

# NIH GUIDE

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**For Grants  
and  
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**U.S. DEPARTMENT OF HEALTH  
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The NIH Guide announces scientific  
initiatives and provides policy and  
administrative information to indi-  
viduals and organizations who need to  
be kept informed of opportunities,  
requirements, and changes in extra-  
mural programs administered by the  
National Institutes of Health.

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NOTICES

CHRISTOPHER COLUMBUS DISCOVERY AWARDS IN BIOMEDICAL RESEARCH: CALL FOR NOMINATIONS ..... 1  
National Institutes of Health  
Index: NATIONAL INSTITUTES OF HEALTH

NOTICES OF AVAILABILITY (RFPs AND RFAs)

MASTER AGREEMENT FOR THE CLINICAL EVALUATION OF ANTIPILEPTIC DRUGS (RFP) .. 2  
National Institute of Neurological Disorders and Stroke  
Index: NEUROLOGICAL DISORDERS, STROKE

SAFE STIMULATION OF THE CENTRAL AND PERIPHERAL NERVOUS SYSTEMS FOR NEURAL PROSTHESES (RFP) ..... 2  
National Institute of Neurological Disorders and Stroke  
Index: NEUROLOGICAL DISORDERS, STROKE

RESEARCH TRAINING AND CAREER DEVELOPMENT AWARDS IN NUTRITION AND OBESITY (RFA DKHD-91-13) ..... 3  
National Institute of Diabetes and Digestive and Kidney Diseases  
National Institute of Child Health and Human Development  
Index: DIABETES, DIGESTIVE DISEASES, KIDNEY DISEASES, CHILD HEALTH, HUMAN DEVELOPMENT

ONGOING PROGRAM ANNOUNCEMENTS

MOLECULAR AND STRUCTURAL BIOLOGY OF HAIR AND ITS DISEASES WITH SPECIAL REFERENCE TO ALOPECIA AREATA (PA-91-59) ..... 4  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Index: ARTHRITIS, MUSCULOSKELETAL DISEASES, SKIN DISEASES

MENTAL HEALTH RESEARCH ON HOMELESS PERSONS (PA-91-60) ..... 7  
National Institute of Mental Health  
Index: MENTAL HEALTH

HEALTH SERVICES RESEARCH CONFERENCE GRANTS (PA-91-61) ..... 9  
Agency for Health Care Policy and Research  
Index: HEALTH CARE POLICY, HEALTH CARE RESEARCH

HEALTH SERVICES RESEARCH PRIORITY AREAS FOR ACCELERATED SMALL GRANT APPLICATION REVIEW (PA-91-62) ..... 12  
Agency for Health Care Policy and Research  
Index: HEALTH CARE POLICY, HEALTH CARE RESEARCH

CUTANEOUS MANIFESTATIONS OF HIV INFECTION AND AIDS (PA-91-63) ..... 16  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Index: ARTHRITIS, MUSCULOSKELETAL DISEASES, SKIN DISEASES

THE HEALTH AND EFFECTIVE FUNCTIONING OF OLDER RURAL POPULATIONS (PA-91-64) .18  
National Institute on Aging  
Index: AGING

NOTICES

CHRISTOPHER COLUMBUS DISCOVERY AWARDS IN BIOMEDICAL RESEARCH  
CALL FOR NOMINATIONS

P.T. 42; K.W. 0710030

National Institutes of Health

The Christopher Columbus Medical Sciences Committee of the National Institutes of Health (CCMSC/NIH) and the CCMSC/Genoa, under the auspices of the Quincentenary Jubilee Commission, will award eight to ten prizes for scientific discoveries that have contributed significantly to the alleviation of disease and disability. The prizes will be a one-time award offer in conjunction with two scientific meetings that are being held as part of the international activities celebrating the 500th anniversary of the Old World discovery of the New World. The CCMSC/NIH activities are being co-sponsored with donations from private sources.

The Awards Subcommittee of the CCMSC/NIH hereby invites and encourages nominations of outstanding scientists, of any nationality, from all areas of

science that have an impact on health, for this award. The closing date for nominations is 30 June 1991. For information regarding the nomination process and selection criteria, please contact:

Dr. James C. Hill  
Deputy Director  
National Institute of Allergy and Infectious Diseases  
Chairman Awards Subcommittee  
National Institutes of Health  
Building 31, Room 7A03  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-9118

NOTICES OF AVAILABILITY (RFPs AND RFAs)

MASTER AGREEMENT FOR THE CLINICAL EVALUATION OF ANTIEPILEPTIC DRUGS

RFP AVAILABLE: Master Agreement Announcement/RFP NIH-NINDS-91-10

P.T. 34; K.W. 0740010, 0755015

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke (NINDS), NIH, is re-issuing the announcement, "Master Agreement for the Clinical Evaluation of Investigational Antiepileptic Drugs." The NINDS is requesting proposals with the intent of awarding Master Agreements (MAs) to sources capable of performing clinical evaluations of investigational antiepileptic drugs in tolerability and preliminary efficacy studies, controlled efficacy and safety trials, or both, in patients with epilepsy. Under this program, only MA holders will be eligible to compete for future Master Agreement Orders (MAOs) that fund the actual clinical evaluation of specific drugs as they become available for testing.

This is not a Master Agreement Announcement/Request for Proposals (MAA/RFP). MAA/RFP No. NIH-NINDS-91-10 will be issued on or about May 31, 1991, with a tentative closing date for receipt of responses on July 31, 1991.

Award of MAs under MAA/RFP No. NIH-NINDS-91-10 will be for a period of five years (estimated to be September 1991 through September 1996). It is anticipated that multiple MA awards will be made.

To receive a copy of MAA/RFP No. NIH-NINDS-91-10, please submit a written request to the following address, and supply this office with two self-addressed mailing labels:

Contracting Officer  
Contracts Management Branch, DEA  
National Institute of Neurological Disorders and Stroke  
Federal Building, Room 901  
7550 Wisconsin Avenue  
Bethesda, MD 20892  
Attention: MAA/RFP No. NIH-NINDS-91-10

All responsible sources may submit a proposal that shall be considered by the Government.

SAFE STIMULATION OF THE CENTRAL AND PERIPHERAL NERVOUS SYSTEMS FOR NEURAL PROSTHESES

RFP AVAILABLE: NIH-NINDS-91-11

P.T. 34; K.W. 0745047, 0740050

National Institute of Neurological Disorders and Stroke

The Neural Prosthesis Program (NPP) of the National Institute of Neurological Disorders and Stroke, NIH, is developing aids for the neurologically handicapped. These neural prostheses involve the use of electrical stimulation for selective activation and/or inhibition of neurons in the central and peripheral nervous systems. The Contractor will be required to exert its best efforts to develop neural stimulating electrodes and to evaluate the effects of electrical stimulation on neural and surrounding

tissue in non-human animals. It is anticipated that one award will be made for a period of three years in January 1992.

This is not a Request for Proposals (RFP). To receive a copy of the RFP, please submit a written request to the following address, and supply this office with two self-addressed mailing labels. All responsible sources shall be considered by the agency. The RFP will be issued on or about June 5, 1991, with proposals due on August 5, 1991.

Contracting Officer  
Contracts Management Branch, DEA  
National Institute of Neurological Disorders and Stroke, NIH  
Federal Building, Room 901  
7550 Wisconsin Avenue  
Bethesda, MD 20892  
Attention: RFP No. NIH-NINDS-91-11

#### RESEARCH TRAINING AND CAREER DEVELOPMENT AWARDS IN NUTRITION AND OBESITY

RFA AVAILABLE: DKHD-91-13

P.T. 34, 44; K.W. 0710095, 0765020, 0715145, 0720005

National Institute of Diabetes and Digestive and Kidney Diseases  
National Institute of Child Health and Human Development

Application Receipt Date: September 18, 1991

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Child Health and Human Development (NICHD) invite applications for research training and career development via the T32, K08, K11, and F32 mechanisms for physicians and basic scientists in the areas of nutrition and obesity-related research. The intent of this Request for Applications (RFA) is to provide research training and career development support to persons who have a commitment to and an aptitude for research in nutrient metabolism, obesity, eating disorders, and/or energy regulation, as well as maternal-fetal, infant, and childhood nutrition.

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 RFA, "Research Training and Career Development in Nutrition and Obesity," is related to the priority areas of nutrition and obesity. 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, D.C. 20402-9325 (telephone 202-783-3238).

#### OBJECTIVE AND SCOPE

Nutrition and obesity-related research needs and opportunities in the early decades of the next century will require an increased number of physicians and basic scientists with nutrition sciences training that can be related to clinical nutrition problems. The NIDDK and NICHD wish to increase the number of physicians and basic scientists who can conduct high quality research in these areas by providing training support for qualified individuals in the areas of nutrient metabolism, obesity, eating disorders, energy regulation, nutrition of low-birth weight infants, nutritional antecedents of adult disease, and dietary therapy of inborn errors of metabolism. This RFA is aimed directly at strengthening the national capacity for nutrition and obesity-related research.

#### MECHANISM OF SUPPORT

The mechanisms of support available are the National Research Service Award Institutional Training Grant (T32), The National Research Service Award Individual Postdoctoral Fellowship (F32), the Physician Scientist Award (K11), and the Clinical Investigator Award (K08).

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

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be

provided. Applications without such documentation will not be accepted for review.

#### APPLICATION SUBMISSION

Applicants are encouraged to read the guidelines for each mechanism to determine the one most suitable for their needs. Guidelines are available from the NIH Office of Grants Inquiries, Westwood Building, Room 449, Bethesda, MD 20892 (telephone 301-496-7441).

Applications received by the deadline of September 18, 1991, will be reviewed by a special review committee convened by the NIDDK and then reviewed subsequently by the NIDDK and NICHD Advisory Councils.

A copy of the complete RFA and consultation may be obtained from:

Dr. Judith Podskalny  
Division of Digestive Diseases and Nutrition  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 3A15  
National Institutes of Health  
Bethesda, MD 20892  
Telephone: (301) 496-7455

or

Dr. Ephraim Levin  
Medical Officer  
National Institute of Child Health and Human Development  
Executive Plaza North, Room 637  
National Institutes of Health  
Bethesda, MD 20892  
Telephone: (301) 496-5593

For information on fiscal matters and payback requirements contact:

Mrs. Nancy C. Dixon  
Supervising Grants Management Specialist  
DDN/KUH Team Leader  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 649  
Bethesda, MD 20892  
Telephone: (301) 496-7467

#### ONGOING PROGRAM ANNOUNCEMENTS

#### MOLECULAR AND STRUCTURAL BIOLOGY OF HAIR AND ITS DISEASES WITH SPECIAL REFERENCE TO ALOPECIA AREATA

PA: PA-91-59

P.T. 34; K.W. 0715185, 1002004, 1002008, 0790015

National Institute of Arthritis and Musculoskeletal and Skin Diseases

#### PURPOSE

The Skin Diseases Program, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), supports research on the structure, function, and diseases of the skin and its appendages. This program announcement is issued to encourage submission of research and fellowship grant applications in the area of molecular and structural biology of hair and its diseases with special reference to alopecia areata.

#### BACKGROUND

The hair follicle is a complex three-dimensionally organized skin appendage that cycles through stages of involution and regeneration over time. It is subject to hormonal influences and genetic effects as well as regional variation with body site. It is also subject to many diseases, both hereditary and acquired. The most common and often the most debilitating among the acquired diseases is alopecia areata. This condition has been thought to be a manifestation of a tissue-specific autoimmune disease, but definitive proof is still lacking.

The current state of knowledge of the molecular and structural biology of hair and the state of research in alopecia areata was summarized at two recent conferences cosponsored by NIAMS. These conferences emphasized the new knowledge being acquired in these areas of hair research but, more importantly, pointed out the many areas in which additional research is necessary to obtain a clear understanding of normal and abnormal processes and disease states.

#### RESEARCH GOALS AND SCOPE

The goal of this program announcement is to stimulate research in these areas of hair biology and disease. Some of the research objectives appropriate for inclusion in applications responsive to this program announcement are:

- o Studies of molecular and structural biology of normal hair during its normal cycle;
- o Hereditary diseases of hair to elucidate the underlying defect and the mechanism by which the disease state is expressed;
- o Hormonal influences on normal and diseased hair;
- o Etiopathogenesis and treatment of acquired hair diseases, particularly alopecia areata;
- o Epidemiologic studies of diseases of hair.

#### MECHANISM OF SUPPORT

Research mechanisms to support these investigations include research grants (R01), Clinical Investigator Awards (K08), First Independent Research and Transition (FIRST) Awards (R29), and Individual National Research Service Awards (F32).

#### SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

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 and fellowship 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), for research grant awards or on form PHS 416-1 (rev. 4/89) for fellowship awards. 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, Maryland 20892, telephone (301) 496-7441.

Applications will be accepted in accordance with the submission dates for new applications on a continuing basis:

February 1, June 1, October 1 for research grant applications. January 10, May 10, September 10 for fellowship applications.

The phrase, "MOLECULAR AND STRUCTURAL BIOLOGY OF HAIR AND ITS DISEASES WITH SPECIAL REFERENCE TO ALOPECIA AREATA, PA-91-59" must be typed on line 2 of the face page of the application. The original and six copies of the PHS 398 or the original and two copies of the PHS 416-1 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:

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 grant 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.

#### MENTAL HEALTH RESEARCH ON HOMELESS PERSONS

PA: PA-91-60

P.T. 34; K.W. 0715095, 0715129

National Institute of Mental Health

The National Institute of Mental Health (NIMH) announces the continuation of an initiative to encourage investigator-initiated research focusing on mental health and homelessness. The target population includes severely mentally ill adults who are homeless or at risk of becoming homeless, homeless adolescents, and homeless families with children who are severely emotionally disturbed or at risk of emotional disturbance.

The purpose of this initiative is to accelerate the development of knowledge about the prevalence, etiology, and treatment of homelessness and mental disorders that can ultimately contribute to more effective delivery of mental health services to homeless persons, reductions in homelessness among severely mentally ill persons, improvements in mental health status among homeless individuals, and better information on how housing and mental health services can be appropriately integrated for homeless, severely mentally ill persons.

This revised announcement supersedes the NIMH December 1988 program announcement entitled "Research and Research Demonstrations on Homeless Severely Mentally Ill Adults and Homeless Families with Children who are at Risk of Severe Emotional Disturbance." This announcement solicits investigator-initiated applications under a range of funding mechanisms. As part of the NIMH Public-Academic Liaison initiative, preference will be given to applications that involve collaboration between academic researchers and public sector agencies in planning and conducting research. Also, the Public Health Service (PHS) encourages applicants to submit work plans that address specific objectives of Healthy People 2000. 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, D.C. 20402-9325 (telephone 202-783-3238).

General areas of interest include studies of processes affecting the mental health of homeless persons, epidemiologic and clinical studies of homeless populations, studies of mental health services to homeless persons, studies exploring housing development for homeless mentally ill persons, studies of systems issues related to the mental health care of homeless persons, and methods and measurement development.

Areas of specific interest include service needs of homeless, severely mentally ill persons dwelling in street or public transportation settings; understudied homeless subgroups such as women, minorities, adolescents, and families with children; the prevalence of a recent history of physical and/or sexual abuse among homeless children or adolescents, and studies of physical and sexual abuse as a risk factor for homelessness; the co-occurrence of severe mental illness with alcohol and/or drug disorders in homeless populations; and the relationships among mental illness, HIV infection, and homelessness.

Generally, applications may be submitted by public or private nonprofit or for-profit organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply. Contact the NIMH staff person listed below for further eligibility requirements.

#### **SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS**

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/offers 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.

Because of the special sensitivity of research focused on homeless and homeless, severely mentally ill persons, particular attention should be given by applicants to considerations of informed consent, confidentiality, subjects rights and welfare, and subject risk.

Support for research may be requested through applications for a research grant (R01), small grant (R03), First Independent Research and Transition (FIRST) award (R29), and program project award (P01). Support for research projects that include funds for services may be requested through applications for research demonstration grants (R18). Other support mechanisms include the Predoctoral Individual National Research Service Award (F31), Postdoctoral National Research Service Award (F32), Institutional National Research Service Award (T32), Scientist Development Award for Clinicians (K20), and Scientist Development Award (K21).

Grant funds may be used for expenses clearly related and necessary to conduct research, including both direct costs and allowable indirect costs. Only if the application is for a research demonstration project (R18) may a substantial portion of grants funds be used to support costs associated with treatment, rehabilitation, or other service programs. Applicants must clearly distinguish services to be supported through research demonstration funds and services supported through other sources.

All research applicants must use the grant application form PHS 398 (rev. 10/88). Applications may request support for up to 5 years for research and up to 3 years for research demonstration projects. Small grant applications are limited to 2 years. Annual awards will be made subject to availability of

funds and, for renewals, progress achieved. Applications for fellowships must use the application form PHS 416-1 (rev. 4/89).

Applications will be received under the usual PHS receipt and review schedule. Applications will be reviewed by an initial review group consisting primarily of non-Federal scientific and technical experts. Applications will receive a second-level review by the appropriate Advisory Council based on policy considerations as well as scientific merit. Only applications recommended for approval by the Advisory Council may be considered for funding.

Subject to the quality of proposals and availability of funds, NIMH hopes to make up to \$3 million available for between 5 and 15 projects funded in fiscal year 1992.

Inquiries regarding this announcement and requests for a copy of the full announcement may be directed to:

Roger B. Straw, Ph.D.  
Office of Programs for the Homeless Mentally Ill  
Room 7C-06  
Telephone: (301) 443-3706

Further information on grants management issues may be obtained from:

Stephen J. Hudak  
Grants Management Branch  
Room 7C-26  
Telephone: (301) 443-4456

The address for both of the above is:

National Institute of Mental Health  
5600 Fishers Lane  
Rockville, MD 20857

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.242, 93.282, and 93.28. Under the authority of Sections 301 and 520 of the Public Health Service Act (42 USC 241 as amended), and subject to availability of funds, the National Institute of Mental Health will accept applications in response to this announcement

#### HEALTH SERVICES RESEARCH CONFERENCE GRANTS

PA: PA-91-61

P.T. 42; K.W. 0730050, 1004017

Agency for Health Care Policy and Research

The Agency for Health Care Policy and Research (AHCPR) announces procedures and criteria for health services and medical effectiveness research conference grants pursuant to Title IX of the Public Health Service (PHS) Act and section 1142 of the Social Security Act and invites applications for such grants.

**TYPES OF CONFERENCES SUPPORTED** - AHCPR awards grants for conferences and workshops related to general health services research and medical effectiveness research activities. AHCPR supports conferences that further the following activities:

- o exchanging information on innovations in health services delivery and technology, and developing and improving methods of disseminating findings and information resulting from health services research activities of AHCPR;
- o promoting the dissemination and adoption of medical practice guidelines, clinical research findings, and health services research data-related products;
- o improving health services research design and methods; and
- o developing research agendas for addressing significant health services problems.

For conference proposals requesting \$50,000 or less in direct costs, AHCPR is particularly interested in applications in areas described in a separate notice appearing in this issue of the NIH Guide for Grants and Contracts

entitled "Health Services Research Priority Areas for Accelerated Small Grants Review."

AHCPR also is particularly interested in conference grant applications that pertain to the above areas and applications that have relevance to the specific objectives of the publication "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (full report; Stock No. 017-001-00474-0) (summary report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C., 20402-9325, telephone 202-783-3238.

#### **SPECIAL INSTRUCTIONS TO APPLICANTS CONCERNING THE INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDY POPULATIONS**

AHCPR observes NIH and ADAMHA policy requiring applicants for research grants 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. Under this policy, special emphasis is placed on the need to include minorities and women in the studies of diseases, disorders and conditions which disproportionately affect them. The policy is intended to apply to males and females of all ages. Although conferences will not conduct research per se, research is usually a primary focus of AHCPR-supported conferences and applications will be expected to demonstrate consideration for the special needs of minorities and women. This consideration should be reflected in the design of the agenda, selection of topics and speakers, as well as in the final product associated with the conference, whether it is a research agenda or conference proceedings.

**REVIEW PROCESS** - Conference grant applications with direct costs of \$50,000 or less over the project period are reviewed for scientific and technical merit by Federal and/or non-Federal experts serving as field readers, rather than a standing advisory committee. Section 922(d)(2) of the PHS Act allows the Administrator of AHCPR to make adjustments in the standard peer review process for applications with direct costs that do not exceed \$50,000. Conference grant applications in excess of \$50,000 over the project period will be reviewed under standard peer review procedures in accordance with section 922 of the PHS Act.

**ELIGIBLE APPLICANTS** - Applications may be submitted by public or private nonprofit institutions, units of State or local government, or individuals. For-profit institutions are not eligible for AHCPR grants.

**APPLICATION PROCEDURES** - Applications must be submitted in accordance with section 924 of the Public Health Service Act and with the instructions in the application kit and 42 CFR 67.13.

**APPLICATION FORMS** - All applicants, except units of State and local government, must use form PHS 398 (rev. 10/88). Applicants from State and local governments may use Form PHS 5161, Application for Federal Assistance (nonconstruction programs). Application materials are available at most institutional business offices and from:

Office of Scientific Review  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A-20  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-3091

**APPLICATION SUBMISSION** - The original and six copies of form PHS 398 (rev. 10/88) must be sent to:

Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 240  
Bethesda, MD 20892\*\*

State and local governments using Form PHS 5161 must submit an original and two copies of the application to the same location.

Those applicants submitting an application with direct costs in excess of \$50,000 must check item 2 of page 1 of the application "Yes," and the PA number PA-91-61 and the title "Conference Grants" must be entered. Those applicants submitting an application with direct costs of \$50,000 or less must check item 2 of page 1 of the application "Yes," and the PA number PA-91-62 and the title "AHCPR Small Grants Program" must be entered.

**SUBMISSION DEADLINES** - The deadline for submission of applications depends on whether or not the amount of direct costs over the project period exceeds \$50,000.

The first deadline for submission of applications in excess of \$50,000 is June 1, 1991. Thereafter, the following deadlines apply to conference grants for any fiscal year: February 1, June 1, and October 1. Funding decisions will be made within approximately eight to ten months after receipt of applications.

The first deadline for applications of \$50,000 or less in direct costs is September 15, 1991. Thereafter, the following deadlines apply to conference grants for any fiscal year: January 15, May 15, and September 15. Funding decisions will be made within approximately six months after receipt of applications.

Applications will be considered on time if they are received on or before the established deadline dates or sent on or before the deadline dates specified in this Notice, unless they are received too late for orderly processing. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing. Late applications not accepted for processing will be held for the next regularly scheduled review cycle.

**REVIEW CRITERIA** - The following are the minimum criteria by which applications for conference grant support are reviewed:

**Significance of the proposed conference:** (1) The importance of the issue or problem addressed in the delivery, cost, quality of, or access to health services, or a methodological or technical issue in dealing with the development and conduct of health services research; (2) the implications of the conference's intended outcome(s) for future health services research, for identifying or resolving methodological problems, and for organizing and managing research activities; and (3) the implications of the conference for technological innovations in health care communications and dissemination of knowledge, information, or for the effective utilization of the material communicated and disseminated.

**Conference Design:** (1) The logic and soundness of the conference's conceptual framework; (2) the role, composition, and expertise of individuals and advisory groups to be utilized in planning or conducting the conference, including the involvement of the potential users of the information or other products of the conference; (3) the reasonableness of the techniques proposed to ensure maximum participation and interaction among participants, e.g., discussion in large and small groups, prior distribution of papers, panels versus individual speakers, and periods for questions and answers; (4) the specificity of the proposed agenda of topics to be addressed, the proposed speakers and panel members for each topic, their credentials, and the criteria for their selection; and (5) the nature and quality of the informational products to be disseminated as a result of the conference (such as proceedings, research agendas, publications, training manuals, and other products), and a plan for dissemination.

**Personnel and Facilities:** (1) The experience and training of the applicant indicating the ability to design, organize, and carry out a health services research conference; and (2) the adequacy of the facilities available for conducting the conference.

**Appropriateness of Budget:** (1) The reasonableness of the overall cost of the conference, given the proposed approach; and (2) the cost effectiveness of the total proposed expenditure in terms of the probable value of the conference results.

**FUNDING AVAILABILITY** - AHCPR anticipates that up to \$300,000 may be expended in a fiscal year for grants with direct costs of \$50,000 or less. Grant applications for more than \$50,000 in direct costs will compete with the total AHCPR grant application pool for funding. AHCPR anticipates that it may award from one to two new conference grants per year with direct costs in excess of \$50,000. Grants made pursuant to this announcement will be reviewed and funded consistent with grant application procedures and policies set out in 42 CFR Part 67, Subpart A, and the PHS Grants Policy Statement. Funding of a conference may be made conditional on grantee acceptance of changes recommended by the field readers or advisory committee members, including substantive changes in the conference design and/or budgetary considerations.

**CONDITIONS OF ACCEPTANCE OF AWARD** - Grantees must agree to: (1) Allow a limited number of AHCPR staff to attend or participate in the conference (the

number of staff will be negotiated at the time of award; they will arrange for their own travel expenses); (2) hold the conference within 12 months of the date of the award; and (3) submit three copies of an executive summary and three copies of a one-page abstract of the proceedings to AHCPR not later than 60 days after the conference, and provide AHCPR with three copies of the conference proceedings as soon as they are available.

**RELATED INFORMATION** - The AHCPR grant program is described in the Catalog of Federal Domestic Assistance as Numbers 93.226 and 93.180. Executive Order 12372 is not applicable to AHCPR grants. Additional guidance on these conference grants is included in the AHCPR publication Conference Grant Information. Copies of this publication will be provided in the application kit. The information in this notice is being published in the Federal Register. AHCPR grants are governed by regulations found in the Code of Federal Regulations, Title 42, Part 67, Subpart A. A copy of the regulations is included in the application kit.

For additional information, contact:

Margaret VanAmringe  
Director, Center for Research Dissemination and Liaison  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A-10  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-2904

For fiscal and administrative matters, contact:

Ralph Sloat  
Chief, Grants Management Branch  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A27  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-4033

**HEALTH SERVICES RESEARCH PRIORITY AREAS FOR ACCELERATED SMALL GRANT APPLICATION REVIEW**

PA: PA-91-62

P.T. 34, 42; K.W. 0730050, 0730000

Agency for Health Care Policy and Research

The Agency for Health Care Policy and Research (AHCPR) announces priority areas for small grant applications for health services research, including conferences, pursuant to Title IX of the Public Health Service (PHS) Act and section 1142 of the Social Security Act and invites applications for such grants. Small grant applications are those with total direct costs of \$50,000 or less over the project period. AHCPR is particularly interested in

NIH GUIDE - Vol. 20, No. 21, May 31, 1991 - Page 11

receiving small grant applications from individuals new to the health services research field.

Small grant applications proposing a conference or research in the priority areas identified below will be accorded an accelerated review. This accelerated review will permit AHCPR to notify applicants of funding decisions approximately six months after receipt of applications. The information in this notice, as well as future changes, will be published in the Federal Register. AHCPR is also issuing a separate Federal Register notice and announcement in the NIH Guide for Grants and Contracts with additional information pertaining to all conference grant proposals, including those in excess of \$50,000.

Research priority areas, including conferences, that qualify small grant proposals for accelerated review are:

1. Research on health care services for underserved/ disadvantaged populations, e.g., minority health issues, rural health issues, methods to improve access;
2. Research on costs, access, and quality of care for the uninsured/underinsured;

3. Research on health care services for individuals with HIV infections, including issues related to costs, access, and quality of care delivered to such individuals;

4. Research on medical liability issues, e.g., determinants of, or alternative approaches to reduce medical liability;

5. Research on clinical practice-oriented primary care; that describes the natural history and the management of conditions commonly encountered in primary care practice; and

6. Conferences on the areas specified above as well as other health services research topics of general interest.

These priority areas supersede previously announced priorities for small grant applications. Comments on the priorities are being solicited through the Federal Register. Any changes in priorities required to address National concerns will be announced before becoming effective.

If the application submitted in response to this RFA is substantially similar to a research grant application already submitted to the NIH for review, but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. Therefore, an application cannot be submitted in response to this RFA that is essentially identical to one that has already been 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.

AHCPR urges applicants to submit priority consideration small grant applications that address specific objectives of the publication "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (full report; Stock No. 017-001-00474-0) (summary report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325, telephone 202-783-3238.

#### **SPECIAL INSTRUCTIONS TO APPLICANTS CONCERNING INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDY POPULATIONS**

AHCPR observes NIH and ADAMHA policy requiring applicants for clinical research grants 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.

The composition of the proposed study group 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, or in the program narrative section of Form PHS 5161 for State and local governments.

If the required information is not contained in the application, the application will be returned. All applications for research submitted to AHCPR are required to address these policies. AHCPR will not award grants that do not comply with these policies.

**REVIEW PROCESS** - The accelerated review process involves technical and scientific review by Federal and/or non-Federal experts serving as field readers, rather than a standing advisory committee. Section 922(d)(2) of the PHS Act allows the Administrator of AHCPR to make adjustments in the usual peer review process for applications whose direct costs do not exceed \$50,000.

Small grant proposals submitted for research on topics not specified above, or for research conferences in excess of \$50,000, will not be accepted for expedited review, although they may be eligible for the established AHCPR peer review process by a committee of non-Federal experts. The final determination as to whether an application qualifies for expedited review is made by AHCPR, based on the application's consistency with the above-listed priority areas. If AHCPR determines that an application intended by the applicant for expedited review is not so qualified, the application will be held for the next regular application deadline for routine grants receipt and peer review procedures.

**ELIGIBLE APPLICANTS** - Applications may be submitted by public or private nonprofit institutions, units of State or local government, or individuals.

**APPLICATION PROCEDURES** - Applications must be submitted in accordance with Section 924 of the PHS Act and with instructions in the application kit and 42 CFR 67.13.

**APPLICATION FORMS** - All applicants, except units of State and local governments, must use form PHS 398 (rev. 10/88). Applicants from State and local governments may use form PHS 5161, Application for Federal Assistance (nonconstruction programs). Grant application materials and instructions are available from: Office of Scientific Review, Office of Planning and Resource Management, AHCPR, 5600 Fishers Lane, Room 18A-20, Rockville, Maryland 20857, telephone (301) 443-3091.

**APPLICATION SUBMISSION** - To receive accelerated review, Item 2 of page 1 of the application should be checked "Yes", and the PA number PA-91-62 and the title "AHCPR Small Grants Program" should be entered.

The original and six copies of the application must be sent to:

Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 240  
Bethesda, MD 20892\*\*

State and local governments using form DHHS 5161 must submit the original and two copies of the completed application form to the same location.

**SUBMISSION DEADLINES** - The first deadline for receipt of priority and conference small grant applications is September 15, 1991. Thereafter, the following deadlines for receipt of applications are January 15, May 15, and September 15 for any year.

Applications will be considered on time if they are received on or before the established deadline dates or sent on or before the deadline dates specified in this Notice, unless they are received too late for orderly processing. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing. Late applications not accepted for processing will be held for the next regularly scheduled review cycle.

**REVIEW CRITERIA** - Research grant applications will be reviewed according to the following criteria: (1) The significance and originality from a scientific or technical standpoint of the goals of the project; (2) the adequacy of the methodology proposed to carry out the project; (3) the availability of data or the proposed plan to collect data required in the analysis; (4) the adequacy and appropriateness of the plan for organizing and carrying out the project; (5) the qualifications of the Principal Investigator and the proposed staff; (6) the reasonableness of the proposed budget in relation to the proposed project; (7) the adequacy of the facilities and resources available to the grantee; and (8) the adequacy of steps proposed to protect human subjects, as appropriate.

Conference grant applications will be reviewed according to the following additional criteria:

**Significance of the Proposed Conference:** (1) The importance of the issue or problem addressed in the delivery, cost, quality of, or access to health services, or a methodological or technical issue in dealing with the development and conduct of health services research; (2) the implications of the conference's intended outcome(s) for future health services research, for identifying or resolving methodological problems, and for organizing and managing research activities; and (3) the implications of the conference for technological innovations in health care communications and dissemination of knowledge, information, or for the effective utilization of the material communicated and disseminated.

**Conference Design:** (1) The logic and soundness of the conference's conceptual framework; (2) the role, composition, and expertise of individuals and advisory groups to be utilized in planning or conducting the conference, including the involvement of the potential users of the information or other products of the conference; (3) the reasonableness of the techniques proposed to ensure maximum participation and interaction among participants, e.g., discussion in large and small groups, prior distribution of papers, panels versus individual speakers, and periods for questions and answers; (4) the specificity of the proposed agenda of topics to be addressed, the proposed

speakers and panel members for each topic, their credentials, and the criteria for their selection; and (5) the nature and quality of the informational products to be disseminated as a result of the conference (such as proceedings, research agendas, publications, training manuals, and other products), and a plan for dissemination.

**Personnel and Facilities:** (1) The experience and training of the applicant indicating the ability to design, organize, and carry out a health services research conference; and (2) the adequacy of the facilities available for conducting the conference.

**Appropriateness of Budget:** (1) The reasonableness of the overall cost of the conference, given the proposed approach; and (2) the cost effectiveness of the total proposed expenditure in terms of the probable value of the conference results.

**FUNDING AVAILABILITY** - AHCPR expects to award up to \$1 million per year for all small grants.

**RELATED INFORMATION** - The AHCPR grant program is described in the Catalog of Federal Domestic Assistance as numbers 93.226 and 93.180. Applications are not subject to Executive Order 12372. All grants funded under this announcement are subject to grant regulations set out in 42 CFR Part 67, Subpart A, and the PHS Grants Policy Statement.

For additional information on research priority areas specified in this notice, contact:

Center for General Health Services  
Extramural Research  
Agency for Health Care Policy and Research  
2101 East Jefferson Street, Room 678  
Rockville, MD 20852-4993  
Telephone: (301) 443-2345

Specific individuals for each area are as follows (address is same as above):

o Rural health issues:

Carole D. Dillard  
Telephone: (301) 443-6990

o Minority health issues:

Frantz C. Wilson  
Telephone: (301) 443-2080

o Cost, access, and quality of care for the uninsured/underinsured:

Fred J. Hellinger, Ph.D.  
Telephone: (301) 443-6990

o HIV/AIDS issues:

Melford Henderson  
Telephone: (301) 443-6990

o Medical liability issues:

Gary J. Young, J.D.

NIH GUIDE - Vol. 20, No. 21, May 31, 1991 - Page 14

o Clinical practice-oriented primary care:

Carolyn Clancy, M.D.  
Telephone: (301) 443-2080

For additional information on program aspects on conferences, contact:

Margaret VanAmringe  
Director, Center for Research Dissemination and Liaison  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A-10  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-2904

For fiscal and administrative matters, contact:



Ralph Sloat  
Chief, Grants Management Branch  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A27  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-4033

CUTANEOUS MANIFESTATIONS OF HIV INFECTION AND AIDS

PA: PA-91-63

P.T. 34; K.W. 0715120, 0715185

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The Skin Diseases Program supports research on the structure, function, and diseases of skin. This program announcement is to encourage submission of research grant applications in the area of cutaneous manifestations of human immunodeficiency virus (HIV) infection and diseases, including AIDS, that are caused by HIV infection. Research grant applications may be basic, clinical, or epidemiologic. Research mechanisms to support these studies include investigator-initiated research grants (R01), Clinical Investigator Awards (K08), First Independent Research and Transition (FIRST) Awards (R29), and Individual National Research Service Awards (F32).

The vast majority of patients with AIDS manifest cutaneous disease at some time during their illness. Patients with HIV infection not meeting the criteria for the diagnosis of AIDS also frequently manifest cutaneous disease. In addition, an exanthem that is associated with initial HIV infection in humans has been described; it precedes seroconversion to HIV positivity by weeks to months. The skin diseases seen in HIV infection encompass diseases for which the pathogenesis has yet to be elucidated, including psoriasis and seborrheic dermatitis; infectious diseases such as candidiasis and viral and bacterial infections; and malignancies, particularly Kaposi's sarcoma.

A previous program announcement (NIH Guide for Grants and Contracts, Vol. 17 No. 11, March 25, 1988) was published to stimulate research in this area. This program announcement is designed to further encourage research grant applications to investigate basic, clinical, and epidemiologic aspects of these diverse cutaneous manifestations of HIV infection. Projects may be oriented specifically towards the cutaneous manifestations of HIV infection. They may also be oriented towards utilizing the high incidence of skin disease in the HIV-infected and AIDS populations to investigate the pathogenesis of the idiopathic skin disease. Thus, we expect to obtain new information relevant to idiopathic skin diseases as well as a better understanding of the coexistence of AIDS and skin disease.

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 cutaneous complications. Epidemiologic studies may focus on the etiology, risk factors for disease development and severity, natural history of disease, and prognosis for developing disease. This includes descriptive studies of incidence, prevalence, morbidity, and mortality.

**SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS**

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/offers 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.

Investigators are encouraged to work with existing, or proposed, longitudinal data collection resources and cohorts of patients. Populations that 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 work with existing patient cohorts, such as the Multicenter AIDS Cohort Study (MACS), The HIV Pulmonary Complication Study, and the AIDS Clinical Trials Group.

#### ELIGIBILITY

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

#### DEADLINE

Applications will be accepted in accordance with receipt dates for unsolicited AIDS R01 and R29 applications: January 2, May 1, and September 1 of each year. AIDS investigator-initiated applications received on these dates by the Division of Research Grants will be subjected to expedited review. Applicants for F32 awards must submit applications to meet the receipt dates listed in the instructions for those mechanisms.

#### REVIEW PROCEDURES AND CRITERIA

All applications, except F32s, must be submitted on form PHS 398, rev. 10/88. Form PHS 416-1 must be used to submit F32 applications. Application kits are available at the business or grants and contracts office at most research and academic institutions. Additional application kits may be obtained from the Office of Grants Inquiries, Division of Research Grants, NIH, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The phrase, "Cutaneous Manifestations of HIV Infection and AIDS, PA-91-63" must be typed at item 2 of the first page of the application form 398 or item 3 of the form 416-1. The original and 24 copies of an R01 or R29 application submitted for expedited review, or the original and 2 copies of a fellowship application must be sent to:

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

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research grant applications 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 welfare verifications must be submitted with the applications. Applications will first be reviewed for technical merit by initial review groups and then by the appropriate national advisory council. The review criteria customarily employed by the NIH for research grant applications will prevail.

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. In such a case, a letter of agreement from the Program Director of the GCRC must be included with the application material.

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

For further information contact:

Dr. Alan N. Moshell  
Director, Skin Diseases Program  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Westwood Building, Room 405  
Bethesda, MD 20892  
Telephone: (301) 496-7326

Reva C. Lawrence, M.P.H.  
Epidemiology/Data Systems Program Officer  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Building 31, Room 4C13  
Bethesda, MD 20892  
Telephone: (301) 496-0434

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 the authority of the Public Health Service Act, Title III, Section 301 (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 intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

#### THE HEALTH AND EFFECTIVE FUNCTIONING OF OLDER RURAL POPULATIONS

PA: PA-91-64

P.T. 34, 44; K.W. 0710010, 0417000, 0408006, 0414000, 0413001, 0730000

National Institute on Aging

#### I. BACKGROUND

The National Institute on Aging (NIA) invites research and research training grant applications on the social, economic, psychological, environmental, and biomedical factors affecting the aging processes and the health and effective functioning of older people in rural areas. Recent governmental and non-governmental reports highlight the special health-care and other services needs of rural people and especially those who are old. People in rural areas are more likely than their urban counterparts to be in fair or poor health, to

suffer from chronic or serious illness, to be without a regular source of health care and health insurance. Moreover, a higher proportion of deaths occur among the nonmetropolitan than the metropolitan population over 65 years of age. The U.S. Congress has called for an increased research effort in order to improve the knowledge base necessary for the promotion of health and the prevention of disease among rural older people and for developing and implementing effective, acceptable, and accessible health care and other services.

## II. SPECIFIC OBJECTIVES

A research agenda is needed for examining the life-long experience, the current circumstances, and the special physical and social nature of rural life as they affect the health, well-being, and functioning of nonmetropolitan older people. Although many research topics are worthy of consideration, NIA consultants and staff have identified five as requiring special attention. Applications proposing activities relevant to these broad topics are especially encouraged. (To obtain more detailed information about these topics from NIA Staff, see Section VII.)

### A) The changing social, economic, demographic, and epidemiologic characteristics of the older rural population

In 1980, 25.5 million Americans were 65 or older, and 25 percent of these lived in rural areas. While older people comprised about 11 percent of both the urban and rural populations, several aspects of the older rural population reflect its diversity and distinguish it from its urban counterparts. These sources of diversity and distinctiveness need to be considered in regard to their possible effects on aging and the health and effective functioning of older rural residents.

### B) The occupational and physiochemical environment

The exposure of older rural residents to particular physiochemical and occupational environments reflects the wide diversity of aging processes and health in rural areas and also distinguishes them from the experiences of older urban residents. This exposure raises the general question of whether or not the effects are cumulative and whether or not it interacts with aging processes (e.g., accelerates aging).

### C) The aging population of rural communities

Attention needs to be paid not only to the health and well-being of older people, but also to the entire infrastructure of the communities in which older people live. A thorough investigation of the health and socioeconomic circumstances of older rural residents implies a need to study older individuals in the context of their social environment. Currently, many rural communities are undergoing massive changes. Some of these changes are brought on by the significant increases in the proportion of the population that is old--the "aging" of the rural population is exacerbated by either the emigration of younger people or the immigration of older people. As rural communities change, complex interactions--among older people, their families, other individuals in the community, and various community organizations, institutions, and agencies--influence the health and psychological, social, and financial well-being of older rural people. As people grow older and live longer, changes may occur in their relationships with their families, their churches, and their membership in informal social groups.

### D) The availability, utilization, and quality of health-care and other services

Research is needed on the origins and consequences for older rural residents of the relative unavailability of health-care (including disease-preventive services, e.g., for hypertension, smoking, and injuries) and social services in rural communities.

### E) Aging rural people as resources

Aspects of rural physical and social environments that may promote health and effective functioning as people grow older deserve attention. Despite the popular stereotype that "old age means dependency," the overwhelming majority of older people are never institutionalized and lead productive and independent lives. Unfortunately, the substantial societal resource that the growing numbers of older people represent is usually overlooked. Research on aging rural people may be the place to begin the process of recognizing older people as a resource.

### III. DEFINITION OF RURAL

This program announcement follows the Bureau of the Census' definitions of "rural vs. urban," "metropolitan vs. nonmetropolitan," and "farm vs. nonfarm." It recognizes that "rural" or "nonmetropolitan" is not synonymous with "agriculture" and/or that appropriate research populations include people living in small towns engaged in nonagricultural occupations.

### IV. MECHANISMS OF SUPPORT AND REVIEW CRITERIA

Research project grant (R01) and First Independent Research Support and Transition (FIRST) Award (R29) applications, fellowships (F32, F33), research career development awards (K04) accepted in response to this program announcement will be assigned to NIH/ADAMHA Institutes and an Initial Review Group in accordance with standard Referral Guidelines. Applications will be reviewed for scientific and technical merit by an appropriate initial review group. Secondary review will be by the appropriate National Advisory Council. Applications will compete on the basis of scientific merit with all other applications.

### V. ELIGIBILITY

Applications may be submitted by public or private, non-profit or for-profit, organizations such as universities, colleges, hospitals, research institutes and organizations, units of State and local governments, and eligible agencies of the Federal government. Women and minority investigators are encouraged to apply.

### VI. INCLUSION OF WOMEN AND MINORITIES

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants 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, together with a rationale for its choice. 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 or 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 review will be deferred until the information is provided.

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.

#### VII. METHOD OF APPLYING

For further information, contact NIA staff in advance of submission.

##### Basic Aging Program

H. Warner  
Telephone: (301) 496-6402

##### Behavioral and Social Research Program

R. P. Abeles  
Telephone: (301) 496-3136

##### Geriatrics Program

S. Slater  
Telephone: (301) 496-6761

##### Neuroscience and Neuropsychology of Aging Program

T. S. Radebaugh  
Telephone: (301) 496-9350

Address financial management questions to:

##### J. Ellis

Grants and Contracts Management Office  
National Institute on Aging  
Building 31, Room 5C07  
Bethesda, MD 20892  
Telephone: (301) 496-1472

For information about the coordinated program of the National Center on Nursing Research (NCNR), see "Rural Health Care Research: Impacting Vulnerable Populations," NIH Guide to Grants and Contracts, Vol. 20, No. 6, February 8, 1991, and/or contact Dr. P. Moritz, NCNR, telephone (301) 496-0523.

Applicants must use the grant application form PHS 398 (rev. 10/88) and fellowship application forms PHS 416-1 (rev. 7/88), which are available at the applicant's institutional Application Control Office and from:

Office of Grants Inquiries  
Division of Research Grants  
National Institute of Health  
Westwood Building, Room 449  
Bethesda, MD 20892  
Telephone: (301) 496-7441

Check the box on the application face sheet indicating that the application is in response to this announcement and print on line 2 "HEF of Older Rural Populations, PA-91-64." The standard receipt dates for applications by the Division of Research Grants apply (for R01, R29, P01, and K04: February 1, June 1, and October 1; for T32, F32, and F33: January 10, May 10, and September 10 of each year). Mail the complete original application and the appropriate number of copies to:

Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 240  
Bethesda, MD 20892\*\*

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Agency Research Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241 and 41 USC 289) and be subject to PHS Grants Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review or Executive Order 12372.

\* U.S. G.P.O.:281-826:20047