

CLINICAL AND EPIDEMIOLOGIC RESEARCH ON SYSTEMIC LUPUS ERYTHEMATOSUS  
IN CARIBBEAN POPULATIONS

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PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases and the Fogarty International Center invite investigator-initiated grant applications and supplemental applications to explore hypotheses concerning the etiology, pathogenesis, treatment, and prevention of systemic lupus erythematosus (SLE) in Caribbean populations. The NIAID also has interest in research projects on the subject of systemic lupus erythematosus. The customary referral guidelines will apply. Applications meeting NIAID referral criteria may be assigned to that institute. Research proposed in response to this announcement may involve clinical, epidemiologic, genetic, or behavioral studies. In addition to SLE, studies of other rheumatic diseases in these populations will be considered.

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, Clinical and Epidemiologic Research on Systemic Lupus Erythematosus in Caribbean and African Populations, is related to the priority area of diabetes and 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 20402-0325 (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 institutions of higher education, research institutions, units of State and local government and eligible agencies of the Federal Government.

Applications from minority individuals and women are encouraged. U.S. and foreign investigators are encouraged to collaborate. Foreign institutions are not eligible for the First Independent Research Support and Transition (FIRST) Award (R29).

## MECHANISMS OF SUPPORT

Applications considered appropriate responses to this announcement are the traditional research project grant (R01) and the FIRST Award (R29). In addition, the Fogarty International Research Collaboration Award (FIRCA) funding mechanism may be used by NIH grantees from the U.S. to collaborate with foreign investigators. Joint efforts between U.S. and Caribbean investigators are strongly encouraged.

## RESEARCH OBJECTIVES

### Background

SLE, a chronic inflammatory disease, appears to result from an immunoregulatory disturbance brought about by the interplay of genetic, hormonal, and environmental factors. During the past three decades, SLE has emerged worldwide as a major rheumatic disease. There is a marked female predominance, with most series reporting a 9:1 female-to-male ratio and an even higher ratio during the childbearing years. Systemic lupus erythematosus appears to be more common in certain racial groups, particularly blacks. Racial differences have also been reported in the natural history and clinical manifestations of SLE.

### Research Objectives and Experimental Approaches

Studies of the general population at risk for SLE and other diseases, as well as on patient populations who have been diagnosed as having the diseases, will be accepted. The research

focus may be on clinical, genetic, epidemiologic, or behavioral studies. Subject matter to be encouraged include:

- o Clinical research oriented to the cellular, organ, or human level
- o Clinical trials as well as projects to develop outcome assessment tools to define the impact of different medical approaches
- o Studies to quantify the side effects of new therapies and identify subpopulations of patients who are at increased risk for serious adverse reactions to treatment
- o Genetic studies, including studies associating susceptibility and clinical subsets with genetic markers
- o Cross-sectional as well as longitudinal epidemiologic studies
- o Studies of the natural history of lupus as well as case-control studies
- o Studies of migrant populations in the U.S. versus those remaining in their country of origin and urban/rural comparisons
- o Studies examining the impact of comorbid conditions, behavioral, environmental, and socioeconomic factors are encouraged

## STUDY POPULATIONS

The Caribbean islands are particularly well-suited for studies of systemic lupus and other diseases that disproportionately affect individuals of African descent. Each island has a substantial minority population. Among the more populated islands, Jamaica has a current population of 2.4 million, 76.3 percent are of African descent. Trinidad and Tobago have a population of 1.3 million with 43 percent African and 40 percent East Indian descent. Africans comprise 80 percent of the Barbados population. Certain diseases, such as lupus, which is known to be more frequent in African-American populations than in Caucasians, can be more readily studied on islands where it may be feasible to attain complete ascertainment of cases. On the Caribbean islands a small number of specialists see patients with certain diagnoses, thus facilitating identification and follow-up of cases.

Also, most of the care is provided by a small number of medical institutions.

While new research projects are desired, applications based on current studies are also encouraged.

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

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be 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 should 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 should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. 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 should be included in the form PHS 398 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.

This policy applies to all studies submitted under this program announcement. The usual NIH policies concerning research on human subjects also apply. 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 are required to address these policies. NIH funding components will not award grants that do not comply with these policies.

#### APPLICATION PROCEDURES

Applicants are to use the research project application form PHS 398 (rev. 9/91) that is available at the applicant's institutional research office and 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. To expedite the application's routing, check the box on the application face sheet indicating that the application is in response to this announcement and type (next to the box) "Clinical and Epidemiologic Research on Systemic Lupus Erythematosus in Caribbean Populations, PA-92-87." The National Institute of Allergy and Infectious Diseases (NIAID) also has interest in research projects on the subject of systemic lupus erythematosus. Normal referral guidelines will apply, and applications meeting NIAID referral criteria may be assigned to that institute.

The application (with five copies) must be mailed to:

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

Receipt dates for new Research Project Grants, FIRST Awards and FIRCA applications are February 1, June 1, and October 1 of each year.

## REVIEW CONSIDERATIONS

R01 and R29 applications will be reviewed for scientific and technical merit by an appropriate Initial Review Group of the Division of Research Grants. FIRCA applications will be reviewed by a Fogarty International Center initial review group. Secondary review will be by the assigned National Advisory Council. Applications compete on the basis of scientific merit.

## AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to that institute, center, or division. 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

## INQUIRIES

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 732-A  
Bethesda, MD 20892  
Telephone: (301) 402-3352

## 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.

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