

ARTHRITIS & SKIN DISEASES (MINORITY POPULATIONS)
NIH GUIDE, Volume 21, Number 36, October 9, 1992

PA NUMBER: PA-93-005

P.T. 34, FF

Keywords:

Arthritis

Skin Diseases

National Institute of Arthritis and Musculoskeletal and Skin Diseases

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases invites investigator-initiated grant applications and supplemental applications to carry out clinical and epidemiologic studies on the etiology, treatment, and prevention of arthritis, musculoskeletal, and skin diseases in minority populations and other populations at special risk.

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 program announcement, Arthritis and Skin Diseases (Minority Populations), is related to the priority area of chronic disabling conditions and surveillance objectives. 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

Research grant applications may be submitted by domestic and foreign for profit and non-profit organizations, public and private, such as local governments, and eligible agencies of the Federal Government. Applications with minority individuals and women as Principal Investigators are encouraged. Foreign institutions are not eligible for First Independent Research Support and

Transition (FIRST) Awards (R29). Applicants for the Clinical Investigator Awards (K08) and Individual National Research Service Awards (F32) must be U.S. citizens, non-citizen nationals, or non-citizens lawfully admitted for permanent residence. Applicants for the F32 Award must have received a doctorate degree as of the beginning date of the NRSA appointment. Applicants for the K08 Award must have an M.D. or equivalent degree. Applicants for the Fogarty International Research Collaboration Award (FIRCA) Award must be U.S. scientists who are Principal Investigators of NIH Research Project Grants (R, P, or U01 series) that are active and funded during the proposed FIRCA grant award period. Recipients of K awards are not eligible. For the FIRCA Award, the foreign collaborator's institution must be located in a country in the geographical regions commonly known as Central and Eastern Europe (including the former USSR), Latin America, and the non-US Caribbean.

MECHANISMS OF SUPPORT

Applications for the following mechanisms are considered appropriate responses to this announcement: the traditional research project grant (R01) and the FIRST Award (R29), the Clinical Investigator Award (K08), and the Individual National Research Service Award (F32). In addition, the FIRCA funding mechanism may be used by NIH grantees in the U.S. to collaborate with foreign investigators. Joint efforts between U.S. and foreign investigators are encouraged.

Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also.

SUMMARY

o Background

Major gaps in knowledge still exist about the incidence, prevalence, and natural history of most of the rheumatic, musculoskeletal, and skin diseases. The skin diseases in particular have lacked epidemiologic research. Although both cross-sectional and longitudinal studies are lacking for many diseases, the greatest need is for longitudinal investigations. Some population-based longitudinal data sources are available for studies of rheumatic diseases and osteoporosis, e.g., Framingham, Massachusetts; Rochester, Minnesota; NHANES I and Followup; and the Study of Osteoporotic Fractures (SOF).

In the past decade, epidemiologic studies have made some progress in describing the frequency of osteoarthritis and some skin diseases, based upon nationally collected data by the National

Center for Health Statistics. Epidemiologic studies from defined populations have contributed knowledge about cohorts at increased risk of disease, e.g., rheumatoid arthritis in Pima Indians and the higher incidence, prevalence, and mortality of systemic lupus erythematosus in Black females than in Caucasian and male populations. However, the key question, why some cohorts remain at increased risk of disease, is still unanswered.

In general, less is known about the occurrence of arthritis, musculoskeletal, and skin diseases in American Blacks than in whites. Even less is known about other American minority groups. Data are also lacking on these diseases in children and the elderly.

o Research Objectives and Scope

The primary objective of this program announcement is to foster epidemiologic research in minority groups and other populations at special disease risk. Studies to be encouraged include:

- o The descriptive pattern of arthritis, musculoskeletal and skin diseases in populations
- o The etiology and modes of transmission of these diseases, including the relative contribution of both genetic and environmental factors influencing both the onset and course of the disease
- o Studies of disease burden, specifically on the frequency, cost, and personal and social sequelae of arthritis and musculoskeletal and skin diseases
- o New diagnostic technologies to update or develop criteria for the diagnosis and staging of many rheumatic and skin diseases and to define homogeneous clinical subsets for epidemiologic and basic science studies
- o Studies to generate and test etiologic hypotheses, especially for less studied rheumatic, musculoskeletal, and skin diseases
- o Family studies to evaluate the interplay of genetic and environmental contributions to the development and progression of rheumatic, musculoskeletal, and skin diseases
- o Longitudinal studies to describe the prognosis and outcomes among patients with rheumatic, musculoskeletal, and skin diseases, and to identify risk factors for disease onset, progression, and disability

o Practical outcome assessment tools to define the impact of different medical, surgical, and rehabilitation management approaches for arthritis, musculoskeletal and skin diseases

STUDY POPULATIONS

Epidemiologic studies of the general population at risk for disease, as well as patient populations that have been diagnosed to have the diseases, will be accepted. Although new research projects are desired, applications based on on-going studies that were conceived for reasons other than the purposes of this program announcement are also encouraged.

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 should 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 must 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.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

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 will be 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.

APPLICATION PROCEDURES

Applications for the R01, R29, K08, and FIRCA awards are to be submitted on the grant application form PHS 398 (rev. 9/91) and will be accepted at the standard application deadlines as indicated in the application kit. FIRST (R29) Award applications must include at least three sealed letters of reference attached to the face page of the original application. First Award applications submitted without the required number of reference letters will be considered incomplete and will be returned to the applicant without review. The receipt dates for applications for AIDS-related research are also found in the PHS 398 (rev. 9/91) application kit. Supplemental application instructions for the K08 Award and the application dates are available in the

publication "The K Awards" (rev. 10/91). Supplemental application instructions for the FIRCA award are available from the John E. Fogarty International Center. Applications for the FIRCA Award must include a letter of collaboration from the foreign investigator and the foreign investigator's biographical sketch, resources, and environment. Applications for the F32 Award are to be submitted on form PHS 416-1 and must include letters of reference and other supplemental material.

Application kits and information booklets including relevant receipt dates are available at most institutional offices of sponsored research and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in Section 2a on the face page of the application.

The completed original application and the appropriate number of legible copies, as specified in the application kits, must be sent or delivered to:

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

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit in accordance with the standard NIH peer review procedures. FIRCA Award applications will be reviewed by an initial review committee convened by the Fogarty International Center.

Following scientific-technical review, the applications will receive a second-level review by an appropriate advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

- o Quality of the proposed project as determined by peer review

- o Availability of funds

- o Program balance among research areas of the announcement

Additional criteria for R29 and F32 applications include the potential for the applicant to carry out independent research, the quality of education, scientific training, research experience, and commitment to a research career, as well as the institutional commitment. Further criteria for F32 applications include the quality of the sponsor and training environment and the reference reports.

INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Ms. Reva C. Lawrence
Epidemiology/Data Systems Program Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Building 31, Room 4C-13
Bethesda, MD 20892
Telephone: (301) 496-0434

Direct inquiries regarding fiscal matters to:

Ms. Diane M. Watson
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 4A15C
Bethesda, MD 20892
Telephone: (301) 496-7257

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 grants 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.

[Return to 1992 Index](#)

[Return to NIH Guide Main Index](#)