Amendment #3
RFP NIH-NIAMS-02-03
CLINICAL CENTERS FOR THE OSTEOARTHRITIS INITIATIVE

Amendment to Solicitation No.:	NIH-NIAMS-02-03
Amendment No.:	3
Amendment Date:	October 16, 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 Telephone: (301) 594-2543 or Email: ew52c@nih.gov
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 From 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-02-03 is hereby amended as follows:

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

Question 1. Does "over the age of 50" actually mean 50 and above or 51 and above?

Answer 1. The “over the age of 50" is intended to capture the appropriate “at risk” population. It includes the age of 50 as written. The offeror can certainly justify including a younger population with other risk factors know to lead to disease during the study period. The purpose of this criteria is to capture a representative population of individuals who would be at high risk of developing Osteoarthritis (OA) or have sub-clinical OA.

Question 2. The Request for Proposals states that the Data Coordinating Center will have primary responsibility for data analysis yet the evaluation criteria lists capabilities for analysis and hardware, software, etc., as experience and facilities to be considered.

Answer 2. The data analysis referred to in Part IV, Representations and Instructions, Section M, Evaluation Factors for Award, Paragraph 3, Technical Evaluation Criteria, subparagraph (b) TECHNICAL APPROACH and the hardware and software referred to in subparagraph (c) INSTITUTIONAL EXPERIENCE AND FACILITIES, relate to that required for appropriate data collection, cleaning, quality assurance, and preliminary analysis prior to transmission of data to the Data Coordinating Center. The Clinical Centers will also be expected to have input into the final design of the study with respect to statistical analyses to be carried out.

Question 3. Will Clinical Centers have a complete dataset and have the opportunity to perform analyses themselves, requiring applicants to budget for statistical analysis costs (such as statistician salary support)? Or would the Data Coordinating Center perform all analyses for the Osteoarthritis Initiative sites, not requiring clinical centers to have these capabilities?

Answer 3. The Clinical Centers will have access to all the data (this will be a public data base) however, analyses will be discussed at the Steering Committee meetings and overall analyses will be carried out by the Data Coordinating Center. Each Clinical Center will have access to the data generated at that center and will be able to analyze the data as they see fit. However, costs for such specific analyses should be considered as ancillary to the Osteoarthritis Initiative and not included in the submitted budget.

Question 4. Should Clinical Centers budget for travel costs, including the training meetings for staff, or would some or all be expected to be covered by the Data Coordinating Center?

Answer 4. Yes, the Clinical Centers are expected to budget travel costs for staff attending meetings and any centralized training that will be required. Please refer to Part I, The Schedule, Section C, Description/Specifications/Work Statement, ARTICLE C.1., Paragraph D, STATEMENT OF WORK, subparagraph 4.a. In some cases, the Data Coordinating Center may provide on-site training for staff.

Question 5. Is it acceptable to use the 2 page PHS 398 style biosketch for Key Personnel resumes?

Answer 5. Yes. It is acceptable to use parts of the PHS 398, grant application form, for submission of proposal information. However, please be sure that the information included in the PHS 398 grant application form addresses all the requirements listed in the RFP, including the NOTES TO OFFERORS, Part I, The Schedule, Section C, Description/Specifications/Work Statement, ARTICLE C.1., STATEMENT OF WORK, and PART IV, SECTION L, Instructions, Conditions, and Notices to Offerors.

Question 6. Is it true that the Government has "preselected" groups to carry out this Initiative?

Answer 6. No, it is not true. The Government encourages all offerors with appropriate capabilities to submit proposals for this project. We welcome and encourage competition.

Question 7. Is it true that the protocol will be designed for this study prior to the award of the OA Initiative contracts?

Answer 7. No it is not true. After the contract awards are made, the Steering Committee will be responsible for the design of the protocol. 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.

Question 8. Could you clarify the statement in Amendment #1 regarding a dedicated Magnetic Resonance (MR) unit? More specifically, if an appropriate unit is already available at our institution or if we decide to rent time from a mobile unit, and we are able to secure some dedicated timeslots for study participants, does this meet the requirement for a dedicated machine or do we need a machine solely used by study participants?

Answer 8. We have requested that you provide a dedicated unit because the precise timing of the measurements and the specific issues related to quality assurance and comparability from clinical center to clinical center will put significant constraints on outside use. We use the word "dedicated" to indicate sole use by the OA Initiative study participants.

Question 9. If we do need a machine solely dedicated to this study, not just dedicated time on a MR machine, will the contractor bear the cost of this machine if our institution bears the cost of the space in which to house the machine?

Answer 9. If your institution cannot provide a dedicated MR unit for sole use by the study, you may include the cost related to purchase/lease of the MR unit in your budget. Costs for space to house the unit should also be included. If your institution will provide such a space at no cost, it would certainly be to your advantage.

Question 10. Will x-rays and MR images be read locally at each Clinical Center, or only centrally?

Answer 10. X-rays and MR images will be transmitted electronically to the Data Coordinating Center for central analysis by the radiology reading group of the Data Coordinating Center. You will most likely also keep copies at your center for local use but the costs associated with local use should not be included in the contract budget.