OMB NO. 0990-0115

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

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

2. **Request For Proposal (RFP) Number**:	3. **Issue Date**:	4. **Just In Time**:	5. **Set Aside**:
NIH-NIAMS-02-03	08/08/01	[ ] NO [x] YES See Part IV Section L	[x] NO [ ] YES See Part IV Section L

6. TITLE: CLINICAL CENTERS FOR THE OSTEOARTHRITIS INITIATIVE

7. ISSUED BY:	8. SUBMIT OFFERS TO:
Contracts Management Branch, EP National Arthritis and Musculoskeletal and Skin Diseases, NIH Natcher Building, Room 5AS13A 45 Center Drive, MSC 6500 Bethesda, Maryland 20892-6500	See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.

9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1 until 4:00PM local time on **November 7, 2001.** Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043."

10. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE CONTRACTS MANAGEMENT BRANCH, NIAMS, AS STATED IN ATTACHMENT 1. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED IN ATTACHMENT 1, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED ON PAGE 40 OF THIS SOLICITATION.

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

12. FOR INFORMATION CALL: Eileen Webster-Cissel
PHONE: 301-594-2543
COLLECT CALLS WILL NOT BE ACCEPTED.

13. Table of Contents on following page.

Eileen Webster-Cissel
Chief Contracting Officer
Contracts Management Branch, EP
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH

13. DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract is for a Clinical Center that will be enrolling subjects and collecting data for the Osteoarthritis Initiative. The objectives of the Clinical Center are to: 1) cooperate with the Data Coordinating Center in implementing the overall Osteoarthritis Initiative; and 2) recruit, enroll and follow for 4 years individuals from the general population, over the age of 50 at high risk for the development of osteoarthritis (i.e., obesity, previous knee injury, low grade knee pain, an abnormal gait, etc.). It is intended that minorities and women will be represented in proportions similar to those found in the U.S. population over the age of 50. Each Clinical Center will recruit 1000-1250 individuals for study.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

A. INTRODUCTION

The National Institute of Arthritis and Musculoskeletal and Skin Diseases and National Institute on Aging invite proposals from investigators to implement a multi-center, longitudinal, prospective, population-based study of knee osteoarthritis (OA) to develop a public domain research resource. The purpose of this resource is to facilitate the scientific evaluation of biomarkers for osteoarthritis (OA) as potential surrogate endpoints for disease onset and progression. The Osteoarthritis Initiative (OAI) is expected to recruit and follow for at least four years approximately 5,000 subjects at high risk for OA initiation and progression.

OA presents a clear and growing public health need. There are no disease modifying pharmacological interventions. Current therapies for OA are palliative, surgical, or pain alleviating modalities despite advances in bone and cartilage biology, which should provide opportunities for developing disease-modifying therapies. Although developing new drugs for osteoarthritis is a high national priority, it is hampered by the lack of surrogate markers of disease activity. However, there are new technologies, particularly for imaging the joint space, bone, and related tissues even at the molecular level that may offer benefits to measure this disease. Because of the chronic nature of OA, clinical trials that test interventions to prevent or delay the onset of disease using clinical endpoints are lengthy and require very large numbers of patients. Characterization of biological markers of OA (e.g., anatomic characteristics and biochemical parameters), in largely population-based observational studies may offer useful measures that accurately predict the course of disease. As valid indicators of disease progression or regression, biomarkers may serve as candidate surrogate endpoints in clinical trials of novel interventions. The goal of this project is to create a public archive of data, biological samples, and joint images collected over time from a very well clinically characterized population of individuals who are at high risk of progressing to clinically significant

osteoarthritis. This public archive is a critical prerequisite to the evaluation and validation of osteoarthritis biomarkers by the private and public scientific communities.

B. BACKGROUND

Osteoarthritis (OA), or degenerative joint disease, is the most common form of arthritis. It is a slowly progressing disease characterized clinically by pain, deformity, enlargement of the joints, and limitation of motion. The disease usually occurs late in life and most commonly affects the hand and large weight bearing joints. The prevalence of OA is difficult to determine because many individuals with radiographic evidence of OA have no symptoms, and the degree of radiological change in symptomatic individuals varies. Approximately 20.7 million adults have physician-diagnosed OA. This number was calculated on the basis of age-specific rates established by clinical examination during the NHANES I survey and by 1990 census data, and it may represent an underestimate. In individuals age 60 and older, OA is estimated to be present (by history) in 17 percent of men and 29.6 percent of women. OA is a significant contributor to disability and loss of independence among the elderly.

The hands are the most commonly affected sites but the knee is the major source of reported disability and loss of function. Age, female gender, previous knee injury or surgery, and obesity are all recognized risk factors for knee OA. Knee OA is associated with a progressive reduction in function, including difficulty in changing from the sitting to the standing position and a decrease in mobility and in the ability to carry out activities of daily living. Advanced disease accounts for the majority (85 percent) of knee joint replacement surgeries among Medicare recipients. In 1994, approximately 230,000 knee replacement procedures were performed in this population.

Collectively, all forms of arthritis represent the leading cause of disability in the US, affecting approximately 43 million persons and costing approximately $65 billion in 1992. The aging of the population underlies the growing need for therapies that prevent or delay degenerative joint diseases. While recent advances have yielded highly effective disease-modifying therapies for rheumatoid arthritis, no such therapies exist for osteoarthritis and current treatment regimens are predominantly designed to relieve pain. Because of the chronic nature of the disease and variable clinical outcomes, clinical trials for new therapies are difficult, take a long time to conduct, and are exceedingly expensive.

In early 1999, a diverse group of experts from academia, government, professional research societies, and volunteer health organizations formed the Osteoarthritis Initiative Steering Group to jointly explore a research agenda that would facilitate the identification and evaluation of biomarkers for osteoarthritis. To date, such identification and evaluation have been severely hampered by the lack of well characterized, longitudinal data, biospecimens, and joint images. This group held a series of public meetings, workshops, and conferences. The group was organized into several subcommittees addressing epidemiological, genetic, and statistical considerations; biochemical markers; structural markers assessed by various imaging techniques; and administrative, infrastructure, and management concerns. The summaries of these meetings can be viewed at: http://www.nih.gov/niams/news/oisg/index.htm.

Additional input to the research initiative was obtained at a meeting February 28-29, 2000 from more than 200 participants (U.S. and abroad) representing many disciplines and organizations: academic and industrial scientists, regulatory agencies, professional research societies, and voluntary health organizations. A scientific plan was developed from these meetings and consultations to establish the fundamental information and specimen resource that would be necessary for discovery and evaluation of biomarkers for osteoarthritis. The experts identified a number of difficulties with drug discovery and clinical testing of disease-modifying therapies for osteoarthritis that would be addressed by the development and validation of biomarkers. As a result of these meetings, the OAI Consortium was formed by the NIH and a group of companies who will collaborate to support the project called the OA Initiative.

As part of the preparation for the meeting in February 2000, a review of the literature on currently existing cohorts was generated. This review identified 25 longitudinal cohort studies that might have provided data toward this end (see http://www.nih.gov/niams/news/oisg/oaepip.htm). However, each of the studies had limitations that preclude using them to develop the biomarkers that are needed. The limitations include: 1) the relatively small number of cases of OA in each cohort, 2) the lack of currently recommended techniques for obtaining images to assess progression of disease, and 3) the absence of the use of magnetic resonance (MR) imaging technology. Although the existing cohorts provide valuable information on OA onset and progression, data from these cohorts are insufficient for the development and validation of biomarkers. It was concluded that a new, longitudinal cohort is needed with large numbers of conversion to and progression of disease, appropriate imaging acquisition, and biospecimen collection. Data from such a cohort would enable validation

of biomarkers for onset and progression of OA. This would streamline the clinical trial process and provide incentives for private sector research and development of novel osteoarthritis interventions. The ultimate purpose of this initiative is to improve public health by preventing or alleviating pain and disability from bone and joint degenerative processes.

A similar review of the status of the development and validation of biochemical markers for OA was generated (see http://www.nih.gov/niams/news/oisg/oabiomarwhipap.htm). Based on this review, it is clear that much work remains to be done to validate any one of the existing biochemical markers or for the development of new markers. Such validated biochemical markers could be used to expedite OA clinical trials enabling more rapid and less costly identification of novel, disease modifying treatments. It is important to establish whether biochemical markers can act as surrogates for OA status, slowing of progression, such as in response to therapy. Biochemical markers must be assessed in longitudinal studies over a period where clinical change can be clearly defined, e.g., by joint space narrowing or some other index. Suitable clinical material must be identified from sufficiently well characterized populations of adequate size for effective assessment of these biochemical markers. Such materials do not currently exist.

C. GOALS AND OBJECTIVES

This Request for Proposals is to solicit the individual Clinical Centers that will be enrolling subjects and collecting data. The objectives of each Clinical Center are to: 1) cooperate with the Data Coordinating Center in establishing and implementing the overall Osteoarthritis Initiative protocol; and 2) recruit, enroll and follow for 4 years individuals from the general population, over the age of 50 at high risk for the development of osteoarthritis (i.e., obesity, previous knee injury, low grade knee pain, an abnormal gait, etc.). It is intended that minorities and women will be represented in proportions similar to those found in the U.S. population over the age of 50. Each Clinical Center will recruit 1000-1250 individuals for study.

The core elements for the research plan will be to initiate a prospective observational study of the characteristics of sub-clinical and early clinical osteoarthritis that predict progression to clinically significant disease in a diverse and representative cohort of men and women over the age of 50. Five thousand men and women will be recruited for an initial examination in this prospective study. The broad age range will permit analysis of important interactions between age and risk factors. The large total number is necessary to ensure the accrual of sufficient conversion to and progression of disease during the study time period. Data collected at baseline will be related to follow-up measurements and to subsequent clinical events over a 4 year period. Serum, plasma and urine specimens will be collected and stored for subsequent analysis. In addition to the focus on the knee joint, x-rays of one hand and the pelvis will be taken at regular intervals to assess the overall burden of disease to enable better interpretation of biomarker data. Blood cells collected at a follow up visit will be used by the Data Coordinating Center to generate any cell lines that will be archived.

The specific objectives of the OA Initiative are as follows:

1. to develop a longitudinal, human subject cohort to characterize the natural history of the onset and progression of osteoarthritis in a generalizable population;

2. to provide appropriate clinical and radiological materials (radiographic and magnetic resonance images) for evaluation of the validity of joint structural markers of the knee as potential surrogate endpoints for disease; and

3. to deposit data, joint images, and biological specimens collected from study subjects into a public domain database and repository (established and operated by the Data Coordinating Center) to enable evaluation of structural, biochemical, and genetic markers by the public and private scientific communities.

D. STATEMENT OF WORK

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

1. Each Contractor shall establish and operate a Clinical Center for the Osteoarthritis Initiative. The study will involve 4-6 Clinical Centers and a Data Coordinating Center. The Clinical Centers shall each be responsible for the screening, recruitment, enrollment, and follow-up of 850-1250 study participants. Each Clinical Center shall collaborate and maintain close communication with the Data Coordinating Center and the NIH Project Officer to ensure that the protocol

is uniformly implemented, quality control is assured, and that any operational problems which may arise are resolved in a timely and appropriate manner. The final protocol, Manual of Operating Procedures (MOOP), and all approved revisions shall be incorporated by reference into this Statement of Work.

2. Work with the Data Coordinating Center (with advice solicited from experts and the OAI Consortium) and the Steering Committee to establish the protocol and MOOP for the study with emphasis on the following:

    a. Selection of optimal timing for return visits, biospecimen collection, and precise protocols for data and biospecimen collection.

    b. The most efficient and precise execution of the required methodologies, including all appropriate quality control and assurance procedures. (The Data Coordinating Center, through their imaging expertise, will oversee image acquisition and analysis).

[NOTE TO OFFERORS: The offeror should provide detailed information on plans for recruitment, data to be collected, methods to be employed, and analytic approaches. This should include plans for optimal utilization of long-term observational data. In addition, the offeror should provide evidence of previous experience in developing protocols in collaborative arrangements and indicate agreement to work cooperatively with the NIH Project Officer and Data Coordinating Center in the establishment of the protocol and MOOP and the implementation and conduct of the study in accordance with these guidelines.]

3. In collaboration with the Data Coordinating Center, investigators from the other Clinical Centers, and the NIH Project Officer, the Contractor shall provide facilities and staff necessary to evaluate individuals for symptoms of osteoarthritis and collect data such as shown in the example below. Data, images, and specimens to be collected and delivered to the Data Coordinating Center are approximated in the following list which will be modified during protocol development based on input from the Steering Committee. Precise intervals for these collections will be determined by the Steering Committee.

    a. **Proposed Baseline Screening Examination**
    Demographic Information: age, sex, race, ethnicity, education, socioeconomic status, work type (physical versus desk); sports history
    Anthropometric (height & weight) data, smoking history; activity index; family history of arthritis (include TKR, THR)
    Medical history with specific reference to musculoskeletal diseases, prior knee injuries or surgeries; fracture history; history of analgesic use; co-morbidity evaluation; use of alternative treatments/dietary supplements for arthritis.
    Muscle strength and functional assessment
    X-rays: (modified Buckland-Wright method suggested; precise protocol to be set by the Steering Committee with advice from experts)
        Right and left knees
        Pelvis
        Right hand
    MR imaging: (conventional, 1.5 Tesla suggested; precise protocol to be set by the Steering Committee with advice from experts)
        Right and left knees
    Health and symptom assessment questionnaires such as:
        WOMAC (knee & hip)
        SF-36 (general health)
        A mental status interview to screen for depression
    Physical Examination of those with knee pain and general assessment of pain tolerance and sensitivity to pain*
    Biologic Specimens:
        Collection of blood: serum: 3 x 10 ml tubes; plasma: 3 x 10 ml tubes
        Collection of urine

    b. **First Follow-up Examination (12 months after baseline)**
    Anthropometric (height & weight) data, smoking history; activity index; family history of arthritis (include TKR, THR)

Medical history with specific reference to rheumatoid disease, prior knee injuries or surgeries; fracture history; analgesic use; co-morbidity evaluation; use of alternative treatments/supplements for arthritis.
Muscle strength and functional assessment
X-rays: (modified Buckland-Wright method suggested; precise protocol to be set by the Steering Committee with advice from experts)
- Right and left knees
- Pelvis
- Right hand

MR imaging: (conventional, 1.5 Tesla suggested; precise protocol to be set by the Steering Committee with advice from experts)
- Right and left knees

Health and symptom assessment questionnaires such as:
- WOMAC (knee & hip)
- SF-36 (general health)
- A mental status interview to screen for depression

Physical Examination of those with knee pain and general assessment of pain tolerance and sensitivity to pain*
Biologic Specimens:
- Collection of blood: serum: 3 x 10 ml tubes; plasma: 3 x 10 ml tubes; separated whole blood: 1 x 10 ml tube for DNA and cell lines
- Collection of urine.

c. **Subsequent Follow-up Examinations (at yearly intervals for 3 additional years)**
Same as described for 1 year follow-up except no whole blood collection.

[NOTE TO OFFERORS: The offeror should show expertise in the indicated areas for the assessment of pain and function associated with osteoarthritis. The offeror is invited to suggest additional assessment measures for more complete evaluation of burden of disease. The offeror should provide evidence of capabilities to provide needed radiological services for subject evaluation (x-ray and MR imaging) with existing equipment within a time frame consistent with proposed recruitment. If such capabilities do not currently exist, the offeror should propose means to meet such needs including appropriate space available and budgetary requirements. The offeror is encouraged to propose alternative approaches to MR imaging capability including working with the Government to obtain mobile units, lease vs. purchase of dedicated MR units, subcontracting to existing facilities, etc.

****Joint pain can be related to a wide variety of conditions, including, anatomical defects, joint tissue degeneration, and abnormal muscular function. To examine the correlation between knee pain, the general sensitivity to pain, and correlates to orofacial pain (in particular pain in the temporomandibular joint), the offeror shall identify/develop a pain assessment questionnaire (including orofacial pain) and propose/develop physical exams for the assessment of the presence or sensitivity towards general painful stimuli. The data provided by the questionnaire and physical tests should yield information sufficient to provide a basis for comparison to data in past studies, and provide a basis for the possible development of more comprehensive studies of pain sensitivity (both general and specific) in patients with OA.]***

4. Become fully conversant with the final study protocol, as operationalized in the MOOP.

   a. Attend study-related Steering Committee meetings on a yearly basis or as needed.

[NOTE TO OFFERORS: It is expected that the Principal Investigator, Recruitment Coordinator, and Nurse Coordinator from the Clinical Centers will attend 3 Steering Committee meetings the first year and 1 meeting per year in subsequent years. The Recruitment Coordinator, 1-2 Clinical staff, and Data Manager will be required to travel for 1-2 day centralized training sessions the first year and 1 Protocol update/Quality Assurance meeting per year for subsequent years.]

   b. Provide appropriate personnel for training in the following areas:

1) Accrual and storage of specimens according to standardized protocol and transport of these to the Data Coordinating Center.

2) Standardization of protocols for administration of questionnaires, imaging techniques, and quality control methodologies for each site and instrument.

3) Participation in on-site training as developed by the Data Coordinating Center.

c. Participate in developing the central staff training and monitoring system needed for implementation of the MOOP for all Clinical Centers.

d. Adapt informed consent materials as needed for the study population particular to the Clinical Center and submit these to the local Institutional Review Board for approval.

5. Recruit appropriate numbers of individuals over the age of 50 at high risk for development of knee OA (i.e., those with obesity, previous knee injury or surgery, low grade knee pain, abnormal gait, etc). Precise inclusion and exclusion criteria and types of enrichment will be established by the Steering Committee prior to recruitment and enrollment of subjects. Develop recruitment strategies appropriate for the target populations. Make necessary arrangements to prepare for recruitment, such as working with the Steering Committee to describe the study population for recruitment and obtaining access to suitable mailing lists.

[NOTE TO OFFERORS: The offeror should provide evidence of ability to recruit large numbers of individuals for study and specific information to show that enrichment populations are available in proposed numbers. The offeror should provide a detailed plan for recruitment of individuals from these populations, including detailed descriptions of particular populations in catchment area and the type of populations routinely served. A recruitment plan should include approaches, sources, and the process to be used. The plan should include a tabulation of the source populations, means and sources of population enrichment with high risk individuals, and the anticipated yield at each stage of the recruitment process. The offeror should also propose relative percentage of enrichment to provide sufficient cases to follow onset and progression of disease over the proposed 4-5 year period. Spanish versions of all resources must be provided to enable appropriate recruitment of minority populations. The offeror can propose the inclusion of younger female recruits if such argument is supported by previous data. Note that the RFP does not specify or preclude that every clinic should have a population-based recruitment strategy, i.e., a convenient sample will be acceptable. Proof of ability to achieve appropriate numbers, mechanisms for screening, consenting and enrolling qualifying participants and retaining such populations for longitudinal study is essential. Evidence of the offeror's ability to schedule procedures such as x-rays with timely turn around is also essential. Wherever possible, tabulations should be used in place of narrative descriptions. Specifically, the offeror's relevant experience in clinical cohorts should be tabulated, and the tabulation should include name of the cohort, short description of the cohort including target population, the names of the investigators from the offeror's team, the recruitment goal number for the center, the goal recruitment period, the actual recruitment number and the actual recruitment period. Graphs of recruitment experience for each cohort should be attached, wherever possible.]

6. Prior to enrollment of subjects, develop, in conjunction with the Data Coordinating Center, other Clinical Centers, and a panel of experts, a workable case definition for prevalent and incident OA for knee, hip and hand and to define parameters that will be considered progression of disease at follow up visits.

7. Enroll participants at high risk (based on historical data from diseased populations and advice from experts to the Steering Committee) of osteoarthritis, in order to estimate prevalence, incidence, and progression rates of knee OA for the populations selected (see 2 above). Each clinical center may focus on enrichment with a particular risk group (e.g., sports injuries) or may choose to recruit a diverse set of people at high risk of OA.

a. Develop local adherence strategies for diverse study populations, including minority groups.
b. Develop strategies for long term retention of study subjects.

[NOTE TO OFFERORS: Since the purpose of the project is to observe development of OA and progression of disease, it is critical to enrich the population with those at increased chance for disease incidence and progression. Although there are few specific data available on progression rates in normal populations, the offeror should estimate rates of progression within selected populations of interest.]

8. Manage the information generated in conjunction with the Data Coordinating Center with respect to: recording, transmitting, analyzing and storing computerized x-ray and MR image data; maintenance of confidentiality; encryption of clinical and imaging data to protect subject identity while allowing for longitudinal additions of data; tracking the recruitment process; data retrieval; and appropriate screens and/or optical scanning for data input. Cooperate with the Data Coordinating Center in the installation at Clinical Centers of any hardware and software needed to acquire and transmit data according to the MOOP.

[NOTE TO OFFERORS: The offeror should provide a plan for managing the flow of relatively large numbers of participants through a complex schedule of visits which will enhance efficient clinic operations (with particular reference to image acquisitions) while minimizing the burden to participants. Guidelines and references related to assurance of patient confidentiality can be found at: http://www.hhs.gov/ocr/hipaa/research.html and http://www.nlm.nih.gov/pubs/cbm/confiden.html]

9. The Contractor shall maintain patient confidentiality in accordance with the requirements of the Privacy Act.

10. Collect, process, store temporarily, and ship biological specimens to the Data Coordinating Center in accordance with the study protocol and MOOP. The Contractor shall provide suitable freezers (-80 degrees) for short term storage of biospecimens.

11. Submit to the Data Coordinating Center, on a monthly basis, recruitment reports that delineate the number of patients screened and enrolled during the reporting period. Included with this monthly report shall be information which delineates the inclusion of women and minorities in the research study.

E. STUDY COMPONENTS

1. Clinical Centers

The Clinical Centers are institutions that are actively involved in the recruitment, evaluation, and follow-up of study participants. For this study, the Clinical Centers will consist of a core team of researchers who are skilled in recruitment and evaluation of clinical OA and the implementation of assessment tools for OA and have experience in collaborative clinical investigation.

[NOTE TO OFFERORS: Offerors should clearly document their experience in recruiting and studying individuals at high risk for development of chronic diseases and in minimizing losses of subjects to follow-up during long term studies. Clinical Centers also should document prior involvement in multi-center studies and success in recruiting from minority populations (see Technical Instructions for more detail). Applicants should provide evidence that the Clinical Center will be capable of recruiting a sufficient number of high risk individuals (individuals over the age of 50 with obesity, history of knee injury or surgery, knee pain, strong family history of OA). The average number of subjects per center is estimated to be 850-1200. An organizational structure for the Clinical Center should be provided in the application, delineating lines of authority and responsibility for dealing with problems in all general areas. There should be evidence of strong institutional support for the Clinical Center, including documentation of adequate space in which to conduct clinical activities and office space for staff].

2. Data Coordinating Center

The Data Coordinating Center, solicited through a separate RFP, will have primary responsibility for all imaging protocols and quality assurance, biostatistical analyses and data management aspects of the study. It will also manage the central laboratory for establishment of cell lines and be responsible for management of the specimen storage repository, establish and manage the web-based databases, and establish a radiology reading facility for interpretation of x-ray and MR images. Preparation of interim and final reports will be collaborative undertakings by all participating

Clinical Centers, the Data Coordinating Center, and NIH. The Data Coordinating Center will cooperate and collaborate with all other study components.

3. **Steering Committee**

The primary governing body of the study will be the Steering Committee, which will have responsibility for overall study design and policy decisions. At a minimum, principal investigators from each of the 4-6 Clinical Centers, the Data Coordinating Center principal investigator, and OAI Consortium Representative from the pharmaceutical sponsors and NIH will form the study Steering Committee. FDA will appoint a representative to serve as a liaison between FDA and the OAI to attend and participate in Steering Committee meetings. Other committees will be assembled to facilitate publication, specimen issues, etc. as needed. Meetings of the Steering Committee will be widely advertized and open to the public.

4. **NIH Project Officer**

The Government will name a NIH Project Officer whose function will be to coordinate all aspects of the study.

5. **Resource Allocation Review Committee**

The NIH will select, based on recommendations from the Steering Committee, a Resource Allocation Review Committee (RARC) that will oversee the allocation and distribution of biological specimens generated from the OA Initiative. The RARC will be made up of individuals not directly involved in the OA Initiative or cartilage-related research and without conflict of interest. Membership on this committee will rotate biannually. Meetings of the RARC will be widely advertized. The RARC will review applications to use the biological specimens. The format of the application and criteria for the use of repository biological specimens will be developed by the RARC with advice from the Steering Committee and made available to all potential users.

6. **Observational Study Monitoring Board**

The NIH will establish and appoint members of an Observational Study Monitoring Board (OSMB) to monitor regularly the data from the observational study, review and assess the study performance, and to make recommendations, as appropriate, to the NIH with respect to 1) the performance of individual centers; 2) issues related to participant safety and informed consent, including notification of and referral for abnormal findings; 3)adequacy of study progress in terms of recruitment, quality control, data analysis, and publications; 4) issues pertaining to participant burden; 5) impact of proposed ancillary studies and sub-studies on participant burden and overall achievement of the main study goals; and 6) overall scientific directions of the study. The NIH will be responsible for organization and scheduling of these meetings. The Data Coordinating Center will provide to the OSMB materials needed to carry out the above described evaluations.

F. **STUDY PHASES**

7. **Phase 1** (Planning, Protocol Development and Approval, and Training Phase, 10 months)

This phase will encompass collaborative development of the study protocol and the MOOP by the Steering Committee. The Steering Committee will hold small meetings of experts to get advice for setting the precise protocol. The Data Coordinating Center will work with NIH personnel to gain OMB clearance for this study (estimated 4 months). The established protocol and MOOP will be distributed to each Clinical Center and training will be carried out with appropriate quality assurance to ensure uniformity of procedures and data collection from site to site and successful transmission of data from Clinical Centers to Data Coordinating Center in appropriate formats.

2. **Phase 2** (Recruitment and Baseline Measurement Phase, 18 months)

   The protocol will be initiated in Phase 2. Clinical Centers will recruit participants over this period, implement the protocol according to the MOOP, collect the data specified in the protocol, and provide study data to the Data Coordinating Center.

3. **Phase 3** (Follow-up Phase, 54 months)

   Clinical Centers will continue to implement the protocol, collect outcome data and specimens, and ship specimens to central facilities for cell line development and storage, and provide study data to the Data Coordinating Center during this period. All participants will continue to be studied throughout Phase 3 (duration of individual follow-up is 48 months).

4. **Phase 4** (Close-out Phase, 6 months)

   The final phase of the study will be for Clinical Center close-out activities, data analysis, and reporting of results.

Time line for Study

Activity	Time Period
Protocol Development (4 months)	July 15, 2002-November 14, 2002
Initial Meeting of All Contractors, Sponsors, and NIH	July 25-26, 2002
OMB Clearance (4 months)	November 15, 2002-March 14, 2003
Protocol review, training, & implementation (2 mos.)	March 15, 2003-May 14, 2003
Subject Recruitment (18 months)	May 15, 2003-November 14, 2004
Baseline Measurements (18 months)	May 15, 2003-November 14, 2004
Follow-up Measurements (54 months)	May 15, 2004-November 14, 2008
Close-out (6 months)	November 15, 2008-May 14, 2009

ARTICLE C.2. REPORTING REQUIREMENTS

A. Technical Progress Reports

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

NOTE: Reports and deliverables submitted to the Government shall not include any personal identifiers of subjects that may be participating in the study.

1. Quarterly progress reports, shall be due 15 days after the end of each quarter, indicating general progress in study activities and administrative issues; personnel with Full Time Equivalent (FTE) levels for the reporting period; changes in personnel; specific problems encountered or anticipated and attempts to resolve such problems; and progress in recruitment activities, study design execution, and publication activities. (3 copies)

2. Annual Technical Progress Report for Clinical Research Study Populations, shall be due on the anniversary date of the

contract. The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. This information shall be submitted in the format indicated in the Attachment entitled "Annual Technical Progress Report Format for Each Study" which is set forth in Section J of this contract. This Report does not replace the Quarterly Progress Reports.

3. Final Report, due on or before the expiration date of the contract, documenting and summarizing the results of the entire contract work, including recommendations and conclusions based on both the general experience and the special viewpoint of the center not to exceed 10 pages. A Quarterly Progress Report is not due for the period when the Final Report is due. (3 copies)

4. Summary of Salient Results to be submitted with the final report. This summary shall not exceed 200 words and shall describe the salient results achieved during the performance of the contract (3 copies).

B. **INVENTION REPORTING REQUIREMENT**

All reports and documentation required by [FAR CLAUSE 52.227-11/FAR CLAUSE 52.227-11 (DEVIATION)/FAR CLAUSE 52.227-13] including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of the annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer at the address listed below. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted within 90 days after contract expiration to the following address:

**** **(NOTE: Include ONLY the applicable clause within the brackets of the first sentence of the above paragraph. Remove the brackets and delete the reference to the inappropriate clauses.)** ****

Contracting Officer
Contracts Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institutes of Health
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
Bethesda, Maryland 20892-6500

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

ARTICLE C.3 SPECIAL PROVISIONS

A. Restricted availability of unique research resources, upon which further studies are dependent, can impede the advancement of research and delivery of medical care. NIH policy requires that investigators make unique research resources readily available for research purposes to qualified individuals within the scientific community when they have been published (NIH Grants Policy Statement may be found at http://grants.nih.gov/grants/policy/nihgps/). The fundamental purpose of the OAI is to develop a public domain research resource for unencumbered utilization by the for-profit and not-for-profit scientific communities to enable and facilitate further research and commercial development in the field of OA. Intellectual property ties to the deliverables of this contract – data, radiologic images, archived cell lines, DNA, and biological specimens, are not consistent with the public domain purpose of the RFP.

To ensure unrestricted availability of the data, radiologic images, DNA, and biological specimens collected and preserved by the awardee, NIH expects to make a Determination of Exceptional Circumstances (DEC) pursuant to 37 C.F.R. 401.3(a)(2) which will cover these deliverables. The purpose of the DEC is to eliminate the potential for patents on the collections of information and biological specimens, as this would undermine the wide availability of the national resource that is the

fundamental purpose of this RFP.

B With regard to other patentable research results, such as new instrumentation, methodologies, software or data systems, NIH requires applicants who respond to this RFP to develop and propose a plan addressing if, and how, they will exercise their intellectual property rights while making available to the broader scientific community research resources produced in this project. This is expected to include an elaboration of the applicant's anticipated plans to generate, or not generate, patents and/or exclusive or non-exclusive licensing of patentable subject matter funded under this RFP. This plan is also expected to include disclosure of any pre-existing intellectual property rights, including options to for-profit research sponsors, that are associated with any of the work that would be funded under this RFP.

The Government will evaluate the proposed plan. The plan also will be considered by NIH program staff in determining whether the contract shall be awarded. The plan as approved, after negotiation with the applicant when necessary, will be a condition of the award. Evaluation of any future renewal applications will include assessment of the awardee's adherence to the proposed plan.

C. Applicants are also reminded that the contractors are required to disclose each subject invention to NIH within two months after the inventor discloses it in writing to the Contractor. NIH reserves the right to monitor awardee activity in this area to ascertain if patents or patent applications on new instrumentation, methodologies, software or data systems or other patentable subject matter are adversely affecting the goals of this RFP.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

ARTICLE D.1. PACKAGING

For the purpose of reports, "immediate usable and acceptable condition" includes securing the pages together in a suitable and reasonable manner to be agreed upon by the Contractor and the NIAMS Project Officer.

Boxes and/or other types of outer packaging, i.e., containers, wraps, etc., shall be suitable to the type of items being transmitted.

ARTICLE D.2. MARKING

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

1. Title: "Clinical Center for the Osteoarthritis Initiative"

2. Contract Number:

3. Name of Contractor:

4. Period Covered by Report:

ARTICLE D.3. SHIPPING

The mode of transportation utilized shall assure that all deliverables will be received in an acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

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

b. For the purpose of this SECTION, the Project Officer indicated in ARTICLE G.1., is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, Bethesda, Maryland.

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from (TBD) through (TBD).

ARTICLE F.2 . DELIVERIES

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

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

Item	Description	Quantity	Delivery Schedule
(1)	Quarterly Performance Report	1 to the P.O. 1 to the C.O.	Due by the 15th calendar day after the end of each quarter.
(2)	Annual Technical Progress Report for Clinical Research Study Populations	1 to the P.O. 1 to the C.O.	Due by the 10th calendar day after the anniversary date of the contract.
(3)	Final Report and Summary of Salient Results	1 to the P.O. 1 to the C.O.	Due on or before the last day of the contract.

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

Addressee	Deliverable Item No.	Quantity
Contracting Officer Contracts Management Branch National Institute of Arthritis and Musculoskeletal and Skin Diseases National Institutes of Health Natcher Building, Room 5AS13A 45 Center Drive, MSC 6500 Bethesda, Maryland 20892-6500	1 2 3	1 1 1
Project Officer National Institute of Arthritis and Musculoskeletal and Skin Diseases National Institutes of Health Natcher Building, Room 45 Center Drive, MSC 6500 Bethesda, Maryland 20892-6500	1 2 3	1 1 1

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:

ARTICLE G.1. PROJECT OFFICER

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

[To be specified prior to award]

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

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

ARTICLE G.2. KEY PERSONNEL

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

NAME	TITLE
[To be specified prior to award]]	

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

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

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

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

Contracting Officer
Contracts Management Branch, EP
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
BETHESDA MD 20892-6500

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 594 -2543.

(3) The Contractor agrees to provide with each invoice/financing request a detailed breakdown of the direct labor/personnel costs which shall include: (1) a list of the individuals by name; (2) their title/position under the contract; (3) the number of hours/percent of effort worked during the current period and the cumulative over the life of the contract; and (4) amount claimed for each individual for the current period as well as the cumulative since the inception of the contract.

(4) The expenditure categories to be reported on the invoice are:

a. Direct Labor *(List individuals by name, title/position, level of effort and amount claimed)*
b. Fringe Benefits *(Cite rate, base and amount)*
c. Consultants *(Identify individuals and amounts)*
d. Subcontracts *(Identify subcontractor by name and attach subcontractor invoices)*
e. Materials and Supplies
f. Accountable Personal Property/Equipment *(identify equipment purchased on HHS 565 and submit with invoice)*
g. Patient Tests
h. Patient Travel
i. Staff Travel *(Indicate names of travelers, purpose of trip, and costs being billed, i.e., airfare, per diem, ground transportation, etc.)*
j. Other Direct Costs
k. Total Direct Costs
l. Indirect Costs/Overhead *(Cite rate, base and amount)*
m. General and Administrative Costs *(if applicable, cite rate, base and amount)*
n. Total Costs
o. Fixed Fee (if applicable)
p. Total Costs [Plus Fixed Fee]

(5) The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H._. of this contract. For billing purposes,

certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. (as stated in ARTICLE H._.b.) and ARTICLE H._. of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES (will be included if the successful offeror is a profit making organization)

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

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

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

ARTICLE G.5. GOVERNMENT PROPERTY

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

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The 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.

b. Electronic Access to Contractor Performance Evaluations

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

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an

alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS (applicable to commercial organizations only)

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

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

ARTICLE H.2. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by NIAMS, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the Optional Form 310.

ARTICLE H.3. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.4. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

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

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

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

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

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

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

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

[Applicable information to be included at award]

ARTICLE H.6. NEEDLE EXCHANGE

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

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

[Applicable information to be included at award]

ARTICLE H.7. PRIVACY ACT

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

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as Attachment 6.

ARTICLE H.8. OMB CLEARANCE

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

ARTICLE H.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

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

April 30th
October 30th

The Report shall be sent to the following address:

Contracting Officer
Contracts Management Branch, EP
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
BETHESDA MD 20892-6500

(2) The Contractor shall submit one (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 Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

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

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

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

ARTICLE H.10. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

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

[Applicable information to be included at award]

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

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

ARTICLE H.11. CONFIDENTIALITY OF INFORMATION

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

Pursuant to the provisions of paragraph (c) of the CONFIDENTIALITY OF INFORMATION clause incorporated into this contract (see SECTION I), the identity of subjects participating in the various studies/protocols is considered confidential information. Identity of subjects shall include name, identifying number or symbol, or any other identifying particular as may be assigned to an individual.

ARTICLE H.12. PUBLICATION AND PUBLICITY

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

"This project has been funded in whole or in part with Federal funds from the National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, under Contract No. (TBD) .

ARTICLE H.13. PRESS RELEASES

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

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

[Applicable information to be included at award]

ARTICLE H.14. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (http://www3.od.nih.gov/oma/manualchapters/management/1754/)

ARTICLE H.15. ANTI -LOBBYING (Applicable to hospitals and state, local, and Indian tribal governments)

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

b. Contract funds shall not be used to pay salary or expenses of the Contractor or any agent acting for the Contractor, related

to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

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

[Applicable information to be included at award]

ARTICLE H.16. YEAR 2000 COMPLIANCE

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

1. Service Involving the Use of Information Technology

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

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

(End of Clause)

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

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

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

52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Mar 2000	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.3")
52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General, Alternate IV (Jun 1987)
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	May 2001	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes

52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-5	Sep 1996	Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions)
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - Rev. 5/2001].

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

FAR Clause 52.216-7, ALLOWABLE COST AND PAYMENT (MARCH 2000), is modified in paragraph (a) to delete the words

"subpart 31.2 of the Federal Acquisition Regulation (FAR)" and substitute the words "45 CFR part 74, appendix E". (Applies only if award is made to a Hospital , either profit or non-profit).

[NOTE TO OFFERORS: NIAMS intends to include the following clause deviation in any contract that results from this solicitation, subject to approval of a determination of exceptional circumstances by the Director, NIH.]

FAR 52-227-14 Rights in Data- General-Deviation, add the following paragraph (f) to the clause at FAR 52.227-17, Rights in Data -Special Works, and use that clause in place of the clause at FAR 52.227-14, Rights in Data-General.

(f) The Contractor agrees that to the extent it receives or is given access to data necessary for the performance of this contract which contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless otherwise specifically authorized in writing by the Contracting Officer.

ALTERNATE II (OCTOBER 2000) of FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (OCTOBER 2000) is added.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

(1) FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

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

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

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

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

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

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

(7) Alternate IV (JUNE 1987), FAR 52.227-14, Rights in Data--General (JUNE 1987). (Applies to Colleges and Universities only).

(8) Alternate V (JUNE 1987), FAR 52.227-14, Rights in Data--General (JUNE 1987).

Specific data items that are not subject to paragraph (j) include: None

(9) FAR 52.230-5, Cost Accounting Standards - Educational Institution (APRIL 1998).

(10) FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).

(11) FAR t2.239-1, Privacy or Security Safeguards (AUGUST 1996).

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

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

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

(1) HHSAR 352-223-70 Safety and Health (JANUARY 2001). (This clause is provided in full text in Section J - Attachments).

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

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

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

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

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

(2) NIH-(RC)-11, Research Patient Care Costs (APRIL 1984).

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

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

This contract incorporates the following clauses in full text.

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

[NOTE TO OFFERORS: NIAMS intends to include the following clause deviation in any contract that results from this solicitation, subject to approval of a determination of exceptional circumstances by the Director, NIH.]

1. **FAR 52.227-11 PATENT RIGHTS - RETENTION BY THE CONTRACTOR (SHORT FORM) JUNE 1989 (DEVIATION)**

(a) Definitions.

(1) "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under title 35 of the United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321, et seq.).

(2) "Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

(3) "Subject Invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of

determination (as defined in section 41 (d) of the Plant Variety Protection Act, 7 U. S.C. 2401 (d)) must also occur during the period of contract performance.

(4) "IP" means intellectual property

(5) "OAI" means the Osteoarthritis Initiative

(6) "NIAMS" means the National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health.

(7) "SIR" means a Statutory Invention Registration as provided for by the United States Patent and Trademark Office

(b) Allocation of principal rights.

(1) The Contractor agrees to assign to NIAMS the entire right, title and interest throughout the world in and to each Subject Invention except to the extent that greater rights are granted by NIAMS to the Contractor pursuant to subparagraph (b)(2).

(2) Contractor Greater Rights

(i) Not withstanding (b)(1) the NIAMS will grant the Contractor blanket greater rights to inventions developed under the OAI subject to the terms contained herein at (b)(3). It is the intent of the NIAMS that the Contractor dedicates the majority of inventions developed under the contract to the public domain in hopes that these resources will help advance scientific knowledge for the public good. Therefore, the Contractor shall dedicate those inventions (e.g., research tools) that do not require patent protection to promote further development of the invention to the public domain. The Contractor may seek an SIR to such inventions, as appropriate. The NIAMS also recognizes the benefit of patent protection for those inventions that require further development and the participation of commercial entities to have a valid impact on the public. As part of the blanket greater rights granted, the Contractor may elect right, title and interest in and to Subject Inventions that require patent protection to advance the technology subject to the terms of (b)(3).

(3) IP Management by Contractor and Government's Rights

(i) The Contractor shall submit an IP management strategy to NIAMS for approval that details how the Contractor intends to administer IP to meet the goals of broad dissemination set forth in (b)(2) within forty-five (45) days of award of this contract. The Contractor's IP strategy will include patenting and licensing of inventions, strategic use of SIRs, identification and distribution of research materials, and organization and dissemination of data. Any changes to the Contractor's IP management strategy during the course of the contract will be implemented only after consultation with and approval of NIAMS.

(ii) The Contractor's IP management strategy and the implementation of said strategy will be reviewed initially and up to twice per year as necessary by NIAMS Project Officer. NIAMS will determine if the Contractor's patenting and licensing activities, dissemination of research materials and overall IP management meets the goals set forth for the OAI. The Contractor will provide copies of all patent or other IP applications, licenses, invention administration agreements, sponsored research agreements or other documents relating to the administration of IP to the NIAMS Contracting Officer promptly after filing or execution per (c).

(iii) During the term of the contract, should the NIAMS find that the Contractor's IP management is inconsistent with the goals set forth for the OAI in (b)(3)(i) of this clause, the NIAMS, at its sole discretion, can prospectively revoke the Contractor's blanket greater rights granted under (b)(2) thus claiming right and title to all future Subject Inventions made under the contract and/or terminate the contract. Upon termination of blanket greater rights granted under (b)(2), the Contractor must request future greater rights to any subsequent inventions on a case-by-case basis.

(iv) The Contractor will be granted 90 days to correct deficiencies in its IP management prior to NIAMS exercising its rights in (b)(3)(iii).

(c) IP disclosure by Contractor.

(1) The Contractor will provide copies of all patent or other IP applications, licenses, invention administration agreements, sponsored research agreements or other documents relating to the administration of IP to the NIAMS Contracting Officer within thirty (30) days after filing or execution.

(2) The Contractor will submit a written report forty-five (45) days prior to each review by the NIAMS Project Officer. The report will contain:

(a) An update on all patent or other IP applications, licenses, invention administration agreements, sponsored research agreements or other IP issues. This update should include prosecution status of IP applications, technology development milestones achieved by licensees and any other appropriate reporting relating to IP.

(b) A summary of non-patented technology created and the effectiveness of the Contractor's dissemination of the technology to the scientific community.

(c) The effectiveness of Contractor's data release, data management and availability of data to the scientific community.

(d) Contractor Action to Protect the Government's Interest.

(1) The Contractor agrees to

(i) manage IP in accordance with the IP strategy approved by the NIAMS per (b)(3), and
(ii) to report all IP in accordance with (c), and
(iii) to establish or confirm the rights the Government has throughout the world in Subject Inventions pursuant to paragraph (b)(1), and

(iv) to assist the Government in obtaining patent protection throughout the world to Subject Inventions which the Government elects title to under paragraph (b)(3)(iii) of this clause.

(2) The Contractor agrees to require, by written agreement, its employees, other than clerical and non-technical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor each Subject Invention made under contract in order that the Contractor can comply with the IP management disclosure provisions of paragraph (c), above, and to execute all papers necessary to file patent applications on Subject Inventions when appropriate. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1), above. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) The Contractor will notify the Federal agency of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response period required by the relevant patent office.

(4) The Contractor agrees to include, within the specification of any United States patent application and any patent issuing thereon covering a Subject Invention, in which it has been granted greater rights, the following statement, "This invention was made with Government support under (identify the contract) awarded by National Institute of Arthritis and Musculoskeletal and Skin Diseases of the National Institutes of Health. The Government has certain rights in the invention."

(5) The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all Subject Inventions or stating that there were none.

(e) Subcontracts

(1) The Contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for the OAI contracts.

(2) In the case of subcontracts, at any tier, the NCI, subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Federal agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (g) of this clause.

(f) Preference for United States industry

Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grantto any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(g) March-in rights.

The Contractor agrees that, with respect to any Subject Invention in which it has acquired title, the Federal agency has the right in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of the agency to require the Contractor, an assignee or exclusive licensee of a Subject Invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the Contractor, assignee, or exclusive licensee refuses such a request the Federal agency has the right to grant such a license itself if the Federal agency determines that--

(1) Such action is necessary because the Contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the Subject Invention in such field of use;
(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Contractor, assignee, or their licensees;
(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the Contractor, assignee, or licensees; or
(4) Such action is necessary because the agreement required by paragraph (f) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any Subject Invention in the United States is in breach of such agreement.

(h) Communications

All invention disclosures and requests for greater rights shall be sent to the NIAMS Contracting Officer at:

Contracts Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institutes of Health
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
Bethesda, MD 20892-6500

2. **FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS** (MAY 2001)

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

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

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

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

(c) (1) The following clauses shall be flowed down to subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(ii) 52.222-26, Equal Opportunity (FEB 1999) (E.O. 11246).
(iii) 52.222-35, Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (APR 1998) (38 U.S.C. 4212(a)).
(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
(v) 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

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

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

1. Packaging and Delivery of Proposal, September 1997, 1 page.
2. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1[4], May 1997, 4 pages.
3. Annual Technical Progress Report Format for Each Study[1] , July 1994, 1 page.
4. Protection of Human Subjects Assurance Identification/Certification/Declaration, Optional Form 310[7], January 1995, 1 page.
5. Privacy Act System of Records, # Number 09-25-0200,[4] 18 pages.
6. Subcontract Plan Format[2] or [3], October 2000, 8 pages.
7. Safety and Health , HHSAR Clause 352.223-70[4], January 2001, 1 page.
8. Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)[4], April 1984, 1 page.
9. Research Patient Care Costs, NIH(RC)-11, April 1984, 1 page.
10. Disclosure of Lobbying Activities, OMB Form SF-LLL[2], December 1989, 3 pages.
11. Proposal Summary and Data Record, NIH-2043 (Rev. 6/82)[2], June. 1982, 2 pages.
12. Contact Points[2], July 1991, 1 page.
13. Technical Proposal Cost Information[1], December 1988, 1 page.
14. Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours[2], September 1992, 2 pages.
15. Summary of Related Activities[1], March 1984, 1 page.
16. Proposal Intent Response Sheet[6], March 1984, 1 page.
17. Government Notice for Handling Proposals[1], January 2001, 1 page.

Footnotes:

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

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following URL:

http://rcb.nci.nih.gov/forms/rcneg.pdf

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

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

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

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

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

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*.

A. The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

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

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

B. **"JUST IN TIME"**

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will not longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total

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

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

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

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

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in Section L.2.c.(1) of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. The information may also include submission and certification of cost or pricing data.

C. **NAICS CODE AND SIZE STANDARD**

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

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

(2) The small business size standard is 500.

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

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

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 0 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

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

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

E. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that 4-6 awards will be made from this solicitation and that the awards will be made on/about July 15, 2002.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type contract completion, with a term of 7 years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

F. ESTIMATE OF EFFORT

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

	% Effort	% Effort	% Effort	% Effort	% Effort	% Effort	% Effort
Personnel	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
PI	30%	30%	30%	30%	30%	30%	20%
RN Coord.	100%	250%	250%	250%	250%	250%	50%
Radiol. Tech.	25%	75%	75%	75%	75%	75%	25%
Recruitment/ Retention Coordinator	100%	100%	100%	100%	100%	100%	0%
Data Mngmt.	50%	100%	100%	100%	100%	100%	50%
Program Asst.	50%	100%	100%	100%	100%	100%	50%
MRI Tech.	20%	75%	75%	75%	75%	75%	20%
Phlebotomist	25%	25%	25%	25%	25%	25%	5%

G. COMMITMENT OF PUBLIC FUNDS

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

H. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

I. RELEASE OF INFORMATION

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

J. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

K. **PREPARATION COSTS**

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

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

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

Contracting Officer
Contracts Management Branch, EP
National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
BETHESDA MD 20892-6500

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

M. **LATE PROPOSALS AND REVISIONS**, **HHSAR 352.215-70**

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

2. INSTRUCTIONS TO OFFERORS

A. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

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

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

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

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL,

Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

(4) **Separation of Technical and Business Proposals**

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

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

(9) **Human Subjects**

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

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (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 Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS). 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 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The 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 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 an 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. (End of Clause) For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/

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

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

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

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. 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_profs_protect.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 the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

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

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 at the following web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html

A complete copy of the updated Guidelines is available at the following web site:

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

The revisions relate to NIH defined Phase III clinical trials and require: a) all proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all contractors to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

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

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

The format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of this RFP) shall be used in proposal preparation.

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

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are 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 exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. 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.

(13) **Privacy Act**

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

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

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

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

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

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

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

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

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

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

(14) **Selection of Offerors**

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

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

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

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

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

proposals for the purpose of establishing the competitive range.

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

While it is NIAMS's policy to conduct discussions with all offerors in the competitive range, NIAMS reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

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

(15) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment 6 to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

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

c) The offeror understands that:

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

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

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

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

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns 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.

d) Each plan must contain the following:

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

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

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

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

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

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

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

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

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

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

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror

shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

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

(16) **HUBZone Small Business Concerns**

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

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

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

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

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

http://www.sba.gov/size/NAICS-cover-page.html

The Department of Commerce website for the annual determination is:

http://www.arnet.gov/References/sdbadjustments.htm .

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

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

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

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

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

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

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

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

(19) **Salary Rate Limitation in Fiscal Year 2001***

Offerors are advised that pursuant to P.L. 106-554, no NIH Fiscal Year 2001 (October 1, 2000 - September 30, 2001) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 106-554 applies only to Fiscal Year 2001 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 106-554 states in pertinent part:

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

***This rate may change periodically. For your information, the rate can be found at:**
http://www.opm.gov/oca/01tables/execses/html/01execsc.htm

(20) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

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

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

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

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

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

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

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

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

from the NIH;

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

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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997). (Applies to Commercial organizations only).

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

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

B. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) **Technical Discussions**

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

a) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

-The specific items or expertise they will provide.

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

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

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

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (Section M.3. hereof).

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

(5) **Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (MB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems" and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

c. BUSINESS PROPOSAL INSTRUCTIONS

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

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

(2) **Proposal Cover Sheet**

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

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

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

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

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

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

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

1. **Direct Labor**

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

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

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

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

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

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

(End of provision)

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

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

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

(5) **Qualifications of the Offeror**

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

(1) **General Experience**

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

(2) **Organizational Experience Related to the RFP**

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

(3) **Performance History**

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

(4) **Pertinent Contracts**

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

(5) **Pertinent Grants**

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

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(6) **Other Administrative Data**

a) **Property**

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

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

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

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

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

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

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

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

c) **Financial Capacity**

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

d) **Incremental Funding**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

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

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

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

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

(End of Provision)

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

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

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

f) **Subcontractors**

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

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

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

g) **Proposer's Annual Financial Report**

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

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

h) **Representations and Certifications**

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

i. **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

In accordance with Title II, section 201 of the Federal Civilian Employee and Contractor Travel Expense Act of 1985 (Public Law 99-234), costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

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

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience), cost/price factors, site diversity, cost/price, plans for intellectual property rights, and Small Disadvantaged Business (SDB) participation. NIAMS intends to establish a geographically balanced program using this Request for Proposals (RFP). This is a multiple award RFP, and the Government will consider possible overlap and under-representation in making the award. Although technical factors are of paramount consideration in the award of the contract, site diversity, cost/price, intellectual property rights, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make awards to those offerors whose proposals provide 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 Request for Proposals (RFP). The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below. Offerors are advised to pay particular attention to providing the information requested in the "NOTES TO OFFERORS" in order to assist the reviewers in evaluating proposals.

If a proposal is received from a foreign organization or involves a foreign component, the peer review group will address the need or appropriateness of accomplishing the work outside the United States.

The estimated cost of an offer must be reasonable for the tasks to be performed and, in accordance with FAR 15.305, will be subject to a cost realism analysis by the Government.

All technical proposals will undergo evaluation by a peer-review group also known as the Source Evaluation Panel (SEP). The final stage of the evaluation is the establishment of an ORDER OF MERIT RANKING in which all competing proposals are ranked on the basis of their respective relevance and scientific merit evaluations. Subsequent awards depend upon the availability of funds, scientific priority, and program balance that the NIAMS determines to exist at the time of the award selection.

2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

(a) Protection of Human Subjects from Research Risks

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

If concerns are identified and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions and in your Final Proposal Revision (FPR). If, after discussions, concerns still exist, your proposal may not be considered further for award.

(b) Women and Minorities

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for Phase III clinical trials, it is required that all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable, unless the

Government has specified in the Statement of Work that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups.

Where the offeror determines that 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 will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss, clarify, or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

(c) **Children**

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

The offeror's proposal must include a description of plans for including children. If children will be excluded from the research, the proposal must present an acceptable justification for the exclusion. If the offeror determines that exclusion of a specific age range of child is appropriate, the proposal must also address the rationale for such exclusion.

If the information about the inclusion of children is absent or considered inadequate and you are included in the competitive range, you will be afforded the opportunity to further discuss, clarify or modify your plan for inclusion in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

3. **TECHNICAL EVALUATION CRITERIA**

Proposals shall be evaluated in accordance with the following technical evaluation criteria, which are weighted in the order of their relative importance, with a maximum total score of 100 points.

A. PERSONNEL - WEIGHT (30%)

1) **Personnel - Weight (40%)**

Clinical Center Staff Medical and support staff with expertise in large clinical cohorts, evaluation and diagnosis of Osteoarthritis (OA), data collection and management. Demonstrated experience in recruitment and retention of subjects for long term clinical studies and studies of similar complexity. The offeror can either provide such expertise on site or negotiate expertise in the form of a collaborative agreement with an outside consultant	25%
Principal Investigator & Project Director Experience and expertise in clinical research in osteoarthritis; clinical management of OA; demonstrated understanding of and experience with clinical and radiographic criteria for the diagnosis of OA; demonstrated expertise with the design, development, and implementation of clinical cohort studies in arthritis or studies of similar complexity; administration and interpretation of outcomes measures; and experience managing large clinical cohorts	15%

2) **Technical Approach - Weight (35%)**

Adequacy of the proposed methods of coordination, monitoring, and management of all activities required by the study protocol, including procedures, coordination of data collection, collection of specimens, and specialized tests	20%
Suitability of the proposed plan for data collection sample data management and data analysis	10%
Adequacy and feasibility facility to develop and carry out the protocol and methods to meet the objectives of the RFP	05%

3) **Institutional Experience and Facilities - Weight (25%)**

Availability and adequacy of the facilities and resources necessary for conducting study, including radiological facilities, suitable space available for dedicated magnetic resonance unit and clinics, capabilities for data management and analysis, including computer hardware, software, and other equipment in order to successfully implement the requirements of the contract	15%
Adequacy of the organizational and administrative structure of the proposed program and institutional commitment to the program	10%
Total	**100%**

4. **Site Diversity**

The proposal must specify which target population is proposed to be studied, and the proportion of individuals from minority groups proposed to be recruited. **Offerors may submit separate proposals for one or both of the following options:** they may propose to enroll a population comprising 60% or more of individuals from minority groups (Pool 1); or they may propose to enroll a population comprising less than 60% of individuals from minority groups (Pool 2). A separate score shall be given for proposals in each of these pools. Proposals will be ranked by technical merit in each of these pools. The number of awards made in each pool will be determined with the objective of achieving an overall study population in which minority individuals will be represented in proportions no less than those found in the U.S. population over the age of 50.

5. **Plan Addressing Intellectual Property Rights**

To ensure unrestricted availability of the data, radiologic images, DNA, and biospecimens collected and preserved by the awardee, NIH expects to make a Determination of Exceptional Circumstances (DEC) pursuant to 37 C.F.R. 401.3(a)(2) which will cover these deliverables. The purpose of the DEC is to eliminate the potential for patents on the collections of information and biospecimens, as this would undermine the wide availability of the national resource that is the fundamental purpose of this RFP.

With regard to patentable research results, such as new instrumentation, methodologies, software or data systems, NIH requires applicants who respond to this RFP to develop and propose a plan addressing if, and how, they will exercise their intellectual property rights while making available to the broader scientific community research resources produced in this project. This is expected to include an elaboration of the applicant's anticipated plans to generate, or not generate, patents and/or exclusive or nonexclusive licensing of patentable subject matter funded under this RFP. This plan is also expected to include disclosure of any pre-existing intellectual property rights, including options to for-profit research sponsors, that are associated with any of the work that would be funded under this RFP.

The Government will evaluate the proposed plan in determining whether the contract will be awarded. The plan as approved, after negotiation with the applicant when necessary, will be a condition of the award. Adherence to the proposed plan will by the applicant will be reviewed by the Government on a continual basis during contract performance.

6. **Past Performance Evaluation**

Past performance is not an evaluation criterion but it will be considered when determining contractor responsibility using the information required by the "Qualifications of the Offeror" portion of Section L of the solicitation.

7. **Extent of Small Disadvantaged Business Participation**

SDB participation will not be reviewed or scored by SEP, 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 order of merit ranking. 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 subfactors:

(a) The extent to which SDB concerns are specifically identified;
(b) The extent of commitment to use SDB concerns;
(c) The complexity and variety of the work SDB concerns are to perform;
(d) The realism of the proposal;
(e) The past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation; and
(f) The extent of participation of SDB concerns in terms of the value of the total acquisition.

PACKAGING AND DELIVERY OF THE PROPOSAL

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

EXTERNAL PACKAGE MARKING

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

"RFP NO. NIH-NIAMS-BAA-02-03 .

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

NUMBER OF COPIES

A.	TECHNICAL PROPOSAL	ORIGINAL* AND 10 COPIES
B.	BUSINESS PROPOSAL	ORIGINAL* AND 4 COPIES

Proposals shall be delivered to:

If hand-delivered or delivery service

Contracts Management Branch, EP
National Institute of Arthritis and
Musculoskeletal and Skin Diseases, NIH
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
BETHESDA MD 20892-6500

If using U.S. Postal Service

Contracts Management Branch, EP
National Institute of Arthritis and
Musculoskeletal and Skin Diseases, NIH
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
BETHESDA MD 20892-6500

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

NOTE: 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."

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS, NIH(RC)-1

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) **Amount Billed for Current Period** — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.

(j) **Cumulative Amount from Inception** — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

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

(l) **Direct Labor** — Include salaries and wages paid (or accrued) for direct performance of the contract.

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

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

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

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

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.

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

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

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

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

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

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

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

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

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

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

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

(q) **Grand Totals**

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

SAMPLE INVOICE/FINANCING REQUEST

(a) Billing Office Name and Address

NATIONAL INSTITUTES OF HEALTH
National Institute of Arthritis and
Musculoskeletal and Skin Diseases
Contracts Management Branch, EP
45 Center Drive, Room 5AS13A-MSC 6500
Bethesda, MD 20892-6500

(b) Invoice/Financing Request No. _____

(c) Date Invoice Prepared _____

(d) Contract No. and Effective Date _____

(e) Payee's Name and Address

ABC CORPORATION
100 Main Street
Anywhere, U.S.A. zip code

(f) Total Estimated Cost of Contract _____

(g) Total Fixed Fee _____

Attention: Name, Title, and Phone Number of Official to Whom Payment is Sent

(h) This invoice/financing request represents reimbursable costs from Aug. l, 1982 through Aug. 31, 1982

		(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception
(k)	Direct Costs		
(l)	Direct Labor	$ 3,400	$ 6,800
(2)	Fringe Benefits	600	1,200
(3)	Accountable Personal Property (Attach Form HHS-565)		
	Permanent Research	3,000	6,000
	General Purpose	2,000	2,000
(4)	Materials and Supplies	2,000	4,000
(5)	Premium Pay	100	150
(6)	Consultant Fee-Dr. Jones 1 day @ 100 (COA #3)	100	100
(7)	Travel (Domestic)	200	200
	(Foreign)	200	200
(8)	Subcontract Costs	-0-	-0-
(9)	Other	-0-	-0-
	Total Direct Costs	$11,600	$20,650
(l)	Cost of Money (Factor) of (Appropriate Base)	2,400	3,600
(m)	Indirect Costs -- Overhead		
	_____% of Direct Labor or Other Base (Formula)	4,000	6,000
(n)	Fixed-Fee Earned (Formula)	700	1,400
(o)	Total Amount Claimed	$18,700	$31,650
(p)	Adjustments		
	Outstanding Suspensions		(1,700)
(q)	Grand Totals	$18,700	$29,950

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

_____ _____
Name of Official) (Title)

ANNUAL TECHNICAL PROGRESS REPORT FORMAT FOR EACH STUDY

Study Title:
Date:

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

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

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

PROTECTION OF HUMAN SUBJECTS ASSURANCE IDENTIFICATION/CERTIFICATION/DECLARATION

OPTIONAL FORM 310, January 1995

This form can be accessed through the following URL: http://amb.nci.nih.gov/reference/amblinks.htm

This page includes Reference Materials and Contracting Links. This form can be accessed by clicking on "Forms." It is included on a page with a list of multiple forms. Click on the form entitled "Protection of Human Subjects Assurance Identification/Certification/Declaration, OF-310."

PRIVACY ACT SYSTEM OF RECORDS

Federal Register: April 7, 1997 (Volume 62, Number 66)
Notices, Pages 16596-16602

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Privacy Act of 1974; New System of Records
agency: National Institutes of Health, HHS.
action: Notification of a new system of records.

Summary: In accordance with the requirements of the Privacy Act, the National Institutes of Health (NIH) is publishing a notice of a new system of records, 09-25-0200, ``Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD." This system notice serves as an umbrella system for most NIH clinical, epidemiologic and biometric research studies. Thirty-eight existing NIH system notices were subsumed under this notice (listed in the system notice under System Manager(s)), to reduce the number and avoid future proliferation of like system notices. We are also proposing routine uses for this new system; with two exceptions, these routine uses were already contained in the preceding system notices. The first new routine use will allow disclosure to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions. The purpose of the disclosure is to plan for or provide such services, bill or collect third-party reimbursements. The second new routine use will allow disclosure for the purpose of reporting child, elder, or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

Dates: NIH invites interested parties to submit comments on the proposed internal and routine uses on or before May 7, 1997. NIH has sent a report of a New System to the Congress and to the Office of Management and Budget (OMB) on November 6, 1996. This system of records will be effective 40 days from the date of publication unless NIH receives comments on the routine uses which would result in a contrary determination.

Address: Please submit comments to: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301-496-2832.

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday. for further information contact: NIH Privacy Act Officer, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075, 301-496-2832.

The numbers listed above are not toll free.

Supplementary information: The National Institutes of Health (NIH) proposes to establish a new system of records: 09-25-0200, ``Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD." This umbrella system of records will be used by NIH staff to document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities. This inclusive system notice will achieve agency administrative efficiencies, avoiding confusion created by the current fragmented pool of Institute, Center and Division (ICD) system notices. Because of its unique organizational structure, NIH has, over the recent decades, experienced a proliferation of almost identical system notices that differ only by disease/disorder under study or ICD interest. This system notice subsumes thirty-eight existing system notices and will offer coverage for research not currently covered by an appropriate system notice. The consolidation of similar research systems of records into one generic-type notice will also serve the public interest. It will alleviate burden on the public associated with multiple attempts at notification, access and correction of record information when individuals are not sure which research system notice applied to their study participation.

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

educators and trainers (including curriculum vitae); and associated correspondence. The amount of information recorded on each individual will be only that which is necessary to accomplish the purpose of the system.

The records in this system will be maintained in a secure manner compatible with their content and use. NIH and contractor staff will be required to adhere to the provisions of the Privacy Act and the HHS Privacy Act Regulations. The System Manager will control access to the data. Only authorized users whose official duties require the use of such information will have regular access to the records in this system. Authorized users are HHS employees, and contractors responsible for implementing the research.

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. Manual and computerized records will be maintained in accordance with the standards of Chapter 45-13 of the HHS General Administration Manual, ``Safeguarding Records Contained in Systems of Records,'' supplementary Chapter PHS hf:45-13, the Department's Automated Information System Security Program Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).Data on computer files is accessed by keyword known only to authorized users. Access to information is thus limited to those with a need to know. Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Researchers authorized to conduct research on biological specimens will typically access to the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual. All authorized users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Depending upon the sensitivity of the information in the record, additional safeguard measures are employed.

The routine uses proposed for this system are compatible with the stated purposes of the system. The first routine use permits disclosure of a record for an authorized research purpose under specified conditions. The second routine use permitting disclosure to a congressional office is proposed to allow subject individuals to obtain assistance from their representatives in Congress, should they so desire. Such disclosure would be made only pursuant to a request of the individual. The third routine use allows disclosure to the Department of Justice for use in litigation. The fourth routine use allows disclosure of records to contractor, grantee, experts, consultants or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. The fifth routine use allows disclosure to certain relevant third parties (e.g., relatives, prior employees, Motor Vehicle Administration, State vita statistics offices) when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. The sixth routine use allows disclosure to tumor registries for maintenance of health statistics. The seventh routine use allows the PHS to inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, or to disclose such information to State or local public health departments under specified circumstances. The eighth routine use allows disclosure of certain diseases and conditions, including infectious diseases, to appropriate representatives of State or Federal Government as required by State or Federal law. The ninth routine use allows records to be disclosed to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements. The tenth routine use allows disclosure to organizations deemed qualified by the Secretary, DHHS, to carry out quality assessment, medical audits or utilization reviews. The eleventh routine use allows information to be disclosed for the purpose of reporting child, elder or spousal abuse or neglect, or any other type of abuse or neglect as required by State or Federal law.

The following notice is written in the present, rather than future tense, in order to avoid the unnecessary expenditure of public funds to republish the notice after the system has become effective.

Dated: October 30, 1996.

Anthony L. Itteilag,
Deputy Director for Management, National Institutes of Health.

09-25-0200

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

SECURITY CLASSIFICATION:None.

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

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

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

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

PURPOSE(S)
To document, track, monitor and evaluate NIH clinical, epidemiologic and biometric research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

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

opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

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

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

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

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social Security numbers, date of birth and other identifiers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social Security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

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

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

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

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

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

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

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING,

AND DISPOSING OF RECORDS IN THE SYSTEM:

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

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

SAFEGUARDS:
1. Authorized Users: Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.

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

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

4. Implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 of the HHS General Administration Manual and Part 6, ``ADP System Security'' of the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL:
Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1--``Keeping and Destroying Records'' (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. William A. White Clinical Research Program medical records (Saint Elizabeths Hospital, NIMH) are retained for 5 years after last discharge or upon death of a patient and then transferred to the Washington National Records Center, where they are retained until 30 years after discharge or death. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions.

SYSTEM MANAGER(S) AND ADDRESS:
See Appendix I for a listing of current system managers. This system is for use by all NIH Institutes, Centers, and Divisions. The following system notices have been subsumed under this umbrella system notice.

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

09-25-0010 Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI
09-25-0015 Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS
09-25-0016 Clinical Research: Collaborative Perinatal Project, HHS/NIH/NINDS
09-25-0026 Clinical Research: Nervous System Studies, HHS/NIH/NINDS
09-25-0028 Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD
09-25-0031 Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS
09-25-0037 Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA
09-25-0038 Clinical Research: Patient Data, HHS/NIH/NIDDK
09-25-0039 Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK
09-25-0040 Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK
09-25-0042 Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR
09-25-0044 Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR
09-25-0046 Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID
09-25-0053 Clinical Research: Vision Studies, HHS/NIH/NEI
09-25-0057 Clinical Research: Burkitt's Lymphonma Registry, HHS/NIH/NCI
09-25-0060 Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI
09-25-0067 Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI
09-25-0069 NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI
09-25-0074 Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI
09-25-0077 Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI
09-25-0126 Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI
09-25-0128 Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS
09-25-0129 Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD
09-25-0130 Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI
09-25-0134 Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS
09-25-0142 Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA
09-25-0143 Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID
09-25-0145 Clinical Trials and Epidemiological Studies Dealing with

Visual Disease and Disorders in the National Eye Institute, HHS/NIH/NEI
09-25-0148 Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD
09-25-0152 Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR
09-25-0153 Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD
09-25-0154 Biomedical Research: Records of Subjects: 1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and 2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD
09-25-0170 Diabetes Control and Complications Trial (DCCT) Data System, HHS/NIH/NIDDK
09-25-0172 Clinical Research: National Center for Human Genome Research, HHS/NIH/NCHGR
09-25-0201 Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH
09-25-0205 Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH
09-25-0212 Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH

NOTIFICATION PROCEDURE:
To determine if a record exists, write to the appropriate ICD Privacy Act Coordinator listed below. In cases where the requestor knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: Individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requestor must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the requestor is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to designate, in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship.

If the requester does not know which Institute, Center or Division Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address: NIH Privacy Act Officer, Office of Management Assessment, Building 31, Room 1B05, 31 Center Drive MSC 2075, Bethesda, MD 20892-2075.

NIH Privacy Act Coordinators

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

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

National Eye Institute (NEI)
Privacy Act Coordinator, NEI, NIH
Building 31, Room 6A-19
31 Center Drive
Bethesda, MD 20892

National Heart, Lung and Blood Institute (NHLBI)
Privacy Act Coordinator, NHLBI, NIH
Building 31, Room 5A08
31 Center Drive
Bethesda, MD 20892

National Institute on Aging (NIA)
Privacy Act Coordinator, NIA, NIH
Building 31, Room 2C12
31 Center Drive
Bethesda, MD 20892

National Institute on Alcohol Abuse and Alcoholism (NIAAA)
Privacy Act Coordinator, NIAAA, NIH
Wilco Building, Suite
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

National Institute of Allergy and Infectious Diseases (NIAID)
Privacy Act Coordinator, NIAID, NIH
Solar Building, Room 3C-23
6003 Executive Blvd.
Bethesda, MD 20892

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
Privacy Act Coordinator, NIAMS, NIH
Natcher Building, Room 5QS49
45 Center Drive
Bethesda, MD 20892

National Institute of Child Health and Human Development (NICHD)
Privacy Act Coordinator, NICHD, NIH
6100 Executive Blvd., Room 5D01
North Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders

NIDCD)
Privacy Act Coordinator, NIDCD, NIH
Building 31, Room 3C02
9000 Rockville Pike
Bethesda, MD 20892

National Institute of Dental Research (NIDR)
Privacy Act Coordinator, NIDR, NIH
Building 31, Room 2C-35
31 Center Drive, MSC 2290
Bethesda, MD 20892-2290

National Institute of Diabetes and Digestive and Kidney Disease
NIDDK)
Privacy Act Coordinator, NIDDK, NIH
Building 31, Room 9A47
31 Center Drive
Bethesda, MD 20892

National Institute on Drug Abuse (NIDA)
Privacy Act Coordinator, NIDA, NIH
Parklawn Building, Room 10A-42
5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Environmental Health Sciences (NIEHS)
Chief, Epidemiology Branch, NIEHS, NIH
P.O. Box 12233
Research Triangle Park
North Carolina 27709

National Institute of Mental Health (NIMH)
Privacy Act Coordinator, NIMH, NIH
Parklawn Building, Room 7C-22
5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Neurological Disorders and Stroke (NINDS)
Privacy Act Coordinator, NINDS, NIH
Federal Building, Room 816
7550 Wisconsin Avenue
Bethesda, MD 20892

National Center for Human Genome Research (NCHGR)
Chief, Office of Human Genome Communications, NGHGR, NIH
Building 38A, Room 617
9000 Rockville Pike
Bethesda, Maryland 20892

RECORD ACCESS PROCEDURE:
Same as notification procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:
Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify

the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:
The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: Referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT: None.

Appendix I: System Managers and Addresses

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

National Cancer Institute
Computer Systems Analyst, DCBD, NCI, NIH
Executive Plaza North, Room 344
Bethesda, MD 20892

American Burkitt's Lymphoma Registry
Division of Cancer Etiology, NCI, NIH
Executive Plaza North, Suite 434
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Genetic Epidemiology Branch, EBP, DCE, NCI, NIH
Executive Plaza North, Suite 439
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Clinical Genetics Section
Clinical Epidemiology Branch, DCE, NCI, NIH
Executive Plaza North, Suite 400
6130 Executive Blvd.
Bethesda, MD 20892

Program Director, Research Resources
Biological Carcinogenesis Branch, DCE, NCI, NIH
Executive Plaza North, Room 540
6130 Executive Blvd.
Bethesda, MD 20892

Chief, Environmental Epidemiology Branch, DCE, NCI, NIH
Executive Plaza North, Room 443
6130 Executive Blvd.
Bethesda, MD 20892

Associate Director, Surveillance Program, DCPC, NCI, NIH
Executive Plaza North, Room 343K
6130 Executive Blvd.
Bethesda, MD 20892

Head, Biostatistics and Data Management Section, DCT, NCI, NIH
8601 Old Georgetown Road
Bethesda, MD 20892

Chief, Clinical Research Branch
Biological Response Modifiers Program
Frederick Cancer Research and Development Center, DCT, NCI, NIH
501 W. 7th Street, Suite #3
Frederick, MD 21701

Deputy Branch Chief, Navy Hospital

NCI--Naval Medical Oncology Branch, DCT, NCI, NIH
Building 8, Room 5101
Bethesda, MD 20814

Chief, Pharmaceutical Management Branch
Cancer Therapy Evaluation Program, DCT, NCI, NIH
Executive Plaza North, Suite 804
Bethesda, MD 20892

Director, Extramural Clinical Studies, BRB, BRMP, DCT, NCI, NIH
Frederick Cancer Research and Development Center
Fort Detrick
Frederick, MD 21701

National Eye Institute
Clinical Director, NEI, NIH
Building 10, Room 10N-202
10 Center Drive
Bethesda, MD 20892

Director, Division of Biometry and Epidemiology, NEI, NIH
Building 31, Room 6A-52
31 Center Drive
Bethesda, MD 20892
National Heart Lung and Blood Institute
Administrative Officer, Division of Intramural Research, NHLBI, NIH
Building 10 Room 7N220
10 Center Drive, MSC 1670
Bethesda, MD 20892-1670

Senior Scientific Advisor, OD
Division of Epidemiology and Clinical Applications, NHLBI, NIH
Federal Building, 220
7550 Wisconsin Avenue
Bethesda, MD 20892

National Institute on Aging
Computer Scientist, Longitudinal Studies Branch, IRP, NIH
Gerontology Research Center, GRC
4940 Eastern Avenue
Baltimore, MD 21224

Associate Director, Epidemiology,
Demography and Biometry Program, NIA, NIH
Gateway Building, Suite 3C309
7201 Wisconsin Avenue
Bethesda, MD 20892

National Institute on Alcohol Abuse and Alcoholism
Deputy Director, Division of Biometry and Epidemiology, NIAAA, NIH
Willco Building, Suite 514
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

Deputy Director, Div. of Clinical and Prevention Res., NIAAA, NIH
Willco Building, Suite 505
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

National Institute of Allergy and Infectious Diseases
Chief, Respiratory Viruses Section, LID, NIAID, NIH
Building 7, Room 106
9000 Rockville Pike
Bethesda, MD 20892

Chief, Hepatitis Virus Section, LID, NIAID, NIH
Building 7, Room 202
9000 Rockville Pike
Bethesda, MD 20892

Chief, Epidemology and Biometry Branch, DMID, NIAID, NIH
Solar Building, Room 3A24
Bethesda, Maryland 20892

Special Assistant, Clinical Research Program, DAIDS, NIAID, NIH
Solar Building, Room 2C-20
6003 Executive Blvd.
Bethesda, MD 20892

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Clinical Director, NIAMS, NIH
Building 10, Room 9S205
10 Center Drive
Bethesda, MD 20892

National Institute of Child Health and Human Development
Chief, Contracts Management Branch, NICHD, NIH
Executive Plaza North, Room 7A07
6100 Executive Blvd.
North Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders
Acting Director of Intramural Research, NIDCD, NIH
Building 31, Room 3C02
31 Center Drive
Bethesda, MD 20892

Director, Division of Human Communication, NIDCD, NIH
Executive Plaza South, Room 400B
6120 Executive Boulevard
Rockville, MD 20852

National Institute of Dental Research

Deputy Clinical Director, NIDR, NIH
Building 10, Room 1N-113
0 Center Drive, MSC 1190
Bethesda, MD 20892-1190

Research Psychologist, Clinical Invsetigations, NIDR, NIH
Building 10, Room 1N114
10 Center Drive, MSC 1190
Bethesda, MD 20892-1190

Chief, Contract Management Section
Extramural Program, NIDR, NIH
Natcher Building, Room 4AN-44B
45 Center Drive, MSC 6402
Bethesda, MD 20892-6402

National Institute of Diabetes and Digestive and Kidney Diseases
Chief, Clinical Investigations, NIDDK, NIH
Building 10, Room 9N222
10 Center Drive
Bethesda, MD 20892

Chief, Phoenix Clinical Research Section, NIDDK, NIH
Phoenix Area Indian Hospital, Room 541
4212 North 16th Street
Phoenix, Arizona 85016

Chief, Diabetes Research Section, DPB, DDEMD, NIDDK, NIH
Natcher Building, Room 5AN-18G
45 Center Drive, MSC 6600
Bethesda, MD 20892

National Institute on Drug Abuse
Privacy Act Coordinator, NIDA, NIH
Parklawn Building, Room 10A-42
5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Environmental Health Sciences
Chief, Epidemiology Branch, NIEHS, NIH
P.O. Box 12233
Research Triangle Park
North Carolina 27709

National Institute of Mental Health
Director, Intramural Research Program, NIMH, NIH
Building 10, Room 4N-224
9000 Rockville Pike
Bethesda, MD 20205

Privacy Act Coordinator, NIMH, NIH
Parklawn Building, Room 7C22
5600 Fishers Lane
Rockville, Maryland 20857

Clinical Director, Neuroscience Research Center, DIRP, NIMH
Saint Elizabeths Hospital,
William A. White Building, Room 133
700 Martin Luther King Jr., Avenue, SE
Washington, DC 20032

National Institute of Neurological Disorders and Stroke
Chief, Epilepsy Branch, NINDS, NIH
Federal Building, Room 114
7750 Wisconsin Avenue
Bethesda, MD 20892

Chief, Development Neurology Branch, NINDS, NIH
Federal Building, NIH
7550 Wisconsin Avenue
Bethesda, MD 20892

Assistant Director, CNP, DIR, NINDS, NIH
Building 10, Room 5N226
10 Center Drive
Bethesda, MD 20892

Deputy Chief, Laboratory of Central Nervous Systems Studies
Intramural Research Program, NINDS, NIH
Building 36, Room 5B21,
9000 Rockville Pike
Bethesda, MD 20892

Director, Division of Fundamental Neurosciences, NINDS, NIH
Federal Building, Room 916
7550 Wisconsin Ave
Bethesda, MD 20892

Director, Division of Convulsive, Developmental and
Neuromuscular Disorders, NINDS, NIH
Federal Building, Room 816
7550 Wisconsin Avenue
Bethesda, MD 20892

Director, Division of Demyelinating Atrophic, and Dementing
Disorders, NINDS, NIH
Federal Building, Room 810
7550 Wisconsin Avenue
Bethesda, MD 20892

Director, Division of Stroke and Trauma, NINDS, NIH
Federal Building, Room 8A08
7550 Wisconsin Avenue
Bethesda, MD 20892

National Center for Human Genome Research
Chief, Office of Human Genome Communications, NCHGR, NIH
Building 38A, Room 617
9000 Rockville Pike
Bethesda, MD 20892

SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN:_____

CONTRACTOR: _____

ADDRESS: _____

_____

_____

DUNN & BRADSTREET NUMBER : _____

SOLICITATION OR CONTRACT NUMBER: _____

ITEM/SERVICE (Description): _____

TOTAL CONTRACT AMOUNT (Breakout Options): **$**_____ **$**_____

Base Year Option #1

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

Option #2 Option #3 Option #4

TOTAL MODIFICATION AMOUNT (If Applicable): _____

TOTAL TASK ORDER AMOUNT (If Applicable): _____

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

The following is a suggested model for use when developing subcontracting plans as required by P.L. 95-507 and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this model plan has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable; however, failure to include the essential information as exemplified in this model may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. Further, the use of this model is not intended to waive other requirements that may be applicable under statute or regulation. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

1. Type of Plan (Check One)

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

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

__ Commercial product/service plan (Contractor sells large quantities of off-the-shelf commodities to many Government agencies. Plans/goals negotiated on a company, division, plant or product line basis reflecting projected annual sales for commercial and non-commercial items. Must be renewed annually and Contractor must provide copy of lead agency approval).

2. Goals

State separate dollar and percentage goals for Small Business Concerns (SB), Small Disadvantaged Business Concerns (SDB), Women-Owned Small Business Concerns, (WOSB), Historically Underutilized business Zone (HUBZone), Veteran-Owned Small Business Concerns (VOSB), and Other than Small Business Concerns (OTHER) as subcontractors, for the base year and each option year, as specified in FAR 19.704 (Break out and append option year goals, if applicable) or project annual subcontracting base and goals under commercial plans.

a. Total estimated dollar value of **ALL** planned subcontracting, i.e., with ALL types of concerns under this contract, is $_____.

b. Total estimated dollar value and percent of planned subcontracting with **SMALL BUSINESS CONCERNS** (includes SDB, WOSB, and HUBZone): (% of "a")

$_____ and _____%

c. Total estimated dollar value and percent of planned subcontracting with **SMALL DISADVANTAGED BUSINESS CONCERNS**: (% of "a")

$_____ and _____%

d. Total estimated dollar value and percent of planned subcontracting with **WOMEN-OWNED SMALL BUSINESS CONCERNS**: (% of "a")

$_____ and _____%

e. Total estimated dollar value and percent of planned subcontracting with **HUBZone SMALL BUSINESS CONCERNS**: (% of "a")

$_____ and _____%

f. Total estimated dollar value and percent of planned subcontracting with **VETERAN-OWNED SMALL BUSINESS CONCERNS**: (% of "a")

$_____ and _____%

g. Total estimated dollar value and percent of planned subcontracting with **OTHER THAN SMALL BUSINESS CONCERNS**: (% of "a")

$_____ and _____%

h. Provide a description of ALL the products and/or services, to be subcontracted under this contract, and indicate the types of businesses supplying them: [i.e. (OTHER), (SB), (SDB), (WOSB), (HUBZone), (VOSB)].

	TYPE OF BUSINESS (Check all that Apply)					
Subcontracted Product/Service	**OTHER**	**SB**	**SDB**	**WOSB**	**HUBZone**	**VOSB**

i. Provide a description of the method used to develop the subcontracting goals for small, small disadvantaged, women-owned, HUBZone, and veteran-owned small business concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to small, small disadvantaged, women-owned, HUBZone, and veteran-owned small business concerns were determined and how the capabilities of these concerns were considered for subcontract opportunities. Identify any source lists or other resources used in the determination process.

(Attach additional sheets, if necessary)

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

k. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to small, small disadvantaged, and women-owned, HUBZone, and veteran-owned small business concerns.

3. Program Administrator

Name, title, and position within the corporate structure as well as duties and responsibilities of the employee who will administer the contractor's subcontracting program.

NAME: _____

TITLE: _____

ADDRESS: _____

_____

TELEPHONE/E-MAIL: _____

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

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to small, small disadvantaged, and women-owned, HUBZone and veteran-owned small business concerns; and for assuring that these concerns are included on the source lists for solicitations for products and services they are capable of providing;

b. Developing and maintaining bidders lists of small, small disadvantaged, women-owned, HUBZone and veteran-owned small business concerns from all possible sources.

c. Ensuring periodic rotation of potential subcontractors on bidder's lists.

d. Ensuring that requests for contracts (RFC) are designed to permit the maximum practicable participation of small, small disadvantaged, women-owned, HUBZone and veteran-owned small businesses;

e. Using various sources for the identification of small, small disadvantaged, and women-owned, HUBZone and veteran-owned small business concerns to include the SBA's PRONET System, the Federal Acquisition Computer Network (FACNET) Contractor Registration Data Base, the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce, and Federal agencys' Small Business Offices;

f Establishing and maintaining contract and subcontract award records;

g. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc.

h. Ensuring small, small disadvantaged, women-owned, HUBZone and veteran-owned small business concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company;

i. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Public Law 95-507 on purchasing;

j. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals;

k. Preparing, and submitting timely, required subcontract reports;

l. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies, and;

m. Other duties _____

4. Equitable Opportunity

Describe efforts the offeror will make to ensure that small, small disadvantaged, women-owned, HUBZone and veteran-owned small business concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

1) Contacting minority and small business trade associations;

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

3) Attending small, small disadvantaged, women-owned, HUBZone and veteran-owned small business procurement conferences and trade fairs;

4) Requesting sources from the Small Business Administration's (SBA) PRONET, and, and other SBA resources, and;

5) Conducting market surveys to identify new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1) Presenting workshops, seminars, and training programs;

2) Establishing, maintaining, and using small, small disadvantaged, women-owned, HUBZone and veteran-owned small business source lists, guides, and other data for soliciting subcontracts, and;

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

c. Additional efforts: _____

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns", in all subcontracts that offer further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $500,000 ($1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (FAR 19.704(a)(4)).

6. Reporting and Cooperation

The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) Submission of Standard Form (SF) 294, "Subcontracting Report for Individual Contracts," and SF-295, "Summary Subcontract Report," in accordance with the instructions on the forms; and (4) ensuring that subcontractors agree to submit Standard Forms 294 and 295.

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	SF-294	4/30
Apr 1 - Sep 30	SF-294	10/30
Oct 1 - Sep 30	SF-295	10/30

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

ADDRESSES

(a) SF-294 to be submitted to: cognizant Contracting Officer

(b) SF-295 to be submitted to cognizant Contracting Officer and to the following office:

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

(c) Submit "info" copy to SBA Commercial Market Representative (CMR); call SBA at (202) 205-6475 to locate CMR.

7. Recordkeeping

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

a. Small, small disadvantaged, women-owned, HUBZone and veteran-owned small business concerns source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate small, small disadvantaged, women-owned, HUBZone and veteran-owned small business sources;

c. On a contract-by-contract basis, records on all subcontract solicitations over $100,000, which indicate for each solicitation (1) whether small business concerns were solicited, and if not, why not; (2) whether small disadvantaged business concerns were solicited, if not, why not; (3) whether women-owned small business concerns were solicited, and if not, why not; (4) whether HUBZone small business concerns were solicited, and if not, why not; (5) whether veteran-owned small business concerns were solicited; and (6) the reason for the failure of solicited small, small disadvantaged, women-owned, and HUBZone small business concerns to receive the subcontract award;

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

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

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

g. Additional records:_____

SIGNATURE PAGE

THIS SUBCONTRACTING PLAN WAS SUBMITTED BY :

CONTRACTOR: _____

CONTRACTOR SIGNATURE: _____

TYPED NAME: _____

TITLE: _____

DATE PREPARED: _____

THIS PLAN (Check One): [ ] INDIVIDUAL [ ] MASTER [ ] COMMERCIAL

IS ACCEPTED BY:

FEDERAL AGENCY: _____

FEDERAL CONTRACTING OFFICER SIGNATURE: _____

TYPED NAME: _____

DATE: _____

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2001)

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

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

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

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

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

(End of clause)

PROCUREMENT OF CERTAIN EQUIPMENT

Notwithstanding any other clause in this contract, the Contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the Contracting Officer.

67 - Photographic Equipment
69 - Training Aids and Devices
70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045-ADP Supplies and Support Equipment.)
71 - Furniture
72 - Household and Commercial Furnishings and Appliances
74 - Office Machines and Visible Record Equipment
77 - Musical Instruments, Phonographs, and Home-type Radios
78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the Contractor and determined essential by the Contracting Officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

RESEARCH PATIENT CARE COSTS

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

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

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

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

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

DISCLOSURE OF LOBBYING ACTIVITIES
OMB Form SF LLL

This form can be accessed through the following URL: http://amb.nci.nih.gov/reference/amblinks.htm

This page includes Reference Materials and Contracting Links. This form can be accessed by clicking on "Forms." It is included on a page with a list of multiple forms. Click on the form entitled "Disclosure of Lobbying Activities, OMB Form SF-LLL."

Proposal Summary and Data Record
NIH-2043 (June 1982)

This form can be accessed through the following URL: http://amb.nci.nih.gov/reference/amblinks.htm

This page includes Reference Materials and Contracting Links. This form can be accessed by clicking on "Forms." It is included on a page with a list of multiple forms. Click on the form entitled "Proposal Summary and Data Record, NIH-2043."

CONTACT POINTS

Complete the following and return with the BUSINESS PROPOSAL.

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

_____ _____
Name Telephone Number

_____ _____
Institutional Title FAX Number

_____ _____
Institutional Office E-Mail Address

_____
Institution Name

_____
**Street Address

_____
City, State Zip Code

Name, Institutional Title and Address of Proposed Principal Investigator

_____ _____
Name Telephone Number

_____ _____
Institutional Title FAX Number

_____ _____
Institutional Division, etc. E-Mail Address

_____
**Street Address

_____
City, State Zip Code

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

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

TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS

DIRECT LABOR:

Labor Category (Title and Name-- use additional pages as necessary)	Year 1 (Hours)	Year 2 (Hours)	Year 3 (Hours)	Year 4 (Hours)	Year 5 (Hours)	Year 6 (Hours)	Year 7 (Hours)	Total
_____								
_____								
_____								
_____								
_____								
Total Hours	___	___	___	___	___	___	___	___
DIRECT LABOR COST:	$	$	$	$	$	$	$	$
MATERIAL COST:	$	$	$	$	$	$	$	$
TRAVEL COST:	$	$	$	$	$	$	$	$
OTHER (Specify)	$	$	$	$	$	$	$	$
OTHER (Specify)	$	$	$	$	$	$	$	$
TOTAL DIRECT COST:	$	$	$	$	$	$	$	$

Specific Instructions:

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

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

INSTRUCTIONS FOR USE OF THE FORMAT

1. Refer to Business Proposal Instructions, Section L of this solicitation. The Instructions contain the requirements for proper submission of cost/price data which must be adhered to.

2. This format has been prepared as a universal guideline for all solicitations issued by the Government. It may require amending to meet the specific requirements of this solicitation. For example, this solicitation may require the submission of cost/price data for three years listed on this form. (See Section L.1., General Information for the estimated duration of this project.) If this solicitation is phased, identify each phase in addition to each year. Total each year, phase, and sub-element.

3. This format must be used to submit the breakdown of all proposed estimated cost elements. List each cost element and sub-element for direct costs, indirect costs and fee, if applicable. In addition, provide detailed calculations for all items. For example:

   a. For all personnel, list the name, title, rate per hour and number of hours proposed. If a pool of personnel is proposed, list the composition of the pool and how the cost proposed was calculated. List the factor used for prorating Year One and the escalation rate applied between years.

      Offeror's proposal should be stated in the same terms as will be used to account for and record direct labor under a contract (i.e. percentage of effort is used for most faculty and professional employees at educational institutions). If percentages of effort are used, the basis to which such percentages are applied must also be submitted by the offeror. The attached format should be revised to accommodate direct labor proposed as a percentage of effort.

   b. For all materials, supplies, and other direct costs, list all unit prices, etc., to detail how the calculations were made.

   c. For all indirect costs, list the rates applied and the base the rate is applied to.

   d. For all travel, list the specifics for each trip.

   e. For any subcontract proposed, submit a separate breakdown format.

   f. Justification for the need of some cost elements may be listed as an attachment, i.e., special equipment, above average consultant fees, etc.

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

5. **It is requested that you use the ELECTRONIC SPREADSHEET (provided below) to prepare your business proposal in lieu of the hardcopy contained in this Attachment. It is in EXCEL format and has instructions for use and submission. It is anticipated that use of this form will help expedite the review and award process. This electronic cost and price spreadsheet can be accessed at the following URL:**

   http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls

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

   For security purposes, please include a hard copy of the completed spreadsheet and submit the electronic file on a diskette with your proposal. The NIAMS Contract Management Branch is currently not capable of decoding encrypted files.

RFP Number: _____
Organization: _____
Date: _____

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

COST ELEMENT		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Total
DIRECT LABOR:									
Labor Category (Title and Name-- use additional pages as necessary)	Rate	Hours Amt	Hours Amt	Hours Amt	Hours Amt	Hours Amt	Hours Amt	Hours Amt	Hours Amt
_____									
_____									
_____									
_____									
_____									
DIRECT LABOR COST:		$____	$____	$____	$____	$____	$____	$____	$____
MATERIAL COST:		$____	$____	$____	$____	$____	$____	$____	$____
TRAVEL COST:	$____	$____	$____	$____	$____	$____	$____	$____	
OTHER (Specify)		$____	$____	$____	$____	$____	$____	$____	$____
OTHER (Specify)		$____	$____	$____	$____	$____	$____	$____	$____
TOTAL DIRECT COST:		$____	$____	$____	$____	$____	$____	$____	$____
FRINGE BENEFIT COST: (if applicable) __% of Direct Labor Cost		$____	$____	$____	$____	$____	$____	$____	$____
INDIRECT COST: __% of Total Direct Cost		$____	$____	$____	$____	$____	$____	$____	$____
TOTAL COST:	$____	$____	$____	$____	$____	$____	$____	$____	
FEE: (if applicable) __% of Total Est. Cost	$____	$____	$____	$____	$____	$____	$____	$____	
GRAND TOTAL ESTIMATED COST (PLUS FIXED FEE)		$____	$____	$____	$____	$____	$____	$____	$____

SUMMARY OF RELATED ACTIVITIES

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

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

Professional's Name and Title/Position: _____

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

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

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

Professional's Name and Title/Position: _____

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

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

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

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

PROPOSAL INTENT RESPONSE SHEET

RFP No.NIH-NIAMS-BAA-02-01

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.

==========

Company/Institution: _____

Company/Institution Address: _____

Principal Investigator Name and Title: _____

_____

Telephone No. and Email Address: _____

Names of Collaborating Institutions and Investigators (including consultants and subcontractors):

_____

_____

_____

[ ] DO INTEND TO SUBMIT A PROPOSAL

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

_____

DATE: _____

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RETURN TO:

National Institutes of Health
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Attention: Eileen Webster-Cissel
Natcher Building, Room 5AS13A
45 Center Drive, MSC 6500
Bethesda, MD 20892-6500

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

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR 352.215-1.

(f) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(g) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)