

## **ASSOCIATION OF ARTHRITIS AND MUSCULOSKELETAL DISEASES WITH HIV POSITIVITY AND AIDS**

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National Institute of Arthritis and Musculoskeletal and Skin Diseases

The Arthritis and Musculoskeletal Programs of the National Institute of Arthritis and Musculoskeletal and Skin Diseases invite grant applications to carry out studies of arthritis and musculoskeletal conditions and their association with HIV infection and/or frank AIDS. This Program Announcement is to encourage research grant applications for basic, clinical and epidemiologic research. Research mechanisms to support these investigations include regular research grants (R01), Clinical Investigator Awards (K08), First Independent Research Support and Transition (FIRST) Awards (R29), and Postdoctoral Individual National Research Service Awards (F32).

Investigators from several laboratories have recently reported the co-occurrence of HIV antibody positivity or frank AIDS with Reiter's syndrome and other arthritides. It is unknown whether a biological connection exists between certain arthritides and HIV infection or whether some of these co-occurrences are merely coincidental.

Certain arthritides and musculoskeletal conditions may be found more frequently in HIV-positive individuals and AIDS patients than in the general population according to reported observations. The frequency, spectrum and natural history of these conditions in HIV-positive individuals, including AIDS cases are unknown. It has also been noted that a spectrum of disease encompassing Reiter's syndrome and psoriasis in particular, appears to be more severe and increasingly difficult to control as signs of immunodeficiency develop.

Safety and efficacy of drugs used in the management of arthritis and musculoskeletal conditions have not been formally assessed in HIV-positive individuals. Recent case reports have suggested that immunosuppressive drugs, particularly methotrexate, used widely at present in the management of rheumatoid arthritis and psoriatic arthritis may accelerate AIDS in HIV-infected individuals.

This solicitation is intended to stimulate basic, clinical and epidemiologic research related to arthritis and musculoskeletal diseases in HIV-positive individuals, including those who have AIDS. In addition, it is hoped that the

increased frequency of these diseases in HIV-positive individuals will provide unusual opportunities for research on the pathogenesis and accelerating factors in Reiter's syndrome and other rheumatic diseases of uncertain etiology.

Among the broad spectrum of basic research projects encouraged are studies of disease pathophysiology and genetics. Clinical studies may include prevention of morbidity and mortality or amelioration of arthritis and musculoskeletal complications. Epidemiologic studies may focus on etiology, risk factors for disease development and severity, natural history of disease, prognosis for developing disease. This includes both AIDS and arthritis and musculoskeletal diseases, as well as descriptive studies of incidence, prevalence, morbidity and mortality.

The NIH encourages applicants to consider the inclusion of women and minorities in the study populations for all clinical research efforts, excepting studies involving pregnant women which may expose the fetus to undue risks. Gender and racial differences should be noted and evaluated. If women or minorities are to be excluded, a clear rationale should be provided for their exclusion.

Investigators are encouraged to work with existing, or proposed, longitudinal data collection resources and cohorts of patients. Populations which may be included are those at increased risk for HIV infection, as well as HIV-positive cohorts who are clearly defined by their source of exposure. Investigators are encouraged to use existing cohorts, such as the Multicenter AIDS Cohort Study (MACS), the HIV Pulmonary Complications Study and the AIDS Clinical Trials Group patients.

#### ELIGIBILITY

Non-profit organizations and institutions, governments and their agencies, for-profit organizations, and individuals are eligible to apply.

#### DEADLINE

Applications will be accepted in accordance with the announced receipt dates for new applications, listed in application kits numbered PHS-398, Rev. 9/86. Also, applicants have the option of submitting AIDS investigator-initiated R01 and R29 applications to the Division of Research Grants on May 1, September 1, or January 2 of each year for expedited review.

#### REVIEW PROCEDURES AND CRITERIA

Applications should be submitted on Form PHS-398, Rev. 9/86, or form 416-1 Rev. 6/85 (for F32), which are available in the institution's collaborative research or business office. Additional application kits may be obtained from the office of Grants Inquiries, Division of Research Grants (DRG), NIH.

The phrase "Prepared in Response to Research Grants Announcement on `Association of Arthritis and Musculoskeletal Diseases with HIV Positivity and AIDS'" should be typed on line 2 of the first page of the application or item 3 of the 416-1. The original and six copies of the form 398 application or the original plus two copies of the form 416-1 should be sent to:

Application Receipt Office  
Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 240  
Bethesda, Maryland 20892\*\*

If expedited review is requested, the original plus 32 copies of R01 or R29 applications should be submitted.

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research grant applications, and in accord with the expedited NIH peer review procedures for AIDS-related research. In order to expedite the review, PHS human subject certifications and animal verifications should be submitted with the applications. Applications will first be reviewed for technical merit by initial review groups and then by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Applications from institutions which have a General Clinical Research Center (GCRC) funded by the NIH Division of Research Resources may wish to identify the Center as a resource for conducting the proposed research. In such a case, a letter of agreement from the Program Director of the GCRC should be included with the application material.

All PHS and NIH grant policies governing regular research project grants apply to applications received in response to this Program Announcement. Applications will be referred in accordance with normal of the NIH Division of Research Grants.

For further information contact:

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