

**Amendment #1**  
**RFP NIH-NIAMS-02-02**  
**DATA COORDINATING CENTER FOR THE OSTEOARTHRITIS INITIATIVE**

Amendment to Solicitation No.: [NIH-NIAMS-02-02](#)

Amendment No.: 1

Amendment Date: September 18, 2001

RFP Issue Date: August 8, 2001

Issued By: Chief 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, MD 20892-6500

Point of Contact: [Eileen Webster-Cissel](#)

Name and Address of Contractor: N/A

The above numbered solicitation is amended as set forth below.

The hour and the date specified for receipt of offers IS NOT EXTENDED. Offerors must acknowledge receipt of the amendment prior to the hour and the date specified in the solicitation or as amended, by one of the following methods:

1. By requesting a copy of the Standard Form 30 for this amendment and completing the information requested in items 8 and 15, and returning 1 copy of the amendment; (a hard copy of this amendment, including the Standard Form 30, may be requested from Ms. Eileen Webster-Cissel).
2. By acknowledging receipt of this amendment on each copy of the offer submitted; or
3. By separate letter, telegram, or Electronic Mail which includes a reference to the solicitation and amendment numbers.

**FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER.**

RFP NIH-NIAMS-02-02 is hereby amended as follows:

We have received several questions regarding the solicitation over the last few weeks. In order to allow us adequate time to answer future questions prior to the due date set for proposal submission, we hereby set a deadline for submission of questions by no later than **12:00 p.m., local time, October 15, 2001**. All questions must be submitted in writing to the Contracting Officer by the aforementioned date and time.

The following questions have arisen regarding this solicitation. Responses to the questions are provided below:

**Question 1.** Is a letter of intent required to submit a proposal, and if so when is it due?

**Answer 1.** Yes, we would like you to submit a Proposal Intent Response Sheet (Attachment 15). We did not set a deadline but will do so with this amendment #1. The deadline for Proposal Intent Notices is **October 22, 2001**.

**Question 2.** Should the Data Coordinating Center (DCC) budget for consultants in the area of biochemical markers of osteoarthritis (OA)? The only immediate objectives with respect to these markers in the scope of work is obtaining the subject samples, but the use of these samples will become an increasingly important issue in the study and the Resource Allocation Committee will not include individuals doing cartilage related research.

**Answer 2.** No, the DCC should not budget for consultants in the area of biochemical markers of OA. The Steering Committee, which will include experts in the area of cartilage related research, will be making recommendations to the Resource Allocation Committee regarding use of the resource.

**Question 3.** Should the DCC budget for expenses related to meetings, including meeting rooms, audiovisual rental, refreshments, etc., for the following?

**Answer 3.** Steering committee and its subcommittees - YES  
Observational Study Monitoring Board (OSMB) - NO, the Government will be responsible for this.  
Resource Allocation Committee - No, the Government will be responsible for this.  
Open public meetings for data users - Yes.

**Question 4.** Should the DCC budget for periodic conference calls for the following?

**Answer 4.** Steering committee and its subcommittees - Yes, this is often proposed as an alternative to face to face meetings.

OSMB - No

Resource Allocation Committee - No

**Question 5.** Should the DCC budget for travel expenses for DCC personnel to attend the open public meetings?

**Answer 5.** Yes, but only for the necessary staff.

**Question 6.** Should the clinic lab supply costs be centrally ordered and included in the DCC budget?

**Answer 6.** This is entirely up to the offeror. The more cost effective offerors are, the better.

**Question 7.** The RFP states that the DCC will: "18. Develop and maintain (with NIH) a public web site for the Osteoarthritis Initiative to facilitate data and image sharing with the broad scientific community." Is it intended that NIH (e.g., NLM) will host or cohost the public web site, and how will costs for maintaining the public site be covered or apportioned?

**Answer 7.** These costs should be included in the offeror's budget. We hope to encourage collaboration with other agencies, but this is not known at this time.

**Question 8.** The RFP states that the DCC will: "10. Establish information technology (IT) and bioinformatics cores, in order to: a. develop an IT architecture for data archiving, data sharing, and data distribution including trade studies of distributed versus centralized data management;..." The phrase "including trade studies of distributed versus centralized data management" is unclear. Is the DCC supposed to propose such studies as part of the proposed contract?

**Answer 8.** The DCC should not propose such studies as part of the contract. We anticipated that previous studies, evaluations, or experience would lead the offeror to propose either a distributed or a centralized data management system.

**Question 9.** Will the Clinical Centers enroll clinic patients with osteoarthritis? (Although this question deals primarily with the clinical centers, it does have impact on the entire project).

**Answer 9.** The Osteoarthritis Initiative (OAI) is intended to recruit a community based, rather than a clinic based population. This is NOT a clinical trial and does not include any treatment protocols. It is stated in the RFP that Clinical Centers will be expected to recruit individuals in the age range of 50-80 who are at "high risk" for OA. The sample inclusion criteria listed are

obesity, previous knee injury, and low grade knee pain. These are examples, only. Exclusion criteria have not yet been defined. The goal is to enroll some individuals with no symptomatic knee osteoarthritis and some with early to mid-stage disease (mild symptoms) in order to capture clinical data associated with knee osteoarthritis onset as well as early progression. This is a challenging goal. After the issuance of the contracts, the OAI Steering Committee will address the most appropriate inclusion and exclusion criteria to be implemented in the actual Manual of Operation Procedures.

**Question 10.** Are foreign organizations restricted from submitting proposals for this project?

**Answer 10.** Foreign organizations are not prohibited from submitting proposals in response to this solicitation. Section M of the RFP, paragraph 1, General, states that “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.”

**Question 11.** On page 9, Task 15.c., "develop appropriate methods of analysis and presentation for data collected during the course of the study including possible needs for interactions with supercomputer sites to facilitate data analysis." Please identify supercomputer sites other than NIH.

**Answer 11.** NIH has computational capabilities but does not have a super computer on campus. However, there are currently 2 NIH funded biomedical computational centers that do complex biomedical computations. These are the National Biomedical Computation Resource at University of California San Diego (Peter W. Arzberger, Ph.D., PI; [parzberger@sdsc.edu](mailto:parzberger@sdsc.edu)) and the High Performance Computing for Biomedical Research at Mellon Pittsburgh Corporation (Ralph Z. Roskies, Ph.D., PI; [roskies@psc.edu](mailto:roskies@psc.edu)). These centers support advanced computational infrastructure for biomedical researchers. They provide supercomputing facilities to the biomedical research community and bridge the gap between complex biomedical problems and the unique computing capabilities of supercomputers.

**Question 12.** On page 11, #4 NIH Project Officer. Please indicate whether the program officer will be in NIAMS or NIA.

**Answer 12.** The Project Officer for this contract will be in NIAMS.