

INDIVIDUAL POSTDOCTORAL NRSA FELLOWSHIPS IN EPIDEMIOLOGY /CLINICAL TRIALS
RESEARCH /OUTCOMES RESEARCH IN SKIN DISEASES

RELEASE DATE: February 19, 2002

RFA: RFA-AR-02-007

PARTICIPATING INSTITUTES AND CENTERS (ICs):

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

(<http://www.niams.nih.gov/>)

LETTER OF INTENT RECEIPT DATE: None

APPLICATION RECEIPT DATE: April 17, 2002

THIS RFA CONTAINS THE FOLLOWING INFORMATION

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- o Research Objectives
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PURPOSE OF THIS RFA

Progress in the treatment of skin diseases has been hampered by a lack of baseline data concerning prevalence and the effectiveness of therapeutic interventions in all but the most

common skin diseases. Part of this problem is the lack of trained individuals within the skin disease community capable of designing and carrying out these studies. This RFA is designed to begin to address this problem.

RESEARCH OBJECTIVES

The NIAMS, along with the Herzog Foundation, announces the availability of individual NRSA postdoctoral fellowships to support the training of physicians with expertise in clinical dermatology to supplement that knowledge with training in epidemiology/clinical trials/outcomes research. These fellowships are intended to support up to two years of advanced training in the relevant methodologies which is to be used to obtain a Master's of Public Health (or similar relevant area of study such as biostatistics, etc) and or a Ph.D. in epidemiology to qualify the fellow to pursue a career in these areas as they relate to skin diseases. Therefore, a special feature of this award is the inclusion of tuition and fees for the necessary course work which is to be taken at a School of Public Health or as part of an appropriate degree granting program within a graduate school. Applicants to this RFA may request activation at any time between July 1, 2002, and July 1, 2003, inclusive. An additional unique feature is the cooperation of the Herzog Foundation which will provide supplementation of approximately \$30,000.00 per year per fellow to supplement the stipend and any other expenses involved in the training. The intent of this announcement is to begin to train a cadre of investigators who will be both experienced clinicians in dermatology as well in the sciences underpinning epidemiology/clinical trials/outcomes research so that in the future this data will be available to the skin disease community. The overall goal of this research training initiative is to increase the number of clinically trained dermatologists who have the appropriate training in epidemiology/clinical trials/outcome research to pursue a career focused on this combined area of investigation. The secondary goal is to enhance the visibility of this discipline at U.S. academic health centers.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) Individual Postdoctoral NRSA Fellowship Award (F32) mechanism. The total project period for an application submitted in response to this RFA may not exceed a total of two years. The requested project period should be reduced by the amount of time a fellow has received support on any prior NRSA post-doctoral fellowship including Institutional NRSA training grants (T32s) so that the total NRSA support does not exceed 3 years. For further information refer to the NIH Guidelines for the NIH National Research Service Awards for Individual Postdoctoral Fellows (F32) published in the NIH Guide for Grants and Contracts (PA-00-104) <http://grants.nih.gov/grants/guide/pa-files/PA-00-104.html>.

FUNDS AVAILABLE

The NIAMS intends to fund up to 5 new applications responding to this RFA in FY 2002 and/or FY 2003 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 this program are \$300,000.

ELIGIBLE INSTITUTIONS

You may submit (an) application(s) if your institution has any of the following characteristics:

- o For-profit or non-profit organizations
- o Public or private institutions, such as universities, colleges, hospitals, and laboratories

INDIVIDUALS ELIGIBLE TO BECOME FELLOWS

Any individuals with the skills, knowledge, and resources necessary to carry out the fellowship training are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

Candidate: The candidate must have an M.D. degree and have completed at least two years of clinical dermatology training in an accredited program prior to the commencement of the fellowship. Clinical dermatology training may not have been completed more than five years prior to submission of the application. The individual must also meet the criteria for NIH National Research Service Awards for Individual Postdoctoral Fellows (F32) described in Program Announcement PA-00-104 available in the NIH Guide for Grants and Contracts (Release date December 11, 1998, available at http://grants.nih.gov/grants/guide/pa_files/PA_00_104.html). Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply. By the time of award, individuals must be citizens or non-citizen nationals of the United States, or have been lawfully admitted to the United States for permanent residence (i.e., possess a currently valid Alien Registration Receipt Card I-551, or other legal verification of such status). Non-citizen nationals are generally persons born in outlying possessions of the United States (i.e., American Samoa and Swains Island). Individuals on temporary or student visas are not eligible.

Sponsorship: Before submitting a fellowship application, the applicant must identify a sponsoring institution and an individual who will serve as a sponsor (also called mentor or supervisor) who will supervise the training and research experience. The sponsoring institution may be private (profit or nonprofit) or public, including the NIH Intramural Programs and other Federal laboratories. The applicant's sponsor should be an active investigator in either skin disease research or epidemiology/clinical trials/outcomes research. In some instances, it may be advisable for a secondary sponsor to complement the primary sponsor's expertise. The sponsor must document the availability of staff research support, didactic training and facilities for high quality research training.

SPECIAL REQUIREMENTS

As didactic work in a degree granting program are a requirement of this award, candidates must indicate the relevant degree granting program in which they intend to enroll, and provide information on tuition and fees.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Alan N. Moshell, M.D.
Skin Disease Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS25L, MSC-6500
Bethesda, MD 20892-6500
Telephone: 301-594-5017
FAX: 301-480-4543
Email: alan_n_moshell@nih.gov

o Direct your questions about peer review issues to:

Tommy L. Broadwater, Ph.D.
Scientific Review Branch

National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS25U, MSC-6500
Bethesda, MD 20892-6500
Telephone: 301-594-4952
FAX: 301-480-4543
Email: Broadwat@mail.nih.gov

o Direct your questions about financial or grants management issues to:

Melinda Nelson
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS49F, MSC-6500
Bethesda, MD 20892-6500
Telephone: 301-594-3535
FAX: 301-480-5450
Email: melinda_nelson@nih.gov

LETTER OF INTENT

No letter of intent is required for this RFA.

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 416-1 (rev. 1/98) application. To obtain application kits with instructions and forms, please contact your institutional office of sponsored research. If application kits are not available at the institution, they may be downloaded from the NIH website at <http://grants.nih.gov/grants/funding/416/phs416.htm> or it may be requested from the:

Division of Extramural Outreach and Information Resources
National Institutes of Health
6701 Rockledge Drive, Room 6207, MSC 7910
Bethesda, Maryland 20892-7910
Telephone: (301) 435-0714
FAX: (301) 480-0525

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and one signed, photocopy, in one package to:

Center For Scientific Review
National Institutes of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, one additional copies of the application must be sent to:

Tommy L. Broadwater, Ph.D.
Scientific Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS25U, MSC-6500
Bethesda, MD 20892-6500

APPLICATION PROCESSING: Applications must be received by the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the NIAMS.

Incomplete applications will be returned to the applicant without further consideration. And, if the application is not responsive to the RFA, CSR staff may contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next appropriate NIH review cycle.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

- o Receive a written critique
- o Receive a second level review by the National Arthritis and Musculoskeletal and Skin Disease Advisory Council.

REVIEW CRITERIA

The review criteria focus on four main components:

Candidate: An assessment of the candidate's previous academic and research performance and the potential to become an important contributor to biomedical, behavioral, or clinical science.

Sponsor and Training Environment: An assessment of the quality of the training environment and the qualifications of the sponsor as a mentor for the proposed research training experience.

Research Proposal: The merit of the scientific proposal and its relationship to the candidate's career plans.

Training Potential: An assessment of the value of the proposed fellowship experience as it relates to the candidate's needs in preparation for a career as an independent researcher.

ADDITIONAL REVIEW CRITERIA: In addition to the above criteria, your application will also be reviewed with respect to the following:

- o **PROTECTIONS:** The adequacy of the proposed protection for humans, animals, or the environment, to the extent they may be adversely affected by the project proposed in the application.

- o **INCLUSION:** The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

o OTHER REVIEW CRITERIA:

Likelihood that the training described will prepare the applicant for a career in epidemiology/clinical trials research/outcomes research in skin diseases and that the individual will pursue a career in these areas.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: None
Application Receipt Date: April 17, 2002
Peer Review Date: June, 2002
Council Review: September 26,2002
Earliest Anticipated Start Date: July 1, 2002

AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o Scientific merit (as determined by peer review)
- o Availability of funds
- o Programmatic priorities.

REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose

of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>);

a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS: The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://grants.nih.gov/grants/stem_cells.htm and at

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>.

Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see <http://escr.nih.gov>). It is the responsibility of the applicant to provide the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this RFA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas.

Potential applicants may obtain a copy of "Healthy People 2010" at

<http://www.health.gov/healthypeople>.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance No. 93.846 and is not subject to the intergovernmental review requirements

of Executive Order 12372 or Health Systems Agency review. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies described at <http://grants.nih.gov/grants/policy/policy.htm> and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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