

MULTIDISCIPLINARY CLINICAL RESEARCH CENTERS FOR ARTHRITIS,
MUSCULOSKELETAL, AND SKIN DISEASES

Release Date: November 3, 1999

RFA: AR-00-001

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: June 5, 2000

Application Receipt Date: August 25, 2000

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for a new program of Multidisciplinary Clinical Research Centers (MCRCs) in arthritis and/or musculoskeletal disorders and/or skin diseases. The goal of this new program is to prevent disease and to assess and improve outcomes for patients with arthritis and other rheumatic diseases; musculoskeletal disorders including orthopaedics, bone diseases and muscle diseases; and skin diseases. For a comprehensive listing of the disease areas covered in the NIAMS extramural programs, please see <http://www.nih.gov/niams/grants/gen2.html>

Each MCRC will be organized around a methodology core and will be expected to include a minimum of three highly meritorious projects encompassing clinical research drawing from different disciplines. The methodology core will be the foundation of the center, providing key support for development and implementation of clinical projects. Each project must address a critical issue that directly involves prevention, assessment and/or outcomes for patients with one or more of the many chronic diseases within the mission of the NIAMS.

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) for Multidisciplinary Clinical Research Centers is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" at <http://odphp.osophs.dhhs.gov/pubs/hp2000>.

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 research program in arthritis and/or musculoskeletal disorders including orthopaedics, bone diseases and muscle diseases; and/or skin 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 comprehensive center grant (P60). 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 April 1, 2001.

FUNDS AVAILABLE

The direct costs requested cannot exceed \$800,000 each year (exclusive of facilities and administrative costs of subcontracts with collaborating organizations). The NIAMS intends to fund up to 4 applications responding to this RFA in FY 2001. The estimated funds (total costs) available for the first year of support of these centers are \$5.8 million.

NIAMS intends to reissue this RFA twice more, once for funding up to three applications in FY 2002 and once for funding up to two applications in FY 2003. Although the financial plans of the NIAMS provide support for this program, awards pursuant to this RFA and future RFAs are contingent upon the availability of funds and the receipt of a sufficient number of applications of outstanding scientific and technical merit.

RESEARCH OBJECTIVES

The goals of the new Multidisciplinary Clinical Research Center (MCRC) program are to prevent disease and to assess and improve outcomes for patients with arthritis and other rheumatic diseases; musculoskeletal disorders including orthopaedics, bone diseases and muscle diseases; and skin diseases. For a comprehensive listing of the disease areas covered in the NIAMS extramural programs, please see <http://www.nih.gov/niams/grants/gen2.html>

- o Any given MCRC will not be expected to include all disease areas defined above or all clinical approaches included in the NIH definition of clinical research. An MCRC can focus on one or more disease areas. However, an MCRC should not focus on one disease. Two or more clinical approaches (patient-oriented research, epidemiologic and behavioral studies, outcomes research and health services research) must be encompassed by the projects supported in the MCRC.

- o Each MCRC will define its research base, goals for promoting clinical research utilizing that research base, and how multidisciplinary research will be promoted. The interaction with a General Clinical Research Center (GCRC), if present, must be documented.

- o An MCRC is not a mechanism to support a large clinical trial, but proof of concept trials may be appropriate. In addition, research on animals and animal models should not be proposed in the MCRC application.

The key elements of an MCRC will include:

- 1) a center director, associate director and an executive committee with outstanding credentials for promoting clinical research;

- 2) a research base that encompasses diseases/disorders within the NIAMS mission and provides professional and patient resources for developing clinical projects using more than one clinical research approach;

- 3) a methodology core that will play a key role in the design and implementation of ALL projects supported through the center; and

- 4) a minimum of three highly meritorious clinical research projects that encompass one or more of the disease areas (but not one disease) within the NIAMS mission and utilize the methodology core.

Optional elements of an MCRC are (a) a developmental project supported by the methodology core and lasting no more than three years and (b) other core(s) supportive of two or more of the proposed projects.

The director of the MCRC, aided by an associate director, an executive committee and the methodology core, is expected to provide leadership to focus all research projects on clinically relevant issues to improve patient outcomes and to assure a rigorous research approach. The

proposed director should document this leadership with examples of the ability to network with colleagues from clinical and other areas of biomedical research.

A methodology core is a required component of the MCRC and must serve all projects proposed in the center. The core should have sufficient professional personnel to provide an interactive leadership role not only in supporting the projects within the MCRC, but also promoting rigorous methodologic and biostatistical support for the research base. Other cores supporting two or more of the research projects proposed may be requested.

A minimum of three highly meritorious clinical research projects, each with a focus to prevent disease or to assess and/or improve outcomes for patients, must be present in an MCRC. Each project will define the patient problem under study and the anticipated improvement in assessment and/or outcome for the patient that might be realized through this project. The projects must represent two or more general areas of clinical research.

An optional component in an MCRC is a development and feasibility project lasting no more than three years. The goal of the development and feasibility project should be to gather preliminary data or to develop a resource for a future study.

SPECIAL REQUIREMENTS

The director and associate 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/notice-files/not94-100.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/guide/notice-files/not98-024.html>

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 June 5, 2000, 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 this RFA. 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 by NIAMS for the MCRC program. 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. Applications 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. 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, "Multidisciplinary Clinical Research Centers" and number, "AR-00-001" must be typed on line 2 of the face page of the application form and the YES box must be marked.

The sample RFA label available at:

<http://grants.nih.gov/grants/funding/phs398/label-bk.pdf> has been modified to allow for this change. Please note this is in pdf format.

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:

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 August 25, 2000. 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 the Center for Scientific Review (CSR) and responsiveness by the NIAMS. Incomplete and/or non-responsive applications will be returned to applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by a peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, a process will be used by the initial review group in which applications receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed, assigned a priority score, and receive a second level of review by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Each proposal should be complete in itself. Revisions will not be accepted after the receipt date. 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.

Since the NIAMS is interested in funding only the most highly meritorious research, individual components of lesser quality may not be funded, even if recommended, under the "umbrella" of the Center grant mechanism. Each project and core (including the administrative unit) will be individually reviewed for scientific merit and a rating assigned. Merit ratings will also be voted for the center elements: qualifications of the center leadership, the research base, the institutional environment and resources. If this is an application from a group that formerly worked under a MAMDC, the progress under the Education, Epidemiology and Health Services Research component progress during the last funding cycle will also be evaluated. To be funded, there must be a highly meritorious methodology core and at least three highly meritorious projects (not including the developmental/feasibility project, if any).

Review Criteria for MCRC leadership:

Do the Director and Associate Director have the leadership and research qualifications to lead a Center? Does the leadership team (Director, Associate Director, and executive committee) have the collective expertise to assure focused development and implementation of high quality and meaningful clinical research projects?

Review Criteria for Research Base:

Is there a substantial productive and funded research base? Is the research base sufficiently broad to foster new interdisciplinary research? Is there a definition of who will be a Center investigator and what this designation might mean?

Review Criteria for Institutional Base:

Is there evidence of a supportive institutional environment for the proposed MCRC? Will the MCRC add an important multidisciplinary element to the institutional environment? Does the proposed MCRC utilize available resources well? Is there support and commitment from the institutional authorities?

Review Criterion for applications from previous Multipurpose Arthritis and Musculoskeletal Diseases Centers (MAMDCs):

Does the progress report reflect significant accomplishments that were derived from the MAMDC clinical component as reflected in new concepts and publications?

Review Criteria for Administrative Unit:

1. Do the proposed MCRC Director, Associate Director and executive committee have the collective expertise and leadership to identify and focus research projects on clinically relevant issues?
2. Is the management proposed appropriate for scientific administration as well as fiscal administration, procurement, property and personnel management, planning, budgeting, etc.?
3. Is there a plan for establishment and maintenance of internal communication and cooperation among the MCRC investigators, core leaders and executive committee? Are there plans for outside review and input?
4. Is there scientific and administrative leadership, commitment and ability, and adequate time commitment of the MCRC Director and Associate Director for the effective management of the MCRC program?
5. Is there documentation of institutional support for the MCRC by the parent institution?

Review Criteria for Methodology Core:

1. Does the methodology core serve all projects proposed in the Center (mandatory)? Have issues relating to data and safety monitoring been addressed? Is there a plan for offering teaching services to the research base?

2. Are the services offered appropriate and of high quality, especially for the projects directly supported? How is cost reimbursement proposed?
3. Will the core likely promote interdisciplinary research? Are unique services offered? Is there a plan for prioritizing services to the research base?
4. Are the qualifications of the professional and support personnel appropriate? Is there a plan for interactive leadership of the methodology core and the proposed projects?
5. Are the facilities and equipment adequate? Is there institutional commitment to the core?

Review Criteria for Other Cores:

1. Will the core have utility to at least two of the MCRC projects?
2. Are the services of high quality? Are there procedures for quality control? Is the core cost effective?
3. Do the services offered best fit within a core structure? If this is an add-on to a preexisting core, what is the benefit to the Center over direct purchase of services from the existing core? If the core offers new services that may be used by non-MCRC projects, how will the non-MCRC projects purchase these services from the core?
4. Are the personnel appropriate?
5. Are the facilities and equipment adequate? Is there institutional commitment to the core?

Review Criteria for Research Projects:

Significance: Does this study address an important clinical issue, especially one not well studied? Is it likely that the research may have a clinically important impact? Will these studies influence concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the investigator acknowledge potential problem areas and consider alternative tactics? Does the project utilize the multidisciplinary resources of the Center, especially the Methodology Core?

Innovation: Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? (The quality of the idea or the extent to which the research will advance theory or practice should outweigh an emphasis on technical excellence.)

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and collaborators?

Environment: Does the scientific environment of the Center contribute to the probability of success? Do the proposed experiments take advantage of unique features of the Center and employ useful collaborative arrangements?

Review Criteria for Development and Feasibility Project (Optional):

Significance: Does this study address an important problem? If the aims of the application are achieved, will the work be the basis for a full research proposal?

Approach: Does the study utilize the expertise of the methodology core? Does the investigator acknowledge potential problem areas and consider alternative tactics? Does the project utilize the multidisciplinary resources of the MCRC?

Innovation: Does the project employ sound concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies? (The quality of the idea or the extent to which the research will advance theory or practice should outweigh an emphasis on technical excellence.)

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and collaborators?

Environment: Does the scientific environment of the Center contribute to the probability of success? Do the proposed experiments take advantage of unique features of the Center and employ useful collaborative arrangements?

AWARD CRITERIA

The anticipated date of award is April 1, 2001. The primary factors determining the award will be the priority score and the availability of funds. Since the NIAMS is interested in funding only the

best research, individual pilot and feasibility projects or cores of lesser quality may not be funded, even if recommended, under the "umbrella" of the MCRC 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 MCRC 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 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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