

HEALTH DISPARITIES IN RHEUMATIC, MUSCULOSKELETAL, AND SKIN DISEASES

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

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

National Eye Institute (NEI)

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

National Institute of Environmental and Health Sciences (NIEHS)

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

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PURPOSE OF THIS PA

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for research to promote the design, development and testing of hypothesis-driven innovative approaches to eliminating health disparities in rheumatic, musculoskeletal, and skin diseases. Attention is to be focused on potentially modifiable environmental, social, and behavioral factors, and on gene-environment interactions, that may underlie ethnic/racial disparities in disease prevalence and outcome. In addition, descriptive and analytic epidemiologic studies are needed to characterize further the health disparities in rheumatic, musculoskeletal,

and skin diseases. This PA is based on the many scientific opportunities identified in the conference "Health Disparities in Arthritis and Skin Diseases". A summary of the conference and research questions raised can be found at:

http://www.niams.nih.gov/ne/reports/sci_wrk/2000/hdreg.htm

RESEARCH OBJECTIVES

Rheumatic, musculoskeletal, and skin diseases are the most frequent chronic health problems in the United States, but not all population groups are equally affected. Marked differences in the incidence, prevalence, severity, process of care, and outcome of a number these conditions exist among racial and ethnic groups. For conditions such as systemic lupus erythematosus (SLE), vitiligo, keloids, and scleroderma, the burden is greatest in particular ethnic groups. Research is needed to increase understanding of these disparities and their causes, and to provide direction for improving standards of care, informing public policy, and identifying strategies aimed at improving the health status and health outcomes of racial and ethnic minorities. Research is needed to enhance our understanding of the underlying factors (i.e., socioeconomic, cultural, societal, behavioral and biologic) that influence the health status of racial and ethnic minority populations across the lifespan.

The NIAMS Strategic Plan for Reducing Health Disparities

(<http://www.niams.nih.gov/an/stratplan/strategicplanhd/strategicplanhd.htm>) outlines five "Areas of Research Focus": Lupus, Scleroderma, Osteoarthritis, Vitiligo, and Keloids. Some of these diseases were covered in a NIAMS-sponsored conference, "Health Disparities in Arthritis and Musculoskeletal and Skin Diseases". A summary of this conference is posted at the URL http://www.niams.nih.gov/ne/reports/sci_wrk/2000/hdreg.htm.

A summary of this conference has also been published [Jordan JM, Lawrence R, Kington R, Fraser P, Karlson E, Lorig K, and Liang MH: Ethnic Health Disparities in Arthritis and Musculoskeletal Diseases, Report of a Scientific Conference. *Arthritis & Rheumatism* 46(9): 2280-2286, 2002].

Racial/ethnic disparities in rheumatic, musculoskeletal, and skin diseases have been identified; Non-Caucasian populations not only have a higher overall occurrence of systemic lupus erythematosus (SLE), but also seem to have lower survival rates. SLE-related organ damage occurs more frequently in Hispanics than in African Americans or Caucasians. Kidney damage is more prevalent in Hispanics and African Americans compared to Caucasians; and there is increased incidence of organ/tissue damage in Hispanics as compared to both Caucasians and

African Americans. Neuropsychiatric problems account for the greatest proportion of damage in Hispanics and Caucasians, while hair loss and skin damage account for the greatest proportion in African Americans. The most important variables influencing early mortality, however, have been found to be socioeconomic and demographic, rather than ethnic/racial or genetic factors. In scleroderma, incidence and prevalence is increased in women of color, with increased disease-related morbidity and mortality. Ethnic disparities in the prevalence, severity, and treatment of osteoarthritis (OA) have been documented as well. African-American women have a higher prevalence of radiographic knee OA than Caucasian women. African-American men of lower socioeconomic status have been found to have more radiographic hip OA and more bilateral hip OA than Caucasian and higher-socioeconomic status African-American men. African Americans, Hispanics, and Asians appear to be less likely than Caucasians to undergo total joint replacements (TJR) for OA of the hip. Further study is needed to determine the nature and mechanisms of these disparities, and to ameliorate them.

Much less is known about the frequency and impact of skin diseases in specific racial/ethnic populations. Keloids, overgrowth of scar tissue after a skin injury, occur more often in African Americans than among other groups, and anecdotal data suggest atopic dermatitis is more prevalent and more severe in African American and Asian/Pacific Islanders. The skin manifestations of lupus, sarcoidosis, and a number of other diseases are more common and more severe in African Americans, in parallel to the findings for SLE. In addition, some racial/ethnic disparities in treatment of skin diseases have been identified. For example, acne vulgaris is a common skin condition in African Americans and isotretinoin is considered an effective therapy, however, the drug is less often prescribed for African-American acne patients than for Caucasians. Finally, the social and psychological burden of some skin diseases is likely to vary depending on skin pigmentation (e.g., the impact of vitiligo, an acquired skin disease characterized by patches of unpigmented skin, on dark-skinned vs. light-skinned individuals), but little research has been directed at elucidating disparities in the burden of disease.

Despite improvements in health care, some of the racial/ethnic disparities seen in the treatment and management of rheumatic, musculoskeletal, and skin diseases may be explained by differences in availability and quality of health services. Individual beliefs, attitudes, and behavior with regard to health care utilization, self-care practices and health-related habits may be important factors to consider. In a study of total joint replacement in African-American and Caucasian male veterans with OA, significant differences in awareness and understanding of this intervention, and in perceptions of the risks and benefits of the procedure were identified. Family variables, culture, socioeconomic status, social support, and other factors no doubt influence these individual beliefs, attitudes, and behaviors, and these factors may vary systematically

across racial/ethnic groups. Little is known about how such factors influence the prevalence, severity, course, or outcomes of rheumatic, musculoskeletal, and skin diseases.

Finally, common approaches to research design, methodology, and measurement may require adaptation to enhance access to minority and lower SES populations, and to increase the validity and reliability of research data. For example, widely used measures of health-related quality of life are written at the sixth- to ninth-grade reading level. Approximately 20% of adults read at or below the fifth grade level, and literacy rates in minority and lower-SES populations can be significantly lower.

The purpose of this announcement is to encourage investigator-initiated research projects (R01) that explore new approaches and hypotheses for understanding and eliminating health disparities in rheumatic, musculoskeletal, and skin diseases. Areas of interest include but are not limited to:

- o Epidemiological studies to determine the nature and source of racial/ethnic differences in the rates and patterns of disease
- o Studies investigating the interaction or additive effects of genetic and environmental factors in health disparities
- o Studies examining the underlying causes of health disparities for specific diseases of joints, muscle, bone, or skin that disproportionately affect ethnic or minority populations
- o Studies examining knowledge, attitudes, behaviors, and social factors relating to differential access to and utilization of health care
- o Development and testing of interventions to decrease disparities in the management of disease
- o Identifying socioeconomic, educational, and behavioral risk factors for increased disability and preventive intervention strategies that target at-risk populations
- o Development and testing of measurement tools and approaches to characterize disease-related health status, health quality of life, or health-related attitudes and beliefs in racial/ethnic and/or low SES samples
- o Studies investigating cultural competence of health care providers and its impact on treatment provision, patient behaviors (e.g., decision-making, adherence), and health outcomes

MECHANISM OF SUPPORT

This PA will use the NIH Research Project Grant (R01) award mechanism. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project. The total project period for an application submitted in response to this PA may not exceed 5 years.

This PA uses just-in-time concepts. It also uses the modular as well as the non-modular budgeting formats (see <http://grants.nih.gov/grants/funding/modular/modular.htm>). Specifically, if you are submitting an application with direct costs in each year of \$250,000 or less, use the modular format. Otherwise follow the instructions for non-modular research grant applications.

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
- o Units of State and local governments
- o Eligible agencies of the Federal government
- o Domestic or foreign
- o Faith-based or community-based organizations

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with his or her institution to develop an application for support. Individuals from underrepresented racial and ethnic groups, faith-based organizations, and individuals with disabilities are always encouraged to apply for NIH programs. Partnerships between principal investigators and faith-based organizations are encouraged as well.

SPECIAL REQUIREMENTS

Investigators who wish to establish new collaborative research programs in health disparities research with laboratories at the NIAMS Intramural Research Program, and apply for funding

under this PA, are encouraged to contact Dr. Barbara Mittleman, Director, Office of Scientific Interchange, NIAMS (mittlemb@mail.nih.gov).

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into two areas: scientific/research and financial or grants management issues:

o Direct your questions about scientific/research issues to:

Deborah N. Ader, Ph.D.
Behavior and Prevention Research Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza, Suite 800
Bethesda, MD 20892-4872
Telephone: (301) 594-5032
Fax: (301) 480-4543
Email: aderd@mail.nih.gov

Richard S. Fisher, Ph.D.
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6120 Executive Blvd
Rockville, MD 20892
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Fax: (301) 402-0528
Email: rf75s@nih.gov

Gayle Lester, Ph.D.
Osteoarthritis Initiative and Diagnostic Imaging Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
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Bernadette Tyree, Ph.D.
Cartilage and Connective Tissue Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza, Suite 800
Bethesda, MD 20892-4872
Telephone: (301) 594-5032
Fax: (301) 480-4543
Email: tyreeb@mail.nih.gov

Frederick Tyson, Ph.D.
Division of Extramural Research and Training
Office of Program Development
Chemical Exposures and Molecular Biology Branch
National Institute of Environmental Health Sciences
MD EC-21
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-0176
Email: tyson2@niehs.nih.gov

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

Melinda Nelson
Grants Management Officer
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
One Democracy Plaza, Suite 800
Bethesda, MD 20892-4872
Telephone: (301) 594-3535
FAX: (301) 480-5450
Email: nelsonm@mail.nih.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at

<http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at <http://grants.nih.gov/grants/dates.htm>.

Application deadlines are also indicated in the PHS 398 application kit.

SPECIFIC INSTRUCTIONS FOR MODULAR GRANT APPLICATIONS: Applications requesting up to \$250,000 per year in direct costs must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) at <http://grants.nih.gov/grants/funding/phs398/phs398.html> includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING \$500,000 OR MORE PER YEAR: Applications requesting \$500,000 or more in direct costs for any year must include a cover letter identifying the NIH staff member within one of the NIH institutes or centers who has agreed to accept assignment of the application.

Applicants requesting more than \$500,000 must carry out the following steps:

- 1) Contact the IC program staff at least 6 weeks before submitting the application, i.e., as you are developing plans for the study;
- 2) Obtain agreement from the IC staff that the IC will accept your application for consideration for award; and,
- 3) Identify, in a cover letter sent with the application, the staff member and IC who agreed to accept assignment of the application.

This policy applies to all investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended or revised version of these grant application types. Additional information on this policy is available in the NIH Guide for Grants and

Contracts, October 19, 2001 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html>.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the checklist, and five signed photocopies 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)

APPLICATION PROCESSING: Applications must be received by or mailed on or before the receipt dates described at <http://grants.nih.gov/grants/funding/submissionschedule.htm>. The CSR will not accept any application in response to this PA 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 a substantial revision of an application already reviewed, but such an application must include an Introduction addressing the previous critique.

PEER REVIEW PROCESS

Applications submitted for this PA will be assigned on the basis of established PHS referral guidelines. An appropriate scientific review group convened in accordance with the standard NIH peer review procedures (<http://www.csr.nih.gov/refrev.htm>) will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications will:

- o Receive a written critique
- o Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score
- o Receive a second level review by the appropriate national advisory council

REVIEW CRITERIA

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of your application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals:

- o Significance
- o Approach
- o Innovation
- o Investigator
- o Environment

The scientific review group will address and consider each of these criteria in assigning your application's overall score, weighting them as appropriate for each application. Your application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, you may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

(1) SIGNIFICANCE: Does your study address an important problem? If the aims of your application are achieved, how do they advance scientific knowledge? What will be the effect of these studies on the concepts or methods that drive this field?

(2) APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Do you acknowledge potential problem areas and consider alternative tactics?

(3) INNOVATION: Does your project employ novel concepts, approaches or methods? Are the aims original and innovative? Does your project challenge existing paradigms or develop new methodologies or technologies?

(4) INVESTIGATOR: Are you appropriately trained and well suited to carry out this work? Is the work proposed appropriate to your experience level as the principal investigator and to that of other researchers (if any)?

(5) ENVIRONMENT: Does the scientific environment in which your work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

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

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.

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)

DATA SHARING: The adequacy of the proposed plan to share data.

BUDGET: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

AWARD CRITERIA

Applications submitted in response to a PA will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

- o Scientific merit of the proposed project as determined by peer review
- o Availability of funds
- o Relevance to program 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>) and Further Guidance on Data and Safety Monitoring for Phase I and Phase II Trials

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html> (released on June 5,2000) provides the detailed description of these policies. The establishment of a NIAMS-initiated DSMB and the DSMB's responsibilities and operating procedures are guided by a charter. The NIAMS has developed a template for the charter as shown in DSMB Charter:

<http://www.niams.nih.gov/rtac/clinical/dsmbcharter.htm>

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 is 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>.

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 PA 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 PA 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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