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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 20, No. 41
November 1, 1991

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

ERRATA

CARDIOVASCULAR IMAGING WORKSHOP

P.T. 42; K.W. 0706030, 0705015, 0715040, 1002061, 0790000

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) is sponsoring a workshop entitled, "Cardiovascular Imaging Workshop," to be held on March 2-4, 1992, at the National Institutes of Health, Lister Hill Auditorium, Building 38A, Bethesda, MD. The objective of this workshop is the identification of opportunities for furthering research in myocardial and vessel wall biology and physiology through imaging and spectroscopic research. Specific topics to be considered are myocardial viability, perfusion and metabolism, and vessel wall biology and plaque.

For registration information and a preliminary agenda, contact:

Rosalie A. Dunn, Ph.D.
Devices and Technology Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 312
Bethesda, MD 20892
Telephone: (301) 496 1586

NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

WEST COAST WORKSHOP

DATES: January 23 and 24, 1992 (REVISED DATES)

WORKSHOP SITE: Los Angeles, CA

SPONSORS:
University of Southern California
Los Angeles, CA 90089-4014

California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202

REGISTRATION CONTACT:
Ms. Lily Patterson
Assistant to the Director
Research and Sponsored Programs
California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202
Telephone: (213) 343-3820

TOPIC: Whose Research is it Anyway? A Workshop on the Protection of Human Subjects in Research

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78284-7972

St. Mary's University
One Camino Santa Maria
San Antonio, TX 78228-8572

REGISTRATION CONTACT:
Ms. Angie Khan
Institutional Coordinator of Research Review
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive (Room 402L)
San Antonio, TX 78284-7972
Telephone: (512) 567-2351

TOPIC: Identifying and Assessing Risks in Human Subject Research

SOUTHWEST WORKSHOP

DATES: March 24, 25, and 26, 1992

WORKSHOP SITE:
Sheraton Old Town Hotel
800 Rio Grande Blvd., N.W.
Albuquerque, NM 87104

SPONSORS:
University of New Mexico
Albuquerque, NM 87131-5126

Navajo Community College
Shiprock, NM 87420

REGISTRATION CONTACT:
University of New Mexico
Office of Continuing Medical Education
Health Sciences and Services Building (Room 140)
Box 713
Albuquerque, NM 87131-5126
Telephone: (505) 277-3942

TOPIC: Ethics, Justice, and Tribal Participation in Research with American Indians

NOTE: In conjunction with this Workshop, a session entitled, "Basic Training for IRB Members," will be held from 1:00 p.m. on March 24 until noon on March 25. During this session the Workshop participants will be divided into four IRBs that will review four different research protocols involving American Indians. The full conference will convene at 1:00 p.m. on March 25 and continue until 6:00 p.m. on March 26.

NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

SPONSORS:
University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246

Lincoln University
Lincoln University, PA 19352

REGISTRATION CONTACT:
Ms. Lynn Bevan
Assistant Director
Office of Research Administration
University of Pennsylvania
133 South 36th Street, Suite 300
Philadelphia, PA 19104-3246
Telephone: (215) 898-2614

TOPIC: The Shifting Ground: Current Issues for the Protection of Human Subjects in Biomedical and Behavioral Research

For further information regarding these workshops and future NIH/FDA National Protection of Human Subjects Workshops, please contact:

Ms. Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

HISPANIC HEALTH AND AGING

RFA AVAILABLE: AG-91-15

P.T. 34, FD; K.W. 0710010, 0730000, 0408006, 0404000, 0417000, 1002019

National Institute on Aging

Letter of Intent Receipt Date: December 1, 1991
Application Receipt Date: January 24, 1992

PURPOSE

The National Institute on Aging (NIA) announces the availability of a Request for Applications (RFA) for research on Hispanic health and aging. Investigations on the influence of genetic, social, environmental, behavioral, and economic factors on morbidity and mortality, as well as applications proposing research on the utilization of health services among the Hispanic elderly are requested. In addition to the development of new data, secondary analyses of existing data are acceptable.

There are currently one million elderly Hispanics living in the continental United States, and this number is expected to grow to 5.6 million in less than 50 years -- a growth rate that is calculated to be four times the rate of the overall elderly population. Despite the growth in the number of older Hispanics, information about their health status, rehabilitation needs, and use of medical services is scarce.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202- 783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority investigators and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the Public Health Service grant-in-aid individual research grant (R01). Awards will be administered under PHS grants policy, as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000, revised October 1, 1990.

The RFA is a one-time solicitation. The award of grants pursuant to the RFA is contingent on the availability of funds for this purpose. Generally, future unsolicited competing renewal applications will compete with all investigator-initiated applications and be reviewed by the Division of Research Grants. However, if the NIA determines that there is a sufficient continuing program need, the RFA will be reissued. The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest feasible start date for the initial awards will be July 1, 1992.

FUNDS AVAILABLE

Up to two million dollars in total (direct and indirect) first-year costs, and additional direct costs for up to five years, will be committed to fund up to six applications from those submitted in response to this RFA. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit.

RESEARCH OBJECTIVES

This RFA solicits research on the following issues:

o Epidemiological studies with a longitudinal focus on the causes and course of selected health problems in elderly Hispanics.

o Descriptive studies that characterize the association of chronic diseases with disability among the Hispanic elderly.

o Comparative studies testing the hypothesis that the Hispanic elderly have more (or less) frailty and disability relative to non-Hispanic subgroups.

o Examination of the role of genetics among elderly Hispanics by studying the relationship of American Indian ancestry to susceptibility to specific diseases.

o Studies of the interface between formal health and human services and informal social supports among elderly Hispanics.

SPECIAL REQUIREMENTS

The Principal Investigators of funded projects, under the terms of the awards, will meet in Bethesda with NIA staff yearly to review the progress of their studies. Funds for such travel must be requested in the application.

STUDY POPULATIONS/SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women in study populations. The nature of this solicitation satisfies the requirement that minorities be included. If women are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

REVIEW CONSIDERATIONS

Applications will be received by the NIH Division of Research Grants. Responsive applications will be assigned to a special review group organized by the NIA. Following this review, applications will be considered by the National Advisory Council on Aging.

APPLICATION PROCEDURES

The deadline for receipt of applications is January 24, 1991. The grant applications may be obtained from the Division of Research Grants, telephone (301) 496-7441. A copy of the RFA contains important information for applicants and may be obtained from Manuel R. Miranda, Ph.D. (address below).

LETTER OF INTENT

A letter of intent to submit an application, while not required, is requested. the letter consists of a brief descriptive title, the name of the Principal Investigator and other key investigators, and the names and addresses of any other participating institutions. The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed. The letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application and does not enter into the review of an application subsequently submitted. This letter is to be addressed to Dr. Manuel Miranda at the address listed below.

INQUIRIES

Written and telephone inquiries concerning the RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Manuel R. Miranda, Ph.D.
National Institute on Aging
Interdisc. Research/Geriatrics Program
Building 31, Room 3B63
Bethesda, MD 20892
Telephone: (301) 402-1115

Direct inquiries regarding fiscal matters to:

Mr. Joe Ellis
Grants Management Officer
National Institute on Aging
Building 31, Room 5C07
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-1572

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.866, Biology of Aging Program. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS Grants Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.

HAZARDOUS MATERIALS AND WASTE WORKER HEALTH AND SAFETY TRAINING

RFA AVAILABLE: ES-92-01

P.T. 34; K.W. 0502017, 1007009, 0725020

National Institute of Environmental Health Sciences

Letter of Intent Receipt Date: December 20, 1991
Application Receipt Date: January 24, 1992

PURPOSE

The National Institute of Environmental Health Sciences (NIEHS) announces the availability of a Request for Applications (RFA) for cooperative agreements for training and education of workers engaged in activities related to hazardous materials and waste generation, removal, containment, transportation, and emergency response.

The major objective of this solicitation is to prevent work-related harm by assisting in the training of workers in the best protection of themselves and their communities from exposure to hazardous materials encountered during hazardous waste operations and emergency response. A variety of sites, such as those involved with chemical waste clean-up and remedial action and transportation-related chemical emergency response, may pose severe health and safety concerns. These are often characterized by the multiplicity of substances present, the presence of unknown substances, and the general uncontrolled condition of the site. A major goal of this program is to assist organizations with the development of institutional competency to provide appropriate training and education to workers in the field of hazardous materials and waste.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a priority-setting process for Federal public health activities. This Request for Applications (RFA), Hazardous Materials and Waste Worker Health and Safety Training, is related to the priority areas of occupational health and environmental health in the health protection initiative. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applicants must be non-profit organizations that demonstrate expertise and experience in implementing and operating training and education programs for workers. Such organizations must demonstrate the ability to reach and involve in training programs the target populations of workers. Any non-profit organization providing worker health and safety education and training may apply.

MECHANISM OF SUPPORT

Awards will be made as cooperative agreements (U01). No commitment of funds will be made beyond Fiscal Year 1994. During FY 1992, the NIEHS plans to fund between 15 and 20 cooperative agreements in response to this RFA. Awards will be made for up to three years with annual renewal based on availability of funds, staff review of progress toward achieving training objectives, and submission to the NIEHS of copies of all training and educational materials used under the award. The anticipated starting date for the initial annual period will be September 1, 1992.

The cooperative agreement is an assistance instrument similar to a grant. It differs in that in addition to the standard stewardship role, the NIEHS program administrator is expected to have a continuing substantive role

in one or more technical aspects of the program. The type and degree of this substantial programmatic involvement is specified in the terms and conditions of the cooperative agreement. The awardee will have lead responsibilities in all aspects of the program, including any technical modifications to the curriculum, conduct of the training, and quality control.

Applicants are expected to furnish their own estimates of the time required to achieve specific training and education objectives of the proposed training program and conduct appropriate program evaluations. Any substantial modifications in the program scope and objectives must be mutually agreed upon by the awardee institution and the NIEHS. Because of the varied target audiences for the proposed training and education programs, it is anticipated that a variety of approaches will be responsive to this announcement and that there will be a range of costs among individual awards.

TRAINING OBJECTIVES

Training programs shall satisfy minimum requirements for hazardous waste workers and emergency responders as specified in Federal Occupational Safety and Health Administration and other regulations that have been or may be promulgated. Training programs shall also meet the minimum requirements specified in the Minimum Criteria for Worker Health and Safety Training for Hazardous Waste Operations and Emergency Response, published April 1990, as a result of an NIEHS-sponsored technical workshop on training quality. Previous successful experience in conducting worker training programs for these purposes will be an important review criterion.

Awards will be made for direct student and worker-trainer training, technical support of training, and training program evaluation. It is believed that adequate curricula and training materials exist for worker training that can be adapted with minimal effort. Means of multiplying training are also encouraged to meet the need; thus programs such as effective train-the-trainer programs are encouraged. Programs targeted to multi-state and nationwide coverage to reach wider worker populations will be given preference in review and funding. Applications will not be considered that cover municipalities or other jurisdictions covering less than two states. Programs are encouraged to develop plans to become self sufficient. Applications must include plans for reaching underserved workers in the proposed target populations, especially those disadvantaged in education, culture, language, or literacy.

REVIEW PROCEDURES

Review of applications will not include a site visit for additional information. Therefore, it is essential that the application be as complete as possible. Applications will be reviewed on a competitive basis for technical merit by an ad hoc peer review committee convened by the NIEHS. This committee will be primarily composed of non-Government members with expertise in occupational health and safety training related to hazardous materials, waste operations, and emergency response. The second level of review will be conducted by the National Advisory Environmental Health Sciences Council.

APPLICATION PROCEDURES

Applications for Hazardous Materials and Waste Worker Health and Safety Training Grants must be submitted on the grant application form PHS 398 (rev. 10/88, reprinted 9/89). This form is usually available in the sponsored programs office at academic institutions. However, since this form is used primarily for traditional NIH research and training assistance, several sections have to be modified and expanded to provide additional information needed for worker training assistance applications. Applicants may request a copy of form PHS 398 from the Office of Grants Inquires, Division of Research Grants, NIH, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892-4500, telephone 301/496-7441. Special instructions for worker training applications are available from the Program Administrator, Worker Training Grants Program, NIEHS, at the address listed below.

INQUIRIES

The NIEHS welcomes the opportunity to clarify any issues or questions from potential applicants concerning this RFA. Technical inquiries regarding the objectives and scope of this RFA and requests for a copy of the RFA may be directed to:

Denny Dobbin
Program Administrator
Worker Training Grants Program
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709-2233
Telephone: (919) 541-0752

Financial management inquiries may be directed to:

Carol Matheny
Grants Management Specialist
Grants Management Branch
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709-2233
Telephone: (919) 541-2930

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.142, Superfund Worker Training Grants. 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 Section 126(g) of the Superfund Amendments and Reauthorization Act of 1986 and administered under PHS grants 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. The program is administered according to 42 CFR 45 -- Part 74 and Part 92, DHHS Administration of Grants; 42 CFR Part 65, Special Regulations for National Institute of Environmental Health Sciences Hazardous Waste Worker Training, the PHS Grants Administration Manual, and PHS Grants Policy Statement.

NATIONAL COOPERATIVE PROGRAM ON MARKERS OF UTERINE RECEPTIVITY FOR NONHUMAN BLASTOCYST IMPLANTATION

RFA AVAILABLE: HD-92-02

P.T. 34; K.W. 0760003, 0413002, 0760025, 1002004, 1002008

National Institute of Child Health and Human Development

Application Receipt Date: April 1, 1992

PURPOSE

This is a notice of availability of a Request for Applications (RFA) from established investigators in the area of blastocyst implantation to participate in a National Cooperative Program to identify and characterize markers indicative of the state of the uterus receptive for blastocyst implantation. Investigators will cooperate in an interdisciplinary and complementary manner to achieve the goals of identification and characterization of the uterine receptivity markers.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This RFA, National Cooperative Program on Markers of Uterine Receptivity for Nonhuman Blastocyst Implantation, is related to the priority area of maternal and infant health. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone 202-783-3238).

BACKGROUND INFORMATION

The National Institute of Child Health and Human Development (NICHD) invites applications from investigators willing to participate, with the assistance of the NICHD, in a multi-site Cooperative Research Program designed to establish assayable markers for uterine receptivity for blastocyst implantation and characterize the involvement of these markers in the process of nonhuman blastocyst implantation.

A Research Coordinator from the NICHD staff will collaborate with the Principal Investigators of the awards in the planning, evaluation, and publication of the research, and serve as a coordinator, facilitator and partner in the conduct of the research program. It is expected that protocols will change as new information is gathered and shared.

There are three program phases: Phase I is to determine the experimental approaches, protocol(s), and other research conditions; Phase II is to implement and conduct the research; and Phase III is to analyze and disseminate the results obtained.

ELIGIBILITY

Any domestic institution, both public and private, is eligible to apply.

MECHANISM OF SUPPORT

The funding mechanism for fiscal assistance in this high priority area of research will be cooperative agreements between participating sites and the NICHD. It is expected that up to six applications will be funded, contingent upon the receipt of a sufficient number of meritorious applications within a total direct cost program budget of $900,000 (average direct cost of $150,000 per award) for the first year. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of the NICHD Research Coordinator above and beyond conventional program and grant management procedures.

REVIEW PROCEDURES

Applications will receive a preliminary review for responsiveness to this RFA and may receive a triage review for relative competitiveness by peer review. Applications judged to be competitive for awards will be reviewed for scientific and technical merit by a review committee convened specifically for this purpose by the Division

of Scientific Review, NICHD. A second-level review will be done by the National Advisory Child Health and Human Development Council.

METHOD OF APPLYING

Applications must be submitted on form PHS 398 (rev. 10/88, reprinted 9/89), that is available in most institutional business offices and from the Division of Research Grants, NIH (telephone 301/496-7441).

INQUIRIES

Potential applicants may request further information and copies of the RFA that outlines the requirements for participation in this program from:

Koji Yoshinaga, Ph.D.
Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health and Human Development
Executive Plaza North, Room 603
Bethesda, MD 20892
Telephone: (301) 496-6515

Administrative Policy:

Ms. Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
National Institutes of Health
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-5481

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards will be made under the authority of the Public Health Service Act 301 (42 USC 241) and 441 (USC 289d) and administered under PHS Grants 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.

COMMUNITY-BASED CARE FOR CHRONICALLY ILL OLDER PERSONS

RFA AVAILABLE: NR-92-01

P.T. 34; K.W. 0710010, 0730000, 0745035, 0785130

National Center for Nursing Research

Letter of Intent Receipt Date: January 22, 1992
Application Receipt Date: March 10, 1992

PURPOSE

The National Center for Nursing Research (NCNR) announces the availability of a Request for Applications (RFA) dealing with the efficacy and effectiveness of clinical interventions for the long term care of chronically ill older persons who reside in the community. The overall purpose of the interventions must be to manage commonly experienced symptoms, prevent the onset of further disabilities, and facilitate the transition among health care settings and home. These outcomes would be expected to encourage independence, enhance health-related quality of life, and enable chronically ill older persons to remain at home.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Community-Based Care for Chronically Ill Older Persons, is related to the priority areas of older persons as a targeted group and to chronically disabling conditions. Potential applicants may obtain a copy of the "Healthy People 2000" (Full Report: Stock No. 017- 001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit, public and private, organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA is a one-time solicitation for research grant (R01) applications. The total project period for applications submitted in response to the present RFA may not exceed four years. The anticipated award date will be September 30, 1992.

FUNDS AVAILABLE

Approximately $1,000,000 in total costs for the first year will be committed to specifically fund applications submitted in response to this RFA. It is anticipated that five applications will be funded. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCNR, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

This initiative builds directly on the work of a panel of scientific experts on long term care convened as part of the development of the National Nursing Research Agenda. The work of this panel is currently nearing completion with the anticipated publication of its report in 1992. The goal of this RFA is to stimulate the development of innovative clinical interventions for community-based chronically ill older persons in order to manage commonly experienced symptoms, prevent the onset of further disabilities, and facilitate the transition between health care settings and home. These outcomes would be expected to encourage independence, enhance health-related quality of life, and enable the chronically ill older person to remain at home. The theoretical basis for the planned study must be clearly explicated and linked to the clinical interventions to be developed and tested. It is important that the interventions be carefully and clearly defined in terms of their purpose, composition, means of implementation and anticipated effect. Particular attention must be paid to ensuring that the anticipated effects have clearly defined outcome measures.

The proportion of the population that is 65 years and greater is increasing rapidly. Most of these older persons live in the community and do not need institutional care. However, the longer a person survives, the more likely he or she is to become chronically ill or disabled and the more likely nursing home care will be needed at some point in the continuum of care. Admission to a nursing home has been described as a terminal event for many older persons, rather than as a useful health care setting for those who need subacute institutional care for a period of time. Studies that have examined the continuity of care for older persons generally have focused on the movement between acute care and nursing homes. The investigation of transitions from the community to nursing home or hospital care and back have not received much emphasis. Clinical interventions are needed to address the transitions across health care settings made by chronically ill, home based older persons.

The functioning of the family and/or informal caregivers can have a significant effect on the health outcomes of the chronically ill older person. There have been indications that certain factors, such as living alone and urinary incontinence, influence the decision to remove older persons from their homes and to admit them to a nursing home. It is possible that well- functioning family systems and community social support networks are instrumental in averting or delaying these admissions and in assisting in the return of these individuals to the community.

In addition to these community-based care issues, the clinical interventions may address the human responses exhibited by older people who have chronic illness. The older adult with chronic illness is at risk for decline in health and functional status due to a number of factors, including those related to adherence to treatment regime, the onset of physical symptoms that impede daily activities, and behavioral responses to the changes occurring with increasing age and length of illness. Because chronic health problems can lead to increased disabilities and frailty, early, efficacious and effective intervention strategies should lead to improved outcomes. In general, there is a paucity of research dealing with symptom management of the chronically ill older person, but what research exists has usually been done in either acute care or nursing home settings. There is clearly a need to identify strategies to deal with symptoms experienced by persons who are community based. Symptoms and conditions such as cognitive or behavioral problems, confusion, decreased mobility, skin integrity problems such as pressure ulcers, incontinence, nutrition and hydration problems, and altered sleep and rest patterns frequently limit the ability to function normally, impair autonomy, and decrease the health-related quality of life. Interventions dealing with these and other symptoms related to chronic illnesses need to address both behavioral and biophysiological/physical components. Applications from interdisciplinary research teams are encouraged.

Applications are invited for support of clinical intervention studies concerning community-based care of chronically ill older persons. Studies may include, but are not limited to:

o design and test interventions to effectively manage physical and behavioral symptoms of frequently occurring chronic illnesses in older persons;

o design and test interventions that prevent complications and minimize disability in older persons with chronic illness;

o design and test clinical interventions to facilitate the coordination of care and transition across health care settings for older adults;

o design and test interventions to support family members or family systems involved in the care of older persons with chronic illness.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION AND REVIEW PROCEDURES

The RFA contains important information for applicants and may be obtained either Patricia Moritz, Ph.D., or Mary D. Lucas, Ph.D. (address below). The application receipt date is March 10, 1992. The research grant application form PHS 398 (rev. 10/88, reprinted 9/89) must be used in applying for these grants. These forms are available from the Division of Research Grants, telephone 301-496-7441. Applications must be submitted to the NIH Division of Research Grants and will be assigned to a special review group organized by NCNR. Following this review, applications will be considered by the NCNR National Advisory Council.

LETTER OF INTENT

A letter of intent while not required, is requested by January 22, 1992. The letter of intent is to include a descriptive title, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel, and any other participating institutions. Letters are to be sent to:

Ethel Jackson, DDS
Chief and Scientific Review Administrator
National Center for Nursing Research
Building 31, Room 5B19
9000 Rockville Pike
Bethesda, MD 20892

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Patricia Moritz, Ph.D., R.N.
Chief, Nursing Systems Branch

or

Mary D. Lucas, Ph.D., R.N.
Chief, Acute and Chronic Illness Branch
National Center for Nursing Research
Building 31, Room 5B03
Bethesda, MD 20892
Telephone: (301) 496-0523

Direct inquiries regarding fiscal matters to:

Sally Nichols
Grants Management Officer
National Center for Nursing Research
Building 31, Room 5B06
Bethesda, MD 20892
Telephone: (301) 496-0237

OTHER INTERESTS IN THIS RESEARCH AREA

The National Institute on Aging and the Agency for Health Care Policy and Research are also interested in research dealing with long-term care issues. The RFA contains additional information and program contacts.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.336, Nursing Research, and No. 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 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, April 6, 1988.

NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS FOR THE TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS INFECTION

RFA AVAILABLE: AI-91-13

P.T. 34; K.W. 0715008, 0740020, 0755025

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: November 28, 1991
Application Receipt Date: January 16, 1992

The National Institute of Allergy and Infectious Diseases (NIAID) announces availability of a Request for Applications (RFA) for funding of the National Cooperative Drug Discovery Groups for the Treatment of Human Immunodeficiency Virus Infection (NCDDG-HIV). It is the purpose of this RFA to invite applications aimed at the discovery of more effective, selective, and diverse new agents that can be used for the treatment of HIV, the etiological agent associated with Acquired Immunodeficiency Syndrome (AIDS).

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, National Cooperative Drug Discovery Groups for the Treatment of HIV Infections (NCDDG-HIV), is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017- 001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

RESEARCH OBJECTIVES AND SCOPE

The prime objective of this RFA is to stimulate original and innovative research of sound scientific rationale, requiring comprehensive team effort, that is likely to result in the discovery of agents effective against HIV. In line with this objective, the NCDDG-HIV program supports and implements projects for innovative and under-exploited studies that are at the cutting edge of biomedical research. Such studies may have a greater risk-to-benefit quotient than is currently acceptable under the more traditional investigator initiated (R01) mechanism but may also have a greater potential for effective, long-term therapeutic returns. In addition to the scientific criteria, these efforts are to be implemented through a collaborative, concerted effort by components of the Group. Applications in which collaboration among components of the Group are not required for the success of Group activities will not be funded and are encouraged to submit an individual investigator-initiated (R01) or equivalent grant application.

Applications that include research projects or a core components from the private sector (e.g., pharmaceutical, chemical, or biotechnological companies) are strongly encouraged. Research directed toward drug discovery in the following major areas will be considered responsive to this RFA:

o Discovery, elucidation, and application of modalities that inhibit HIV gene expression via interference with HIV regulatory elements;

o Inhibition of critical steps in HIV replication via intracellular delivery or expression (gene therapy) of antagonists using viral vectors or other delivery strategies;

o Intervention with cellular biochemical pathways required for induction from latency and/or for enhancement of HIV growth cycle;

o Innovative approaches to exploit the humoral and cellular arms of the immune system in a targeted anti-HIV affront;

o Other sound and conceptually new strategies, currently not being pursued, for the discovery of new entities or combinations with potential for treatment of HIV infection, such as inhibitors of viral penetration, ribozymes, and agents that disrupt virus structure.

Examples of proposed research in these major areas are: studies to delineate structure-function of HIV encoded target proteins; evaluate drug metabolism; devise and evaluate innovative drug delivery strategies; appraise the emergence of resistance to drugs targeted to specific HIV enzymatic, structural, or regulatory function; identify early events in viral replication suitable for drug targeting; and decipher biochemical pathways and host interactions critical to virus replication and/or drug action.

Projects or cores with proposed animal model development or efficacy testing in animal models must be integrated into and required to attain the Group's objectives. Animal model component(s) may be requested by the NIAID to evaluate in vivo compounds other than compounds generated by the Group. Funds awarded for the evaluation of new agents in animal models will be withheld until compounds generated by the Group or provided by the NIAID are available for animal efficacy studies. Projects utilizing non-random cell-based assays for screening natural products, biologics and/or synthetic compounds must not exceed 25 percent of the total level of effort of the Group.

The following research areas currently under intense investigation or that have already been integrated into other NIH initiatives are specifically excluded from this RFA: (i) synthesis or development of analogues or prodrugs of known anti-HIV nucleosides and non-nucleosides; (ii) reverse transcriptase screens; (iii) evaluation of recombinant human cytokines; (iv) development of exogenous, soluble CD4 or its conjugated congeners; (v) anti-protease screens and peptide-based protease inhibitors; (vi) evaluation and synthesis of myristoylation inhibitors; (vii) mechanism of action studies unlinked to inhibitor identification; (viii) large-scale random screening of compounds with potential activity against HIV in cell culture-based systems (such a program is operated by the National Cancer Institute); (ix) research on the opportunistic infections associated with AIDS (a separate RFA for the National Cooperative Drug Discovery Groups for the Treatment of Opportunistic Infections Associated with AIDS has been re-issued (NIH GCG, Vol. , No., date), for the third consecutive year). Scientists whose research does not lie within the areas defined as responsive to this RFA are encouraged to apply for investigator-initiated research (R01) grants.

Each NCDDG-HIV will be assembled by the Principal Investigator to form a multi-disciplinary consortium representing the various skills needed to successfully design, implement, and evaluate - at the preclinical level - therapeutic entities and strategies for the treatment of AIDS. Inasmuch as it is unlikely that all of the outstanding talents required to exploit fundamental leads from various scientific disciplines will be found in a single institution, each Group is envisioned as being multi- institutional as well. Thus, each NCDDG-HIV will consist of a number of research projects representing the scientific disciplines required to attain the Group's goals and objectives. The various research projects, including that of the Principal Investigator, may be mobilized from academia, research institutions, and/or industry; the incorporation of a component from the private sector is strongly encouraged. It is expected that the rationale for design of potential treatments, the synthesis of specific agents, and the preclinical models for evaluation will originate within the Group and be based on leads from the group and the fundamental research of others. Specifically excluded from the Group's activities are activities related to clinical evaluation of the drug.

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

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

MECHANISMS OF SUPPORT

Awards will be made as Cooperative Agreements (U01). The Cooperative Agreement funding mechanism differs from the traditional research grant in that the Government component (NIAID) awarding the Cooperative Agreement anticipates substantial programmatic involvement during performance. The nature of the NIAID staff participation is described in the RFA. However, the applying Group must define its objectives in accord with its own interests and perceptions of approaches to combat HIV infection.

REVIEW PROCEDURES

Applications will be reviewed by the appropriate subcommittee of the NIAID AIDS Research Review Committee. NIAID has set aside $2.2 million total cost for the initial year funding. An NCDDG-HIV award is subject to a current limit of $1,000,000 in total costs (direct plus indirect costs) for the first year. The amount spent will be dependent on the continuing availability of funds for this purpose and the quality and diversity of approved applications.

TERMS OF AWARD

The proposed applicant institution will be responsible for the Group application. Awards will be made to the applicant's institution on behalf of the Group as a whole and not to individual research projects within the Group. The applicant institution will provide a Central Operations Office for the Group. The applicant institution will be responsible for the performance of the entire Group and will be accountable for the funds awarded. The active participation of the Government through the NIAID extramural staff is aimed at enhancing and expediting a concerted effort by the Group by making available biological materials for testing, appropriate existing data bases, and appropriate ancillary testing and other resources available under existing contracts. The interaction of academic and non-profit research institutions with commercial organizations and Government is strongly encouraged and is expected to promote innovative discoveries of anti-HIV treatment and will facilitate their subsequent development to clinical trial.

METHOD OF APPLYING

The deadline for receipt of applications is January 16, 1992. Applications received after this date will be considered as not responsive to this RFA and will be returned without review.

The regular research grant application forms PHS 398 (rev. 10/88 or 9/89) are available at most institutional business offices. If not available there, they may be obtained from: Office of Grants Inquiry, Division of Research Grants, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, telephone: 301/496-7441.

LETTER OF INTENT

Prospective applicants are asked to submit by November 28, 1991, a letter of intent that includes a descriptive title of the overall proposed research, the name and institution of the Principal Investigator, a title for each component research project and brief descriptions of the proposed projects. Names of prospective Project Leaders and other key investigators and their institutions should be included (maximum of two pages). The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed and in order to allow early preparations for review as well as promote early interactions between applicants and NIAID staff. The letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application. The letter of intent is to be sent to:

Nava Sarver, Ph.D.
Chief, Targeted Drug Discovery Section
Developmental Therapeutics Branch Division of AIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Room 246P
Bethesda, MD 20892
Telephone: (301) 496-8197

INQUIRIES

This RFA is available from:

Ms. Besita Wyche
Targeted Drug Discovery Section
Developmental Therapeutics Branch Division of AIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8197

Inquiries regarding matters pertaining to the review of this application should be addressed to Dr. Hornbeak.

Hortencia Hornbeak, Ph.D.
Deputy Chief, Program and Project, DEA
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-0123

Inquiries regarding fiscal matters may be addressed to Mr. Thompson.

Mr. Gary Thompson
Chief, Grants Management Branch
Review Branch, DEA
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7231

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, 93.856 - Microbiology and Infectious Diseases Research and 93.855 - Immunology, Allergic and Immunological Diseases Research. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under the PHS grants policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of the Executive Order 12372 or Health Systems Agency Review.

BASIC AND CLINICAL STUDIES ON THE MORBIDITY AND MORTALITY OF THE END-STAGE RENAL DISEASE PATIENT

RFA AVAILABLE: DK-92-07

P.T. 34; K.W. 0755015, 0785095, 0785165, 0745025, 0745065

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: December 11, 1991
Application Receipt Dates: January 23, 1992

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announces the availability of a Request for Applications (RFA) on the above subject.

BACKGROUND

Most organ systems are affected by the development of renal failure and the uremic state. The treatment regimen for these patients consists of either a dialysis modality or a renal allograft. The annual mortality rate of the dialysis patient population in the United States is approximately 20 percent, almost double that reported by European countries and Japan. This high mortality rate underscores the need for research on the causes of morbidity and mortality in the end-stage renal disease (ESRD) population.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of HEALTHY PEOPLE 2000, a PHS-led national activity for setting priority areas. This RFA is related to the priority area of "Diabetes and Chronic Disabling Conditions." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

RESEARCH GOALS AND SCOPE

It is the objective of this RFA to stimulate fundamental, clinical and applied research activity towards: (1) better understanding of the causes of ESRD; (2) decreasing the rate at which chronic renal failure progresses; (3) enhancing the quality and effectiveness of dialysis and transplantation; and (4) reducing the complications associated with these therapies.

The following are some suggested topics that might be addressed to achieve the objectives of this solicitation:

o Cardiovascular Influences: The effects on cell and organ function that result from the acute fluid and electrolyte shifts induced by dialysis treatment; organ specificity of these changes in the volume and composition of the body fluids, and laboratory indicators that might have clinical utility in the management of dialysis patients.

o Vascular Access: Development of new access concepts, materials, and designs; tissue reactions to new biomaterials. Studies of the roles of coagulation, fibrinolytic, complement, and other mediator systems.

o Hormonal and Metabolic Influences: Studies to assess the quantitative impact of various hormones, especially insulin, on protein and amino acid metabolism in chronic renal failure.

o Infection and Immunity Problems: Studies directed at elucidating the role of cytokines in the morbid and mortal events in the uremic state. Fundamental studies of immune dysfunction in uremia.

o Nutritional Influences: In vivo studies assessing whole body protein turnover (synthesis and breakdown) and of regional aspects of protein and amino acid metabolism. Studies to better define optimal nutrition interventional approaches for patients on dialysis.

o Epidemiologic Studies: Studies addressing the role of nutritional factors in the pathogenesis of infections, and the influence of biomaterials on infection rates in the dialysis population.

ELIGIBILITY

Research grant applications may be submitted by domestic and foreign, non-profit and profit-making organizations and institutions, State and local governments and their agencies, and eligible agencies of the Federal Government. Applications from women and minorities are encouraged.

MECHANISMS OF SUPPORT

Applications may be submitted for the traditional, investigator-initiated research project grant (R01). Support will be provided for up to five years (renewable for subsequent periods), subject to the availability of funds and progress achieved.

REVIEW PROCEDURES AND CRITERIA

Upon receipt, applications will initially be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Applications will then be reviewed by program staff for their responsiveness to the objectives of this RFA. If an application is considered unresponsive, the applicant will be contacted and given an opportunity to withdraw the application or have it considered an unsolicited grant application in the next review cycle.

METHOD OF APPLYING

Applications must be submitted using form PHS 398 (rev. 10/88). This form is available in the business or grants office of most academic or research institutions and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449 Bethesda, MD 20892, telephone 301/496-7441.

LETTER OF INTENT

Prospective applicants are encouraged to submit an optional letter of intent, that includes the title of the proposed project and identification of all participating institutions. Such letters are requested only for the purpose of obtaining an indication of the number and scope of applications to be received. A letter of intent is not binding, is not a requirement of submission, and it will not enter into the review of the application subsequently submitted. This letter is to be received no later than December 11, 1991, and is to be sent to:

Robert D. Hammond, Ph.D.
Chief, Review Branch, Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 406
Bethesda, MD 20816

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

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations of clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

FUNDS AVAILABLE

For FY 1992, $1.5 million in total costs per year will be committed to fund applications submitted in response to this RFA. It is anticipated that eight to ten awards will be made. In order to meet NIDDK goals for managing the costs of biomedical research, applicants must limit their requests to not more than $160,000 in direct costs for the first year. Awards are contingent upon the availability of funds. The earliest award date will be July 1, 1992.

INQUIRIES

It is essential that prospective applicants obtain the RFA prior to developing an application. The RFA can be obtained from:

M. James Scherbenske, Ph.D.
Program Director, Renal Physiology/Cell Biology
Division of Kidney, Urologic, and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 3A-04A
Bethesda, MD 20892
Telephone: (301) 496-7458

For fiscal and administrative matters, contact:

Mrs. Helen Y.S. Ling
Grants Management Specialist
Grants Management Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
Bethesda, MD 20892
Telephone: (301) 496-7467

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99- 158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 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.

GENETICS AND KIDNEY MATURATION, WITH AN EMPHASIS ON POLYCYSTIC KIDNEY DISEASE

RFA AVAILABLE: DK-92-08

P.T. 34; K.W. 1002019, 1002027, 1002004, 1002008, 0710075, 0785095

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: December 16, 1991
Application Receipt Date: January 22, 1992

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announces the availability of a Request for Applications (RFA) on the

above subject. The mechanism of support will be limited to the investigator-initiated research grants (R01) funding mechanism.

BACKGROUND

The cross-fertilization of the disciplines of genetics and molecular biology, cell chemistry and biology, immunology, physiology, microbiology, and pathology have resulted in new and extremely useful experimental tools that allow scientists to address and seek answers to questions at a fundamental level. The regulation of cellular growth is one of the most exciting areas of kidney research. Investigators and researchers have identified several growth factors and determined their exact chemical composition. The powerful tools of molecular biology (e.g., polymerase chain reaction and in situ hybridization techniques) offer further promise for expanding our knowledge about the regulatory genes that control differentiation and encode the signals that establish the precise topographical patterns essential to the function of the fully developed kidney.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This RFA, Genetics and Kidney Maturation, with an Emphasis on Polycystic Kidney Disease, is related to the priority area of diabetes and chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

RESEARCH GOALS AND SCOPE

This special initiative will support fundamental research, with an emphasis on fostering collaboration among the basic sciences, including biochemistry, cell biology, embryology, endocrinology, molecular biology, genetics, nutrition, pathology, pharmacology, renal physiology, and pathophysiology. The intent of this solicitation is to engage investigators with diverse research interests who wish to apply their technologies and expertise in elucidating and extending the current understanding of the genetic aspects of kidney disease and the cellular and integrated mechanisms in the developing kidney.

The following are some suggested directions that might be taken to achieve the objectives of this solicitation:

o Basic studies on the physiology and pathophysiology of the developing normal and genetically-affected kidney.

o Assessment of function of the developing kidney, both normal and genetically affected by: (a) developing new methodology that could detect abnormal renal function at an earlier stage, than possible using the existing methodology; and (b) assessing and comparing endocrine function of the normal and genetically impaired developing kidney.

o Research on genetic or developmental disorders of the kidney, including the pathophysiology of kidney diseases that develop in the pediatric age group and may become clinically evident in adolescence and adulthood. Examples include, polycystic kidney and other cystic diseases, renal dysplasias or hypoplasias, congenital nephrotic syndrome, and congenital obstructive nephropathy or uropathy, and diseases more prevalent in minority populations.

ELIGIBILITY

Research grant applications may be submitted by domestic and foreign, non-profit and profit-making organizations and institutions, State and local governments and their agencies, and eligible agencies of the Federal Government. Applications from women and minorities are encouraged.

MECHANISM OF SUPPORT

The mechanism of support for this program will be the traditional research grant (R01). The regulations (Code of Federal Regulation, Title 42, Part 52 and, as applicable to the State and local governments, Title 45, Part 74) and policies that govern the research programs of the National Institutes of Health will prevail.

FUNDS AVAILABLE

For FY 1992, $2.0 million in total costs per year will be committed to fund applications submitted in response to this RFA. It is anticipated that 10 to 12 awards will be made. In order to help meet NIDDK goals for managing the costs of biomedical research, applicants must limit their requests to not more than $160,000 in direct costs for the first year. The earliest award date will be July 1, 1992.

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

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations of clinical studies, a specific justification for this exclusion must be provided. Applications without such ocumentation will not be accepted for review.

APPLICATION AND REVIEW PROCEDURES

Applications must be submitted using Form PHS 398 (rev. 10/88), "Application for Public Health Service Grant", available in the business or grants office of most academic or research institutions, and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications in response to this RFA will first be reviewed for scientific and technical merit by an Initial Review Group (IRG) convened by the Division of Research Grants. A secondary review for policy and program relevance to the mission of the National Institute of Diabetes and Digestive and Kidney Diseases will be provided by its Advisory Council.

LETTER OF INTENT

Prospective applicants are encouraged to submit an optional letter of intent, that includes the title of the proposed project and identification of all participating institutions. Such letters are requested only for the purpose of obtaining 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 the application subsequently submitted. This letter is to be received no later than December 16, 1991, and is to be sent to:

Chief, Review Branch
National Institute of Diabetes and
Digestive and Kidney Diseases
Westwood Bldg., Room 406
Bethesda, MD 20892

INQUIRIES

It is essential that prospective applicants obtain the RFA prior to developing an application. The RFA can be obtained from:

M. James Scherbenske, Ph.D.
Program Director, Renal Physiology/Cell Biology, DKUHD
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Bldg., Room 3A-04A
Bethesda, MD 20892
Telephone: (301) 496-7458

Gladys H. Hirschman, M.D.
Program Director, Chronic Renal Diseases, DKUHD
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Bldg., Room 3A-07B
Bethesda, MD 20892
Telephone: (301) 496-8218

AUTHORITY AND REGULATIONS

This program is described in the catalog of Federal Domestic Assistance No. 93.849. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 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.

ONGOING PROGRAM ANNOUNCEMENTS

STUDIES ON THE MEDICAL AND HEALTH CONSEQUENCES OF DRUG ABUSE

PA: PA-92-16

P.T. 34; K.W. 0404009, 0715006, 0755030, 0715129

National Institute on Drug Abuse

PURPOSE

The purpose of this announcement is to stimulate research on the role of drug abuse in the etiology and progression of medical, including psychiatric, disorders. Research on the relationship between drug abuse and broader health issues is also solicited. Epidemiological, clinical, human laboratory based, and animal studies are encouraged.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This Program Announcement, Studies on the Medical and Health Consequences of Drug Abuse, is primarily related to the priority area of alcohol and other drugs. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone 202-783-3238).

BACKGROUND

Drug abuse has been linked with a number of medical disorders. These may arise either through the direct mechanisms of cytopathic effects of intoxication, withdrawal, or long-term exposure or through the indirect mechanisms of increased exposure to pathogens, toxins, carcinogens, or other dangers due to the behavioral alterations associated with drug abuse. Some infectious sequelae of drug abuse, Hepatitis B and HIV, are well known, but evidence also supports a number of other medical disorders arising from drug abuse. These include psychiatric disturbance, cancers, trauma, cardiovascular events, endocrine dysfunction, and alterations of normal child development, for example. Studying specific drug-outcome relationships is important, but it is also fruitful to study drug abuse as an entity relatively independent of specific substances because of (1) poly-drug abuse, (2) events related to mode of abuse independent of the drug (e.g., injection), and (3) changes in drugs of choice while other variables remain constant (e.g., biological substrate, modes of administration).

Primary care physicians may not aggressively pursue substance abuse as an underlying etiology. There is evidence that despite growing awareness of alcohol abuse in general, physicians are actually attending less to assessing the possibility of alcohol abuse in their patients than they did a decade ago. Coordination between drug abuse treatment programs and primary care resources is lacking, and the AIDS crisis makes this lack even more significant. Research on determining and treating drug abuse related medical conditions is sorely needed.

RESEARCH OBJECTIVES

The major objectives of this Program Announcement are to stimulate research in the drug-related etiology and progression of medical disorders, including psychiatric disease, and to stimulate studies of the application of such knowledge to clinical situations. Epidemiological, controlled population, and animal studies are encouraged, and these must attempt to isolate direct mechanisms from indirect effects whenever possible. Thus, study designs must address the total picture of risk factors for medical conditions in drug abusers including: (1) genetic/biologic predispositions; (2) in- utero exposure, e.g., cocaine, alcohol, and other drugs of abuse; (3) demographic and behavioral variables; and (4) life history of exposure to pathogens and non-drug related factors. It is further recognized that either a history of drug abuse or ongoing drug abuse may have both direct and indirect effects on the natural history of the medical sequelae and their treatment. In the context of the proposed studies, programmatic emphasis will be on the clinical relevance of both the isolation of direct cytopathic effects and the behavioral effects of ongoing drug abuse that mediate diagnosis and response to treatment.

Examples of possible research topics relevant to this announcement include:

o Epidemiological investigations that document the occurrence of various medical disorders in the drug abusing population, especially studies that examine disorders not already recognized as associated with drug abuse. Case-control or cohort studies to determine relationships between disorders and substances would be appropriate.

o Studies of the interaction of individual behaviors or traits with the medical outcomes of substance abuse.

o Epidemiologic and controlled studies of nitrite inhalant and other drug use among those whose behavior puts them at risk for HIV infection, such as intravenous drug users, hemophiliacs, prostitutes, and heterosexual partners of bisexual men, to determine relationships between substance abuse and health outcomes.

o Studies of the mechanisms by which substance abuse affects individuals, their organ systems and tissues with reference to medical outcomes. Studies may be in vitro or in vivo (if the cost is justifiable) investigations. Such studies could elucidate the pathophysiological processes initiated or potentiated by particular substances or combinations of substances. For example, studies of oncogenesis by drugs alone or in combination with viral infection would be responsive. Specific investigations linking drug pharmacokinetic or pharmacodynamic parameters to relevant medical outcomes would also be responsive.

o Cancer epidemiologic studies among drug abusers (such as hepatocellular cancer) using cancer registers and death certificate data.

o Further exploration of the association of maternal marijuana use during pregnancy and childhood leukemias and other associations of drug abuse and health conditions affecting pregnant women and their offspring. Health outcomes of children of "crack" using mothers would also be responsive.

o Psychiatric, neuropsychiatric, and neuropsychological investigations that examine the acute and chronic effects of drug abuse on systems that may interact with neurological systems (e.g., reduced vascular supply to cerebral cortex, hepatic function). Chronic abuse effects on neurologic tissues and neuropsychiatric functioning are also of interest.

o Research into the metabolic, nutritional, immunologic, psychological, or other medical/health outcomes that drug abuse that may mediate through an effect on more than one substrate or on an already established disease process. Vulnerability studies that examine the effects of drug abuse on systems and later medical/health outcomes would be appropriate.

o Evaluation of and clarification of feedback loops or reciprocal causality, in which an existing health condition leads to substance abuse that in turn leads to worsening of the original symptoms. Examples of such relationships include self-medication of psychiatric disorders that leads to exacerbation of the disorder or substance abuse that arises after a closed-head injury and that leads to delayed recovery.

o Relationships between infectious agents and disease processes in drug abusers. Such studies could examine the interplay of host and pathogen factors or the influence of cofactors on natural history of disease.

o Identification, evaluation, and surveillance of diseases as surrogate markers of drug abuse.

o Development and modification of treatments for diseases associated with drug abuse, such as alternatives to parenteral therapy for patients with "poor veins" or innovative antibiotic regimens applicable to drug abusers with infections.

o Examinations of primary care settings and integration of drug abuse treatment and the impact of this integration on health outcomes. Conversely, examination of utilization of primary medical care in drug abuse treatment settings and relation to health outcomes. Studies on early identification of substance abuse in primary medical care settings or early identification of medical problems in substance abuse/mental health settings would be of particular interest.

o Studies of the feasibility of specific health programs targeted at drug abusers, such as vaccination programs. Vaccination development may also be a part of such programs, given clear emphasis on benefits to drug abusing populations.

o Evaluation of the patterns of clinical use of prescription, potentially abusable drugs (e.g., pain medications) in precipitating or preventing medical/psychiatric complications or conditions in vulnerable adult and pediatric populations.

Because of the inter-disciplinary nature of many of these topics, potential applicants are encouraged to secure the complete Program Announcement from the resources listed at the end of this notice. Applicants are advised to contact National Institute on Drug Abuse staff to ensure appropriate coordination of PHS program resources.

MECHANISMS OF SUPPORT

The funding mechanisms that will be used to support this program are: Research Projects (R01), Small Grants (R03), First Independent Research Support and Transition Awards (R29), and Program Projects (P01), Predoctoral and Postdoctoral Individual National Research Service Awards (F31 and F32), Research Scientist Development Awards (K02, K05), Scientist Development Awards (K21), and Scientist Development Awards for Clinicians (K20).

ELIGIBILITY

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

Individual fellows applicants must be citizens or non-citizen nationals of the United States for permanent residence and have in their possession an Alien Registration Receipt Card (I-151 or I-551) at the time of application. Individuals on temporary or student visas are not eligible. See National Research Service Awards for Individual Fellows, January 1988, for additional information.

REVIEW PROCESS AND CRITERIA

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an initial review group (IRG) in accordance with established Public Health Service Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by the appropriate National Advisory Council whose review may be based on policy as well as scientific merit considerations. Only applications recommended for approval by the Council may be considered for funding. Criteria for scientific/technical merit review of research grant applications will include the following: significance and originality from a scientific or technical standpoint of the goals of the proposed research; adequacy of the research methodology proposed to carry out the study; feasibility of the proposed research; qualifications and research experience of the Principal Investigator and other key research personnel; availability of adequate facilities, other resources, and collaborative arrangements necessary for the research; appropriateness of budget estimates for the proposed research activities; and adequacy of provisions for the protection of human and animal subjects.

For individual fellows, major considerations in the review are the applicant's potential for a productive scientific career, the need for the proposed training requested, and the possibility that the research training proposal will meet that need. See the program announcement for additional details.

INCLUSION OF WOMEN AND MINORITIES

For projects involving clinical research, ADAMHA requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and minorities are not included in the study populations, a specific and compelling justification for this exclusion must be provided. Applications that do not include women and minorities and that are without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Applicants must use the application form PHS 398 (rev. 10/88) for research grants and the PHS 416-1 for fellowship applications.

Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material: Division of Research Grants, NIH, Westwood Building, Room 436, 5333 Westbard Avenue, Bethesda, MD 20892, telephone (301) 496-9797.

The announcement may obtained from:

Grants Management Branch, OPRM
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

or the individuals listed in INQUIRIES

INQUIRIES

For further information, investigators are encouraged to contact the following individuals:

Sander G. Genser, M.D., M.P.H.
or
William C. Grace, Ph.D.
Clinical Medicine Branch,
National Institute on Drug Abuse
5600 Fishers Lane, Room 11A-33,
Rockville, MD 20857
Telephone: (301) 443-1801

For fiscal and administrative matters, contact:

Shirley McKenney
Chief, Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20857
Telephone: (301) 443-6710

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.279. Grants will be awarded under the authority of sections 301 and 515 of the Public Health Service Act, (42 U.S.C. 241 and 290cc) and administered in accordance with the PHS Grants Policy Statement and Federal regulations at 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.

ERRATA

RESEARCH SCIENTIST DEVELOPMENT AWARD, RESEARCH SCIENTIST AWARD

PAs: PA-91-101, PA-91-102

P.T. 34; K.W. 1014002, 1014006

Alcohol, Drug Abuse, and Mental Health Administration

ADAMHA published updated announcements for the Research Scientist Development Award (K02) (PA-91-101) and the Research Scientist Award (K05) (PA-91-102) in September 27, 1991 (NIH Guide for Grants and Contracts, Vol. 20,

No. 36). The review criteria outlined in these announcements will be effective for all applications received as of February 1, 1992, and will be applied beginning with the June peer review by the Initial Review Groups.

SPECIALIZED PROGRAMS OF RESEARCH EXCELLENCE IN BREAST CANCER

RFA: CA-91-33

P.T. 34; K.W. 07150350, 710030, 0745027, 0745070

SPECIALIZED PROGRAMS OF RESEARCH EXCELLENCE IN LUNG CANCER

RFA: CA-91-34

P.T. 34; K.W. 0715035, 0715165

SPECIALIZED PROGRAMS OF RESEARCH EXCELLENCE IN PROSTATE CANCER

RFA: CA-91-35

P.T. 34; K.W. 0715030, 0715167

National Cancer Institute

Letter of Intent Receipt Date: November 22, 1991 (revised)
Application Receipt Date: January 17, 1991

The Requests for Applications (RFAs) listed above were published in the NIH Guide for Grants and Contracts on September 13, 1991, Vol. 20, No. 34. As a result of the Specialized Programs of Research Excellence (SPOREs) briefing held by the National Cancer Institute (NCI) in St. Louis on October 8, 1991, the NCI is announcing three modifications to these RFAs:

1. Under ELIGIBILITY REQUIREMENTS, an alternative to a minimum of three independent investigators who are successful in obtaining peer-reviewed research directly related to the relevant cancer, is a minimum of three independent investigators, each having published articles that significantly address the relevant cancer in peer-reviewed research journals, and who, when combined, represent experience in both laboratory and clinical research. Because of the scarcity of peer-reviewed research support for prostate cancer, the NCI will be as flexible as possible in its interpretation of this eligibility requirement for SPOREs addressing prostate cancer.

2. In complying with the DIRECT COST CAP of $1.5 million, the indirect costs related to subcontracts with other institutions or organizations will not apply toward the cap, but the total dollar request may not exceed $2.5 million.

3. The deadline for the LETTER OF INTENT is extended from October 25, 1991, to November 22, 1991. Although this document is not required, it provides an opportunity for all potential applicants to establish a dialogue with NCI staff.

INQUIRIES

Potential applicants are strongly encouraged to contact NCI staff regarding these RFAs. Direct inquiries concerning the revisions of these RFAs and requests for the RFA to:

Andrew Chiarodo, Ph.D.
Chief, Organ Systems Coordinating Branch
Division of Cancer Biology, Diagnosis, and Centers
National Cancer Institute
Executive Plaza North, Suite 316
Bethesda, MD 20892
Telephone: (301) 496-8528

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, MD 20816