

SPECIALIZED CENTERS OF RESEARCH (SCORs) IN RHEUMATOID ARTHRITIS AND IN OSTEOPOROSIS

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National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Letter of Intent Receipt Date: September 16, 2002

Application Receipt Date: October 16, 2002

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for Specialized Centers of Research (SCORs) in osteoporosis or in rheumatoid arthritis. A SCOR should foster a coordinated research effort that strongly emphasizes basic disciplines, but also involves significant interaction between basic research and clinical investigations in one of these two disease areas. A SCOR is envisioned as a national resource associated with one or more major medical complexes and dedicated to working with the NIAMS in furthering the research effort to translate basic research to clinical application.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Specialized Centers of Research, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople/>.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. An established clinical and research program in the disease area should be present. Foreign organizations are not eligible.

International collaborations in domestic applications will only be accepted if the resources are clearly shown to be unavailable in the United States. Applications from racial/ethnic minority individuals and women and persons with disabilities are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the NIH specialized center (P50) award. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Investigators are to request five years of support. The anticipated award date is July 1, 2003.

FUNDS AVAILABLE

The direct costs requested cannot exceed \$750,000 each year (exclusive of facilities and administrative costs of subcontracts with collaborating organizations). The NIAMS intends to fund up to 2 new and/or competing continuation applications responding to this RFA in FY 2003 subject to the availability of resources and receipt of sufficiently meritorious applications. The estimated funds (total costs) available for the first year of support of these centers are \$2.2 million.

RESEARCH OBJECTIVES

The objective of the SCOR program is to expedite development and application of new knowledge to human diseases, to learn more about the etiology of these diseases, and to foster improved approaches to treatment and/or prevention. A SCOR consists of at least three individual, but interrelated, research projects, each with high scientific merit and clear research objectives and, in the aggregate, devoted to a specific major health area. Each SCOR should provide a multidisciplinary approach utilizing both laboratory and clinical research to focus on a particular health problem and provide for a mutually supportive interaction between basic scientists and clinical investigators.

Clinical research is defined as (1) patient-oriented research, (2) epidemiologic and behavioral studies, and (3) outcomes research and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues

but do not deal directly with patients. Patient-oriented research includes mechanisms of human disease, therapeutic interventions, clinical trials and development of new technologies.

Although research programs will vary among institutions according to local expertise, interests, and resources, each SCOR should have a central theme related to the disease area to which individual projects relate and which serves as an integrating force. Emphasis in proposed projects should be on development of innovative approaches, elaboration of new and significant hypotheses, and generation of improved strategies for approaching current issues relating to the disease area addressed. Collaboration among institutions is encouraged within a given SCOR to share scarce patient resources.

Funding may also be requested for one or more core resources. A core is defined as a resource shared by multiple investigators that enhances research productivity and increases the functional capacity of the SCOR. Ongoing projects may be absorbed into the SCOR if their original funding source is relinquished.

Support for large clinical trials or for applications that contain exclusively clinical or exclusively basic studies will not be provided within this SCOR program.

Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the SCOR staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

SPECIAL REQUIREMENTS

The director and co-director should budget for an annual one-day meeting in Bethesda, MD with NIAMS staff. The director should be prepared to devote at least 15 percent effort as the director and 20 percent effort as a project PI. Each project and core PI should be prepared to devote at least 20 percent effort.

To be funded, a SCOR must include at least three highly meritorious projects approved for five years. One of these must have the SCOR director as the principal investigator, and the highly meritorious projects must include both basic and clinical research.

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 clinical research projects unless a clear and compelling justification is 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 clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>); a complete copy of the updated Guidelines are available at

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

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must 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) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

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" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

Investigators also may obtain a copy of this policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals 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>.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

LETTER OF INTENT

Prospective applicants are asked to submit, by September 16, 2002, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIAMS staff to estimate the potential review workload and plan the review. The letter of intent is to be sent to Dr. Julia B. Freeman at the address listed under INQUIRIES.

APPLICATION PROCEDURES

Special guidelines have been developed by NIAMS for the SCOR program. These guidelines should be used in assembling the application. See INQUIRIES for obtaining a copy of these guidelines.

The PHS 398 research grant application instructions and forms (rev. 5/2001) available at

<http://grants.nih.gov/grants/funding/phs398/phs398.html> must be used in applying for these grants. This version of the PHS 398 is available in an interactive, searchable format. For further assistance contact GrantsInfo, Telephone 301/435-0714, Email: GrantsInfo@nih.gov.

The RFA label available in the PHS 398 (rev. 5/01) application form must be affixed to the bottom of the face page of the application. The sample RFA label is available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf>. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title, "Specialized Centers of Research" and number, "AR-02-005" must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed photocopies of the application in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, send two additional copies of the application to:

Tommy L. Broadwater, Ph.D.
Chief, Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS.25U - MSC 6500
Bethesda, MD 20892-6500
Bethesda, MD 20814 (for express/courier service)

Applications must be received by October 16, 2002. If an application is received after that date, it will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR and for responsiveness to the RFA by the NIAMS staff. Incomplete and/or non-responsive applications will be returned to

the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, a process may be used by the initial review group in which all applications receive a written critique and undergo a process in which only those applications with the highest scientific and technical merit will be discussed, assigned a priority score, and receive a second level review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Site visits will not be made.

Review Criteria

Major factors to be considered in evaluation of applications will include:

1. How the proposed SCOR combines basic and clinical research into the scientific goals and research theme;
2. If a competing continuation application, the quality and significance of the progress made in the previous funding period;
3. Scientific merit of each proposed project. [Each project will receive a priority score. This score reflects not only the feasibility of the project and adequacy of the experimental design, but also the design of the project to advance both the theme of the SCOR and the interaction between basic research and clinical investigation];
4. Scientific merit of combining the component parts into a SCOR;
5. Technical merit and justification of each core unit;
6. Competence of the investigators to accomplish the proposed research goals, their commitment, and the time they will devote to the research program;
7. Adequacy of facilities to perform the proposed research, including laboratory and clinical facilities, instrumentation, and data management systems, when needed;

8. Adequacy of plans for interaction among investigators, and the integration of the various projects and core units;
9. Qualifications, experience and commitment of the SCOR Director and his/her ability to devote time and effort to provide effective leadership;
10. Scientific and administrative structure, including internal and external procedures for monitoring and evaluating the proposed research and for providing ongoing quality control and scientific review;
11. Institutional commitment to the program, and the appropriateness of resources and policies for the administration of a SCOR;
12. Adequacy of plans to include both genders and minorities and their subgroups and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

AWARD CRITERIA

The anticipated award date is July 1, 2003. The primary factors determining the award will be the priority score, the overall balance of meritorious projects (clinical and basic research) within the application relative to the disease area, and the availability of funds. Since the NIAMS is interested in funding only the best research, individual projects or cores of lesser quality may not be funded, even if approved, under the "umbrella" of the SCOR mechanism.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Inquiries regarding programmatic issues and letters of intent may be directed to:

Dr. Julia B. Freeman
Centers Program, EP
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS.19F - MSC 6500
Bethesda, MD 20892-6500
Bethesda, MD 20814 (for express/courier service)
Telephone: (301) 594-5052

FAX: (301) 480-4543

Email: Julia_B_Freeman@nih.gov

Copies of the guidelines for the NIAMS SCOR program may be obtained from:

NIAMS Clearinghouse

1 AMS Circle

Bethesda, MD 20892-3675

Telephone: (301) 495-4484

FAX: (301) 587-4352

Guidelines are also available on the internet:

<http://www.nih.gov/niams/grants/ep7.htm>

<http://www.niams.nih.gov/rtac/funding/grants/scorwww.htm>

Direct inquiries regarding fiscal matters to:

Melinda Nelson

Chief Grants Management Officer

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natcher Building Room 5AS.49F - MSC 6500

Bethesda, MD 20892-6500

Telephone: (301) 594-3535

FAX: (301) 480-5450

Email: nelsonm@exchange.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grant policies and Federal regulations 42 CFR Parts 52 and 45 CFR Parts 74 and 92. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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