding levels.

- l) Consider how to complement and leverage existing data collection efforts and describe how the planned program articulates with other existing programs.

- m) Develop a report detailing the recommended designs and their scientific rationale based in part on the requirements detailed above. The report should contain details as appropriate pertaining to:
 - i. The overall model(s) for a program of research and data collection and its scientific rationale.
 - ii. Priorities of design features and topic areas to be covered.
 - iii. For each component, as appropriate:
 1. The theory(ies) and hypotheses to be tested.
 2. The study design(s).
 3. The sampling design(s), as appropriate.
 4. Questionnaire content or substantive content of observation.
 5. Sample sizes.
 - iv. Cost estimates.
 - v. The relationships of the proposed program to other existing data collection efforts, including ways in which the proposed program will complement and leverage other efforts.

SECTION D - PACKAGING AND MARKING

[FOR THIS SOLICITATION, THERE ARE NO CLAUSES IN THIS SECTION]

SECTION E - INSPECTION AND ACCEPTANCE

E.1 NOTICE LISTING CONTRACT CLAUSES INCORPORATED BY REFERENCE

The following contract clauses pertinent to this section are hereby incorporated by reference (by Citation Number, Title, and Date) in accordance with the clause at FAR "52.252-2 CLAUSES INCORPORATED BY REFERENCE" in Section I of this contract. See FAR 52.252-2 for an internet address (if specified) for electronic access to the full text of a clause.

NUMBER	TITLE	DATE
	FEDERAL ACQUISITION REGULATION (48 CFR Chapter 1)	
52.246-9	INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM)	APR 1984

E.2 INSPECTION AND ACCEPTANCE (NIH 3045) (MAY 1989)

- (a) The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- (b) For the purposes of this CLAUSE the designated Project Officer is the authorized representative of the Contracting Officer.
- (c) Inspection and acceptance will be performed by the Project Officer at the address listed in the clause "Project Officer" in Section G.
- (d) Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

SECTION F - DELIVERIES OR PERFORMANCE**F.1 NOTICE LISTING CONTRACT CLAUSES INCORPORATED BY REFERENCE**

The following contract clauses pertinent to this section are hereby incorporated by reference (by Citation Number, Title, and Date) in accordance with the clause at FAR "52.252-2 CLAUSES INCORPORATED BY REFERENCE" in Section I of this contract. See FAR 52.252-2 for an Internet address (if specified) for electronic access to the full text of a clause.

NUMBER	TITLE	DATE
	FEDERAL ACQUISITION REGULATION (48 CFR Chapter 1)	
52.242-15	STOP-WORK ORDER ALTERNATE I (APR 1984)	AUG 1989
52.247-34	F.O.B. DESTINATION	NOV 1991

F.2 PERIOD OF PERFORMANCE (NIH 1060) (MAY 1989)

The period of performance of this contract is anticipated to be from August 1, 2003 through July 30, 2006 . The period of performance includes submission of any final report and all other deliverables set forth in this Section F and/or in the work statement/specifications of Section C.

F.3 REPORTING REQUIREMENTS (NIH 3055) (JUL 1986)

In addition to other terms of the contract, the Contractor shall submit Technical/Activity Progress Reports covering the work accomplished during each reporting period as stated below.

- a) The Contractor must submit a progress report (two copies to Project Officer, one copy to Contracting Officer) within 60 days of the beginning of the contract. This report will contain a summary of the work to date, work planned in the remaining contract period, problems encountered, their resolution, and impact on the completion of the Statement of Work.
- b) The Contractor must submit a progress report annually (two copies to Project Officer, one copy to Contracting Officer). Each annual report must be submitted within 30 days of the end of each year of the contract. The annual reports must indicate progress to date, problems encountered and their resolution.
- c) The Contractor must submit to the Project Officer for comment and approval drafts of the proposed composition of the core working group, committees and subcommittees, and the list of key individuals in agencies and foundations.
- d) The Contractor must submit to the Project Officer for comment drafts of substantive, theoretical, and methodological reviews, and any workshop proceedings, working papers or other products of a substantive nature.
- e) The Contractor must submit two printed copies, and one electronic copy of all final reports of a substantive or technical nature including required scientific reviews, workshop proceedings, and other documents used to generate the model research and data collection design.
- f) The Contractor must prepare a Final Report to include a recommended model or alternative models for the research and data collection program. Twenty paper copies and one electronic copy must be submitted to the Project Officer. The final report is due on or before the expiration date of the contract.

The Contractor must prepare a letter report summarizing the conclusions of the core working group and the results of deliberations about the process used to complete this project. Two copies must be submitted to the Project Officer and one copy to the Contracting Officer within 60 days of the expiration of the contract.

F.4 ANNUAL TECHNICAL PROGRESS REPORT FORMAT FOR CLINICAL RESEARCH STUDY POPULATIONS (NIH 3092) (APR 1997)

The Contractor shall submit an annual report showing the status of the inclusion of women and members of minority groups and their sub-populations for each study being performed under this contract as of each September 30 or the completion of subject enrollment if earlier than September 30.

The first report shall be due October 31 and annually thereafter following the September 30 status date. One additional report shall be due 30 days following completion of subject enrollment for each study being performed.

Two copies of the report shall be sent to the Contracting Officer identified in block 20A on the first page of the resultant contract at the contracting office address listed in block 5.

The format for the report shall be as follows (see following page, G-2, and as an Attachment to Section L of the RFP electronic document):

Principal Investigator/Program Director (Last, first, middle):

Inclusion Enrollment Report Table

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				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaskan 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/Alaskan 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.

SECTION G - CONTRACT ADMINISTRATION DATA**G.1 KEY PERSONNEL (NIH 3060) (JUL 1986)**

(a) The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this clause. The contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

(b) The following individual(s) is/are considered to be essential to the performance hereunder:

NAME	TITLE
------	-------

G.2 PROJECT OFFICER (NIH 1900) (NOV 1988)

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

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 acceptance 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.

G.3 INVOICE SUBMISSION (NIH RC-1) (DEC 1988)

Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made part of this contract (See Attachment in Section J). The instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" payment request, pursuant to FAR 32.9.

(a) Invoices/financing requests shall be submitted as follows:

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

Contracts Management Branch, OAM, NICHHD
National Institutes of Health, DHHS
Executive Building, Suite 7A07
6100 EXECUTIVE BLVD MSC 7510
BETHESDA MD 20892-7510

(b) Inquiries regarding payments should be directed to the designated Contracting office on page 1 of Section A at (301) 435-6947 (general office number is 301-496-4611).

G.4 CONTRACT FINANCIAL REPORT (NIH 2706) (MAY 1997)

(See Attachment in Section J)

(a) Financial reports on the attached Form NIH-2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the instructions which accompany the form, in an original and two copies, not later than thirty (30) working days after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) that shall be reported within the total contract are listed in paragraph (e) below. Subsequent, changes and/or additions in the line entries shall be made in writing.

(b) The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports shall be submitted on a QUARTERLY basis.

(c) The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

(d) Unless otherwise stated in that part of the NIH 2706, Instructions, entitled "Preparation Instructions", all columns A through J, shall be completed for each report submitted.

(e) The Government may unilaterally revise the NIH-2706 to reflect the allotment of additional funds.

(f) The following expenditure categories shall be reported:

**G.5 POST AWARD EVALUATION OF PAST PERFORMANCE
(NIH 3800) (FEB 1998)**

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS**H.1 HHSAR 352.270-6 PUBLICATIONS AND PUBLICITY (JUL 1991)**

(a) Unless otherwise specified in this contract, the Contractor is encouraged to publish the results of its work under this contract. A copy of each article submitted by the Contractor for publication shall be promptly sent to the Project Officer. The Contractor shall also inform the Project Officer when the article or other publication is published, and furnish a copy of it as finally published.

(b) The Contractor shall include in any publication resulting from work performed under this contract a disclaimer reading as follows:

The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

H.2 SMALL, SMALL DISADVANTAGED, AND WOMEN-OWNED SMALL BUSINESS SUBCONTRACTING PLAN (NIH 1185) (JUL 1986)

The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract in Section J.

The failure of any contractor or subcontractor to comply in good faith with the FAR clause 52.219-8, entitled UTILIZATION OF SMALL, SMALL DISADVANTAGED, AND WOMEN-OWNED SMALL BUSINESS CONCERNS incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, LIQUIDATED DAMAGES--SUBCONTRACTING PLAN.

H.3 SUBCONTRACTING REPORTS

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

April 30
October 30

The Report shall be sent to the following address:

Contracts Management Branch, OAM, NICHD
National Institutes of Health, DHHS
Executive Building, Suite 7A07
6100 EXECUTIVE BLVD MSC 7510
BETHESDA, MD 20892-7510

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

October 30

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

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

H.4 HUMAN SUBJECTS (NIH 3085) (AUG 1992) ALTERNATE II

Under governing regulations, federal funds administered by the Department of Health and Human Services shall not be expended for and individuals shall not be enrolled in research involving human subjects, without prior approval by the Office for Protection from Research Risks (OPRR) of an assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all performance sites without OPRR-Approved assurances, whether domestic or foreign.

H.5 PRIVACY ACT (NIH 3100) (JUL 1986)

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 in Section J.

Upon completion of the contract, the following disposition will be made of the system of records identified above:

All records (manual and automated) will be disposed of in accordance with instructions to be furnished by the Government on or before expiration of the contract.

The design, development, or operation work is specified in SECTION C of this contract.

H.6 SALARY RATE LIMITATIONS LEGISLATION (NIH 3102) (OCT 1993)

(a) Pursuant to Public Law cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown for the fiscal year covered. Direct salary is exclusive of overhead, fringe benefits, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative [F&A] costs"). 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
P.L. 107-116	2002	Executive Level I*

* FY 02 Executive Level Salaries can be found at <http://www.opm.gov/oca/02tables/ex.pdf>

H.7 REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

1. 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 (September 1985)

(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 for Protection from Research Risks (OPRR), National Institutes of Health, 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 (1) data through intervention or interaction with the individual, or (2) 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 DFR 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 Public Health Service 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 ORRP. (telephone :301-496-7401), 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.

2. 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 a description of education in the protection of human subjects that has been completed (or will be completed at the time of contract award) by the principal investigator and any other individuals working under the contract who are responsible for

the design and/or conduct of the research. 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/>. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and 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_rofs_protct.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also 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 information in writing to the contracting officer describing the education in the protection of human subjects that has been completed by the replacement.

H.8 DATA AND SAFETY MONITORING IN CLINICAL TRIALS

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

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

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

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

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

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

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

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, FDA and NIH. The frequency of reporting of the conclusions of the monitoring activities should also be described in the plan. The overall elements of each plan may vary depending on the size and complexity of the trial. Examples of monitoring activities to be considered are described in the NIH Policy for Data and Safety Monitoring at <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

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

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

H.9 PUBLICATION AND PUBLICITY (NIH 3480) (FEB 1992)

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 acknowledgement substantially as follows:

This project has been funded in whole or in part with Federal funds from the National Institute of Child Health and Human Development, National Institutes of Health, under Contract Number xxxxx.

H.10 CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH (NIH 3750) (MAR 1997)

Pursuant to Public Law 107-116, 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 embryo's 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" include any organism, not protected as a human subject under 45 CFR 46 as of the date of the Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

H.11 YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY (NIH 3810) (FEB 1998)

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 2000 and leap year calculations.

H.12 REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE (NIH 3820) (FEB 1998)

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

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on <http://www1.od.nih.gov/oma/manualchapters/management/1754/>.

H.13 NEEDLE EXCHANGE (APR 1998)

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

b. Public Law and Section No.	Fiscal Year	Period Covered
P.L. 107-116, Section 505	2002	10/1/01-9/30/02

H.14 PRESS RELEASES (APR 1998)

Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that; (1) the percentage of the total Costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

H.15 SMALL, SMALL DISADVANTAGED, AND WOMEN-OWNED SMALL BUSINESS SUBCONTRACTING PLAN (NIH 1185) (JUL 1986)

The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract in Section J.

The failure of any contractor or subcontractor to comply in good faith with the FAR clause 52.219-8, entitled UTILIZATION OF SMALL, SMALL DISADVANTAGED, AND WOMEN-OWNED SMALL BUSINESS CONCERNS incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, LIQUIDATED DAMAGES--SUBCONTRACTING PLAN.

H.16 LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES (APR 1998)

a. Pursuant to Public Law(s) cited in paragraph b. below, contract funds shall not be used to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812). This limitation shall not apply when the contractor makes it known to the contracting officer that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

b. Public Law and Section	Fiscal Year	Period Covered
P.L. 107-116, Section 511(a)&(b)	2002	10/1/01 - 9/30/02

H.17 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 the 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	Fiscal Year	Period Covered
for a. above: P.L 107-116, Section 503(a)	2002	10/1/01 - 9/30/02
for b. above: P.L 107-116, Section 503(b)	2002	10/1/01 - 9/30/02

H.18 HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

H.19 PLAIN LANGUAGE

The NIH supports the June 1, 1998 Presidential Memorandum on Plain Language and accordingly encourages clear communication. The contractor shall prepare all reports that are required by this contract with the need to communicate clearly in mind. The key to plain writing is identifying the audience. The contractor should recognize its audience and write accordingly. Information about the plain language initiative can be accessed at: <http://www.plainlanguage.gov> .

H.20 SAFETY AND HEALTH (HHSAR 352.223-70) (JAN 2001)

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

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

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

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

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

PART II - CONTRACT CLAUSES**SECTION I - CONTRACT CLAUSES****I.1 SPECIAL NOTE FOR SOLICITATION PURPOSES
(NIH 3105) (JUL 1986)**

This Section I uses as an example clauses appropriate for the award of a contract with an educational institution. Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded. Any additional clauses required by Public Law, Executive Order, or acquisition regulation, in effect at the time of execution of the proposed contract, will be included in this Section I.

A listing of the clauses appropriate for the award of other types of contracts will be provided upon request to the Contracting Officer listed on page A-1 of this solicitation.

I.2 CLAUSES INCORPORATED IN FULL TEXT (NIH 3110) (JUL 1986)

The following National Institutes of Health clauses are incorporated in full text elsewhere and as attachments listed in Section J:

NIH(RC)-1 MAY 1997 Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts

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

I.3 NOTICE LISTING CONTRACT CLAUSES INCORPORATED BY REFERENCE

The following contract clauses pertinent to this section are hereby incorporated by reference (by Citation Number, Title, and Date) in accordance with the clause at FAR "52.252-2 CLAUSES INCORPORATED BY REFERENCE" in Section I of this contract. See FAR 52.252-2 for an Internet address (if specified) for electronic access to the full text of a clause.

NUMBER	TITLE	DATE
	FEDERAL ACQUISITION REGULATION (48 CFR Chapter 1)	
52.202-1	DEFINITIONS	DEC 2001
52.203-3	GRATUITIES	APR 1984
52.203-5	COVENANT AGAINST CONTINGENT FEES	APR 1984
52.203-6	RESTRICTIONS ON SUBCONTRACTOR SALES TO THE GOVERNMENT	JUL 1995
52.203-7	ANTI-KICKBACK PROCEDURES	JUL 1995
52.203-8	CANCELLATION, RESCISSION, AND RECOVERY OF FUNDS FOR ILLEGAL OR IMPROPER ACTIVITY	JAN 1997
52.203-10	PRICE OR FEE ADJUSTMENT FOR ILLEGAL OR IMPROPER ACTIVITY	JAN 1997
52.203-12	LIMITATION ON PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS	JUN 1997
52.204-4	PRINTED OR COPIED DOUBLE-SIDED ON RECYCLED PAPER	AUG 2000

NUMBER	TITLE	DATE
	FEDERAL ACQUISITION REGULATION (48 CFR Chapter 1)	
52.209-6	PROTECTING THE GOVERNMENT'S INTEREST WHEN SUBCONTRACTING WITH CONTRACTORS DEBARRED, SUSPENDED, OR PROPOSED FOR DEBARMENT	JUL 1995
52.215-2	AUDIT AND RECORDS--NEGOTIATION ALTERNATE II (APR 1998)	JUN 1999
52.215-8	ORDER OF PRECEDENCE--UNIFORM CONTRACT FORMAT	OCT 1997
52.215-10	PRICE REDUCTION FOR DEFECTIVE COST OR PRICING DATA	OCT 1997
52.215-12	SUBCONTRACTOR COST OR PRICING DATA	OCT 1997
52.215-15	PENSION ADJUSTMENTS AND ASSET REVERSIONS (DEC 1998)	DEC 1998
52.215-18	REVERSION OR ADJUSTMENT OF PLANS FOR POSTRETIREMENT BENEFITS OTHER THAN PENSIONS (PRB)	OCT 1997
52.215-19	NOTIFICATION OF OWNERSHIP CHANGES	OCT 1997
52.215-21	REQUIREMENTS FOR COST OR PRICING DATA OR INFORMATION OTHER THAN COST OR PRICING DATA - MODIFICATIONS	OCT 1997
52.216-7	ALLOWABLE COST AND PAYMENT	FEB 2002
	In paragraph (a) delete the words "Subpart 31.2" and substitute the words "Subpart 31.3".	
52.216-11	COST CONTRACT--NO FEE ALTERNATE I (APR 1984)	APR 1984
52.216-15	PREDETERMINED INDIRECT COST RATES	APR 1998
52.219-4	NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS (JAN 1999)	JAN 1999
52.219-8	UTILIZATION OF SMALL BUSINESS CONCERNS	OCT 2000
52.219-9	SMALL BUSINESS SUBCONTRACTING PLAN	JAN 2002
52.219-16	LIQUIDATED DAMAGES--SMALL BUSINESS SUBCONTRACTING PLAN	JAN 1999
52.222-2	PAYMENT FOR OVERTIME PREMIUM (OVER \$100,000)	JUL 1990
	[NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract]	
52.222-3	CONVICT LABOR	AUG 1996
52.222-26	EQUAL OPPORTUNITY	APR 2002
52.222-35	EQUAL OPPORTUNITY FOR SPECIAL DISABLED VETERANS, OF THE VIETNAM ERA, AND OTHER ELIGIBLE VETERANS	DEC 2001
52.222-36	AFFIRMATIVE ACTION FOR WORKERS WITH DISABILITIES	JUN 1998
52.222-37	EMPLOYMENT REPORTS ON SPECIAL DISABLED VETERANS, VETERANS OF THE VIETNAM ERA, AND OTHER ELIGIBLE VETERANS	DEC 2001
52.222-38	COMPLIANCE WITH VETERANS' EMPLOYMENT REPORTING REQUIREMENTS	DEC 2001
52.223-6	DRUG-FREE WORKPLACE	MAY 2001
52.223-14	TOXIC CHEMICAL RELEASE REPORTING	OCT 2000
52.224-1	PRIVACY ACT NOTIFICATION	APR 1984
52.224-2	PRIVACY ACT	APR 1984

NUMBER	TITLE	DATE
	FEDERAL ACQUISITION REGULATION (48 CFR Chapter 1)	
52.225-1	BUY AMERICAN ACT - SUPPLIES	MAY 2002
52.225-13	RESTRICTIONS ON CERTAIN FOREIGN PURCHASES	JUL 2000
52.227-1	AUTHORIZATION AND CONSENT ALTERNATE I (APR 1984)	JUL 1995
52.227-2	NOTICE AND ASSISTANCE REGARDING PATENT AND COPYRIGHT INFRINGEMENT	AUG 1996
52.227-11	PATENT RIGHTS -- RETENTION BY THE CONTRACTOR (SHORT FORM)	JUN 1997
NOTE: In accordance with FAR 27.303(a)(2) paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) thru (iv). The frequency of reporting in (i) is annual.		
52.227-14	RIGHTS IN DATA--GENERAL	JUN 1987
52.227-16	ADDITIONAL DATA REQUIREMENTS	JUN 1987
52.230-5	COST ACCOUNTING STANDARDS--EDUCATIONAL INSTITUTION	APR 1996
52.230-6	ADMINISTRATION OF COST ACCOUNTING STANDARDS	NOV 1999
52.232-9	LIMITATION ON WITHHOLDING OF PAYMENTS	APR 1984
52.232-17	INTEREST	JUN 1996
52.232-18	AVAILABILITY OF FUNDS	APR 1984
52.232-22	LIMITATION OF FUNDS	APR 1984
52.232-23	ASSIGNMENT OF CLAIMS	JAN 1986
52.232-25	PROMPT PAYMENT	FEB 2002
52.232-34	PAYMENT BY ELECTRONIC FUNDS TRANSFER-- OTHER THAN CENTRAL CONTRACTOR REGISTRATION	MAY 1999
52.233-1	DISPUTES	JUL 2002
52.233-3	PROTEST AFTER AWARD ALTERNATE I (JUN 1985)	AUG 1996
52.242-1	NOTICE OF INTENT TO DISALLOW COSTS	APR 1984
52.242-3	PENALTIES FOR UNALLOWABLE COSTS	MAY 2001
52.242-4	CERTIFICATION OF FINAL INDIRECT COSTS	JAN 1997
52.242-13	BANKRUPTCY	JUL 1995
52.243-2	CHANGES--COST REIMBURSEMENT ALTERNATE V (APR 1984)	AUG 1987
52.244-2	SUBCONTRACTS ALTERNATE II (AUG 1998)	AUG 1998
52.244-5	COMPETITION IN SUBCONTRACTING	DEC 1996
52.245-5	GOVERNMENT PROPERTY (COST-REIMBURSEMENT, TIME & MATERIAL OR LABOR-HOUR CONTRACT), ALTERNATE 1 (JUL 1985)	JAN 1986
52.246-23	LIMITATION OF LIABILITY	FEB 1997
52.246-25	LIMITATION OF LIABILITY--SERVICES	FEB 1997
52.247-63	PREFERENCE FOR U.S.-FLAG AIR CARRIERS	JAN 1997
52.247-67	SUBMISSION OF COMMERCIAL TRANSPORTATION BILLS TO THE GENERAL SERVICES ADMINISTRATION FOR AUDIT	JUN 1997
52.249-5	TERMINATION FOR CONVENIENCE OF THE GOVERNMENT (EDUCATIONAL AND OTHER NONPROFIT INSTITUTIONS)	SEP 1996
52.253-1	COMPUTER GENERATED FORMS	JAN 1991

**HEALTH AND HUMAN SERVICES ACQUISITION REGULATION
(48 CFR Chapter 3) CLAUSES:**

HHSAR NUMBER	TITLE	DATE
352.202-1	DEFINITIONS ALTERNATE I (APR 1984)	APR 1984
352.228-7	INSURANCE--LIABILITY TO THIRD PERSONS	DEC 1991
352.232-9	WITHHOLDING OF CONTRACT PAYMENTS	APR 1984
352.233-70	LITIGATION AND CLAIMS	APR 1984
352.242-71	FINAL DECISIONS ON AUDIT FINDINGS	APR 1984
352.249-14	EXCUSABLE DELAYS	APR 1984
352.270-7	PAPERWORK REDUCTION ACT	JAN 2001

**PUBLIC HEALTH SERVICES ACQUISITION REGULATIONS
(48 CFR Chapter 3, Appendix A) CLAUSES:**

PHSAR NUMBER	TITLE	DATE
352.280-1(b)	PROTECTION OF HUMAN SUBJECTS	OCT 1986

**I.4 52.219-23 NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL
DISADVANTAGED BUSINESS CONCERNS (MAY 2001)
ALTERNATE I (OCT 1998)**

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

Small disadvantaged business concern means an offeror that represents, as part of its offer, that it is a small business under the size standard applicable to this acquisition; and either--

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

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

(ii) 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

(iii) 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).

(2) 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. In this case, in order to receive the benefit of a price evaluation adjustment, an offeror must receive certification as a small disadvantaged business concern by the Small Business Administration prior to contract award; or

(3) Is a joint venture as defined in 13 CFR 124.1002(f).

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 (DoD), the National Aeronautics and Space Administration (NASA), 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)).

United States means the United States, its territories and possessions, the Commonwealth of Puerto Rico, the U.S. Trust Territory of the Pacific Islands, and the District of Columbia.

(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of 0 percent to the price of all offers, except--

(i) Offers from small disadvantaged business concerns that have not waived the adjustment;

(ii) An otherwise successful offer of eligible products under the Trade Agreements Act when the dollar threshold for application of the Act is equaled or exceeded (see section 25.402 of the Federal Acquisition Regulation (FAR));

(iii) An otherwise successful offer where application of the factor would be inconsistent with a Memorandum of Understanding or other international agreement with a foreign government;

(iv) For DoD, NASA, and Coast Guard acquisitions, an otherwise successful offer from a historically black college or university or minority institution; and

(v) For DoD acquisitions, an otherwise successful offer of qualifying country end products (see sections 225.000-70 and 252.225-7001 of the Defense FAR Supplement).

(2) The Contracting Officer will apply the factor to a line item or a group of line items on which award may be made. The Contracting Officer will apply other evaluation factors described in the solicitation before application of the factor. The factor may not be applied if using the adjustment would cause the contract award to be made at a price that exceeds the fair market price by more than the factor in paragraph (b)(1) of this clause.

(c) Waiver of evaluation adjustment. A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of this clause do not apply to offers that waive the adjustment.

[] Offeror elects to waive the adjustment.

(d) Agreements. (1) A small disadvantaged business concern, that did not waive the adjustment, agrees that in performance of the contract, in the case of a contract for --

(i) Services, except construction, at least 50 percent of the cost of personnel for contract performance will be spent for employees of the concern;

(ii) Supplies (other than procurement from a non-manufacturer of such supplies), at least 50 percent of the cost of manufacturing, excluding the cost of materials, will be performed by the concern;

(iii) General construction, at least 15 percent of the cost of the contract, excluding the cost of materials, will be performed by employees of the concern; or

(iv) Construction by special trade contractors, at least 25 percent of the cost of the contract, excluding the cost of materials, will be performed by employees of the concern.

(2) A small disadvantaged business concern submitting an offer in its own name agrees to furnish in performing this contract only end items manufactured or produced by small business concerns in the United States. This paragraph does not apply in connection with construction or service contracts.

I.5 52.222-2 PAYMENT FOR OVERTIME PREMIUMS (JUL 1990)

(a) The use of overtime is authorized under this contract if the overtime premium cost does not exceed \$0 or the overtime premium is paid for work--

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;

(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;

(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or

(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above shall include all estimated overtime for contract completion and shall--

(1) Identify the work unit; e.g., department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;

(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;

(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and

(4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

I.6 52.222-21 PROHIBITION OF SEGREGATED FACILITIES (FEB 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.

I.7 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more 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/these address(es):

<http://www.arnet.gov/far>

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

ATTACH NO.	DESCRIPTION	DATE	PAGES
1	Small/Disadvantaged Business Subcontracting Plan (http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm) Go to "Contracts Negotiating Forms and Attachments"	11/2002	8
2	Financial Report of Individual Project/Contract, NIH Form 2706 (http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm) Go to "Contracts Negotiating Forms and Attachments"	5/1997	3
3	Procurement of Certain Equipment, NIH(RC)-7 (http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm) Go to "Contracts Negotiating Forms and Attachments"	4/1998	1
4	Privacy Act System of Records (http://oma.od.nih.gov/ms/privacy/) Go to "Fed. Reg. Notice of NIH System Update 2001" (NIH System of Records is just the first three pages)	9/26/2002	3
5	Project Objectives - NIH Form 1688 (on page following this Section J)	9/2002	1
6	Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1 (http://www4.od.nih.gov/ocm/contracts/frps/forms1.htm) Go to "Contracts Negotiating Forms and Attachments"	1/1997	6

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

PROJECT OBJECTIVES

SOLICITATION NUMBER: _____

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

OFFEROR NAME AND ADDRESS:

OFFEROR PHONE NUMBER (WITH AREA CODE) _____

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

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

RFP TITLE: _____

PRINCIPAL INVESTIGATOR: _____

SUMMARY OF OBJECTIVES:

INSTRUCTIONS: The information supplied on this form MUST meet the following requirements: The summary of objectives MUST fit in the space provided. The height of the letters must not be smaller than 10 point; Helvetica or Arial 12 point is the NIH-suggested font. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi. No more than 6 lines of type within a vertical inch. Margins, in all directions, must be at least 1/2 inch.

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

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

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

K.1 REPRESENTATIONS AND CERTIFICATIONS

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 or 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.

K.2 52.204-3 TAXPAYER IDENTIFICATION (OCT 1998)

(a) 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.

(b) 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(c) 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.

(c) 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.

(d) 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.

(e) 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 _____

(f) 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 _____

K.3 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, [] is not a women-owned business concern.

**K.4 52.209-5 CERTIFICATION REGARDING DEBARMENT, SUSPENSION,
PROPOSED DEBARMENT, AND OTHER RESPONSIBILITY MATTERS
(DEC 2001)**

(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.

(ii) The Offeror has [] has not [], within a 3-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 non-responsible.

(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 award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in

(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 as a small business concern in paragraph (b)(1) of this provision.] The offeror represents, as part of its offer, that--

(i) 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

(ii) 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 of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations 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, as used in this provision, 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.

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.

Women-owned small business concern, as used in this provision, 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.

(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.

K.7 52.219-22 SMALL DISADVANTAGED BUSINESS STATUS (OCT 1999)

(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.

**K.8 52.222-22 PREVIOUS CONTRACTS AND COMPLIANCE REPORTS
(FEB 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; the clause originally contained in Section 310 of Executive Order No. 10925, or the clause contained in Section 201 of Executive Order No. 11114;

(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.

K.9 52.222-25 AFFIRMATIVE ACTION COMPLIANCE (APR 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.

**K.10 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.

**K.11 52.227-15 STATEMENT OF LIMITED RIGHTS DATA AND RESTRICTED COMPUTER
SOFTWARE (MAY 1999)**

(a) This solicitation sets forth the work to be performed if a contract award results, and the Government's known delivery requirements for data (as defined in FAR 27.401). Any resulting contract may also provide the Government the option to order additional data under the Additional Data Requirements clause at 52.227-16 of the FAR, if included in the contract. Any data delivered under the resulting contract will be subject to the Rights in Data--General clause at 52.227-14 that is to be included in this contract. Under the latter clause, a Contractor may withhold from delivery data that qualify as

limited rights data or restricted computer software, and deliver form, fit, and function data in lieu thereof. The latter clause also may be used with its Alternates II and/or III to obtain delivery of limited rights data or restricted computer software, marked with limited rights or restricted rights notices, as appropriate. In addition, use of Alternate V with this latter clause provides the Government the right to inspect such data at the Contractor's facility.

(b) As an aid in determining the Government's need to include Alternate II or Alternate III in the clause at 52.227-14, Rights in Data--General, the offeror shall complete paragraph (c) of this provision to either state that none of the data qualify as limited rights data or restricted computer software, or identify, to the extent feasible, which of the data qualifies as limited rights data or restricted computer software. Any identification of limited rights data or restricted computer software in the offeror's response is not determinative of the status of such data should a contract be awarded to the offeror.

(c) The offeror has reviewed the requirements for the delivery of data or software and states [offeror check appropriate block]--

[] None of the data proposed for fulfilling such requirements qualifies as limited rights data or restricted computer software.

[] Data proposed for fulfilling such requirements qualify as limited rights data or restricted computer software and are identified as follows:

Note: "Limited rights data" and "Restricted computer software" are defined in the contract clause entitled "Rights in Data--General."

**K.12 52.230-1 COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION
(JUNE 2000) ALTERNATE I (APR 1996)**

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.

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.

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

I. DISCLOSURE STATEMENT-COST ACCOUNTING PRACTICES AND CERTIFICATION

(a) Any contract in excess of \$500,000 resulting from this solicitation, except contracts in which the price negotiated is based on (1) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (2) prices set by law or regulation, 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 48 CFR 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 48 CFR 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 (c) 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 a 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 loose-leaf 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 \$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 subparagraphs (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. 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 subpart 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

K.13 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (JAN 1990) (FAR 52.203-11 DEVIATION)

(a) The definitions and prohibitions contained in the clause, at FAR 52.203-12, Limitation 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 as of December 23, 1989 that

(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, 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 of 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.

**K.14 CERTIFICATE OF CURRENT COST OR PRICING DATA
(FAR 15.406-2)**

(When a certificate of cost or pricing data is required to be submitted in accordance with Federal Acquisition Regulation (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 by offerors 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 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 _____

NAME _____

TITLE _____

AUTHORIZED SIGNATURE _____

DATE OF EXECUTION*** _____

*Identify the proposal, quotation, 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.

***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.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS**L.1 NOTICE LISTING SOLICITATION PROVISIONS INCORPORATED BY REFERENCE**

The following solicitation provisions pertinent to this section are hereby incorporated by reference (by Citation Number, Title, and Date) in accordance with the FAR provision at FAR "52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE" in Section L of this solicitation. See FAR 52.252-1 for an Internet address (if specified) for electronic access to the full text of a provision.

NUMBER	TITLE	DATE
	FEDERAL ACQUISITION REGULATION (48 CFR Chapter 1)	
52.215-1	INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION ALTERNATE I (OCT 1997)	MAY 2001
52.215-1	INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION ALTERNATE II (OCT 1997)	MAY 2001
52.222-24	PREAWARD ON-SITE EQUAL OPPORTUNITY COMPLIANCE EVALUATION	FEB 1999

**HEALTH AND HUMAN SERVICES ACQUISITION REGULATION
(48 CFR Chapter 3) SOLICITATION PROVISIONS:**

HHSAR NUMBER	TITLE	DATE
352.215-12	RESTRICTION ON DISCLOSURE AND USE OF DATA	APR 1984
352.232-75	INCREMENTAL FUNDING	APR 1984

**L.2 52.215-20 REQUIREMENTS FOR COST OR PRICING DATA OR
INFORMATION OTHER THAN COST OR PRICING DATA (OCT 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.

L.3 52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a Cost Reimbursable type of contract resulting from this solicitation.

L.4 52.227-6 ROYALTY INFORMATION (APR 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.

L.5 52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 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 of those 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/these address(es):

<http://www.arnet.gov/far>

I. GENERAL INFORMATION

L.6 SIC CODE AND SMALL BUSINESS SIZE STANDARD (NIH 3150) (JUL 1993)

(a) The standard industrial classification (SIC) code for this acquisition is 8733.

(b)(1) The small business size standard is \$5 million [average annual receipts for 3 preceding fiscal yrs].

(2) 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.

(c) This requirement is NOT Set-Aside for Small Business. However, the Federal Acquisition Regulation (FAR) requires in every solicitation (except for foreign acquisitions) the inclusion of the Standard Industrial Classification (SIC) Code and corresponding size standard that best describes the nature of the requirement in the solicitation.

L.7 TYPE OF CONTRACT AND NUMBER OF AWARD(S) (NIH 2980) (APR 1984)

It is anticipated that one (1) award will be made from this solicitation and that award will be made on or about July 1, 2003.

It is anticipated that the award(s) from this solicitation will be multiple-year cost reimbursement type contract(s) with a term of 3 years, and that incremental funding will be used. (See Incremental Funding Provision in this Section L.)

L.8 ESTIMATE OF EFFORT (NIH 2985A) (OCT 1994)

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 perform this contract to be approximately 23.5 person years for the total of three years (1 full time equivalent or 100% effort = 1 person year). This number is furnished for your information only and is not to be considered restrictive for proposal purposes.

L.9 COMMITMENT OF PUBLIC FUNDS (NIH 2455) (JUL 1986)

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.

L.10 COMMUNICATIONS PRIOR TO CONTRACT AWARD (NIH 2345) (FEB 1990)

Offerors shall direct all communications to the attention of the 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.

L.11 RELEASE OF INFORMATION (NIH 3170) (JUL 1994)

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.

L.12 COMPARATIVE IMPORTANCE OF PROPOSALS (NIH 3171) (JUL 1994)

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. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

L.13 PREPARATION COSTS (NIH 3173) (JUL 1994)

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

L.14 52.233-2 SERVICE OF PROTEST (AUG 1996)

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

Virginia A. DeSeau

Hand-Carried Address:

Contracts Management Branch, OAM
National Institute of Child Health
and Human Development
6100 EXECUTIVE BLVD Suite 7A07
ROCKVILLE MD 20852

Mailing Address:

Contracts Management Branch, OAM, NICHD
National Institutes of Health, DHHS
Executive Building, Suite 7A07
6100 EXECUTIVE BLVD MSC 7510
BETHESDA MD 20892-7510

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

L.15 ROTC ACCESS AND FEDERAL MILITARY RECRUITING ON CAMPUS (NIH 3760) (MAR 1997)

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

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

II. INSTRUCTIONS TO OFFERORS--GENERAL

L.16 PACKAGING AND DELIVERY OF THE PROPOSAL (NIH 2995) (JUL 1994)

Your proposal shall be organized as specified in Section L (III - V below). 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. RFP NICHHD-2003-03 "

"TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY:

Number of Copies

Technical Proposal: Original and 12 copies.

Business Proposal: Original and 6 copies.

If hand delivered or delivery service

Contracts Management Branch, OAM
National Institute of Child Health
and Human Development
6100 EXECUTIVE BLVD Suite 7A07
ROCKVILLE MD 20852

If using U.S. Postal Service

Contracts Management Branch, OAM, NICHHD
National Institutes of Health, DHHS
Executive Building, Suite 7A07
6100 EXECUTIVE BLVD MSC 7510
BETHESDA MD 20892-7510

*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".

L.17 CONTRACT CLAUSES (NIH 3120) (JUN 1986)

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 procurement regulations in effect at the time of the execution of the proposed contract.

L.18 FORMAT AND CONTENT OF PROPOSALS (NIH 3121) (JUL 1994)**(a) INTRODUCTION**

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

(b) AUTHORIZED OFFICIAL AND PROPOSAL FORMAT

An official authorized to bind your organization must sign your proposal. Your proposal must be submitted in the number of copies, to the address, and marked as indicated this Section L. Proposals must be typewritten, reproduced on letter size paper, and be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to this RFP should be placed in the following order:

(1) **COVER PAGE.** Include RFP title, number, name of your organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

(2) **TECHNICAL PROPOSAL.** It is recommended that your technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions.

(3) **BUSINESS PROPOSAL.** It is recommended that your business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions.

(c) PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

You 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.

**L.19 SEPARATION OF TECHNICAL AND BUSINESS PROPOSALS
(NIH 3122) (JUL 1994)**

Your proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts must be separate and complete in it so that evaluation of one may be accomplished independently of, and concurrently with, the evaluation of the other. The Technical Proposal must include direct cost and resource information, such as labor hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that your understanding of the project may be evaluated. 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 must disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the Technical Proposal instructions.

L.20 ALTERNATE PROPOSALS (NIH 3123) (JUL 1994)

You may, at your discretion, submit alternate proposals, or proposals that deviate from the work requirements, provided that you also submit a proposal for performance of the work as specified in the statement of work. These 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, must be clearly identified.

L.21 CONFIDENTIALITY OF PROPOSALS (NIH 3124) (JUL 1994)

Your proposal submitted in response to this request for proposals may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which you, including your prospective subcontractor(s), do 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 you mark 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:

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 the 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 that 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)

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

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

NOTE: Offerors are cautioned that proposals submitted with the 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.

L.22 EVALUATION OF PROPOSALS (NIH 3125) (JUL 1986)

The Government will evaluate Proposals in accordance with the evaluation criteria set forth in Section M of this Request for Proposals.

**L.23 USE OF THE METRIC SYSTEM OF MEASUREMENT
(NIH 3126) (JUL 1994)**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such is impractical 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 substitutions 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 produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

L.24 HUMAN SUBJECTS**NOTICE TO OFFERORS OF REQUIREMENTS OF 45 CFR PART 46, PROTECTION OF HUMAN SUBJECTS (JAN 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 for Human Research Protection (OHRP), National Institutes of Health, Bethesda, Maryland 20892 (or at <http://ohrp.osophs.dhhs.gov/index.html>). 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 (or at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html - the spaces that appear to be empty are actually underline marks).

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention of interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organ, 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 non-involvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service 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 consultation with OHRP, (telephone: 301-496-7005), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP 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 OHRP and given detailed instructions for establishing an institutional review board and filing and Assurance of Compliance.

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

L.25 PRIVACY ACT (NIH 3131) (JUL 1994)

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(g) of the Public Health Services 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 purposes 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, Sec. 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 305 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.

L.26 INCLUSION OF WOMEN AND MINORITIES AS SUBJECTS IN RESEARCH PROPOSAL INSTRUCTIONS (NIH 3475) (JUL 1994)

It is the policy of NIH that woman and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law

103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) that have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research" which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), [(this was reprinted to correct typesetting errors from the Federal Register dated march 9, 1994 (FR 59 11146-11151)], and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Offerors may obtain copies from these sources or from the contact person listed in the RFP.

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

The format for reporting women and minority information with your proposal is contained in an attachment to this Section L.

L.27 INCLUSION OF CHILDREN IN RESEARCH INVOLVING HUMAN SUBJECTS (APR 1998)

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 scientific or ethical reasons not to include them. 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.

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 exempt 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. In the technical proposal, the offeror should create a section titled "Participation of Children." This section 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. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

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

L.28 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 a description of education in the protection of human subjects that the Principal Investigator and any other individuals working under the contract, who are responsible for the design and /or conduct of the research, have completed. In addition, the 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 written information to the Contracting Officer describing the title of the education program and a brief description of the program that has been completed by successor personnel.

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, In.. at http://www.cnetwatch.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.

L.29 DATA AND SAFETY MONITORING IN CLINICAL TRIALS

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

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

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

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

The Data and Safety Monitoring [BOARD and PLAN] shall be established and approved prior to beginning the conduct of the clinical trial.

L.30 SELECTION OF OFFERORS (NIH 3130) (JUL 1986)

Technical review advisors will evaluate the acceptability of the scientific and technical portion of each research contract proposal. They will evaluate each proposal in strict conformity with the evaluation criteria of this RFP, utilizing point scores and written critiques. They may suggest that the Contracting Officer request clarifying information from an Offeror.

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

If the Government intends to conduct discussions prior to awarding a contract, the Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. Oral or written discussions will be conducted

with all offerors in the competitive range. While it is NIH's policy to conduct discussions with all offers in the competitive range, NIH reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach and contractual terms and conditions. At the conclusion of discussions, each offer still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations after Final Proposal Revisions (FPRs) in accordance with HHSAR 15.351.670.

A final best-buy analysis will be performed taking into consideration the results of the technical evaluation, cost analysis, and ability to complete the work within the Government's required schedule. The Government reserves the right to make an award to the best advantage of the Government, technical merit, cost, and other factors considered.

The Government reserves the right to make 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 our requirements. Synopses of awards exceeding \$25,000 will be published in the Federal Business Opportunities website (<http://www.fedbizopps.gov>).

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.

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.

L.31 SMALL, SMALL DISADVANTAGED, AND WOMEN-OWNED SMALL BUSINESS SUBCONTRACTING PLAN (NIH 3135) (JUL 1986)

This provision does not apply to small business concerns.

If your proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance and you are the apparent successful Offeror, you shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small, Small Disadvantaged and Women-Owned Business Subcontracting Plan (Negotiated)." Section J includes as an attachment an example of such a plan.

The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes but is not limited to agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

The Offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer, which plan will be incorporated into the contract as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the Offeror, the Offeror shall be ineligible for an award. The Contracting Officer shall notify the Offeror in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Offeror to modify the plan within the time limits prescribed.

(4) Prior compliance of the Offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the Offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to both small business concerns and small business concerns owned and controlled by socially and economically disadvantaged individuals and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

(6) The Offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime contractor's designated small and disadvantaged business liaison.

Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, and women-owned small business concerns as subcontractors.

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

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies services are expected to be subcontracted to small, small disadvantaged, and/or women-owned small business concerns.

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

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

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged and women-owned small business concerns.

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

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged and women-owned small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small, Small Disadvantaged and Women-Owned Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged and women-owned small business concerns and award to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-10 Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in Section J.

L.32 SALARY RATE LIMITATION INFORMATION FOR OFFERORS (NIH 3101) (OCT 1993)

(a) Pursuant to Public Law cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown for the fiscal year covered. Direct salary is exclusive of overhead, fringe benefits, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative [F&A] costs"). 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
P.L. 107-116	2002	Executive Level I*

* FY 02 Executive Level Salaries can be found at <http://www.opm.gov/oca/02tables/ex.pdf>

III. INSTRUCTIONS TO OFFERORS--TECHNICAL PROPOSALS**L.33 TECHNICAL PROPOSAL INSTRUCTIONS (NIH 3500) (JUL 1994)**

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.

L.34 TECHNICAL DISCUSSIONS (NIH 3505) (JUL 1994)

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 a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless this RFP indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based on the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

(b) RESOURCES

Provide a schedule for the type and quantity of direct labor proposed for the project. Identify levels of effort for specific personnel where known or otherwise by job title. Also provide a description or tabulation of types and quantities of materials, equipment, services, subcontracts, and other resources to be funded by, and necessary for, performance of the proposed contract. Indirect costs (overhead), fixed fee (if any), salary and wages, and total costs shall not be included in the Technical Proposal.

(c) PERSONNEL

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention must 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.** 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 individual 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. If the principal investigator proposed for this RFP is committed in excess of 100% of his/her time the proposal must include appropriate explanations.

(2) **OTHER INVESTIGATORS.** List all other investigators who will be participating in the project. Discuss their qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(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 shall be indicated and the anticipated sources shall be specified and qualified. For all proposed personnel who are not currently members of your 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 education background, recent experience, and specific or technical accomplishments, and a listing of relevant publications.

L.35 TECHNICAL EVALUATION (NIH 3510) (JUL 1994)

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

L.36 ADDITIONAL TECHNICAL PROPOSAL INFORMATION (NIH 3515) (JUL 1994)

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

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 only in your proposal.

L.37 PROJECT OBJECTIVES - NIH 1688-1 (SEP 2002)

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

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

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "INSTRUCTIONS" (located at the bottom of the form).

L.38 OTHER CONSIDERATIONS (NIH 3520) (JUL 1994)

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

Unique arrangements, equipment, etc., which none or very few organizations are likely to have, which may be advantageous for effective implementation of this program.

Equipment and unusual operating procedures established to protect personnel from hazards associated with this program.

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

Recommendations for changing reporting requirements if such changes would be more compatible with your proposed schedules.

IV. INSTRUCTIONS TO OFFERORS--BUSINESS PROPOSALS**L.39 COST AND PRICING DATA (NIH 3600) (FEB 1998)**

a. 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.

1. General Instructions

A. You must provide the following information 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 of contract administration office (if available);
- (5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
- (6) Proposed cost; profit or fee; and total;
- (7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
- (8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
- (9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
- (10) Date of submission; and
- (11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and

(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. Materials and services. Provide a consolidated priced 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.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when the subcontractor submits cost or pricing data. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) Adequate Price Competition. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For inter-organizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) All Other. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or

pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For inter-organizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

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

C. Indirect Costs. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. Other Costs. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. Royalties. If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:

- (1) Name and address of licensor.
- (2) Date of license agreement. (3) Patent numbers.
- (4) Patent application serial numbers, or other basis on which the royalty is payable.
- (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
- (6) Percentage or dollar rate of royalty per unit.
- (7) Unit price of contract item.
- (8) Number of units.
- (9) Total dollar amount of royalties.
- (10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. Facilities Capital Cost of Money. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. Formats for Submission of Line Item Summaries

The detailed breakdown shall be in the format as shown on the form Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a

breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

L.40 NH3670 PAST PERFORMANCE INFORMATION

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

A list of the last six contracts completed during the past three years and all contracts currently in process that are similar in nature to the solicitation work scope. 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 Manger's Name and Telephone Number
8. Standard Industrial Code

(b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations and as an evaluation factor against which offeror's relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration. 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.

L.41 QUALIFICATIONS OF THE OFFEROR (NIH 3615) (JUL 1994)

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

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

(2) "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 or individuals who are proposed as personnel involved with the Statement of Work in this RFP.

(3) "Performance history" is defined as meeting contract objectives within DELIVERY and COST SCHEDULES on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

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

(5) "Pertinent grants" - list grants supported by the Government that involve 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.

L.42 PROPERTY/EQUIPMENT/FACILITIES (NIH 3620) (JUL 1994)

(a) It is HHS 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 you are proposing additional equipment to be provided by the Government, you must include in your proposal the description and estimated cost of each item. You must include comprehensive justification that includes:

(1) 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.

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

(b) You must identify Government-owned property in your possession and/or Contractor titled property acquired from Federal funds, which you propose to use in the performance of the prospective contract.

(c) If an offeror intends to use existing Government-owned facilities in the performance of this proposed contract, the following shall be furnished with the offer: (1) Description and value of all Government production and research property which the offeror or his/her anticipated subcontractors propose to use on a rent-free basis and the cognizant Government Contract Number; (2) Written permission of the Contracting Officer having cognizance of the property for use of that

property without charges; (3) Amount of use (in months) to be made of such property, and (4) Amount of rent which would otherwise be charged for such use, computed in accordance with applicable procurement regulations.

(d) The management and control of Government property must 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.

L.43 ROYALTIES (NIH 3625) (JUL 1994)

Furnish information concerning any royalties that are anticipated to be paid in connection with the performance of work under the proposed contract.

L.44 FINANCIAL CAPACITY (NIH 3630) (JUL 1994)

Indicate if you have 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.

L.45 SUBCONTRACTORS (NIH 3635) (JUL 1994)

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

- (1) Willingness to perform as a subcontractor for specific duties (list duties).
- (2) What priority the work will be given and how it will relate to other work.
- (3) The amount of time and facilities available to this project.
- (4) Information on their cognizant field audit office.
- (5) How rights to publications and patents are to be handled.
- (6) A completed cost proposal in the same format as the offeror's cost proposal.

L.46 INCREMENTAL FUNDING (NIH 3640) (JUL 1994)

The Government intends to award an incrementally funded contract. 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. In addition, the following provisions of HHSAR 352.232-75 are applicable:

(a) Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, it is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover 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 at FAR 52.232-20.

L.47 REPRESENTATIONS AND CERTIFICATIONS (NIH 3645) (JUL 1994)

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.

Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

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

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

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

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interest 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 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 interests 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 interest include, but are not limited to:

- (i) public disclosure of significant financial interests;
 - (ii) monitoring of research by independent reviews;
 - (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.

L.48 EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

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

<http://www.sba.gov/regulations/siccodes/siccodes.pdf>

or

<http://www.sba.gov/regulations/siccodes/siccodes.doc>

The Department of Commerce website for the annual determination is:

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

V. NOTICES TO OFFERORS

L.49 NOTICES TO OFFERORS - FORMS/FORMATS/ATTACHMENTS (APPENDED AT THE END OF THIS SECTION L) (NIH 3145) (JUL 1986)

	TITLE	DATE	# of PAGES
1.	Disclosure of Lobbying Activities, SF-LLL http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm	DEC 1989	3
2.	Proposal Summary and Data Record, NIH-2043 http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm	JUN 1982	2
3.	Technical Proposal Cost Information http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm	DEC 1988	1
4.	Business Proposal Cost Information (Optional Format) http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm	SEP 1992	
5.	Summary of Current and Proposed Activities http://www4.od.nih.gov/ocm/contracts/rfps/forms1.htm	MAR 1984	1
6.	Inclusion Enrollment Report Table for Women and Minority Inclusion Monitoring, PHS 398/2590 (attached following this index)	MAY 2001	1
7.	Proposal Intent Form (attached following this index)	NOV 2002	1
8.	Specific Notes to Offerors (attached following this index)	NOV 2002	2

"Note: The Technical Proposal Cost Information and Business Proposal Cost Information forms above are provided as an example. Offerors may develop and provide the same required cost information using their own form or spreadsheet. It should also be noted that the cost forms are boilerplates that allow for entry of up to five and seven years of cost information, respectively. Offerors should review Section F of this RFP, for the Government's estimated period of performance, and section C of the RFP, for the Statement of Work, in order to determine their proposed period of performance. Additionally, the Business Proposal Cost Information form provides a link to an electronic spreadsheet that you may use to assist in the preparation of your business Proposal."

**Section L - Attachment #6
Inclusion Enrollment Report Table**

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

Principal Investigator/Program Director (Last, first, middle):

Study Title:

Total Enrollment: _____ **Protocol Number:** _____

Contract Number: _____

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaskan 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/Alaskan 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.

Section L - Attachment #7

PROPOSAL INTENT RESPONSE SHEET

RFP No. NICHD-2003-03

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

=====

DO INTEND TO SUBMIT A PROPOSAL

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

COMPANY/INSTITUTION NAME:

AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

=====

RETURN TO:

National Institutes of Health
National Institute of Child Health and Human Development
6100 EXECUTIVE BLVD MSC 7510
BETHESDA, MD 20892- 7510

Attention: Virginia A. DeSeau, Contracting Officer

OR FAX TO: Virginia A. DeSeau at 301-402-3676

OR SEND BY E-MAIL TO: VD9T@NIH.GOV

Section L - Attachment #8**SPECIFIC NOTES TO OFFERS FOR RFP NICHD-2003-03**

1. The offeror should provide a statement regarding their credentials for leading this project, including describing their substantive and research design expertise, their organizational and managerial skills, the ability to work with a diverse interdisciplinary group of scholars and other administrative abilities.
2. The offeror should provide detailed preliminary plans for forming the core working group, committees and subcommittees and for how they will operate, including a discussion of:
 - a) The qualifications, qualities and fields of expertise of potential members (NOTE: offerors should not name specific individuals for working group membership).
 - b) The amount of time commitment expected of work group members, committee members, subcommittee members and consultants, as appropriate.
 - c) The approximate number of committees, subcommittees and their functions.
 - d) The number of meetings and how they will be conducted.
 - e) Plans to identify relevant policy makers and foundations and how their needs will be addressed.
3. As evidence of substantive comprehension of the requirement of the RFP, the offeror should provide a statement discussing the potential questions to be addressed and relevant theories and methods to be considered in developing a model research and data collection program. Topics to be addressed should include, but not be limited to:
 - a) A brief overview of current trends and variations in family behavior (e.g., marriage, divorce, cohabitation, fertility, etc.), their relation to public policy, and the extent, strengths, and limitations of existing knowledge about their causes.
 - b) Theoretical approaches to studying the causes of family change and variations in family change.
 - c) Theoretical approaches to examining how the study of family and fertility are related.
 - d) The importance of theory in guiding a research and data collection effort.
 - e) Methodological issues in the study of causal processes, and in the development of research designs to address causal issues in studying family change.
 - f) The value of thinking outside the box, beyond old models of demographic research to consider new sample designs, methods and theories.
 - g) The value of inclusive collaboration extended to other disciplines and substantive interests.
 - h) The importance of the utility of large-scale and/or integrated data collection efforts to the broader scientific community and the trade-offs between the research design and public access to the data.
4. The offeror should detail plans for the manner in which tasks described under the Statement of Work will be accomplished. Offerors should provide detailed descriptions of:
 - a) A timeline for all project activities and tasks.
 - b) Preliminary plans for conducting substantive, methodological and theoretical reviews; for designing and conducting original research activities (e.g., meta-analyses, qualitative studies, methodological studies)*; for synthesizing findings; and for developing and refining a theoretically based model program (or alternative model programs) of research and data collection.
 - c) Strategies for successfully engaging, motivating, and completing work within a diverse, multidisciplinary group of researchers.
 - d) Strategies for consulting with the Project Officer in forming working groups, committees, subcommittees, in developing workshops, planning and conducting reviews, and in planning and conducting original research activities.
 - e) Trade-offs to be considered in designing a model program in the context of uncertain funding levels. [Ability of research and data collection program to expand or contract, maintain periodicity (as applicable), be

sustained over time, incorporate new scientific developments, while preserving the ability of the model program to address key issues].

*NOTE: Original research studies supported under this contract that involve more than nine research subjects will require approval from the Office of Management and Budget (OMB). Detailed plans for the additional timing of this clearance should be provided if such studies are proposed as part of this project. Offerors are also encouraged to consider seeking outside support for these activities and should provide a plan for obtaining such funding, if appropriate. If outside support is obtained for original research studies, there is not a need for OMB clearance.

5. Where proposals reflect significant contributions of other individuals, and those individuals will play a substantive role in completing the work under the contract, they should be listed as collaborators and their role detailed and reflected in the proposed budget. Such individuals will be considered for membership in the working group, as appropriate.

6. There are no restrictions on the structure of the proposal in terms of organizations combining efforts as partners towards this effort, i.e., subcontracts and consultant provisions are acceptable approaches to this project.

FUTURE ACTIVITIES

This solicitation includes only development of models for research and data collection. Following completion of the contract, NICHD will evaluate whether and how to support the implementation of the resulting models in the context of priorities at that time, available resources and the most appropriate funding mechanism.

SECTION M - EVALUATION FACTORS FOR AWARD

M.1 GENERAL (NIH 1090) (OCT 1991)

Selection of an offeror for contract award shall be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost/price, past performance and small disadvantaged business participation.

Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance, and small disadvantaged business (SDB) participation are also important to the overall contract award decision. All evaluation factors other than cost/ price, when combined are more important than cost or price..

Offerors are advised that award will be made 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 shall 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, under Technical Evaluation Criteria, below. Proposals submitted in response to this solicitation will be reviewed by a special emphasis panel (SEP). The evaluation will be based on the demonstrated capabilities of the prospective contractors in relation to the needs of the project as set forth below. The merits of each proposal will be evaluated carefully, based on responsiveness to the RFP and thoroughness and feasibility of the substantive and technical approaches taken. Offerors must submit information sufficient to evaluate their proposal based on the detailed criteria listed below. While high competency is sought, capabilities that exceed those needed for successful performance of the contract work statement are not requested.

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The four factors, in order of importance, are: technical, cost/price, past performance, and small disadvantaged business (SDB) participation. Although the technical proposal will receive paramount consideration in the selection of the Contractor for this acquisition, cost/price, past performance, and small disadvantaged business participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. During the source selection process, the closer that offerors are determined to be in terms of technical ability, the greater the importance of cost or price. When proposals are considered to be technically equal, a best value analysis, considering cost or price, will be conducted to determine the awardee.

The Government reserves the right to make an award based on the best value to the Government in terms of cost or price, and other factors. Proposals submitted in response to the RFP will be evaluated based on the factors listed in the next section. Proposals will be judged solely on the written material provided by the offeror. It is anticipated that one (1) award will be made as a result of this acquisition, dependent upon the availability of funds.

PROPOSAL EVALUATION CRITERIA TOTAL POINTS: 100

a) PERSONNEL QUALIFICATIONS (50 points)

Demonstration of the requirements for the qualifications of the Principal Investigator as set forth in the RFP, including:

QUALIFICATIONS OF PROPOSED PRINCIPAL INVESTIGATOR: (40 points)

2. Evidence of experience in substantive scientific leadership in the following areas:
 - a) Substantive expertise in family and fertility research.

- b) Understanding the theories relevant to family change from diverse disciplines.
 - c) The capacity to design and conduct exploratory or original research studies.
 - d) The use of innovation in prior research projects.
 - e) Other accomplishments.
3. Evidence of strong organizational and management skills including,:
- a) The ability to plan and lead a complex project to completion.
 - b) The ability to effectively lead a diverse, interdisciplinary group of scholars in a multidisciplinary effort and evidence of inclusive collaboration.

INSTITUTIONAL EXPERIENCE: (10 points)

4. Evidence of past ability to hire staff for projects in a way that reflects flexibility and responsiveness to changing needs and the logistical adequacy of the staffing plan for the conduct of the project, including the time commitment of the professional and technical staff.
5. Evidence of the ability to manage complex projects involving workshops, multiple consultants, meetings, task orders, travel, etc.

b) SUBSTANTIVE APPROACH (Understanding the Requirement) (25 points)

Demonstration of comprehension of the requirements set forth in the RFP, as evidenced by a statement addressing the substantive issues involved in developing a model research and data collection program to study family change (see RFP's Section L – Specific Notes to the Offerors, item 3). Reviewers will evaluate the offeror's:

1. Breadth, scientific merit, and innovation in addressing how the study of family and fertility are related.
2. Breadth, scientific merit, and innovation in addressing theoretical approaches to studying the causes of family change and variations in family change.
3. Understanding of how theory may guide a research and data collection effort, and of methodological issues involved in designing a model for research and data collection.
4. Ability to think outside the box, beyond old models of demographic research to consider new sample designs, methods, and theories.
5. Understanding of the value of inclusive collaboration extended to other disciplines and substantive interests.
6. Understanding of the importance of the utility of large-scale and/or integrated data collection efforts to the broader scientific and policy communities and the importance of the research design for assuring public use access

c) MANAGERIAL APPROACH (25 points)

Demonstration of comprehension of the requirements set forth in the RFP for the approach to management used in developing a model research and data collection program to study family change, as evidenced by a detailed managerial plan for conducting the work described in the Statement of Work (see RFP's Section L – Specific Notes to the Offerors, item 4). Reviewers will evaluate the offeror's:

1. Strategies for successfully completing work within a diverse multidisciplinary group of researchers.
2. Strategies for consulting with the Project Officer in forming working groups, committees, subcommittees and in developing workshops, studies of original research, and other research activities.
3. Completeness and likely effectiveness of plans for organizing and implementing the various tasks and ensuring their timely completion.
4. Understanding of trade-offs to be considered in the context of varying funding levels. (Ability of

research and data collection program to expand or contract, maintain periodicity, be sustained over time, incorporate new scientific developments, all without sacrificing integrity of the study).

M.2 EVALUATION OF MINORITY GROUP AND GENDER REPRESENTATION (NIH 3185) (JUL 1994)

This research project involves human subjects. NIH Policy requires that woman 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 is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women and minority populations is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIH will review the exclusion rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the Government does not consider the rationale acceptable and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women and minorities in your final proposal revision. If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

M.3 PAST PERFORMANCE FACTOR

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

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

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

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.

M.4 EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Extent of commitment to use SDB concerns
- (c) Complexity and variety of the work SDB concerns are to perform
- (d) Realism of the proposal
- (e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- (f) Extent of participation of SDB concerns in terms of the value of the total acquisition.