

## **Program Announcements (PA'S)**

ETIOPATHOGENESIS AND TREATMENT OF PSORIASIS  
NIH GUIDE - Volume 20, Number 24, June 21, 1991

PA: PA-91-70

P.T. 34; K.W. 0715185, 0755030, 0765033, 0745070

National Institute of Arthritis and Musculoskeletal and Skin Diseases

### **I. PURPOSE**

The Skin Diseases Program of the National Institute of Arthritis and Musculoskeletal and Skin Diseases supports research on the structure, function, and diseases of the skin. This program announcement is to encourage submission of research grant applications in the area of etiopathogenesis and treatment of psoriasis.

### **II. BACKGROUND**

Psoriasis is a common skin disease affecting several million Americans. It may be disfiguring and even disabling. Treatments exist and are reasonably satisfactory for mild cases; but an understanding of the underlying etiopathogenesis of the disease is lacking and, thus, treatments for the more severe forms of the disease are empiric, often less than completely satisfactory in terms of efficacy, and may have significant, even life-threatening, side effects.

Psoriasis is characterized by a hyperproliferation of epidermis. Much of the prior treatment and research have been directed at this aspect of the disease. However, the recognition that psoriasis responds to Cyclosporin A, an immune suppressive agent that does not affect proliferation to any significant degree, and that psoriasis may develop or become more severe with HIV infection and then may respond to treatment of the immune deficit caused by HIV infection, has resulted in new lines of research focusing on immune mechanisms in the development of psoriasis. In addition, advances in molecular biology and the development of new knowledge in relation to cytokines and other intermediary proteins that may tie together immunologic effects with hyperproliferative effects have prepared the way for new advances in understanding and treating psoriasis.

Psoriasis often runs in families. This genetic aspect has, in the past, not been studied to any great degree, but, with recent advances in molecular genetics and the development of techniques for linkage analysis, an approach to this aspect of the etiopathogenesis of psoriasis would seem appropriate. Toward this end, the National Psoriasis Foundation has announced the availability of a contract to

support the development of a tissue bank for well-established, informative families to act as a source of material to aid in the molecular genetic investigations of psoriasis. This tissue bank will be available in July 1992. (For further information, contact Gail M. Zimmerman, Executive Director, National Psoriasis Foundation, 6443 S.W. Beaverton Highway, Suite 210, Portland, OR 97221, (503) 297-1545).

Much of the current state of knowledge in regard to psoriasis research was summarized at a psoriasis workshop held in September 1989 and published as a supplement to the Journal of Investigative Dermatology in November 1990. A psoriasis workshop emphasizing the molecular genetic aspects of the disease is planned for September 1991. It is expected that these workshops, in combination with the availability of the tissue bank, will encourage the preparation and submission of grant applications investigating the etiopathogenesis and treatment of psoriasis.

#### RESEARCH GOALS AND SCOPE

The goals of this program announcement is to stimulate research in various areas related to the etiopathogenesis and treatment of psoriasis. Some research objectives appropriate for inclusion in applications responding to this announcement are:

- o Studies of the molecular mechanisms involved in the hyperproliferative state of psoriasis.
- o Investigations of immune interactions with and control of the hyperproliferation of psoriasis.
- o Molecular genetic investigations of the hereditary basis of psoriasis.
- o Development of new therapeutic approaches to psoriasis based upon new information regarding etiopathogenesis and the characteristics of the disease state.

#### MECHANISMS OF SUPPORT

Funding mechanisms to support these investigations include research grants (RO1), Clinical Investigator Awards (KO8), First Independent Research and Transition (FIRST) Awards (R29), and Individual National Research Service Awards (F32).

#### SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

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. 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 Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors 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 includes 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 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 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 AND REVIEW PROCEDURES

Applications in response to this announcement will be reviewed in accordance with the usual Public Health Service peer review procedures for research grants. Review criteria include: significance and originality of the research goals and approaches; feasibility of the research and adequacy of the experimental design; training, research competence, and dedication of the investigator(s); adequacy of available facilities; and provision for the humane care of animals. Decisions will be based on initial review group and National Advisory Council recommendations.

Applications must be submitted on form PHS 398 (rev. 10/88), or the appropriate fellowship application form (PHS 416-1), available in the business or grants office at most academic or research institutions and from the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. Applications will be accepted in accordance with the submission dates for new applications on a continuing basis:

The phrase, "ETIOPATHOGENESIS AND TREATMENT OF PSORIASISi, PA-91-70" must be typed on line 2 of the face page of the application. The original and six copies must be sent or delivered to:

Grant Application Receipt Office  
Division of Research Grants  
Westwood Building, Room 240  
National Institutes of Health  
Bethesda, MD 20892-4500\*\*

For further information, investigators are encouraged to contact the following individuals:

Alan N. Moshell, M.D.  
Skin Diseases Program Director  
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Westwood Building, Room 405  
Bethesda, MD 20892  
Telephone: (301) 496-7326

For fiscal and administrative matters, contact:

Diane M. Watson  
Grants Management Officer  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Westwood Building, Room 407-A  
Bethesda, MD 20892  
Telephone: (301) 496-7495

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 authorization of the Public Health Service Act, Title III, Section 301 (c) (public Law 78-410, 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 the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

**\*\*THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue  
Bethesda, Maryland 20816