

Full Text AR-93-03

SKIN DISEASES RESEARCH CORE CENTERS

NIH GUIDE, Volume 21, Number 44, December 11, 1992

RFA: AR-93-03

P.T. 04

Keywords:

Skin Diseases

Biochemistry

Immunology

Biomedical Research, Multidiscipl

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: May 10, 1993

Application Receipt Date: June 18, 1993

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for research core centers (P30s) in skin diseases. The Skin Diseases Research Centers (SDRCs) will provide the resources for a number of established, currently funded investigators, often from different disciplines, to adopt a multidisciplinary approach to common research problems in skin diseases and to ensure greater productivity than from each of the separate projects.

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), Skin Diseases Research Core Centers, 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. An established clinical and research program in skin diseases should be present. Foreign organizations are not eligible. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) core research center grant (P30). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA is five years. The direct costs requested cannot exceed \$400,000 each year. The anticipated award date is March 1, 1994.

FUNDS AVAILABLE

The NIAMS intends to fund three SDRCs from this RFA in FY 1994, subject to the availability of resources and receipt of sufficiently meritorious applications. The estimated funds (total costs) available for the first year of support of these centers are \$1.0 million.

RESEARCH OBJECTIVES

Research in skin diseases is at a stage where a number of areas are making broad advances that can be effectively fostered by research core centers. Examples of these areas include, but are not limited to:

- o stratum corneum: biochemistry, structure, function
- o epidermis: differentiation, keratinization, cellular constituents
- o dermal-epidermal junction: structure, functions, diseases
- o skin as an immunological organ
- o autoimmune skin diseases

o dermis: structural components, diseases

The choice of research problem upon which the SDRC would focus is made by the principal and collaborating currently funded investigators.

The SDRCs will provide support for:

1. Core resources and facilities to be used by investigators of individually supported research projects in order to enhance and coordinate their activities. This support may include personnel, equipment, supplies, services, and facilities.
2. Limited funds for pilot and feasibility studies.
3. Program enrichment activities.

An SDRC should be an identifiable organizational unit within a university-affiliated medical center. An Administrative Core should be proposed to coordinate the Center and administer the program enrichment activities. One or more research cores may be proposed. A research core is a facility shared by two or more Center investigators that enables them to conduct their independently funded individual research projects more efficiently and/or more effectively. Cores generally fall into one of four categories: (1) provision of a technology that lends itself to automation or preparation in large batches (e.g., histology and tissue culture); (2) complex instrumentation (e.g., electron microscopy); (3) animal preparation and care; and (4) service and training (e.g., molecular biology, biostatistics).

A pilot and feasibility study program provides modest research support for a limited time (three years or less) to enable eligible investigators to explore the feasibility of a skin diseases-related concept and amass sufficient data to pursue it through other funding mechanisms. Eligible investigators include:

1. an established investigator in skin diseases or related areas with a proposal for testing the feasibility of a new or innovative idea that is skin diseases-related but represents a clear and distinct departure from the investigator's ongoing research interest;
2. an established, supported investigator with no previous work in skin diseases or related areas who is willing to test the applicability of his/her expertise on a skin diseases-related problem; and

3. a new investigator who has not been a principal investigator in a past or current NIH research project grant (R01, R29, P01). New investigators should be clearly independent and have a faculty appointment higher than that of postdoctoral fellow or research associate.

SPECIAL REQUIREMENTS

Specific guidelines have been developed for the SDRC application and program. These guidelines may be obtained from the contact person listed under INQUIRIES.

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 interactions of the SDRC staff 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.

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 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 May 10, 1993, a letter of intent that includes a descriptive title of the proposed research, 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, 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

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 and 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.

Special guidelines have been developed for the SDRC program in the NIAMS. These guidelines must be used in 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 June 18, 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 Division of Research Grants (DRG) and responsiveness by the NIAMS. Incomplete applications will be returned to the applicant without further consideration.

Applications that are received after the June 18, 1993, receipt date, that exceed the budget limit of \$400,000 in direct costs, or that are otherwise unresponsive to the major criteria of the RFA will be returned to the applicant.

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. It is unlikely that a site visit will be conducted. Each proposal should therefore be complete in itself and be prepared as if no site visit is expected.

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 Advisory 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 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;
- o appropriateness of the proposed budget and duration in relation to the proposed research.

Factors to be considered in evaluation of the scientific merit of each application will include an evaluation of the independently funded biomedical research base, the appropriateness of the proposed cores, the quality of the proposed pilot and feasibility studies, and their proposed management. The evaluation of the biomedical research base will encompass the record of research training and the institution's commitment to the Center program.

AWARD CRITERIA

The anticipated date of award is March 1, 1994.

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 SDRC 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:

Mary L. Graham
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 722A
Bethesda, MD 20892
Telephone: (301) 402-3361

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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