RHEUMATIC DISEASES CORE CENTERS

Release Date: August 2, 1999

RFA: AR-99-005

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: December 13, 1999
Application Receipt Date: February 17, 2000

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for research core centers (P30s) in rheumatic diseases. The Rheumatic Diseases Core Centers (RDCCs) will provide the resources for a number of established, currently funded investigators, often from different disciplines, to adopt a multidisciplinary approach to common research problems in rheumatic diseases and to ensure greater productivity than from each of the separate projects.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Rheumatic Diseases Core Centers, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" http://www.crisny.org/health/us/health7.html

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. Foreign institutions are not eligible for center grants. An established clinical and basic research program in rheumatic diseases must be present. Applications from racial/ethnic minority individuals and women and persons with disabilities are encouraged.

MECHANISM OF SUPPORT

This RFA will use the NIH Core Center Grant (P30). 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 January 2001.

FUNDS AVAILABLE

The direct costs requested cannot exceed $400,000 each year. The NIAMS intends to fund up to 3 RDCCs in FY 2001, 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 $1.8 million.

RESEARCH OBJECTIVES

Research in rheumatic diseases is at a stage where a number of areas are making broad advances that can be effectively fostered by research core centers. Examples of these areas include, but are not limited to:

o Mechanisms of autoimmunity underlying rheumatic diseases, including animal models and defined clinical populations. This also includes identification of environmental factors which contribute to development of rheumatic diseases.

o Genetic basis of rheumatic diseases and their manifestations, including animal models and defined clinical populations.

o Mechanisms underlying organ damage in rheumatic diseases, including inflammatory processes.

The choice of research area upon which the RDCC would focus is made by the investigators.

The RDCCs will provide support for:

1. Core resources and facilities to be used by investigators of individually supported research projects in order to enhance and coordinate their activities. This support may include personnel, equipment, supplies, services, and facilities.

2. Up to $100,000 yearly in direct costs for pilot and feasibility studies.

3. Program enrichment activities.

4. Administrative Core

A RDCC should be an identifiable organizational unit within a university-affiliated medical center. An Administrative Core should be proposed to coordinate the Center and administer the program enrichment activities. Two or more research cores must be proposed. A research core is a facility shared by two or more Center investigators that enables them to conduct their independently funded individual research projects more efficiently and/or more effectively. Cores generally fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., histology and tissue culture); (2) complex instrumentation (e.g., electron microscopy); (3) animal preparation and care; and (4) service and training (e.g., molecular biology, biostatistics).

A pilot and feasibility study program provides modest research support ($20,000 - $50,000 yearly) for a limited time (1 to 3 years) to enable eligible investigators to explore the feasibility of a rheumatic diseases-related concept and amass sufficient data to pursue it through other funding mechanisms. An investigator is eligible only once every 5 years. Eligible investigators include:

1. an established investigator in rheumatic diseases or related areas with a proposal for testing the feasibility of a new or innovative idea that is rheumatic diseases-related but represents a clear and distinct departure from the investigator's ongoing research interest;

2. an established, supported investigator with no previous work in rheumatic diseases or related areas who is willing to test the applicability of his/her expertise on a rheumatic diseases-related problem; and

3. a new investigator who has not been a principal investigator in a past or current NIH research project grant (R01, R29, P01) or a current R55 grant. New investigators should be clearly independent and have a faculty appointment higher than that of postdoctoral fellow or research associate.

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 RDCC 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.

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 subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This 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 "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which was published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 18, 1994, available on the web at: http://grants.nih.gov/grants/guide/1994/94.03.18/notice-nih-guideline008.html

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/funding/children/children.htm

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Prospective applicants are asked to submit, by December 13, 1999, 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 to avoid conflict of interest in the selection of reviewers. 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 for Core Centers supported by NIAMS.
These guidelines should be used in assembling the application. See INQUIRIES for obtaining a copy of these guidelines.

The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: grantsinfo@nih.gov and on the internet at http://grants.nih.gov/grants/forms.htm

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. The RFA label and line 2 of the application should both indicate the RFA number. 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, "Rheumatic Diseases Core Centers", and number, "AR-99-005" 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 and all copies of any appendices to:

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 February 17, 2000. If an application is received after that date, it will be returned to the applicant without review.

REVIEW CONSIDERATIONS

Applications for Core Center grants will first be screened for completeness by the Center for Scientific Review and for responsiveness by NIAMS staff. Applications which are complete and responsive will be further evaluated for scientific merit by a group of expert consultants convened by the Review Branch of the NIAMS. Each proposal should be complete in itself. Revisions will not be accepted after the receipt date. As part of the initial merit review, all applications will receive a written critique and may undergo a peer review in which only those applications deemed to have the highest scientific merit will be discussed, assigned a priority score, and receive a secondary level review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council. Site visits are not anticipated. It is strongly recommended that, if appropriate, Institutional Review Board (IRB) and Institutional Animal Care and Use committee (IACUC) approval be secured before the application is submitted. Otherwise, it is the applicant's responsibility to ensure these certifications are sent to the NIAMS Review Branch within 60 days of the receipt date. Applications failing to comply with this requirement will be returned without review.

Review criteria

Applicants should clearly demonstrate the ways in which the RDCC will build the local research program, will support on-going projects and will attract both senior and new investigators to

rheumatic diseases research. Review criteria which will be used by the initial review group (IRG) in the evaluation of the Core Center applications follow:

1. Evaluation of Cores

A research core is evaluated on the facilities and services provided.
Important factors include:

Significance: Will the core have utility to the Core Center research base (minimum: two independently funded investigators)?

Approach: Is the quality of services high? Are there procedures for quality control? Is the core cost effective? How is cost reimbursement proposed?

Innovation: Will the core likely promote interdisciplinary research? Are unique services offered?

Investigator: Are the personnel appropriate?

Environment: Are the facilities and equipment adequate? Is there institutional commitment to the core?

2. Evaluation of Pilot and Feasibility Studies (P&Fs)

For individual P&Fs:

Significance: Will the proposed work likely yield meaningful preliminary data leading to a research proposal?

Approach: Are the experimental approaches adequate?

Innovation: Is the research topic one that promotes innovative new research related to the core center?

Investigator: Does the investigator meet one of the criteria for P&F investigators? (If not, the project should not be considered further.)

Environment: Is the project appropriate to the research base of the core center? Does one or more of the cores offer needed materials/assistance?

3. Evaluation of the Administrative Core

The Administrative Core is evaluated on the leadership provided. Important factors include:

Significance: Does the proposed Core Center document coordination of ongoing research between the separately funded projects and the Core Center including mechanisms for internal monitoring?

Approach: Is the management proposed appropriate for: 1) fiscal administration, procurement, property and personnel management, planning, budgeting, etc.; and 2) reviewing the use of, and administering funds for, the pilot and feasibility program? Are the Core Center budgets appropriate for the proposed and approved work to be done in core facilities, for pilot and feasibility studies, and for enrichment in relation to the total Core Center program?

Innovation: Is there a plan for the establishment and maintenance of internal communication and cooperation among the Core Center investigators and for an enrichment program that provides outside review and input?

Investigators: Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the Core Center Director and Associate Director for the effective management of the Core Center program?

Environment: Have institutional lines of authority and sanction been documented for the Core Center?

4. Overall Core Center Evaluation

An overall priority score will be assigned to the application. This score will reflect not only the quality of the cores, administration, and pilot and feasibility studies, but also the quality of the research base and how the proposed Core Center will enhance the research base.

The following elements will be evaluated:

a. The scientific excellence of the Core Center's research base as well as the relevance and interrelation of these separately funded research projects to the central themes of the Core Center and the likelihood for meaningful collaboration among Core Center investigators. Existence of a base of established independently supported biomedical research of high quality is a prerequisite for establishment of a Core Center.

b. The application must convey how the proposed Core Center will enhance significantly the cited research base established at the host institution. This includes the qualifications, experience, and commitment of the Core Center investigators and their willingness to interact with each other. This also includes efficient and effective use and/or planned use of enrichment funds including the contribution of these activities in enhancing the realization of the Core Center concept.

c. The appropriateness, quality and relevance of the proposed cores, and the modes of operation, facilities, and potential for contribution to ongoing research.

d. The proposed management of the pilot and feasibility program and the scientific merit of the pilot and feasibility projects for which funds are requested from the Core Center grant. The effectiveness of the proposed program will serve as a basis for recommendations concerning the level at which pilot and feasibility studies will be supported throughout the project period.

e. The overall environment for a Core Center. This includes the institutional commitment to the program, including lines of accountability regarding management of the Core Center, and the institution's partnership with the Core Center, and the institutional commitment to individuals responsible for conducting essential Core Center functions. This also includes the academic environment and resources in which the activities will be conducted, including the availability of space, equipment, facilities, and the potential for interaction with scientists from other departments and schools.

Since the NIAMS is interested in funding only the best research, individual components of lesser quality may not be funded, even if recommended, under the "umbrella" of the Core Center grant mechanism. It is primarily for this reason that each component will be assigned a separate merit rating, taking into consideration only its merit as an individual pilot and feasibility study or core.

AWARD CRITERIA

The anticipated date of award is January 2001. The primary factors determining the award will be the priority score and the availability of funds.

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 RESEARCH CORE CENTER 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

Direct inquiries regarding fiscal matters to:

Sally A. Nichols
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: nicholss@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 Part 52 and 45 CFR Part 74. 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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