

Full Text AR-93-01

JUVENILE RHEUMATIC DISEASES RESEARCH CENTER PLANNING GRANT

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National Institute of Arthritis and Musculoskeletal and Skin Diseases

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Application Receipt Date: April 20, 1993

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for a planning grant for a juvenile rheumatic diseases research center.

The goal of the planning grant is to establish a Juvenile Rheumatic Diseases Research Center (JRDRC). The JRDRC planning grant will allow the applicant to develop key multidisciplinary research areas needed to establish a JRDRC. A JRDRC is envisioned to be a resource center for research in juvenile arthritis and musculoskeletal diseases. This center will be associated with a major medical complex or consortium and dedicated to furthering the research effort related to juvenile arthritis and musculoskeletal diseases.

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), Juvenile Rheumatic Diseases Research Center Planning Grant, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

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 that have an established program for pediatric rheumatology and a relevant research base. Foreign research organizations are ineligible. International collaborations in domestic applications will only be accepted if the resources are clearly shown to be unavailable in the United States. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) planning grant (P20). Responsibility for the planning, direction, and execution of the proposed program will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should be three years. The anticipated award date is September 30, 1993. The direct costs requested cannot exceed \$200,000 each year. The award will not be renewed, but may be converted to another funding mechanism.

FUNDS AVAILABLE

The estimated funds (total costs) available for the first year of support for a JRDRC planning grant is \$300,000. One award is anticipated. Funding will depend on receiving applications judged highly meritorious by peer review.

RESEARCH OBJECTIVES

Chronic rheumatic diseases represent an important entity among chronic conditions affecting children. Among the rheumatic diseases seen in juvenile populations are rheumatoid arthritis, chronic arthritis (systemic, polyarthritic, and pauciarticular), spondyloarthropathy, systemic lupus erythematosus, dermatomyositis, scleroderma and other vasculopathies and connective tissue disorders. Many childhood rheumatic diseases have orthopaedic aspects. A research agenda for the genetic, infectious, and immunologic aspects of juvenile rheumatic diseases will benefit from a multidisciplinary approach. Because the research issues for juvenile arthritis and musculoskeletal diseases are complex, the NIAMS seeks to use a planning grant to explore the potential for establishing a JRDRC through a planning grant.

Applications for a JRDRC planning grant should propose a program of multidisciplinary research development as a resource for research in arthritis and musculoskeletal diseases in children and for research to develop effective education programs for children, their families, and the public.

The goal of the planning grant will be to develop those areas needed at the applicant institution or consortium. The applicant should outline the areas that may be part of a future JRDRC and the research projects presented in the planning grant should relate to the development of key areas in that center. A major goal of a JRDRC is to promote bench to bedside application of research. Clinical projects are required.

The planning grant will provide funds for an Administrative and Planning Core and for Pilot Studies to develop and expand the research base.

An Administrative and Planning Core will manage the overall activities related to developing the JRDRC. There must be a Director (Principal Investigator of the planning grant), a discrete administrative structure, and an Advisory Committee. The Core may also include the administration of shared resources, such as data sets or community or clinical research facilities, or provide research design and data analysis/statistical service.

The Director will be the key figure in the scientific administration and management of the planning grant. The Director must be an experienced researcher with demonstrated leadership appropriate to the coordination and development of a Center.

Although the final administrative structure of a Center will be left to the discretion of the applicant institution, experience demonstrates that effective development of Center programs requires interaction among the Director, the Principal Investigators of the pilot studies, appropriate institutional administrative personnel, and the staff of the NIAMS. Like other interdisciplinary

grant programs, the success of a Center is dependent upon the involvement of scientific and professional personnel representing a variety of disciplines who must be willing to relate to and collaborate with each other in order to facilitate the development of new knowledge.

The Advisory Committee assists the Director in making the scientific and administrative decisions relating to a Center. With the Director, the Advisory Committee will have the responsibility of evaluating the pilot studies proposed in the initial application and to be developed during subsequent years. (This does not preclude the applicant institution from developing a separate external review process to evaluate the scientific merit of the individual pilot studies developed during subsequent years. The final evaluation of the pilot studies, however, will rest with the Advisory Committee and the Director). The Advisory Committee may perform other duties as deemed appropriate by the applicant institution. The Advisory Committee must be composed of scientists and administrators with expertise and experience relevant to the Center's scientific program. Members may be employees of the applicant institution or of other institutions. However, at least two members of this committee must be from outside the Director's supervision (i.e., either at the applicant institution or another institution).

The program areas of a JRDRRC are to be related to arthritis and musculoskeletal diseases in children and may include treatment strategies. In the planning grant, pilot studies are to be proposed to expand the research base at the applicant institution. The P20 funding mechanism is intended to furnish modest support that will allow the investigators the opportunity to develop preliminary data sufficient to provide the basis for applications for independent research through conventional granting mechanisms. Pilot studies are typically limited to a nonrenewable period of one to two years.

Applications submitted in response to this RFA must propose a minimum of three pilot studies to be supported during at least the first year of the award. Subsequent preliminary research projects may be developed during the course of the award. The Advisory Committee will have final approval for future pilot studies after a local peer review of the proposals.

Appropriate research areas may include, but are not limited to:

- o Basic and clinical research leading to understanding the cause(s), diagnoses, improved treatment, and ultimate prevention of arthritis and musculoskeletal diseases in children is a critical aspect of the JRDRRC. Clinical studies may address such research areas as: providing critical data for the design of larger clinical trials, testing the feasibility of new pharmacologic interventions, and devising improved diagnostic strategies. Studies integrating physical therapy

and/or orthopaedic research with functional outcome may be included, as may epidemiologic studies that offer new insights.

o Research development and evaluation of new programs, techniques or methodologies for the education of health professionals, patients, families of patients, and the public are appropriate. Evaluation and validation of patient assessment tools for the pediatric population may be proposed. Psychosocial research leading to improved intervention strategies, counseling, and enhancing the coping skills of children and their families are appropriate.

SPECIAL REQUIREMENTS

Investigators will be asked to meet periodically with NIAMS staff in Bethesda to review progress and plans for future work.

Applicants from institutions that 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 interaction of the planning center staff and pilot study members 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.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues must be addressed in developing a research design and sample size appropriate for the scientific objectives of the study.

This information must be included in the form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including, but not limited to, clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 1, 1993 a letter of intent that includes a descriptive title of the proposed research projects, 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 review.

The letter of intent is to be sent to:

Dr. Julia B. Freeman
Centers Program, Extramural Programs
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 402-3348
FAX: (301) 480-7881

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441; and from the NIAMS program administrator listed under INQUIRIES.

Special guidelines have been developed for the JRDRRC planning grant. These guidelines must be used in writing and assembling the application. The guidelines may be obtained by contacting the Centers Program Director listed under INQUIRIES.

The RFA label available in the 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 and number must be typed on line 2a 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, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Dr. Tommy L. Broadwater
Chief, Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, MD 20892

Applications must be received by April 20, 1993. 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 DRG and responsiveness by the NIAMS. Incomplete applications will be returned to the applicant without further consideration.

Applications may be triaged by an NIAMS peer review group on the basis of relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIAMS. The second level of review will be provided by the National Arthritis and Musculoskeletal and Skin Diseases Council.

Review criteria for RFAs are generally the same as those for unsolicited research grant applications:

- o scientific, technical, or medical significance and originality of proposed research;
- o appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;
- o qualifications and research experience of the Director (Principal Investigator) and staff, particularly, but not exclusively, in the area of the proposed research;
- o availability of the resources necessary to perform the research; and
- o appropriateness of the proposed budget and duration in relation to the proposed research.

Additional scientific/technical merit criteria specific to the objectives of a JRDR program include:

- o qualifications, experience and commitment of the Director (Principal Investigator) and his/her ability to devote time and effort to provide effective leadership;
- o 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;
- o adequacy of plans for interaction among investigators, and the integration of the various projects;
- o potential for developing a JRDR from the resources and projects described; and
- o commitment to developing a JRDR as a national resource.

AWARD CRITERIA

The anticipated date of award is September 30, 1993.

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 research projects of lesser quality may not be funded, even if approved, under the "umbrella" of the planning grant (P20) mechanism.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged.

The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Julia B. Freeman
Centers Program, EP
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 402-3348
FAX: (301) 480-7881

Direct inquiries regarding fiscal matters to:

Mara H. DeKemper
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 732
Bethesda, MD 20892
Telephone: (301) 496-0552

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.

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