

NIH Guide for Grants and Contracts

U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Vol. 13, No. 13, December 7, 1984

IN THIS ISSUE:

Erratum

The Oldest Old Page 1
National Institute on Aging
Index - AGING

Notice

Support of Research Center and Program
Project Grants Page 1
National Institute of General Medical Sciences
Index - GENERAL MEDICAL SCIENCES

Notice

National Research Service Awards for Short-Term
Training: Students in Health Professional
Schools Page 2
Division of Research Resources
Index - RESEARCH RESOURCES

Notice

Change in Application Receipt Date
Cancer Control Research Units: RFA
84-CA-08 Page 3
National Cancer Institute
Index - CANCER

Announcement

Availability of Request for Applications:
RFA 85-RR-01 - Developing and Improving
Institutional Animal Resources Page 4
Division of Research Resources
Index - RESEARCH RESOURCES

Continued

The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

Have You Moved?

If you present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

Announcement

Request for Applications: RFA - 85-OD-01
Academic Research Enhancement Award Page 6
National Institutes of Health
Index - NATIONAL INSTITUTES OF HEALTH

Announcement

Availability of Request for Applications: RFA
85-HL-26 - Alterations and Renovations to
Establish NHLBI Shared Research Facilities..... Page 7
National Heart, Lung, and Blood Institute
Index - HEART, LUNG, AND BLOOD

Announcement

Availability of Request for Applications:
RFA 85-HD-03 - Reproductive Disorders Page 9
National Institute of Child Health
and Human Development
Index - CHILD HEALTH AND HUMAN DEVELOPMENT

Announcement

Availability of Request for Applications:
RFA FDA-OP-85-1 - Clinical Studies of Safety
and Effectiveness of Orphan Products..... Page 10
Food and Drug Administration
Index - FOOD AND DRUG ADMINISTRATION

Announcement

Availability of Request for Applications:
MH-86-02 - American Indian Mental Health
Research and Development Center Page 12
National Institute of Mental Health
Index - NATIONAL INSTITUTE OF MENTAL HEALTH

Announcement

Availability of Request for Applications:
RFA 85-CA-07 - Smoking Prevention and
Cessation Among Women..... Page 15
National Cancer Institute
Index - CANCER

Announcement

Availability of Request for Applications:
RFA 85-CA-08 - Prevention and Cessation of
Use of Smokeless Tobacco..... Page 17
National Cancer Institute
Index - CANCER

Continued

Announcement

Specialized Centers of Research - General
Program Announcement Page 20
National Institute of Environmental Health Sciences
Index - ENVIRONMENTAL HEALTH SCIENCES

Announcement

Specialized Centers of Research (SCORs) in
Central Nervous System Neurotoxicology Page 25
National Institute of Environmental Health Sciences
Index - ENVIRONMENTAL HEALTH SCIENCES

Announcement

Specialized Centers of Research in Marine
and Freshwater Biomedical Sciences (MFBS SCORs) Page 27
National Institute of Environmental Health Sciences
Index - ENVIRONMENTAL HEALTH SCIENCES

Announcement

Specialized Centers of Research in
Genetic Toxicology Page 29
National Institute of Environmental Health Sciences
Index - ENVIRONMENTAL HEALTH SCIENCES

Announcement

NIADDK, DDEMD Scientific Instrumentation Grants Page 31
National Institute of Arthritis, Diabetes,
Digestive and Kidney Diseases
Index - ARTHRITIS, DIABETES, DIGESTIVE
AND KIDNEY DISEASES

Announcement

NIAID Minority Research Enhancement Program Page 34
National Institute of Allergy
and Infectious Diseases
Index - ALLERGY AND INFECTIOUS DISEASES

Announcement

The NCI Clinical Investigator Award Page 37
National Cancer Institute
Index - CANCER

Announcement

Research and Demonstrations Relating to
Occupational Safety and Health Page 41
National Institute for Occupational Safety
and Health
Index - OCCUPATIONAL SAFETY AND HEALTH

Continued

Announcement
 The Oldest Old Page 48
 National Institute on Aging
 Index - AGING

ERRATUM

THE OLDEST OLD

P.T. 34; K.W. 0404002, 0701013, 0413001, 0408006, 0701016, 0701010, 1201230

THE NATIONAL INSTITUTE ON AGING

Pages 32 and 33 of the November issue of the Guide (Vol. 13, No. 12) were out of order. The full text of NIA's announcement "The Oldest Old" may be found on page 48 of this issue.

NOTICE

SUPPORT OF RESEARCH CENTER AND PROGRAM PROJECT GRANTS

P.T. 34, 04; K.W. 1200180

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Refer to NIH GUIDE FOR GRANTS AND CONTRACTS, Vol. 10, No. 4, March 6, 1981

In 1981 the National Institute of General Medical Sciences (NIGMS) published guidelines for support of research center and program project grants which included a budget limit of \$2,750,000 over a 5-year period. Because of increases in the cost of research since then, the NIGMS has decided to raise this limit to \$3,000,000 for all competing applications as of Fiscal Year 1985. All other parts of the 1981 announcement still apply.

For further information call Dr. Elke Jordan, 301 496-7061.

NOTICENATIONAL RESEARCH SERVICE AWARDS FOR SHORT-TERM TRAINING: STUDENTS
IN HEALTH PROFESSIONAL SCHOOLS

P.T. 44; K.W. 1200170

DIVISION OF RESEARCH RESOURCES

The Division of Research Resources (DRR) wishes to announce its withdrawal from participation in the T35, "Short-Term Training: Students in Health Professional Schools", program. This decision is based on a recommendation from the National Advisory Research Resources Council which noted that the T35 program is similar to an activity of the Animal Resources Program (ARP), DRR.

The ARP, DRR supports a summer training program for veterinary students. The students spend up to three months at institutions where ARP-supported diagnostic resources, training grants and Primate Centers are located. Funding is provided by the resource grant and institutional sources, and the students are paid as summer employees. The students are actively involved in ongoing research activities at the centers, usually presenting seminars and frequently co-authoring short papers, as well as gaining clinical experience in laboratory animal medicine. This program will continue and an announcement listing participating institutions and program directors will be sent to all schools of veterinary medicine by January 1, 1985.

NOTICE

CHANGE IN APPLICATION RECEIPT DATE

CANCER CONTROL RESEARCH UNITS: RFA

84-CA-08

P.T. 34; K.W. 1002014, 0701042, 0403004

NATIONAL CANCER INSTITUTE

Revised Application Receipt Date - June 11, 1985
Revised Letters of Intent Receipt Date - February 4, 1985

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites grant applications from interested investigators for the support of Cancer Control Research Units (CCRU).

The receipt dates for applications and letters of intent are revised from those announced for RFA 84-CA-08 in the NIH Guide for Grants and Contracts, Vol. 13, No. 4, March 30, 1984. The new dates are shown above.

Copies of the complete RFA and the 1983 Cancer Control Program Guidelines may be obtained from:

Carlos E. Caban, Ph.D.
Program Director
Cancer Control Applications Branch, DCPC
Blair Building - Room 4A01
National Cancer Institute
National Institutes of Health
9000 Wisconsin Avenue
Bethesda, Maryland 20205

Telephone: (301) 427-8735

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****85-RR-01****DEVELOPING AND IMPROVING INSTITUTIONAL ANIMAL RESOURCES****P.T. 14, 36; K.W. 1002002****DIVISION OF RESEARCH RESOURCES**

Application Receipt Date: March 1, 1985

I. BACKGROUND

As part of its mission to create, develop and maintain animal resources needed by NIH-supported biomedical investigators throughout the nation, the Division of Research Resources (DRR) is continuing its competitive grant program to help institutions upgrade and develop their animal facilities. The DRR Fiscal Year 1985 appropriation includes up to \$7,369,000 for this purpose.

II. RESEARCH GOALS AND SCOPE

Institutional animal resource improvement projects are awarded to assist biomedical research and educational institutions to upgrade their animal facilities and develop centralized programs of animal care. A major objective is to enable institutions to comply with the Animal Welfare Act and DHHS policies on the care and treatment of animals. Requests of this type may include alterations and renovations to improve laboratory animal facilities and equipment, such as animal cages and cage washers. Other costs directed at improvement of the animal resource may be supported; but it is not the purpose of the improvement grant to provide a general subsidy for the resource; e.g., funding for currently established positions, consumable supplies for routine animal care, etc. The projects are supported for one year, after which the applicant institution is expected to assume complete financial responsibility for its basic animal resource.

This program is described in the Catalog of Federal Domestic Assistance No. 13.306, Laboratory Animal Sciences and Primate 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 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.

To gain approval and support, both the need for resource improvement and a sound plan to bring the entire animal resource up to the required standards must be demonstrated, presented and described in the context of the biomedical research and research training program of the institution. Alteration, renovation and equipment grant requests, per se, will not be acceptable; i.e., requests for such needs will be considered only in relationship to the overall project plan to improve institutional animal resources.

III. ELIGIBILITY AND REVIEW

Nonprofit institutions engaged in health-related research supported by the National Institutes of Health are eligible to apply for animal resource project grants. In general, applicants are expected to develop a single animal resource improvement proposal for campus-wide service.

Applications will be received by the NIH Division of Research Grants (DRG). All applications submitted in response to this RFA will be reviewed in competition with each other by the Animal Resources Review Committee for scientific merit review and the National Advisory Research Resources Council of the DRR for program considerations.

IV. MECHANISM OF SUPPORT

Awards will be made as competitive resource grants for a project period limited to one year. It is expected that from 20 to 30 awards will be made in Fiscal Year 1985. All policies and requirements which govern the grant programs of the PHS apply. The requirement for cost sharing will be fulfilled by the use of matching funds for alterations and renovations.

V. TERMS OF AWARD

Alterations and renovations are limited to a maximum of \$500,000 from this grant program. Equal matching funds are required from nonfederal sources. Support for new construction is not authorized. Funds awarded for alterations and renovations may not be expended until final drawings, specifications, and updated cost estimates are received and approved by the Animal Resources Program, DRR.

VI. INQUIRIES

Inquiries and requests for this RFA should be directed to:

Dr. William I. Gay

or

Dr. John E. Holman

Animal Resources Program

Division of Research Resources

Building 31 - Room 5B59

National Institutes of Health

Bethesda, Maryland 20205

Telephone: (301) 496-5175

ANNOUNCEMENTREQUEST FOR APPLICATIONS: RFA85-OD-01ACADEMIC RESEARCH ENHANCEMENT AWARD

P.T. 34, 14; K.W. 1200180

NATIONAL INSTITUTES OF HEALTH

Application Receipt Date: April 1, 1985

In its report accompanying the Fiscal Year 1985 appropriation for the National Institutes of Health (NIH), Congress called for an initiative to strengthen the research milieu of non-research-intensive, four year, colleges and universities, which provide undergraduate training for a significant number of our nation's research scientists. The NIH will make up to \$5,000,000 available for this purpose through a new type of award entitled the "Academic Research Enhancement Award" (AREA). This award is designed to enhance the research environment of the educational institutions that have not been traditional recipients of the National Institutes of Health (NIH) research funds. The award is intended for the use of faculty members of these institutions to develop new research projects or expand ongoing research activities in areas related to the health sciences.

Institutions eligible for the AREA are defined as those four-year academic institutions that have: 1) provided baccalaureate degrees for 25 or more individuals (irrespective of field of specialization) who have obtained doctoral degrees in the health related sciences since 1977; and 2) received less than \$200,000 (total costs) in Public Health Service (PHS) research grants (exclusive of training grants) in fiscal year 1984. The awards will be made on a competitive basis. Applicants may request support for up to \$50,000 in direct costs (plus applicable indirect costs) over a 24-month period. While this award is non-renewable, it will enable qualified individual scientists within the eligible institutions to receive support for feasibility studies and other small-scale projects preparatory to seeking more substantial funding through the traditional NIH grant mechanisms.

Applications for this award will be accepted through the regular application submission procedures of the NIH through its Division of Research Grants (DRG). Grant applications must be prepared and submitted on PHS 398 grant application forms. An abbreviated format and simplified instruction will be provided for use in preparing these applications. The receipt date is April 1, 1985.

Those individuals and institutions qualifying and wishing to receive further information and/or application materials should write to:

AREA
Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
Bethesda, Maryland 20205

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HL-26

ALTERATIONS AND RENOVATIONS TO ESTABLISH NHLBI SHARED RESEARCH
FACILITIES

P.T. 02; K.W. 1200180

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application Receipt Date: March 1, 1985

The National Heart, Lung, and Blood Institute (NHLBI) announces a grant program to support the improvement, renovation, and establishment of modern research facilities relevant to contemporary biomedical sciences (e.g., molecular biology) in organizations with substantial, ongoing research activities in heart, lung, and blood diseases. The goal of this program is to expand and/or create physical resources for the application of modern, sophisticated technology to fundamental research in heart, lung, and blood diseases. Any domestic, nonprofit organization with existing, high quality research activities in heart, lung, and blood diseases (that receives at least \$5 million/year total costs, in peer-reviewed NIH support for such research) may apply.

The Institute's appropriation for Fiscal Year 1985 includes \$3.3 million for construction and renovation of research facilities. The use of these funds is limited to the repair, renovation, remodeling, improvement, or creation of facilities utilized by groups of investigators currently being supported by NHLBI. These grants, awarded on a competitive basis, will be limited to a maximum of \$500,000 total costs.

An organization applying for these grants must clearly show that the core research facilities to be established will expand and improve the existing research activities in at least two of the three program areas of the NHLBI--i.e., heart, lung, and blood.

After competitive review, awards (limited to a maximum of \$500,000) will be issued on a matching basis--at least 1/3 to be provided from non-Federal sources.

An institution may submit only one application in response to this Request for Applications. An application may, however, request funds for more than one shared research facility.

TIMETABLE

| | |
|-------------------------|----------------------------|
| Letter of Intent | February 1, 1985 |
| Receipt of Applications | On or before March 1, 1985 |
| Initial Review | June-July 1985 |
| Advisory Council Review | September 12-13, 1985 |
| Award Date | September 30, 1985 |

INQUIRIES

Inquiries concerning this program and requests for copies of the RFA should be addressed to:

Dr. Jerome G. Green
Director
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building - Room 7A17B
Bethesda, Maryland 20205

Telephone: (301) 496-7416

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-HD-03

REPRODUCTIVE DISORDERS

P.T. 34; K.W. 0413002, 1201070, 1201010

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: April 1, 1985

The Reproductive Sciences Branch (RSB) of the Center for Population Research (CPR) of the National Institute of Child Health and Human Development (NICHD), invites research grant applications for clinical studies in reproductive disorders in women. An important component of increasing human age-specific infertility rates appears to be comprised of some relatively common functional and structural disturbances of the female reproductive tract leading to impaired fertility and sterility. In some cases evidence of the increased incidence of these disturbances of function has been well documented. Seeking to encourage investigator interest in these specific research areas appropriate to the mission of the Institute, the RSB hopes to receive grant-in-aid requests (R01) for studies conducted in the human pertinent to disturbances in hypothalamic-ovarian function, pelvic endometriosis, and ectopic pregnancy. It is anticipated that such studies will deal with pathophysiology and disturbances of biological mechanisms, the delineation of the natural course of disease, and the application of new modes of investigation to these topics. The Reproductive Sciences Branch anticipates that 10-12 applications will be funded as a result of this RFA.

For further information and a copy of the RFA, contact the following:

Thomas H. Kirschbaum, M.D.
or
Julia Lobotsky, M.S.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health
and Human Development
Landow Building - Room 7C33
Bethesda, Maryland 20205

Telephone: 301/496-6515

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA****FDA-OP-85-1****CLINICAL STUDIES OF SAFETY AND EFFECTIVENESS OF ORPHAN PRODUCTS****P.T. 34; K.W. 1200270, 0701038****FOOD AND DRUG ADMINISTRATION**

Application Receipt Date: February 5, 1985

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of funds for Fiscal Year 1985 for awarding grants to support clinical trials on safety and effectiveness of orphan products. FDA has funds to award approximately 20 to 30 grants ranging from \$20,000 to \$70,000. The agency will consider grants greater than \$70,000 if they extend over a 2- or 3-year period.

I. BACKGROUND

FDA has established an Office for Orphan Products Development to identify and facilitate the availability of orphan products. Orphan products are drugs, biologics, medical devices (including in vitro diagnostics), foods for medical purposes, and veterinary products that may be useful in an uncommon or common disease but lack committed commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products for which there is evidence suggesting usefulness in an uncommon, serious disease but which are not labeled for that disease because substantial evidence is lacking.

One way to make orphan products more easily available is to support research to determine whether the products are safe and effective. FDA has allocated funds to support such research.

II. RESEARCH GOALS AND OBJECTIVES

Clinical Studies: FDA will consider only clinical studies for determining whether the products are safe and effective for premarket approval under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), including the addition of new uses to marketed drugs. Ordinarily, there should already be available at least some preliminary clinical research suggesting effectiveness and relative safety. FDA will also consider applications where persuasive pharmacologic evidence is available that a product has a reasonable possibility of being effective even though no clinical trials have yet been performed. All studies subject to requirements for clinical investigations under the Federal Food, Drug, and Cosmetic Act are to be conducted in accordance with those requirements in addition to the requirements of the request for application (RFA).

Because funds are relatively limited, FDA cannot consider large research projects involving many subjects (human, or animal in the case of a veterinary drug) and long-term followup. The typical study considered for support may involve up to several dozen subjects, will be well-controlled and directed to providing substantial evidence of the product's safety and effectiveness. Pharmacokinetic studies will also be considered if they are necessary to determine safe and effective doses in subjects with serious organ disease that might affect drug disposition. But pharmacokinetic studies will be considered only if they are part of studies for determining effectiveness of a drug or are proposed as desirable information to obtain for drugs that are already shown to be effective. In designing a well-controlled study, the investigator should keep in mind that historical controls or use of the subject as his or her own control are generally less desirable and reliable than active control or, when ethical, placebo controls.

Each investigator submitting a grant application (human or veterinary use) in response to this RFA must include a 1/2 to 1 page rationale as to why his or her product is appropriate to the objectives of the orphan products grants program as outlined in this notice. In the case of veterinary products, research studies should be directed to the following area only: a true orphan animal product for which the animal disease being studied can be transmitted to man.

In addition to FDA's general interest in clinical studies for the safety and effectiveness of orphan products, the agency is also interested in receipt of applications on gamma-hydroxybutyrate for the treatment of narcolepsy. These applications will compete with others received in response to this RFA. Only one application for this purpose will be awarded, however.

III. STAFF CONTACT

Copies of the complete RFA and additional information may be obtained from:

Benjamin P. Lewis
Health Scientist Administrator
Office of Orphan Products Development (HF-35)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4903

ANNOUNCEMENT**AVAILABILITY OF REQUEST FOR APPLICATIONS:****MH-86-02****AMERICAN INDIAN MENTAL HEALTH RESEARCH AND DEVELOPMENT CENTER****P.T. 34, 04; K.W. 1200180, 0701029, 0403004, 1200170****NATIONAL INSTITUTE OF MENTAL HEALTH**

Application Receipt Date: March 1, 1985

I. PURPOSE

The National Institute of Mental Health (NIMH) will award a grant to support an American Indian Mental Health Research and Development Center which will develop and carry out innovative, multidisciplinary studies on the mental health problems and needs of American Indians. The Center should have a nucleus of experienced mental health researchers who will direct their energies toward the conceptualization, development, and conduct of research programs addressing the incidence, diagnosis, treatment, and prevention of mental illness among American Indian populations. Research activities that primarily focus on gaining insight into the nature of mental illness and its expression in American Indian populations through the development of methodologically sound studies should be a major objective of the Center. In addition, the Center should serve as a resource for the training of both new and established American Indian mental health researchers; disseminate information stemming from the Center's ongoing research programs via appropriate scientific and professional outlets; and provide an environment which will assure high-level research leadership in the area of American Indian mental health.

II. CENTER CHARACTERISTICS

The Center should develop a program in accordance with its resources, talents, opportunities, objectives, and constraints. While there is no one prescribed focus for the Center, it should have a rich research environment wherein hypothesis development and testing can unfold in the context of both pilot and more comprehensive studies, and where new methodologies and data-gathering techniques can be formulated, tested, and developed.

The Center must be problem oriented, comprehensive, and integrative, as well as multidisciplinary when possible. It is expected that:

- o The Center will provide an environment of research excellence which will ensure the promotion and conduct of scientifically sound investigation in the area of Indian mental health. In these activities, the Center should be regarded as a national resource by the surrounding scientific and American Indian communities in research areas of importance to the American Indian populations.

- o The Center will focus on a clearly defined set of research objectives or set of scientific problems of major importance to the understanding of American Indian mental health needs. The attempt to provide insights into the resolution of these problems should stem from the development and implementation of theoretically and methodologically sound investigations. The Center's research focus must fall within the research areas described in the July 1984 revised announcement of "NIMH Research Support Programs."
- o The Principal Investigator will be the Director of the Center, providing leadership for the scientific program and having responsibility for the scientific, administrative, and operational aspects of the Center's programs. He or she is responsible for the overall development of the Center as a resource to the scientific community and, as such, is expected to devote full time to the project. The Director must be a highly knowledgeable, experienced research investigator with appropriate administrative skills who will ensure the highest standards of scientific investigation.
- o The Center is expected to have an administrative structure that will ensure maximum effectiveness and efficiency of operation and sound financial practices. The administration will be responsible for program planning, monitoring, and execution and preparation of the budget and control of expenditures, staff appointments, and space allocation.
- o While the primary purpose of the Center is the development and implementation of research investigations, the training of both pre- and post-doctoral researchers in the area of American Indian mental health research issues, and the special methodological problems encountered in the systematic investigation of these populations, should be an important activity of the Center. Accordingly, the Center should specify its relationships with other institutional professional and academic training programs, particularly as these apply to graduate and post-graduate levels of training. While the Center should be appropriately involved in training researchers, funds from the Center grant may not be used to support training activities. Funds to support research training may be sought under the National Research Service Award Program.
- o In addition, the Center may provide supervised research experiences for up to two preceptees annually (precepteeships are defined as supervised work experience). Funds for these precepteeships may be included in the requested budget.
- o It is expected that the Center will build a technical assistance capability steadily over the period of the grant. Such technical assistance should involve consultation to agencies and groups which conduct research programs on the mental health needs of American Indians, and include participation and leadership in workshops, conferences, and meetings designed to share research knowledge on American Indian mental health issues with other researchers and interested agencies and groups.
- o The Center is expected to disseminate information from its research activities through publication in appropriate scientific and professional outlets; the development of a bibliographic resource; the publication of monographs, occasional papers, and research bulletins; and the presentation of papers at scientific meetings.

- o The Center is expected to demonstrate a capability to recruit experienced researchers, especially American Indians.

III. ELIGIBLE APPLICANTS

The American Indian Mental Health Research and Development Center applicant must be an organization which demonstrates experience and capability in conducting mental health research. Furthermore, it must have a strong relationship or base in a research-oriented facility, agency, or institution. In-depth experience with American Indian mental health issues and access to American Indian populations are vital. Eligible applicants include any U.S. nonprofit or for-profit organizations capable of meeting the stated criteria.

IV. STAFF CONTACT

For guidelines specific to Center applications and for General Instructions for Application for Research Grant, applicants should contact:

Dr. James R. Ralph
Chief, Center for Studies of Minority Group
Mental Health
Division of Prevention and Special Mental
Health Programs
National Institute of Mental Health
Parklawn Building - Room 11-95
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-3724

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-07

SMOKING PREVENTION AND CESSATION AMONG WOMEN

P.T. 34; K.W. 0404019, 0701013

NATIONAL CANCER INSTITUTE

Application Receipt Date: March 15, 1985
Letter of Intent Receipt Date: February 15, 1985

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute (NCI), is interested in supporting studies to determine the long-term effect of interventions designed to prevent the onset and/or reduce the prevalence of cigarette smoking among women.

The proposed studies should seek to: (1) develop and evaluate innovative intervention strategies to prevent or reduce cigarette smoking among women and (2) develop and evaluate assessment procedures for determining the long-term effectiveness of smoking interventions among women.

The purpose of this RFA is to solicit applications from qualified investigators interested in developing innovative intervention programs focused on U.S. female populations and determining the long-term effectiveness of these programs on the prevention and cessation of habitual cigarette smoking among women.

The focus of the studies envisioned thus must be on the long-term effectiveness of interventions aimed at women. It is anticipated, in keeping with the goals of the National Cancer Institute Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of results of the larger population) and Phase IV (i.e., interventions designed and carried out with a sample of the population in such a way that the results obtained are representative of results in large target populations) investigations.

It is recognized, however, that there are substantial gaps in our knowledge concerning smoking among women, and, in particular, knowledge that may be tion program. Therefore, where necessary and specifically justified in the application, highly controlled studies of the acquisition process, epidemiological issues or other related research questions which could influence the effectiveness of prevention/cessation efforts may be addressed in the intervention studies. These research questions should not, however, become the overriding interest of the study but, rather, be integrated as complementary adjuncts to the interventions.

Prospective investigators should note (1) that the outcome measure of these studies should be incidence of smoking behavior, not cancer incidence; and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; d) generalizable; and e) readily adoptable by others with only minor modifications and little or no external economic or technical aid.

I. ELIGIBILITY REQUIREMENTS

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group. Assignments for possible funding will be governed by the usual referral guidelines.

II. MECHANISM OF SUPPORT

Awards will be made as grants. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed five years.

III. ANTICIPATED NUMBER OF AWARDS

The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.5 million for the first year.

IV. LETTER OF INTENT AND APPLICATION RECEIPT DATE

Prospective applicants are asked to submit a one-page letter of intent, including a brief synopsis of proposed areas of research and identification of any other participating institutions, to Dr. Gayle M. Boyd (see address in Section V.) by February 15, 1985.

Applications prepared on Form PHS 398 should be received by the Division of Research Grants, NIH, by March 15, 1985, to ensure their review.

V. REQUESTS FOR COPIES OF RFA AND INFORMATION

To obtain a copy and/or other information, please contact:

Gayle M. Boyd, PH.D.
Smoking, Tobacco, and Cancer Program
Office of the Director, DCPC
National Cancer Institute
National Institutes of Health
Balir Building - Room 425A
9000 Rockville Pike
Bethesda, Maryland 20205 - 4200

Telephone: (301) 427-8620

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-CA-08

PREVENTION AND CESSATION OF USE OF SMOKELESS TOBACCO

P.T. 34; K.W. 0701042, 0404001

NATIONAL CANCER INSTITUTE

Application Receipt Date: March 15, 1985
Letter of Intent Receipt Date: February 15, 1985

The Smoking, Tobacco, and Cancer Program (STCP), National Cancer Institute (NCI) is interested in supporting studies designed to develop and evaluate the effectiveness of interventions to prevent the onset and reduce the prevalence of smokeless tobacco use in the United States.

The proposed studies should seek to: (a) identify patterns of smokeless tobacco use and the primary factors influencing such use; (b) develop and evaluate intervention strategies to reduce the incidence and prevalence of smokeless tobacco use; and (c) develop and evaluate assessment procedures to determine the long-term effectiveness of these intervention strategies.

I. OBJECTIVES AND SCOPE

The purpose of this RFA is to solicit applications from qualified investigators interested in developing innovative intervention programs focused on the use of smokeless tobacco and determining the long-term effectiveness of these programs on the prevention and cessation of smokeless tobacco use. The focus of the studies envisioned must be on the long-term effectiveness of interventions.

It is anticipated, in keeping with the goals of the NCI Cancer Control Program, that studies funded under this RFA will be Phase III (i.e., for the purposes of this RFA, controlled studies of cancer control interventions in sizeable groups which may not, however, be representative of the larger population) and Phase IV (i.e., interventions designed and carried out within a large and defined population in such a way that the results obtained are representative of results in large target populations) investigations.

It is anticipated that proposals will use a phased-in approach in which, during the first year, data describing the target population, prevalence, and patterns of use are obtained, unless such data are already available, and proposed interventions are pilot tested. Only at this point would interventions be initiated on a full scale. Information collected during the first year could be used to modify and adapt the proposed interventions as needed. In subsequent years interventions should be expanded with a major focus on evaluation of the interventions' effectiveness.

The objective of these studies is to develop intervention strategies and to evaluate their effectiveness in preventing or reducing the prevalence of smokeless tobacco use. No restrictions are placed on the type of interventions. Any population subgroup may be chosen for study provided there is reasonable evidence that it contains a sizeable number of smokeless tobacco users or individuals who are at risk for initiating use (e.g., targeted by tobacco advertising; observed trends toward increased use; use by an immediately older cohort).

Prospective investigators should note (1) that the outcome measure of these studies should be smokeless tobacco use, not cancer incidence/mortality, and (2) that the desired overall outcome of studies eventually supported through this RFA are interventions that are a) cost-beneficial; b) cost-effective; c) durable in their effects; and d) readily adoptable by others with only those modifications that are necessary for a broad community/population impact.

II. ELIGIBILITY REQUIREMENTS

Grants may be awarded to profit and nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. All applications received in response to this RFA will be reviewed by an appropriate NIH Initial Review Group. Assignments for possible funding will be governed by the usual referral guidelines.

III. MECHANISM OF SUPPORT

Awards will be made as grants. Responsibility for the planning, direction and execution of the proposed research will be solely that of the applicant.

The total project period for applications submitted in response to the present RFA should not exceed five years.

IV. ANTICIPATED NUMBER OF AWARDS

The intent is to fund up to five projects, with total costs for all projects amounting to approximately \$1.5 million for the first year.

V. LETTER OF INTENT AND APPLICATION RECEIPT DATE

Prospective applicants are asked to submit a one-page letter of intent, including a brief synopsis of proposed areas of research and identification of any other participating institutions, to Dr. Gayle M. Boyd (see address in Section VI) by February 15, 1985.

Applications prepared on Form PHS 398 should be received by the Division of Research Grants, NIH, by March 15, 1985, to ensure their review.

VI. REQUESTS FOR COPIES OF RFA AND INFORMATION

To obtain a copy and/or other information, please contact:

Gayle M. Boyd, Ph.D.
Smoking, Tobacco, and Cancer Program
Office of the Director, DCPC
National Cancer Institute
National Institutes of Health
Blair Building - Room 425A
9000 Rockville Pike
Bethesda, Maryland 20205-4200

Telephone: (301) 427-8620

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH - GENERAL PROGRAM ANNOUNCEMENT

P.T. 34, 04; K.W. 0701018, 1200180

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Initial Application Receipt Date: March 1, 1985
Subsequent Receipt Dates: June 1, October 1, February 1

I. INTRODUCTION

The National Institute of Environmental Health Sciences (NIEHS) serves as a national resource and focal point for support of environmental health research and research training. Its mission is to develop understanding of pathological processes as they relate to the etiology, diagnosis, treatment and prevention of diseases and disorders caused by environmental factors, and to facilitate research training of environmental health scientists in accordance with identified national needs. A number of support mechanisms are used by the extramural program to provide funding for research in environmental health sciences. The regular research project grant (R01) is the major mechanism for support of individual projects. Other mechanisms such as core center grants and program project grants are utilized where multiple, interdisciplinary, and closely related projects are proposed or where core support is deemed appropriate to support centers of excellence in environmental health research. These guidelines introduce the NIEHS Specialized Center of Research (SCOR) for support of core facilities and related research projects. Specific scientific areas to be supported by this mechanism will be announced separately.¹

II. DEFINITION OF A SCOR

A. Mechanisms for Funding

The funding mechanism most commonly used by the Institute to support a group of closely related, but discrete projects is the Program Project Grant (P01). Such grants support a minimum of three related research projects which focus on a single research topic within the Institute's purview. Although not a center grant, a program project grant may receive funds for the laboratory facilities, research services, and administrative assistance shared by the projects in the grant. Funding for support services used jointly is called "core support."

For a research field deemed to be of special importance and one requiring a funding mechanism beyond the scope of a program project grant, the Institute

¹ For areas of research currently eligible for SCOR funding, see the following three announcements.

makes funds available under the center grant mechanism. Two types of center grants are available: a Center Core Grant (P30) or a Specialized Center of Research Grant (P50).

A Center Core Grant (P30) is the appropriate funding mechanism when a large number of funded research projects of high quality relevant to the mission of the NIEHS exists in an institution and core support only is needed. This core support serves to enhance quality and productivity, promote collaboration, encourage additional research in the field, and improve cost-effectiveness.

A Specialized Center of Research Grant (P50) provides support for both the research projects and the core support services in one grant. An application for a P50 grant is developed in response to a request by the NIEHS when the Institute seeks to stimulate research in a given field by encouraging collaborative interdisciplinary research on one or more problems.

B. Scope

A NIEHS SCOR grant is an institutional award, made in the name of a principal investigator, for the support of a large interrelated research program developed in response to a request by the NIEHS for research focused on a specific problem. It is awarded competitively, initially for not less than 3 or more than 5 years, and may be renewed for periods up to 5 years. It provides support for both research projects and the core support services used by those projects. The activities included in the supported research comprise a multidisciplinary approach to environmental biomedical and/or behavioral problems.

Beyond meeting the standard eligibility criteria for institutions applying for NIH research grants, an applicant for a P50 Specialized Center of Research (SCOR) Grant must propose a program of three or more related and integrated research projects of high quality that provided a multidisciplinary, yet unified, approach to the problem(s) to be investigated. Scientific personnel and institutional resources capable of providing a strong research base in the field specified must be available. The institution and pertinent departments have to show a strong commitment to the center's support.

C. Characteristics

A NIEHS Specialized Center of Research (SCOR) is an identifiable unit within a sponsoring institution with a strong commitment to a specific activity in the field of environmental health. Each SCOR conducts its own research program based on local interest and talents. Each research program consists of a sustained series of individual, but closely related, research projects, each with high scientific merit and clear research objectives. A SCOR may address more than one issue; however, a central theme unifying the research projects is required. A SCOR may also include one or more core resources, which perform specialized service activities such as biochemical analysis, pathology, or data management. These activities are shared by several or all investigators. The core investigators, in addition to performing service functions, may also conduct research projects.

Investigators participating in a SCOR must be of recognized ability, capable of conducting independent research, and willing to make long term commitments to the goals of the SCOR. SCOR scientists should have access to facilities where innovative fundamental and/or clinical investigations can be conducted.

D. SCOR Director

The SCOR Director must provide strong, effective administrative and scientific leadership. The Director is responsible for the organization and operation of the center and for communication with the NIEHS on all scientific and operational matters. The SCOR Director is responsible for maintaining high quality research throughout the funding period. New projects within the budgetary and scientific scope of the grant may be incorporated into the program at any time at the discretion of the Director with final review and approval by the NIEHS. SCOR grantees are thus encouraged to pursue promising research leads. By the same token, if a Director deems it advisable to discontinue a project, NIEHS staff should be consulted before implementing the decision. Each SCOR Director must encourage and support close collaboration between individual SCOR investigators by means of frequent seminars and scientific meetings.

Each SCOR Director must establish both internal and external advisory committees which will periodically assess the overall program as well as the progress of individual projects. The external advisory committee must consist of expert consultants from outside the grantee institution and must meet annually. The NIEHS program officer may attend these meetings as an observer.

E. Relation to the NIEHS

A SCOR is a grant-in-aid which differs from other research grants in its focused goal orientation. The award of a SCOR grant will establish a special relation between the NIEHS and the grantee institution. The NIEHS program officer will monitor the program and, when requested, provide advice to the Director and staff of each SCOR. SCORs may be asked to perform additional studies on research problems within the scientific scope of the SCOR in order to respond to unexpected opportunities or problems of special public concern. They may serve as a regional or national resource for special purpose research. Funding for such activities would be provided through supplements to the award provided by established NIH/NIEHS procedures.

III. Mechanism of Support

The support mechanism will be the research grant-in-aid for a period of up to five years. However, it will differ from other research grants in the expected communication among Centers and periodic structured review of progress by the NIEHS.

Applicants are expected to furnish their own estimates of the time required to achieve specific objectives of the proposed work, a schedule for completion of the work, and an outline of the phases or segments into which the proposed program

can be logically divided. The NIEHS-SCOR will plan, direct and execute its own research program. As with any research grant, substantial modifications must be mutually agreed upon by the NIEHS-SCOR institution and the NIEHS.

Additionally, a two-day meeting of all SCOR Program Directors and one or two senior investigators, and NIEHS program staff, will be held at least annually. Applicants should include a request for travel funds for these meetings in each year of the budget. Applicants should also include a statement in the application indicating willingness to participate in such meetings.

IV. Review Procedures and Criteria

The applications will be evaluated in national competition with each other. Primary review will be conducted by a review group of predominantly non-federal consultants with selected scientific expertise and may include a site visit. Secondary review will be by the National Advisory Environmental Health Sciences Council.

Applications considered non-responsive will be returned to the investigator. Major factors to be considered in the evaluation of responsive applications will include:

1. The scientific merit of each proposed project, including the novelty, originality and feasibility of the approach and the adequacy of the experimental design.
2. The technical merit and justification of each core unit.
3. The competence of the investigators to accomplish the proposed research goals, their commitment, and the time they will devote to the program.
4. The adequacy of facilities to perform the proposed research including the laboratory and clinical facilities, if applicable, and the proposed instrumentation and data management systems, when needed.
5. The integration of the various projects and core units into an effective center, and the adequacy of plans for interaction and dissemination of information among investigators.
6. The qualifications, experience and commitment of the SCOR Director and the ability to devote adequate time and effort to provide effective leadership to the Center.
7. The scientific and administrative structure of the program, including adequate internal and external procedures for monitoring the proposed research and for providing ongoing quality control and scientific review.
8. The institutional commitment to the program, and the appropriateness of its resources and policies for the administration of a research program of the type proposed.
9. The willingness to work cooperatively with other NIEHS Centers, Specialized Centers of Research, and with the NIEHS.

10. The appropriateness of the budget for the proposed program.

V. Method of Application

A. Letter of Intent

Prospective applicants are asked to submit a letter of intent which includes a synopsis of proposed areas of research and identification of any other participating institutions. This letter should be received no later than six weeks prior to the NIH Division of Research Grant receipt dates for these proposals (February 1, June 1, October 1)¹ and should be addressed to:

Christopher O. Schonwalder, Ph.D.
Program Director, Centers and Manpower
Development Programs
Extramural Program
National Institute of Environmental
Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709

The Institute requests such letters only to provide an indication of the number and scope of applications to be received. A letter of intent is not binding, and it will not enter into the review of any proposal subsequently submitted, nor is it a necessary requirement for application.

B. Format for Application

Applications should be prepared on PHS Form 398, available at most institutional business offices or from the Division of Research Grants, NIH. Supplemental instructions for using the form PHS 398 for SCOR applications are available from the Program Director indicated above and should be obtained by prospective applicants

C. Application Procedure

The signed original and four copies of the application should be mailed to the Division of Research Grants (DRG) (see PHS 398 instructions, p. 8). Two copies should be sent to the Program Director indicated above.

This program is described in the Catalog of Federal Domestic Assistance No. 13.894, Resource and Manpower Development. 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 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.

¹ For the first cycle of applications, the receipt date will be March 1, 1985.

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH (SCORs) IN CENTRAL NERVOUS SYSTEM

NEUROTOXICOLOGY

P.T. 34, 04; K.W. 1007009, 1200460, 1007001, 1002028, 1201270, 1002014

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency for the support of research dealing with the effects of environmental agents on human health. The Institute supports efforts to develop new knowledge to better understand the means by which exposures to environmental agents cause deleterious health effects in humans. Though not participating directly in this announcement for research centers, the National Institute of Neurological and Communicative Disorders and Stroke (NIADDK) also has major responsibilities for a research grant program in neurotoxicology.

I. BACKGROUND

The National Institute of Environmental Health Sciences (NIEHS) pursues its mission by supporting basic and applied research on the consequences of the exposure of man to potentially toxic or harmful agents in the environment. Research of interest encompasses studies which relate to the biological effects of environmental chemicals and other factors to which humans might be exposed through air, food, or water in the general, home, recreational, or work-place environments.

Therefore, the NIEHS supports research to attempt to learn the causal associations between human disease and hazardous chemical, physical, and biological environmental factors and the processes by which these environmental agents affect biological systems and result in human diseases and disorders. In addition, the Institute is interested in supporting research projects to develop reliable test systems for determining which environmental agents are potentially hazardous to humans due to their mutagenic, teratogenic, carcinogenic, or otherwise toxic actions. Underlying the NIEHS support programs is the desire for a better understanding of the molecular and cellular mechanisms of the toxic actions of these agents.

II. RESEARCH GOALS AND SCOPE

The NIEHS wishes, through the establishment of Specialized Centers of Research (SCOR(s)), to focus research on the fundamental mechanisms involved in neurotoxic actions of environmental chemicals on human brain cells. A direct approach on this problem has become feasible since it is now possible to fractionate complex brain tissues into homogeneous parts and to maintain these individual nerve cells in vitro. This should allow biochemical approaches to be used to study the effects of environmental toxins on these tissues and to relate these to previous and current studies of neuropathological and behavioral changes.

A NIEHS SCOR in Neurotoxicology, therefore, should have as its theme the mechanisms of action of xenobiotics on specifically located neurons in the mammalian brain. This may include studies of metabolism and activation of the parent compound, functional changes due to the xenobiotic, etc.

It is expected that proposed studies will be of a collaborative nature involving a number of different scientists and scientific projects supported by common core facilities. Reference is made to the general program announcement for NIEHS SCORs published elsewhere in this issue of the NIH Guide for Grants and Contracts.

Individuals wishing additional information or having questions concerning this program announcement should contact:

Christopher O. Schonwalder, Ph.D.
Program Director, Centers and Manpower
Development Programs
Extramural Program
National Institute of Environmental
Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-7634

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH IN MARINE AND FRESHWATER BIOMEDICAL
SCIENCES (MFBS SCORs)

P.T. 34, 04; K.W. 1007001, 1007002, 1007003, 1200460

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency for the support of research dealing with the effects of environmental agents on human health. The Institute supports efforts to develop new knowledge to better understand the means by which exposures to environmental agents cause deleterious health effects in humans.

I. BACKGROUND

The National Institute of Environmental Health Sciences (NIEHS) pursues its mission by supporting basic and applied research on the consequences of the exposure of man to potentially toxic or harmful agents in the environment. Research of interest encompasses studies which relate to the biological effects of environmental chemicals and other factors to which humans might be exposed through air, food, or water in the general, home, recreational, or work-place environments.

Therefore, the NIEHS supports research to attempt to learn the causal associations between human disease and hazardous chemical, physical, and biological environmental factors and the processes by which these environmental agents affect biological systems and result in human diseases and disorders. In addition, the Institute is interested in supporting research projects to develop reliable test systems for determining which environmental agents are potentially hazardous to humans due to their mutagenic, teratogenic, carcinogenic, or otherwise toxic actions. Underlying the NIEHS support programs is the desire for a better understanding of the molecular and cellular mechanisms of the toxic actions of these agents.

II. RESEARCH GOALS AND SCOPE

The NIEHS is interested in receiving applications for Marine and Freshwater Biomedical Sciences Specialized Centers of Research (MFBS SCORs) to support marine and freshwater biomedical programs which would be of significant value to the NIEHS in carrying out its mission of generating new knowledge on the direct effects of environmental chemicals and other factors on human health. The goal of this program, therefore, is to encourage groups of researchers involved in marine and freshwater biomedical research to focus their efforts on the utilization of aquatic species as models for these disease processes.

It is expected that proposed studies will be of a collaborative nature supported by common core facilities. Reference is made to the general program announcement for NIEHS SCORs published elsewhere in this issue of the NIH Guide for Grants and Contracts.

Individuals wishing additional information or having questions concerning this program announcement should contact:

Christopher O. Schonwalder, Ph.D.
Program Director, Centers and Manpower
Development Programs
Extramural Program
National Institute of Environmental
Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709

Telephone: (919) 541-7634

ANNOUNCEMENT

SPECIALIZED CENTERS OF RESEARCH IN GENETIC TOXICOLOGY

P.T. 34, 04; K.W. 1002019, 100703, 1002008, 1002028, 1200460

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency for the support of research dealing with the effects of environmental agents on human health. The Institute supports efforts to develop new knowledge to better understand the means by which exposures to environmental agents cause deleterious health effects in humans.

I. BACKGROUND

The National Institute of Environmental Health Sciences (NIEHS) pursues its mission by supporting basic and applied research on the consequences of the exposure of man to potentially toxic or harmful agents in the environment. Research of interest encompasses studies which relate to the biological effects of environmental chemicals and other factors to which humans might be exposed through air, food, or water in the general, home, recreational, or work-place environments.

Therefore, the NIEHS supports research to attempt to learn the causal associations between human disease and hazardous chemical, physical, and biological environmental factors and the processes by which these environmental agents affect biological systems and result in human diseases and disorders. In addition, the Institute is interested in supporting research projects to develop reliable test systems for determining which environmental agents are potentially hazardous to humans due to their mutagenic, teratogenic, carcinogenic, or otherwise toxic actions. Underlying the NIEHS support programs is the desire for a better understanding of the molecular and cellular mechanisms of the toxic actions of these agents.

II. RESEARCH GOALS AND SCOPE

The NIEHS, as part of its mission, attempts to elucidate the possible causes of environmentally-induced mutations. It has now become possible to identify and measure DNA reaction products and the particular kinds of genetic changes in animal tissues and in bacterial and mammalian cells. The identification and quantitation of these DNA adducts indicates metabolic pathways and the identity of the most probable premutagenic lesions for each compound studied. Thus, insight into the potential mutagenicity of environmental agents can be obtained.

Through the establishment of a NIEHS SCOR (or SCORs) in Genetic Toxicology, the Institute wishes to focus efforts on this goal. Proposals, therefore, should have as their theme the investigation of the molecular mechanisms of the genetic effects of environmental agents. Examples of activities within this theme include the development of methods to reliably quantify DNA reaction products in human tissues, chromosomal structure changes and replication sequelae subsequent to interaction with environmental chemicals, the relationship between these DNA

reaction products and the metabolism of the chemical, the use of DNA reaction product analysis to determine cases of exposures to agents, the degree of competence of repair mechanisms, etc.

It is expected that proposed studies will be of a collaborative nature involving a number of different scientists and scientific projects supported by common core facilities. Reference is made to the general program announcement for NIEHS SCORs published elsewhere in this issue of the NIH Guide for Grants and Contracts.

Individuals wishing additional information or having questions concerning this program announcement should contact:

Christopher O. Schonwalder, Ph.D.
Program Director, Centers and Manpower
Development Programs
Extramural Program
National Institute of Environmental
Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709

Telephone: (919) 541-7634

ANNOUNCEMENT

NIADDK, DDEMD SCIENTIFIC INSTRUMENTATION GRANTS

P.T. 18; K.W. 1002024, 1004019, 1014001

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, DIGESTIVE AND KIDNEY DISEASES

Application Receipt Date: April 15

The Division of Diabetes, Endocrinology and Metabolic Diseases (DDEMD), NIADDK, announces the availability of funds for the purchase of moderately priced scientific instrumentation (\$5,000 to \$50,000).

I. PROGRAM SPECIFICATIONS

A. Program Objectives

This program is being established to provide a mechanism for biomedical researchers to update and expand their capabilities to perform state-of-the-art research. This program is designed to fill the gap between large, expensive instrumentation grants provided by the Biomedical Research Support Grant Program (BRS) of the Division of Research Resources (DRR) (greater than \$100,000) and individual project grants (R01).

B. Research Scope

Applications under this program will be limited from \$5,000 to \$50,000 (direct costs) for a single instrument system (may be multi-component). Potential instruments might include high pressure liquid chromatography, centrifuge/ultracentrifuge/rotors, scintillation/gamma counter, personal computer, amino acid analyzer/sequencer, spectrophotometer, incubator, tissue culture hood, microscope/electron microscope (partial) or mass spectrometer/gas chromatograph (partial). The preceding list should not be construed to be all inclusive. Funds will not be provided for space renovation, installation, maintenance contracts, technical personnel or operation of commercial instruments.

C. Mechanism of Support

The mechanism of support will be the grant-in-aid. Grants will be awarded as supplements to the Principal Investigator's active R01 grant.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.847, Diabetes, Endocrinology, and Metabolic Diseases. 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 grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

II. METHOD AND CRITERIA OF REVIEW

A. Eligibility

The Principal Investigator (P.I.) must hold an active R01 grant supported by DDEMD related to the proposed use of the instrument. Co-investigators must have active research grant support (R01) from the NIH. Each P.I. and co-investigator can only have his/her name listed on one application under this Program Announcement per year.

B. Criteria for Review

The specific type and model of instrument chosen should be justified by identification and comparison with other available instruments. Comparable instruments at the submitting institution or to which the applicant might have access, should be inventoried and the reason they are unavailable or unsuitable for the proposed research explained. It is important to describe how maintenance and operation costs will be met (where applicable), how time on the instrument will be allocated and the qualifications of the person(s) immediately in charge of the instrument. Shared costs with other sources (i.e., institutional, private, other NIH support) are strongly recommended. Assumption of part of the capital costs by the submitting institution is highly desirable as an indication of its commitment to the proposed research.

The inclusion of multiple investigators and/or projects to share the proposed equipment is strongly recommended. The scientific merit of the underlying R01's will not be an issue during review of this proposal but each investigator must describe their research projects in sufficient detail to permit evaluation of relevance and capability of the requested instrument to experimental goals. Each investigator should limit this description to no more than four pages. A short biographical sketch, list of recent publications and a listing of current and pending research support from all sources for each investigator should be included (as in form PHS 398).

C. Mechanism of Review

Applications in response to this solicitation will be reviewed in competition with each other by an initial review group of scientific consultants established in accord with the usual National Institutes of Health (NIH) peer review procedures. The Advisory Council of the NIADDK will then provide secondary review. This process will be expedited so that awards may be made approximately six months from the application deadline.

III. METHOD OF APPLICATION

A single yearly reply date of April 15 will be strictly established.

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. On the face page of form PHS 398 use the title of the P.I.'s active R01 grant followed by "Supplement" as the project title (line 1), and indicate that the application was prepared in response to the Program Announcement entitled "NIADDK, DDEMD Scientific Instrumentation Grants" (line 2).

The original and six copies of the application should be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Inquiries can be addressed to

Dr. Robert E. Silverman
DPB/DDEMD/NIADDK
Westwood Building - Room 605
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7888

ANNOUNCEMENT

NIAID MINORITY RESEARCH ENHANCEMENT PROGRAM

P.T. 34, 144;; K.W. 1200180, 0403013

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

I. DESCRIPTION

The National Institute of Allergy and Infectious Diseases (NIAID) will provide support for under-represented minority researchers through the Minority Research Enhancement Program (MREP). A minority investigator is defined as a Black, Hispanic, Native American, Asian or Pacific Islander.

Institutions with NIAID grants and interested in including under-represented minority investigators in such research endeavors may submit a supplemental grant application for this purpose. Meritorious applications will be funded as supplements to previously peer-reviewed active grants. These may include, but are not limited to, regular research project (R01) and program project (P01) grants.

II. OBJECTIVES

The MREP will provide this support to NIAID-supported principal investigators for the purpose of (1) increasing the number of under-represented minorities actively pursuing research objectives relevant to the mission of the institute, and (2) strengthening funded projects by enlarging the pool of scientific talent.

III. PROJECT EVALUATION

A group composed of NIAID staff will evaluate applications for responsiveness of the requested supplemental support to this announcement using as criteria the degree to which:

- o Activities proposed under the supplemental request would fit within the scope of the funded project.

This program is described in the Catalog of Federal Domestic Assistance No. 13.855, Immunology, Allergic and Immunologic Diseases Research and No. 13.856 Microbiology and Infectious 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 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.

- o The background of the minority scientist indicates that the research objectives will be achieved.
- o A fit exists between the time requested and the comprehensiveness and complexity of the project as proposed for revision/expansion.

The initial review for scientific merit will be conducted and managed by the Extramural Activities Program, NIAID. Recommendations will be forwarded through the director of the program responsible for the prime award to the National Advisory Allergy and Infectious Diseases Council.

IV. ELIGIBILITY

Any institution with an active NIAID research grant is eligible to submit a supplemental application on behalf of a principal investigator for the purpose of including under-represented minority researcher(s) in the project.

- A. Under-represented Minority Investigator - The minority investigator may be affiliated with the applicant institution(s) or some other institution. This investigator is expected to provide a complete curriculum vitae which includes a list of any research publications and other evidence of meritorious scientific achievements. The program is not intended to pay stipends for student trainees or support candidates without any research background. The minority investigator must be willing to devote a minimum of 30 percent of his/her time to the research project.
- B. Research Project - The proposed research project for the supplement must be closely related to the currently funded research grant. It may represent an increased effort in an already approved objective of the research project or propose a new objective related to those already approved. The nature of the research should provide the minority investigator an opportunity to contribute intellectually to the program and to broaden his/her own potential. The scope of the proposed research project should generally be comprehensive enough to require at least two years for completion and the supplemental application should include such a research plan and projected budget sheets. While not encouraged, a one-year application may be acceptable with appropriate justification. No new supplemental applications will be accepted in the final year of the current award.

V. FUNDING

Funding will be provided in accordance with the usual NIH policy for supplements. Awards will be issued on an annual basis. Continuing support for the second (or subsequent) year will depend upon approval of a satisfactory annual progress report and proposed budget from the minority investigator submitted with the principal investigator's non-competing continuation application. Funding for the supplement is always contingent on funding of the parent grant. Each supplemental budget shall not exceed \$25,000 in direct costs and may not include equipment. Supplemental awards made under this program are for the sole purpose of facilitating participation by minority investigators as described above.

VI. HOW TO APPLY

The principal investigator should submit a supplemental grant application through the institution on the Standard Form PHS 398, limited to the following: (1) Face page, at the top of which the applicant must designate the grant number of the active grant and specifically state "**Minority Investigator Supplement**" (For example, grant number **AI-12345-01 "Minority Research Enhancement Program"**); (2) budget page; (3) biographical sketch of the minority researcher; and (4) outline of the research project as it relates to the parent grant.

Applications received later than 90 days prior to a scheduled NAAID Council meeting may be reviewed at the subsequent NAAID Council meeting.

The original and four (4) copies of the application should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

Please send two (2) copies to:

Dr. William E. Bennett
Chief, Research Manpower
Development Staff, EAP,
National Institute of Allergy
and Infectious Diseases
Westwood Building - Room 7A-03
5333 Westbard Avenue
Bethesda, Maryland 20205

ANNOUNCEMENT

THE NCI CLINICAL INVESTIGATOR AWARD

P.T. 34; K.W. 1200180, 1200270, 1002014

NATIONAL CANCER INSTITUTE

Application Receipt Dates: June 1, October 1, February 1

I. SUMMARY AND PURPOSE

The National Cancer Institute (NCI) announces the availability of Clinical Investigator Awards for the purpose of developing physician-researchers in basic and applied cancer sciences. The initiation of this award is intended to encourage recently-trained highly-qualified physicians (M.D. or D.O.) to undertake careers in cancer research. The award is prompted by the chronic shortage of physician-investigators, particularly surgical oncologists, therapeutic radiologists, diagnostic radiologist, preventive oncologists, physiatrists, nutritionists and epidemiologists. It is expected to facilitate the awardee's transition to independent basic or applied research. This three to five year award will enable successful candidates to investigate from three to five years of defined cancer problem under the guidance of an active researcher(s) who has the knowledge, background and research experience required to be a mentor in that field.

II. ELIGIBILITY

A. Candidate

The award is designed to provide intensive, supervised research experience primarily for those holding only a medical doctorate. Applications will be accepted from M.D.s or D.O.s holding the Ph.D or an equivalent degree. These applications will receive case by case consideration of special circumstances, such as a Ph.D. in unrelated field or an intervening period of clinical training since the completion of the Ph.D.

This program is described in the Catalog of Federal Domestic Assistance No. 13.398, Cancer Research Manpower. Award 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 grant policies and Federal Regulations 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 Clearinghouse or Health Systems Agency review.

- o Generally a person must have more than two years, and less than seven years, of postdoctoral experience at the time of application. Candidates not meeting this requirement must include in the application a strong justification for an exception.
- o A person who is or has been principal investigator on any NIH research grant or cooperative agreement or research and development contract or is or has been program director of a program project is not eligible to apply for a Clinical Investigator Award.

Candidates should have broad clinical training, demonstrate individual competence in clinical activities, and show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for engaging in research and/or academic careers. Only United States citizens, nationals or people admitted as permanent residents may be presented as candidates for this award.

B. Institution

The sponsoring institution must have a strong, well-established research program in the candidate's area of interest, and experienced faculty members in the clinical and basic departments relevant to the candidate's proposed training. The institution must include a plan for the candidate's research and academic development. Only domestic institutions are eligible.

C. Preceptor

The candidate's primary preceptor must be a competent investigator in the area of the candidate's proposed research activity. The preceptor must be active currently as an investigator, and prepared to provide personally much of the candidate's research supervision. The award is intended to provide an intensive, supervised research experience for the successful candidate.

III. PROVISIONS OF THE AWARD

The Clinical Investigator Award is made for a minimum period of three years and a maximum of five years. The award is nonrenewable and nontransferable. Support is based upon a full-time, twelve-month appointment. The award will provide salary support not to exceed \$40,000 annually from NCI funds. The actual salary must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience, and rank. This salary may be supplemented by the grantee institution in conformance with PHS policy. Up to a total of \$10,000 annually will be provided in years 01 and 02, and up to \$20,000 annually in new succeeding years for supplies, equipment, travel, etc., necessary for pursuit of the awardee's research program. Funds will be provided for the reimbursement of indirect cost at a rate not to exceed eight percent of the total allowable direct costs. When requested, the grantee institution's share of the fringe benefits may be paid as a direct cost (if not treated as an indirect cost) on that portion of the employee's salary provided by the NCI Clinical Investigator Award.

It is expected that the candidate will spend at least 75 percent of his/her time in research during the period, with the remaining 25 percent being divided among other activities such as teaching, clinical training directly related to the research projects and course work. An appropriate sponsor must assume responsibility and provide guidance for the research development in the chosen areas.

Institutions may apply for awards on behalf of named individuals meeting the above criteria. It is not essential for the applicant institution to commit itself in the application to eventual placement of the candidate on its permanent, full-time faculty. However, it is expected that institutions will choose candidates of such caliber that they could meet the criteria for selection to such an appointment. Evidence of commitment to the candidate's research development must be provided by the institution.

Candidates for this award may not concurrently apply for a Research Career Development Award, an Academic Award or a New Investigator Research Award. The recipient of an NCI Clinical Investigator Award may apply for research grants during the term of his/her Clinical Investigator Award.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation and potential for an academic or research career. Candidates must have one or more sponsors at the institution who are recognized as accomplished researchers or teachers in the candidate's area of proposed development. The sponsor(s) must provide (1) his/her concept of a development and research plan for the candidates; (2) his/her updated curriculum vitae with a complete bibliography and research support; and (3) a letter indicating willingness to provide guidance and support for the award's duration.

Candidates must provide a full description of the proposed research and career development plan for the full period of the award. The candidate must be prepared to commit full-time effort to the objectives of this award.

Candidates must agree to inform the NCI annually for a period of ten years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

IV. REVIEW CRITERIA

Applications will undergo initial merit review in the Grants Review Branch, Division of Extramural Activities, NCI. Secondary review will be by the National Cancer Advisory Board. Criteria for review include:

- o The candidate's potential for a career in independent research.
- o The candidate's commitment to a research career.
- o The overall merit of the candidate's plan for research and the development of research skills.
- o The quality of the candidate's clinical training and experience.
- o The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development.

- o Presence of highly trained faculty in clinical and basic science departments relative to the area of study.
- o The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

V. HOW TO APPLY

Please read a copy of the "Program Guidelines" before applying for one of these awards. These are obtainable from the Program Director. An application for this award should be made on form PHS 398 (Rev. 5/82). The name of the program announcement should be typed in Section 2 on the face page of the application form. Application receipt dates are: February 1, June 1, and October 1.

This announcement and the program guidelines mentioned above are effective for all K08 applications reviewed by NCI for the June 1, 1985 and later receipt dates.

Please send two complete copies of the application to:

Referral Officer
Grants Review Branch
Division of Extramural Activities
National Cancer Institute
2115 East Jefferson Street - Room 401
Rockville, Maryland 20852

The original and four (4) copies should be sent to the Division of Research Grants as indicated in the instructions furnished in the application kit. Questions should be addressed to:

Program Director
Clinical Investigator Awards
Division of Cancer Prevention and Control
Blair Building - Room 424
Bethesda, Maryland 20205-4200

Telephone: (301) 427-8898

ANNOUNCEMENT

RESEARCH AND DEMONSTRATIONS RELATING TO OCCUPATIONAL SAFETY AND HEALTH

P.T. 34, 12; K.W. 0701034

CENTERS FOR DISEASE CONTROL

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

The Centers for Disease Control (CDC), National Institute for Occupational Safety and Health (NIOSH) announces that competitive grant applications are being accepted for research and demonstrations relating to occupational safety and health. These include innovative methods, techniques, and approaches for dealing with occupational safety and health problems in general industry and in the mining industry.

Support in the form of project grants will be awarded for annual budget periods, within a project period not to exceed five years.

I. AUTHORITY

These grants will be awarded and administered by NIOSH under the research and demonstration grant authority of Section 20(a)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(1) and Section 501) of the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951). Program Regulations applicable to these grants are contained in Part 87 of Title 42, Code of Federal Regulations, "National Institute for Occupational Safety and Health Research and Demonstration Grants." Except as otherwise indicated, the basic grant administration policies of the Department of Health and Human Services and the Public Health Service are applicable to this program.

II. ELIGIBLE APPLICANTS

Eligible applicants include non-profit and for-profit organizations. Thus universities, colleges, research institutions and other public and private organizations including State and local governments and small, minority and/or woman-owned businesses are eligible for these research and demonstration grants. For-profit organizations will be required to submit a certification as to their status as part of their application.

III. PROGRAM REQUIREMENTS

A. Research Project Grants

A research project grant application should be intended and designed to establish, discover, develop, elucidate, or confirm information relating to occupational safety and health, including innovative methods, techniques, and approaches for dealing with occupational safety and health problems. These studies may generate information that is readily available to solve problems or contribute to a better understanding of underlying causes and mechanisms.

B. Demonstration Grants

A demonstration grant application should address, either on a pilot or full-scale basis, the technical or economic feasibility or application of: (1) a new or improved occupational safety or health procedure, method, technique, or system, or (2) an innovative method, technique, or approach for preventing occupational safety or health problems.

C. Special Emphasis Research Career Award (SERCA) Grants

The SERCA is designed to enhance the research capability of individuals in the formative stages of their careers who have demonstrated outstanding potential for contributing as independent investigators to health-related research. Candidates must have had two or more years of relevant postdoctoral experience prior to the submission date. The application must document accomplishments in this period that demonstrate research potential; it must also present a plan for additional experience in a productive scientific environment at domestic institutions that will foster development of a career of independent research in the area of occupational safety and health. The SERCA is not intended for untried investigators, or for productive, independent investigators with significant numbers of publications of high quality, or for persons of senior academic rank (above associate professor or tenured). Moreover, the award is not intended to substitute one source of salary support for another for an individual who is already conducting full-time research, nor is it intended to be a mechanism for providing institutional support. The application must demonstrate that the award will make a difference in and enhance the candidate's development as an independent investigator.

Candidates must indicate a commitment of at least 60 percent time (not necessarily 60% salary) devoted to research under the SERCA grant, although full-time is desirable. Other work in the area of occupational safety and health will enhance the candidate's qualifications but is not a substitute for this requirement. While working closely with the advisor(s), the awardee is expected to develop capabilities in fundamental, applied, and/or clinical research in one of the areas in section IV. At the end of the award period, evidence of independent investigative capability should be present such that the individual is better able to compete in traditional NIOSH research grant activities.

The total grant award may comprise direct costs of up to \$30,000 per year and up to eight percent additional indirect costs. Direct costs may include salary plus fringe benefits, technical assistance, equipment, supplies, consultant costs, domestic travel, publication, and other costs. If the awardee already holds a small grant on the same research topic, the amount of the SERCA may be reduced up to the amount of the small grant. Awards may be up to three years and will not be renewable.

D. Small Grants

A small grant application is intended to provide financial support to carry out exploratory or pilot studies, to develop or test new techniques or methods, or to analyze data previously collected. This small grant program is intended for predoctoral graduate students, post-doctoral researchers (within three years following completion of doctoral degree or completion of residency or public health training) and junior faculty members (no higher than assistant professor). If university policy requires that a more senior person be listed as principal investigator, the application should specify that the funds are for the use of a particular student or junior-level person and should include appropriate justification for this arrangement. Though biographical sketches are required only for the person actually doing the work, the application should indicate who would be supervising the research. Small grant applications should be identified as such on the application form.

The total small grant award may comprise direct costs of up to \$15,000 per year and additional indirect costs, as appropriate. The grants may be awarded for up to two years and are thereafter continuable by competitive renewal as a regular research grant. Salary of the principal investigator as well as that of the junior investigator, if university policy requires a senior person to be listed as the principal investigator, will not be allowed on a small grant, though salaries can be requested for necessary support staff such as laboratory technicians, interviewers, etc.

E. Program Project Grants

NIOSH will also accept applications for program project grants, but only after discussion with the individuals listed in this announcement.

IV. PROGRAMMATIC INTEREST

Examples of work-related programmatic interest to NIOSH which are applicable to all of the above types of grants are:

1. Occupational lung disease: asbestosis, byssinosis, silicosis, coal workers' pneumoconiosis, lung cancer, occupational asthma*
2. Musculoskeletal injuries: disorders of the back, trunk, upper extremity, neck, lower extremity: traumatically induced Raynaud's phenomenon*
3. Occupational cancers (other than lung): leukemia; mesothelioma; cancers of the bladder, nose and liver*
4. Amputations, fractures: eye loss, lacerations, and traumatic deaths*
5. Cardiovascular diseases: hypertension, coronary artery disease, acute myocardial infarction*
6. Disorders of reproduction: infertility, spontaneous abortion, teratogenesis*
7. Neurotoxic disorders: peripheral neuropathy, toxic encephalitis, psychoses, extreme personality changes (exposure-related)*

8. Noise-induced loss of hearing*
9. Dermatologic conditions: dermatoses, burns (scalding), chemical burns, contusions (abrasions)*
10. Psychologic disorders: neuroses, personality disorders, alcoholism, drug dependency*
11. Control technology research: application of scientific principles to control strategies; preconstruction review; technology forcing/new source performance concepts; technology transfer; substitution; unit operations approaches*
12. Respirator research: new and innovative respiratory protective devices; techniques to predict performance; effectiveness of respirator programs; physiologic and ergonomic factors; medical surveillance strategies; psychological and motivational aspects; effectiveness of sorbents and filters, including chemical and physical properties*

*The conditions or examples listed under each category are to be viewed as selected examples, not comprehensive definitions of the category. It should be noted, however, that investigators may apply in any areas related to occupational safety and health. Applications responding to this announcement will be reviewed by staff for their responsiveness and relevance to occupational safety and health. Assignment for program responsibility and funding will be according to established referral guidelines. Potential applicants with questions concerning the acceptability of their proposed work should contact the individuals listed in this announcement.

V. CRITERIA FOR REVIEW

Applications will be evaluated by a dual review process. The primary (peer) review is based on scientific merit and significance of the project, competence of the proposed staff in relation to the type of research involved, feasibility of the project, likelihood of its producing meaningful results, appropriateness of the proposed project period, adequacy of the applicant's resources available for the project, and appropriateness of the budget request.

Demonstration grant applications will be reviewed additionally on the basis of the following criteria:

- o Degree to which project objectives are clearly established, obtainable, and for which progress toward attainment can and will be measured.
- o Availability, adequacy, and competence of personnel, facilities, and other resources needed to carry out the project.
- o Degree to which the project can be expected to yield or demonstrate results that will be useful and desirable on a national or regional basis.
- o Extent of cooperation expected from industry, unions, or other participants in the project, where applicable.

SERCA grant applications will be reviewed additionally on the basis of the following criteria:

- o The review process will consider the applicant's scientific achievements, evidence of demonstrated commitment to a research career in occupational safety and health, and supportive nature of the research environment (including letter(s) of reference from advisor(s) which should accompany the application).

Small grant applications will be reviewed additionally on the basis of the following criteria:

- o The review process will take into consideration the fact that the applicants do not have extensive experience with the grant process.

A secondary review will also be conducted. Factors considered in the secondary review will include:

- o The results of the initial review.
- o The significance of the proposed study to the research programs of NIOSH.
- o National needs and program balance.
- o Policy and budgetary considerations.

VI. APPLICATION AND AWARD

Applications should be submitted on Form PHS-398 (revised May 1982) or PHS-5161-1 for State and local government applications. Forms should be available from the institutional business offices or from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building - Room 449
5333 Westbard Avenue
Bethesda, Maryland 20205

The original and six copies of the application must be submitted to the address below on or before the specified receipt dates in accordance with the instructions in the PHS-398 packet:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
Bethesda, Maryland 20205

In developing the application please note that the conventional presentation for grant applications should be used and the points identified under "CRITERIA FOR REVIEW" must be fulfilled.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application that are made available to outside reviewing groups. If the applicant's organization elects to exercise this option, use asterisks on the original and six copies of the application to indicate those individuals for whom salaries and fringe benefits are being requested; the subtotals must still be shown. In addition, submit an additional copy of page four of Form PHS-398, completed in full with the asterisks replaced by the amount of the salary and fringe benefits requested for each individual listed. This budget page will be reserved for internal PHS staff use only.

The instructions in the Form PHS-398 packet should be followed concerning deadlines for either delivering or mailing the applications. The application should be sent or delivered using the mailing label in the Form PHS-398 packet.

The proposed timetable for receiving applications and awarding grants is as follows:

All Except SERCA Grants and Small Grants

| <u>Application Deadline</u> | <u>Primary Review Group Meeting</u> | <u>Secondary Review Meeting</u> | <u>Expected Start Date</u> |
|-----------------------------|-------------------------------------|---------------------------------|----------------------------|
| March 1 | June | September | December 1 |
| July 1 | Oct./Nov. | January | April 1 |
| November 1 | Feb./Mar. | May | July 1 |

SERCA Grants and Small Grants

| | | | |
|------------|-----------|-----------|------------|
| February 1 | June | September | December 1 |
| June 1 | Oct./Nov. | January | April 1 |
| October 1 | Feb./Mar. | May | July 1 |

Awards will be made based on priority score ranking and emphasis area, as well as availability of funds.

VII. COST SHARING

Grantees will be expected to cost share a minimum of five percent.

VIII. FOR TECHNICAL INFORMATION CONTACT:

Roy M. Fleming, Sc.D.
Chief, Grants Administration and Review Branch
National Institute for Occupational Safety
and Health
Centers for Disease Control
1600 Clifton Road, N.E.
Building 1 - Room 3053
Atlanta, Georgia 30333

Telephone: (404) 329-3343

FOR BUSINESS INFORMATION CONTACT:

Leo A. Sanders
Grants Management Officer
Centers for Disease Control
255 E. Paces Ferry Road, N.E., Room 107A
Atlanta, Georgia 30305

Telephone: (404) 262-6575

(This program is described in the Catalog of Federal Domestic Assistance Program No. 13.262, Occupational Safety and Health Research Grants. It is not subject to Health Systems Agency nor Executive Order 12372 review.)

ANNOUNCEMENT

THE OLDEST OLD

P.T. 34; K.W. 0404002, 0701013, 0413001, 0408006, 0701016, 0701010, 1201230

THE NATIONAL INSTITUTE ON AGING

I. BACKGROUND AND GOALS

The National Institute on Aging (NIA) invites qualified researchers to submit new and supplemental applications for research projects which focus on the oldest old--those over age 85. Although the over age 85 population is still small in absolute numbers (about 2.6 million), it is forecast to be the fastest growing segment of the population for the period 1980-1990. For the last several decades the over age 85 population has been growing at almost three times the rate of that of all persons over age 65. While comprising only one percent of the total U.S. population today, this segment is projected to rise to 1.9 percent (5 million) by the year 2000, and 5.2 percent by 2050 (16 million). Assumptions about the future direction of the mortality rates of this age group powerfully influence these projections.

The oldest old are very substantial users of health care and other services. While about 6 percent of those aged 75-84 are institutionalized, the rate for those over age 85 is about 23 percent. The 1979 National Health Interview Survey data showed that in just the non-institutionalized elderly, the need for help from another person in one or more activities of daily living increased substantially. Seven percent of those aged 65-74 required help as compared to 16 percent for those aged 75-84, and to over 40 percent for those over 85. This gradient was even steeper in the female population, which greatly outnumbers the male population at older ages. If the current utilization rates for health and other services for this age group are extrapolated simply as a function of the projected growth of the oldest old population, then the implications for society are considerable.

The Federal Government provides, by some estimates, \$51 billion in major benefits to those 80 and over. Yet, at almost all levels, from the demographic to the physiologic, less is known about this age group than about any other. For example, federal statistics rarely provide detailed information on those over age 85. Our lack of knowledge about the oldest old results from a number of factors. Until recently their absolute numbers have been small, the available data have often been perceived to be of low quality, and this age group has been considered difficult to study.

This program is described in the Catalog of Federal Domestic Assistance No.13.866, Aging Research. Awards will be made under the authority of the Public Health Service Act, Section 472, 42 USC 2891-1, and administered under PHS grants policy and Federal Regulations 42 CFR Part 66, and Public Health Service Act, Title III, Section 301 (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.

This announcement of NIA's special initiative on the Oldest Old supplements, but does not replace, such prior announcements as "Social and Behavioral Research" and "Health and Effective Functioning in the Middle and Later Years".¹ This initiative is being sponsored jointly by the Behavioral Sciences Research and Biomedical Research and Clinical Medicine Programs of the NIA, and is coordinated with related programs in the National Institute of Mental Health and the National Institute of Child Health and Human Development.

II. SPECIFIC OBJECTIVES

This announcement indicates the wide array of knowledge needed, starting with the urgently needed assessment of the quality of the existing data, and the development of improved sources of information and methodologies for studying the oldest old. Also needed are descriptive and analytic studies. Among the broad topics of concern are:

A. Assessment of Existing Data and Methodological Innovations

1. Studies assessing the quality of existing data, and methodological innovations to improve data quality; e.g.:
 - o Studies which improve the representativeness and reliability of data for those over 85, including studies to sharpen current definitions of the household by delineating new types of living arrangements. Improved methods for interviewing and obtaining valid and reliable data for persons with limitations of hearing, vision, memory or comprehension. Improved methods of collecting data in institutions; analyses of the differences in the quality of data collected from the individual versus that from administrative records or from proxy respondents. Studies leading to improved record collecting, cause-of-death reporting, and an increased autopsy rate. Studies which improve the measurement of the various forms of functional ability.
 - o Studies to improve the ability to project and forecast changes in life expectancy and active life expectancy. Development of improved methods for assigning confidence bands to projection.

B. General Characteristics of the Oldest Old

1. Socio-demographic studies within both the United States and other industrialized nations such as:
 - o Distribution and projections by, e.g., sex, race, education, income, residence, and living arrangements. Investigations of migration. Analyses of the composition and proximity of surviving kin.

¹/ See NIH Guide for Grants and Contracts, Vol. 12, No. 6, June 17, 1983, pp.5-15, Vol. 10, No. 10, September 4, 1981.

- o Analyses of sociodemographic historical trends in the oldest old, and the impact of cohort succession (e.g., in the percent foreign born and of increasing levels of education, etc.) on their characteristics.
 - o Economic issues such as the distribution of income and wealth in sub-populations, and the conditions under which financial reserves become exhausted; the impact of anticipated institutionalization on saving and consumption; the transmission of assets and patterns of exchange between generations; illiquidity and the implications of reverse mortgages; the assessment of income adequacy measures; relationships between financial status and sense of financial well-being; conditions of daily life of those below, or close to, the poverty line; the economic determinants of living arrangements.
2. Descriptions and analyses of patterns of functioning, morbidity, and disease-specific causes of death. For example:
- o Studies of stability and decline in such abilities as memory and problem solving; individual reactions to reduced competency; the epidemiology of sensory and communication problems.
 - o Clinical, pathologic, and epidemiological data on the prevalence, course, morbidity, and mortality of diseases.
 - o Physiologic factors (e.g., metabolic, endocrine, immune, skeletal-muscular, sensory, and cardiovascular) which increase or diminish risk for decrements in functioning, specific diseases, and mortality from disease.
 - o The interaction of multiple disease processes to determine the effects of co-existent diseases on functioning, morbidity, mortality, and implications for intervention and therapy.
 - o Studies of variation in mortality, morbidity, and patterns of functioning among the population sub-groups of the oldest old within the U.S. and other nations. Studies of the reported "mortality cross-over" phenomenon between black elderly and their white counterparts. Factors which may be associated with differential survival, health, and functioning at the oldest ages, including lifestyle, health behaviors, medical and self care, and genetic and familial background.

C. Interactions with the Society Including Care Systems

1. Studies of the care systems of the oldest old in areas such as:
- o The impact of the changing family and increasing participation of women in the labor force on the provision of care for future cohorts of the oldest old. Social and economic effects on families caring for the frail oldest old. The impact of health care reimbursement policies on relationships between formal and informal care systems. Assessment of the resources which allow

functioning outside of long-term care settings.

- o Studies of the last year of life including interactions among patients, family, care providers, nursing homes, and the legal system, and implications for costs and patient well-being.
2. Factors affecting institutionalization and use of services, e.g.:
- o Dementia and other cognitive impairments; osteoarthritis and other causes of impaired mobility; falls and other injuries; and urinary and fecal incontinence.
 - o Living arrangements and the physical characteristics of housing units, including innovations designed to keep the frail in the community, and the availability of support. Comparative analyses among jurisdictions, social, ethnic, and racial groups, or other nations with different rates of institutionalization.
3. Interactions between the oldest old population and society, e.g.:
- o Forecasting and modeling the impact of the rapid growth of the oldest old population on e.g., the economy, the social security system, the insurance industry, the distribution of income, the health care system, housing, the political system, intergenerational solidarity; and the family structure. Dynamics of resource allocation among age strata. Comparisons of the adaptation of institutions to the growth of the over 85 population across industrialized nations experiencing different rates of structural aging. The impact of social trends.
 - o Special socio-legal problems of this age category; comparison among jurisdictions in the United States of the impact of laws (and their changes) affecting the oldest old and their families; studies of their interactions with the legal system, including analyses of conservatorships, the right of patients to refuse or terminate care and the reactions of institutions to such requests.

III. METHODOLOGY

Research applications need not be limited to any particular methodology of data collection or analysis. Designs will frequently need to include comparisons with age groups below age 85. Designs may include demographic, epidemiological, econometric, and clinical studies with cross-sectional, longitudinal, or cohort designs. Cross-national (and multi-state) comparisons are strongly encouraged. Secondary analysis of existing data is encouraged, although collection of new data will be necessary to meet particular objectives. Where new data are collected, very careful consideration should be given to human subject concerns (see NIH Guide for Grants and Contracts, Vol. 10, No. 4, March 6, 1981).

IV. APPLICATION SUBMISSION AND REVIEW

Applications received in response to this announcement will be assigned to regular peer review groups and will be considered in accordance with NIH guidelines.

Interest in some of the above areas is shared by the National Institute of Mental Health (NIMH). Applications will be assigned according to standing referral guidelines. Information on NIMH program interests can be obtained from;

Center for Studies of the Mental Health
of the Aging
Parklawn Building - Room 11C-03
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-1185.

The review criteria are the traditional considerations underlying scientific merit.

Investigators are encouraged to discuss their projects and the range of available grant mechanisms with NIA staff in advance of formal submission. This can be done through a telephone conversation or brief (4-5 page) research prospectus. Applicants should use the regular research project application form (PHS 398), which is available at the applicant's institutional Application Control Office or from:

Office of Grants Inquiries
Division of Research Grants (DRG)
National Institutes of Health

Telephone: (301) 496-7441

In order to expedite the routing of applications within NIH, please (1) check the box on the application face sheet indicating that your proposal is in response to this announcement and print (next to the checked box) "NIA: THE OLDEST OLD" and (2) enclose a cover letter repeating that your application is in response to this announcement.

Mail the cover letter and the completed application (with 6 copies) to:

Division of Research Grants
National Institutes of Health
Westwood Building - Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Receipt dates for Research Project Grant and New Investigator Award applications are: March 1, July 1, and November 1; for others, including Postdoctoral Fellow and Program Project applications: February 1, June 1, October 1.

Address requests for additional information (e.g., sources of data) research prospectuses, and/or letters of intent to:

For all topics other than biomedical:

National Institute on Aging
Behavioral Sciences Research
Attention: "Oldest Old"
Building 31C - Room 4C32
Bethesda, Maryland 20205

Telephone: (301) 496-3136

For biomedical topics:

National Institute on Aging
Biomedical Research and
Clinical Medicine
Attention: "Oldest Old"
Building 31C - Room 5C21
Bethesda, Maryland 20205

Telephone: (301) 496-1033