NIH GUIDE

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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. 21, No. 1
January 10, 1992

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

USE OF THE STATEMENT OF APPOINTMENT FORM (PHS 2271) FOR INDIVIDUALS APPOINTED TO MINORITY SUPPLEMENT AWARDS AND PROGRAM CAREER AWARDS

P.T. 44; K.W. 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

Beginning in Fiscal Year 1992, a "Statement of Appointment" form (PHS 2271, revision 9/91) must be completed and sent to the PHS Awarding Component whenever an individual is appointed to one of the following programs:

o Any NIH Career Development Program Award (K12 or K16)

o Any Research Supplement for Underrepresented Minorities

The form MUST be completed and submitted to the PHS at the time an individual STARTS an appointment, a reappointment, or when the name or permanent mailing address of the appointed individual changes. A reappointment includes the extension of an appointment into a new budget period. The form must be signed by both the appointed individual and the Principal Investigator of the Career Development Program Award or the supplemented research grant.

The Statement of Appointment form will continue to be required for all appointments to National Research Service Award Institutional Research Training Grants (T32, T34). This requirement does not apply to individual NIH career awards (K04, K07, K08, K11, K14, K15, K16; ADAMHA - K20, K21).

The Statement of Appointment form has been substantially revised, and the new form dated Rev. 9/91 must replace all previous versions. Only the revised form will be accepted after May 10, 1992.

The form dated Rev. 9/91 is available from the Office of Administrative Services, Division of Research Grants, National Institutes of Health, Westwood Building, Room 436, Bethesda, MD 20892, telephone 301-496-9797.

INQUIRIES

Inquiries may be directed to:

Dr. Walter T. Schaffer
Director, Research Training and Special Programs Office
Office of Extramural Programs
National Institutes of Health
Building 31, Room 5B44
Bethesda, MD 20892
Telephone: (301) 496-9743

NOTICE OF REGIONAL MEETINGS

P.T. 42; K.W. 1014006, 1014002

National Institutes of Health

The National Institutes of Health (NIH) has been engaged in a strategic planning process aimed at developing the Agency's first corporate long-range Strategic Plan. The purpose of the NIH Strategic Plan is to: (1) identify areas of research that promise extraordinary dividends for the Nation's future health, (2) nurture the intellectual base of biomedical research and the conditions that lead to breakthroughs on the cutting edge of science, and (3) provide approaches for addressing broad administrative and science policy issues that affect the ability of the NIH to carry out its mandate. The Strategic Plan incorporates the ideas of all the organizational components of the NIH as well as the research components of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

The NIH will convene two regional meetings to provide a forum for the extramural community to comment on the draft Strategic Plan before it is finalized. The first meeting will take place on February 12, 1992, at Occidental College, Los Angeles, California, and will be co-hosted by Occidental College and the Charles R. Drew University of Medicine and Science. The second meeting will be held on February 25, at the University of Connecticut Health Center, Farmington, Connecticut.

Each of the regional meetings will be of one day duration, beginning at 9 a.m. and ending at 3 p.m. The meetings will begin with the NIH Director presenting an overview of the NIH Strategic Plan. Immediately afterwards, representatives of concerned organizations and institutions will be invited to present testimony before a panel of senior NIH officials, to be chaired by the Director, NIH. Due to time constraints, it would be appreciated if only one representative from each organization would present testimony; oral presentations will be limited to five minutes. Written testimony may be any length and should include a brief description of the organization presenting. Testimony will be scheduled based upon when notification of intent to present testimony is received. If the number of organizations that want to present oral testimony exceeds the time available on the agenda, the individual written statements will serve as testimony presented. All testimony, whether oral or written, will form a part of the official record of the NIH Strategic Plan.

If you or others from your organization who plan to attend one of these regional meetings have any special needs that require assistance, please inform the office listed below. If you have questions concerning either of the two regional meetings, please contact Ms. Mary Demory (301) 496-1454.

If you will be attending one of the regional meetings or if your organization would like to testify before the NIH panel, please provide the name, title, institution, telephone number, and mailing address of the individual attending. Indicate which regional meeting and whether or not testimony will be presented. The requested information is to be sent by mail or facsimile no later than December 16, 1991 to:

NIH Strategic Plan Regional Meetings
c/o Dr. Jay Moskowitz
NIH, Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892
FAX: (301) 402-1759

A copy of the Draft NIH Strategic Plan and additional information will be sent prior to the regional meetings to participants attending and/or testifying.

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 on 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

CONFERENCE: "AGING--THE QUALITY OF LIFE"

P.T. 42; K.W. 0710010, 0745035

National Institutes of Health

The Christopher Columbus Medical Sciences Committee of the National Institutes of Health, in conjunction with several NIH institutes, the Food and Drug Administration, and the Italian National Research Council, has organized a major international conference that will be held at the Omni Shoreham Hotel in Washington, DC, February 10-12, 1992. The conference is part of the commemoration of the Quincentenary of Christopher Columbus' epic voyage to the Americas.

A banquet will be held in the evening of February 11. Presentation of the prestigious Christopher Columbus Discovery Awards to outstanding scientists in biomedical research will be the highlight of the banquet.

Topics and speakers at the Plenary Session on Monday, February 10, will be:

o Searching for the Fountain of Youth: 500 Years of Research to Understand Aging; Dr. Robert N. Butler, Mt. Sinai Medical Center, New York;

o Age Associated Changes in Cardiovascular Function in Response to Exercise; Dr. Myron Weisfeldt, Columbia University, New York;

o Nutrition, Aging and Disease: The Metabolic Crossroads; Dr. Edwin L. Bierman, University of Washington;

o Drug Metabolism/Pharmacology in the Aging; Dr. Grant R. Wilkenson, Vanderbilt University;

o The Brain: Lighthouse of the Aging Years; Dr. Fred Plum, Cornell Medical Center;

o Osteoporosis, Osteoarthrosis, and Other Musculoskeletal Disorders in the Elderly; Dr. Lawrence E. Shulman, National Institutes of Health;

o The Effect of Chronological Age on Cancer Biology and Therapy; Dr. Emil J. Freireich, M.D. Anderson Hospital;

o Implications of Aging for the Individual and Society; Dr. Robert H. Binstock, Case Western Reserve; and

o Medicare: What is Covered?/What is not Covered?; Dr. Gail Wilensky, Administrator, Health Care Financing Administration.

Concurrent sessions dealing with cardiovascular, brain, cancer, musculoskeletal, healthy aging, nutrition, obesity and urogenital research, featuring outstanding biomedical scientists, will be held on the second and third days. An interdisciplinary poster session will be held on Tuesday, February 11. Summary reports and future challenges will be presented at the final plenary session to close the conference on the third day.

The conference will be of interest to scientists, public health officials, policy makers and analysts, and the general public.

Continuing Medical Education credits for 21.5 hours in Category 1 of the Physician's Recognition Award of the American Medical Association are available.

Registration for the three-day conference is $200 if paid in advance or $250 on site. Early registration of $150 has been extended to December 15, 1991. Those interested in program and registration information should contact:

Aging: Quality of Life Conference
Suzanne Kuntz, Conference Coordinator
655 Fifteenth St., N.W., Suite 300
Washington, DC 20005
Telephone: (202) 639-4524
FAX: (202) 347-6109

CONFERENCE: CARDIOVASCULAR BIOMATERIALS, DEVICES, AND BIOCOMPATIBILITY

P.T. 42; K.W. 0750005, 0715040, 0706040

National Heart, Lung, and Blood Institute

This conference is being sponsored by the National Heart, Lung, and Blood Institute (NHLBI) to be held on February 22, 1992, at the Hyatt Regency, Bethesda, MD.

PURPOSE

1. To present state-of-the-art reviews on cardiovascular biomaterials, devices, and biocompatibility for basic and clinical investigators in the field of biomaterials and biocompatibility and for persons in the device manufacturing industry and regulatory agencies.

2. To preview the contents of the revision of the widely used, NHLBI-sponsored book, "Guidelines for Blood-Material Interactions." This book was first published in 1980 and revised in 1985. The new edition is due to be published in 1993.

PROGRAM

The speakers at this meeting are chapter authors of the new edition of "Guidelines for Blood-Material Interactions." The meeting is being coordinated by Paul Didisheim, M.D., Head, Biomaterials Program, Devices and Technology Branch, NHLBI, Bethesda, MD, and will be co-chaired by Laurence Harker, M.D., Director, Division of Hematology-Oncology, Emory University School of Medicine, Atlanta, Georgia, and Buddy Ratner, Ph.D., Director, National ESCA and Surface Analysis Center for Biomedical Problems, University of Washington, Seattle, Washington.

Vincent Turitto	Fluid Mechanics and Hemorheology
Edward Leonard	Principles of Cardiovascular Device Design
Robert Colman	Mechanisms of Device-Related Thrombosis and Hemostatic Failure
James Anderson	Mechanisms of Inflammation and Infection With Implanted Devices
Peter Libby	Role of Growth Factors in Device-Related Vascular Lesion Formation
Buddy Ratner	New Techniques for Surface Analysis of Biomaterials
Jeffrey Hubbell	Basis for Selecting Materials
Stuart Cooper	Bulk Characterization of Materials
Arthur Coury	Preparation of Specimens for Blood Compatibility Testing
Ken Stokes	Biodegradation
Jeffrey Hubbell	Pharmacologic Modification of Surfaces
Sharon Northup	Cytotoxicity and Mutagenicity Testing
Dan Daniels	Mechanical Performance Testing Following Use
Thomas Horbett	Protein Adsorption
Deane Mosher	Protein-Cell-Surface Interactions
Stephen Hanson	Device Thrombosis and Thromboembolism
Don Giddens	Mechanisms of Heart Valve Failure
Alexander Clowes	Mechanisms of Vascular Graft Failure
Raymond Hakim	Systemic Effects of Extracorporeal Membrane Devices
James Anderson	Device Retrieval and Evaluation
Frederick Schoen	Approaches to Therapy and Future Directions
John Watson	Importance of Biomaterials and Biocompatibility to the Mission of NHLBI

For further information regarding the conference on "Cardiovascular Biomaterials, Devices, and Biocompatibility," contact Marla Hollander, telephone (301) 468-6555.

CME credits: The Foundation for Advanced Education in the Sciences/National Institutes of Health is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

A separate meeting, "Research Initiatives in Vascular Diseases," co-sponsored by the NHLBI, the Society for Vascular Surgery, and the International Society for Cardiovascular Surgery, will be held at the Hyatt Regency Hotel in Bethesda on February 20-21, 1992. The theme of the meeting is "Molecular Biology and Vascular Surgery."

INQUIRIES

For further information, contact Darlene Janis, telephone (508) 526-8330, fax (508) 526-4018.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

PREPARATION AND DELIVERY OF HOMOGENEOUS CERAMIDETRIHEXOSIDASE

RFP AVAILABLE: NIH-NINDS-92-03

P.T. 34; K.W. 0780005, 0760080, 0760013

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, has a requirement to develop a method of producing ceramidetrihexosidase by recombinant means, isolating the enzyme, and supplying it in a form suitable for intravenous injection into patients with Fabry's disease. The enzyme preparation shall consist of a single (homogeneous) protein. The purified enzyme shall catalyze the hydrolysis of a minimum of 2.0 x 1,000,000 nanomoles of 4-methylumbelliferyl-alpha-D-galactopyranoside per milligram of protein per hour at 37 degrees. The enzyme shall also catalyze the hydrolytic cleavage of 800,000 nanomoles of the terminal molecule of galactose from ceramidetrihexoside per milligram of protein per hour. At the time of proposal submission, the offeror's facilities must meet Food and Drug Administration standards in accordance with the Current Good Manufacturing Practices. Non-compliance with the above requirement shall immediately render the proposal technically unacceptable without the consideration of other evaluation criteria. It is anticipated that one award will be made in July 1991 for a period of three years.

This is not a Request for Proposals (RFP). To receive a copy of the RFP, submit a written request to the following address, and supply this office with two self-addressed mailing labels. All responsible sources shall be considered by the agency. The RFP will be issued on or about January 2, 1992, with proposals due on March 2, 1992.

Contracting Officer
Contracts Management Branch, DEA
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892

Attention: RFP No. NIH-NINDS-92-03

ALZHEIMER'S DISEASE CENTER COMMUNITY OUTREACH EDUCATION PROGRAMS

RFA AVAILABLE: AG-92-01

P.T. 04; K.W. 0403004, 0715180, 0502017, 0745020

National Institute on Aging

Letter of Intent Receipt Date: February 21, 1992
Application Receipt Date: March 24, 1992

THE REQUEST FOR APPLICATIONS (RFA) ANNOUNCED IN THIS NOTICE CONTAINS ESSENTIAL INFORMATION FOR THE PREPARATION OF AN APPLICATION. POTENTIAL APPLICANTS MAY OBTAIN THE RFA FROM THE CONTACT NAMED IN INQUIRIES, BELOW.

PURPOSE

The purpose of this RFA is to invite grant applications for the support of community outreach education programs from recipients of National Institute on Aging (NIA) Alzheimer's Disease Research Centers (P50) and Alzheimer's Disease Center Core Grants (P30) and institutions that have equivalent programs. It is anticipated that these education programs will result in increased community efforts related to Alzheimer's disease, to earlier detection of dementing disorders, to better education and assistance programs for the families, and to the systematic application of the best available methods for treatment and care of Alzheimer's disease patients. Underserved, women, and minority populations should receive high priority in carrying out these objectives.

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, Alzheimer's Disease Center Community Outreach Education Programs, is related to the priority area of health promotion: educational and community-based Programs. 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

Research grant applications may be submitted by domestic and foreign, 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 individuals and women are encouraged.

MECHANISM OF SUPPORT

Support of this program will be through the National Institute on Aging Education Projects Grant (R25). The total project period for applications submitted in response to this RFA may not exceed three years. The earliest start date will be September 30, 1992.

This RFA is a one-time solicitation. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary NIH peer review procedures.

FUNDS AVAILABLE

The NIA will commit up to $500,000 per year for three years to fund applications that are submitted in response to this RFA. It is anticipated that up to five awards will be made. Awards will be limited to a maximum of $100,000 per year in direct costs plus eight percent indirect costs.

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 NIA, awards pursuant to this RFA are also contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

The purpose of this RFA is to provide funding, on a competitive basis, for the development and implementation of Alzheimer's disease education programs for Alzheimer's Disease Centers that have been awarded a P30 or P50 grant by the National Institute on Aging and institutions that have equivalent programs. These education programs must provide state-of-the-art knowledge related to the detection, diagnosis, treatment, management, and family care of the dementia patient to local and regional health care professionals, community leaders, and staff of relevant community organizations. Topics should be selected on the basis of their relevance to the day-to-day activities and problems of the community health care professionals and to the welfare of Alzheimer's disease patients and their families.

These outreach programs are intended to be of particular benefit to underserved communities and to areas with disproportionately large populations of older people. High priority local and regional needs for specific types of Alzheimer's disease education programs should be addressed by the proposed programs and described in the application.

SPECIAL REQUIREMENTS

The application must describe examples of specific topics and approaches that might be included in the Alzheimer's disease education programs. Emphasis should be given to outreach education topics that would have the greatest impact upon improving the diagnosis, treatment and management of Alzheimer's disease and on improving the quality of life of the Alzheimer's disease patient and his/her family.

An area of special interest to the NIA is educational programs designed to improve the quality of diagnosis, treatment, and management in women and ethnic, minority, low socioeconomic, and other underserved populations in the U.S.

STUDY POPULATIONS

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.

LETTER OF INTENT

Prospective applicants are asked to submit by February 21, 1992, a letter of intent that includes a descriptive title of the proposed project, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of the applications to be reviewed.

The letter of intent is to be sent to:

Dr. Teresa Sluss Radebaugh
Chief, Dementias of Aging Branch
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Gateway Building, Suite 3C307
Bethesda, MD 20892
Telephone: (301) 496-9350
FAX: (301) 496-1494

APPLICATION PROCEDURES

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 at most institutional business offices; 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; and from the NIH program administrator named below.

Applications must be received by March 24, 1992. If an application is received after that date, it will be returned to the applicant.

Detailed instructions on application submission are described in the RFA.

REVIEW CONSIDERATIONS

Applications that are not responsive to the goals and scope of this RFA will be returned to the investigator. Applications may be triaged by an NIA peer review group on the basis of relative competitiveness. Acceptable applications received in response to this RFA will be reviewed for scientific and technical merit by an appropriate peer review group convened by the National Institute on Aging. The second level of review will be provided by the National Advisory Council on Aging.

INQUIRIES

Written and telephone requests for the RFA and the opportunity to clarify any issues or questions from potential applicants are welcome.

Direct requests for the RFA and inquiries regarding programmatic issues to:

Dr. Teresa Sluss Radebaugh
Chief, Dementias of Aging Branch
Neuroscience and Neuropsychology of Aging Program
National Institute on Aging
Gateway Building, Suite 3C307
Bethesda, MD 20892
Telephone: (301) 496-9350
FAX: (301) 496-1494

Direct inquiries regarding fiscal matters to:

Mr. Joseph Ellis
Grants Management Office
National Institute on Aging
Gateway Building, Suite 2N212
Bethesda, MD 20892
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 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.

LONG-TERM CARE AND MINORITY AGING

RFA AVAILABLE: AG/NR-92-02

P.T. 34, FF; K.W. 0730000, 0710010, 0408006

National Institute on Aging
National Center for Nursing Research

Letter of Intent Receipt Date: February 4, 1992
Application Receipt Date: March 19, 1992

PURPOSE

The National Institute on Aging (NIA) and the National Center for Nursing Research (NCNR) announce the availability of a Request for Applications (RFA) for research on formal and informal long-term care patterns, determinants of such patterns, and emergent long-term care needs among African American, Asian, Pacific Islander, Hispanic, and Native American older people. Available national data show overall proportionally lower use of many formal long-term care services among minorities compared to the overall population. Use of other health and aging services, actual living arrangements of frail minority elders, and informal care networks of older minority individuals are poorly documented. Knowledge of, or data on, long-term care preferences among minority groups and subpopulations are similarly neglected. Other reasons that may contribute to ethnic and racial differences in long-term care patterns are attitudes, economic barriers, language, or institutional characteristics that are insensitive to minorities. Studies of minority long-term care have immediate practical and policy implications as well as importance for long-range planning.

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, Long-Term Care and Minority Aging, is related to the priority area of older adults, specifically, key services and protection objectives targeting older adults, and to the priority area of special populations. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or Health 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 for research grants may be made by public or private, for-profit or non-profit organizations such as universities, colleges, hospitals, or laboratories. Minority and women investigators in particular are encouraged to apply. Where appropriate, applicants must demonstrate access to and ability to work with the selected minority research populations. Applications from or collaboration with minority institutions and organizations are also encouraged. Foreign institutions are eligible to apply but are advised to consult NIA

or NCNR staff, are encouraged to apply in association with a U.S. institution, and the research must deal with a U.S. minority population.

MECHANISM OF SUPPORT

This RFA will use the National Institute of Health (NIH) traditional research project grant (R01) mechanism. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement.

FUNDS AVAILABLE

It is estimated that up to $2.05 million will be committed to fund the first-year total costs of up to nine grants in response to this RFA. Costs of each grant may vary according to research designs. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit and the availability of funds. The total project period for applications submitted in response to this RFA may not exceed four years. The anticipated award date will be September 30, 1992. This RFA is a one-time solicitation. Extensions may be proposed only through application as a competing continuation project.

RESEARCH OBJECTIVES

o Identify and understand current patterns of informal care and use of formal aging services among minority older people that differ from other populations.

o Examine determinants (e.g., culturally related attitudes, cultural preferences, economic barriers, institutional characteristics) that account for patterns of use and access to formal and informal care services among minority older people.

o Determine the consequences of variations in long-term care for the well being of minority older people (e.g., health status, continued community involvement), their families (e.g., quality of family relationships in multigeneration households, decisions about formal care), and for service delivery (e.g., institutional admission and placement policies, impact of special programs to reach minorities).

STUDY POPULATIONS

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

Because of the nature of this RFA, minority populations are to be included in each application. The minority or other population(s) must be carefully delineated. NIH requires applicants to give special attention to the inclusion of women in study population. If women are not included in the study populations, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

The RFA, which contains important information for applicants, may be requested from Dr. Katrina Johnson at the address below. Applicants must use the research project application form (PHS 398, revised 10/88, reprinted 9/89) that is available at the applicant's institutional research office and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892, telephone 301-496-7441).

Applications must be received by March 19, 1992.

LETTER OF INTENT

Prospective applicants are asked to submit, by February 4, 1992, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application is being submitted. The letter of intent is to be sent to Dr. Katrina Johnson at the address below.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is helpful in planning for the review of applications. It allows Institute staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

REVIEW PROCEDURES

A complete description of the review procedures and criteria is provided in the RFA.

INQUIRIES

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

Requests for the RFA and inquiries and the letter of intent are to be sent to:

Katrina W. Johnson, Ph.D.
National Institute on Aging
Gateway Building, Room 2C-234
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-3136

or to:

Patricia Moritz, R.N., Ph.D.
National Center for Nursing Research
Building 31, Room 5B-03
Bethesda, MD 20892
Telephone: (301) 496-0523

Direct inquiries regarding fiscal matters to:

Ms. Linda Whipp
National Institute on Aging
Gateway Building, Room 2N-212
7201 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1472

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 79- 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 Executive Order 12372 or Health Systems Agency review.

COOPERATIVE CONTRACEPTIVE DEVELOPMENT RESEARCH CENTERS PROGRAM

RFA AVAILABLE: HD-92-06

P.T. 04; K.W. 0750020, 1003006, 1003012, 0413002, 0710100, 0710030

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: January 31, 1992
Application Receipt Date: April 24, 1992

OVERVIEW

The National Institute of Child Health and Human Development (NICHD) announces the availability of a Request for Applications (RFA) for cooperative agreements from investigators willing to participate with the NICHD in establishing a Centers program designed to conduct comprehensive research to develop new methods to regulate fertility. The aim of this Center will be to conduct a wide range of research activities that, with time, will result in clinically useful products. The scope of the proposed program should involve the concurrent development of at least three projects. Each project comprises activities related to the development of a specific method for fertility regulation. Thus, research dealing with the development of a compound for male fertility regulation would be classified as a single project. Investigators are invited to propose development of methods, other than abortion related, that can serve the needs of the American public.

It is the intent of the NICHD to establish a total of three Contraceptive Development Research Centers. Two Centers were funded under a prior RFA and one Center will be funded as a result of the present RFA. Grantee institutions in the United States that meet the requirements are eligible to participate.

MECHANISM OF SUPPORT

The funding mechanism to be used to assist the scientific community in establishing this Center will be the U54 Specialized Center cooperative agreement between the participating Center and NICHD. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of NICHD staff above and beyond the levels required for traditional program management of grants. It is expected one application will be funded for a five-year period, contingent upon the receipt of a sufficient number of meritorious proposals, within the total cost limit of $750,000 available for the first year of this award.

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, Cooperative Contraceptive Development Research Centers Program, is related to the priority area of family planning.

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).

REVIEW PROCEDURES

A preliminary review will be done by NICHD staff upon receipt of the applications. Any application that does not meet the minimal requirements of this RFA will be judged to be unresponsive to this RFA and will be returned to the applicant without technical review. Applications that are complete and responsive may be subjected to a triage procedure by peer review to determine competitiveness among the applications. Applications judged to be competitive for awards will be reviewed in detail in accordance with established NIH peer review procedures for research grants. Project site visits are neither planned nor a prerequisite of the review procedure. The review will be conducted for scientific and technical merit by a special review committee convened specifically for this purpose by the Division of Scientific Review, NICHD. This will be followed by a second-level review by the National Advisory Child Health and Human Development (NACHHD) Council in September 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 or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

APPLICATION PROCEDURES

Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the names of the Principal and Co-Investigators, identify the cooperating institutions, and indicate whether the application will be for a Field Center, Coordinating Center, or both. The NICHD requests such letters only for the purpose of providing an indication of the number and scope of applications to be received and, usually does not acknowledge their receipt. A letter of intent is not binding, it will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for applications. This letter of intent is to be received no later than January 31, 1992, and is to be sent to Dr. Gabriel Bialy at the address listed below.

Applications must be submitted on form PHS 398 (revised 10/88, reprinted 9/89), which is available in most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, NIH, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

INQUIRIES

Direct requests for the RFA and inquiries on programmatic issues to:

Gabriel Bialy, Ph.D.
Contraceptive Development Branch
National Institute of Child Health and Human Development
Executive Plaza North, Room 600
Bethesda, MD 20892
Telephone: (301) 496-1661

Direct inquiries regarding fiscal matters to:

Ms. Melinda Nelson
Office of Grants and Contracts
National Institute of Child Health and Human Development
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 the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NCI/MARC SUMMER TRAINING SUPPLEMENT

PA: PA-92-26

P.T. 44, FF; K.W. 0720005, 0715035

National Cancer Institute

Application Receipt Date: February 1, 1992

PURPOSE

The Comprehensive Minority Biomedical Program (CMBP) of the Division of Extramural Activities (DEA), National Cancer Institute (NCI), invites interested grantee institutions that have Minority Access to Research Careers (MARC) grants to apply for CMBP support of MARC scholars interested in obtaining laboratory research experience at the NCI. This program announcement shall be re-issued on an annual basis.

The NCI, through a co-funding arrangement with the MARC program of the National Institute of General Medical Sciences (NIGMS), provides support for research training to minority individuals and institutions and conference grant support to further address and enhance the mission of the National Cancer Program. The NCI/MARC Summer Training Program is an extension of the co-funding process.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Health People 2000," a PHS-led national activity for setting priority areas. This program announcement, NCI/MARC Summer Training Supplement, is related to the priority area of cancer research. 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).

ELIGIBILITY CRITERIA

All domestic institutions with active MARC research training grants are eligible to apply.

MECHANISM OF SUPPORT

A MARC honors training grant (T34) to the academic institution requesting support for a student will be administratively supplemented. Unless otherwise noted, all PHS and NIH grants policies apply to applications received in response to this announcement.

The supplement will provide the following: (1) A subsistence of $300 per week ($3,000 for a maximum ten-week period), and (2) round-trip transportation (from MARC student's academic institution to the National Institutes of Health, Bethesda, Maryland, and return to student's academic institution). Indirect costs may be awarded to the institution for up to a maximum of eight percent of the direct costs.

RESEARCH OBJECTIVES

The purpose of this award is to increase research training opportunities in the NCI for underrepresented minority scholars and to increase the number of minority scholars entering cancer-related research careers through the influence of short-term laboratory training at the NCI.

REVIEW PROCEDURES

Applications in response to this announcement will be considered by NCI Staff; final selection for laboratory experience will be made by the relevant laboratory directors. Selection will be made on the following criteria:

o The strength of the interest in pursuing a laboratory experience in the biomedical sciences based on the statement from the student;

o The strength of the letters of recommendation;

o Cumulative grade point average (2.75 or more based on 4.0 maximum).

Applications found to be responsive to the announcement shall be considered; those found to be unresponsive shall not be considered. A letter from CMBP Director will be sent to the grantee institution stating the reason for the outcome of the evaluation.

METHOD OF APPLYING

In lieu of submitting a form PHS 398, the Principal Investigator must submit a letter, countersigned by an authorizing official of the grantee institution, requesting support of a student for short-term laboratory training at the NCI.

This letter shall constitute an application and must include or be accompanied by the following:

o A statement from the student that describes his/her research interests and career objectives and a brief resume;

o Two letters of recommendation;

o A current official college/university transcript;

o The student's selection of three NCI laboratory choices prioritized by level of interest;

o The title of the announcement;

o A copy of the face page of the active MARC grant including the grant number and period of award; and

o A description of the personnel to which the student shall report his/her NCI laboratory experience.

A list of NCI laboratory choices will be available to all applicants through the CMBP office.

Application packages must be received by the CMBP no later than February 1, 1992.

The 10-week training period may be between May 1992 and August 1992, inclusive. Under this announcement funding is available for this period only.

More than one supplemental application may be submitted by each grantee institution.

Supplemental applications to active MARC undergraduate training grants must be submitted directly to the CMBP, with a copy to the MARC program, at the addresses listed below:

INQUIRIES

Direct inquiries regarding programmatic issues to:

Program Director
Comprehensive Minority Biomedical Program
Division of Extramural Activities
National Cancer Institute
9000 Rockville Pike
Building 31, Room 10A04
Bethesda, MD 20892
Telephone: (301) 496-7344

Program Director
Minority Access to Research Careers
National Institute of General Medical Sciences
9000 Rockville Pike
Westwood Building, Room 9A18
Bethesda, MD 20892
Telephone: (301) 496-7941

Direct inquiries regarding fiscal matters to:

Ms. Carolyn Mason
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
Bethesda, MD 20892
Telephone: (301) 496-7800, Extension 59

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.398 Cancer Research Manpower. National Institutes of Health, Public Health Service, Department of Health and Human Services Authorization: Public Health Service Act, Service 413, as amended by Public Law 99-158, 42 U.S.C. 288. Federal Agency: National Institutes of Health, Public Health Service, Department of Health and Human Services Authorization: Public Health Service Act, Section 301, Public Law 78- 410, 42 U.S.C. 241, and Section 412, as amended by Public Law 99.158, 42 U.S.C. 285a-1. Executive Order 12372 applicable.

STUDIES ON BREAST, PROSTATE, OVARIAN, AND CERVICAL CANCER

PA: PA-92-27

P.T. 34; K.W. 0715035, 0705075, 0413002, 0745020, 0745027, 0745070

National Cancer Institute

PURPOSE

The United States Congress included the following language in the Conference Report accompanying the Fiscal Year 1992 appropriation bill for Labor, Health and Human Services, Education and Related Agencies: "The conferees express their serious concern about the growing epidemic of breast and prostate cancer in the United States. The conferees urge, in the strongest way, that the National Cancer Institute make breast, prostate, ovarian, and cervical cancer its top priorities and treat these diseases with utmost urgency."

Despite significant strides in prevention, diagnosis, and treatment, cancer continues to be a leading cause of death. It has been estimated that approximately 500,000 people will die of cancer in the United States in 1991. It is estimated that 18 percent of this cancer mortality will be due to malignancies of the breast, prostate, ovary, and cervix. The National Cancer Institute (NCI) has devoted, and will continue to devote, significant resources to studies of these cancers. However, much remains to be accomplished so that more effective preventive, diagnostic, and therapeutic modalities can be established. This program announcement serves to notify and reaffirm to the scientific community the continuing commitment and interest of the NCI in expanding research support in basic and applied studies of the etiology, biology, diagnosis, treatment, and prevention of these specific cancers as a matter of high Institute priority.

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 PA, Studies on Breast, Prostate, Ovarian, and Cervical Cancer, is related to the priority area of cancer. 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 20402-0325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Research grant applications may be submitted by domestic and foreign, 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 individuals and women are encouraged.

MECHANISMS OF SUPPORT

Support of this program will be by research project grants (R01), program project grants (P01), First Independent Research Support and Transition (FIRST) Awards (R29), Outstanding Investigator Grants (R35), and Method to Extend Research in Time (MERIT) Awards (R37). In addition, competing supplemental applications to active grants under these support mechanisms and research project cooperative agreements (U01), except for the FIRST Award, are specifically encouraged to pursue new promising avenues of research.

RESEARCH OBJECTIVES

The NCI is composed of four program Divisions that support extramural research relevant to this program announcement. The spectrum of research supported by these Divisions is as follows:

The NCI's Division of Cancer Etiology plans and directs a national program of basic research including laboratory, field, and epidemiologic and biometric research on the cause and natural history of cancer and means for preventing cancer, and evaluates mechanisms of cancer induction and promotion by chemicals, viruses, and environmental agents. Representative types of research activities appropriate to this program announcement include, but are not limited to, assessment of the relative contributions and interactions of lifestyle, environment, occupation, genetic factors, viruses, and/or metabolism on the risk of cancers of the breast, prostate, ovaries, and cervix. In addition, integrated multidisciplinary studies in chemical carcinogenesis are encouraged to identify epithelial cell markers for various stages of transformation, to identify inhibitors of carcinogenesis including natural inhibitors in the human environment, and to determine the specific molecular changes that occur as epithelial cells are transformed. Finally, studies are specifically solicited to identify protective epitopes of the human papillomaviruses associated with cervical carcinoma, that are necessary for the preparation, testing, and eventual production of protective or therapeutic vaccines for this form of cancer.

The Division of Cancer Biology, Diagnosis, and Centers supports research on the cellular and molecular biology of malignant cells, the role of the immune system in tumor growth and progression and on the transfer of basic research findings to clinical application for the improved diagnosis/prognosis of cancer. In the area of cancer biology, areas of emphasis include, but are not limited to: soluble factors (e.g., hormones, growth factors), and matrix and membrane macromolecules that modulate the growth of tumor cells; the regulation of the expression of these effectors and the mechanism of action; and the genetic events responsible for progression of tumors to a highly malignant and metastatic state. In the area of cancer immunology, specific interests include, but are not limited to: cellular and humoral immune recognition of tumor antigens, methods of improving immune killing of tumor cells, immune control of tumor metastasis, other regulatory effects of the immune system on tumor growth, and tumor modulation of host immune function. Studies are specifically solicited for further research in these areas of immunology aimed at the eventual development of vaccines for the primary or secondary prevention of these cancers. In the area of cancer diagnosis, areas of emphasis include, but are not limited to: more precise staging of tumors for prognostic and therapeutic decision making, more effective monitoring of response to therapy, earlier detection of both initial and recurrent tumors, and identification of populations at risk for developing particular cancers.

The Division of Cancer Prevention and Control plans, develops, directs, and coordinates research on prevention, control, and community oncology. Representative studies involve the identification and evaluation of agents that may inhibit carcinogenesis (initiation, promotion, transformation, and/or progression). These studies could include identification of appropriate agents through literature searches or laboratory methods, efficacy and toxicology studies in animals to aid in selection of materials for human studies, and phase I and II clinical trials of potential preventive agents. Other research could focus on reduction of cancer morbidity and mortality through early detection including identification of biological markers of risk, exposure, and pre-malignant events of progression. Research on the roles of nutrients, food groups, and other dietary components in cancer incidence is appropriate including the influence of dietary factors on the modulation of cancer risk markers or intermediate endpoints. Cancer control includes research on the development and testing of intervention strategies to modify personal, social, and lifestyle factors known to contribute to the development and/or increased risk of cancer, and multidisciplinary intervention research aimed at addressing minority, underserved, and other special populations. Research under the program announcement also may include data collection, statistical analysis and mathematical modeling, health services research, and information database linkage studies to monitor progress toward cancer control, particularly pertaining to the PHS "Healthy People 2000" National Goals.

The Division of Cancer Treatment plans, directs, and coordinates an integrated program of preclinical and clinical cancer treatment research with the objective of curing or controlling cancer in humans by utilizing single or combination treatment modalities. The tumors addressed by this program announcement currently require multimodality treatment for optimal management of all stages and presentations of disease, but these treatment methods cause serious morbidity and fail to cure most patients with advanced disease. In preclinical cancer treatment research, there is an urgent need to translate recent developments in the molecular biology of cancer into the discovery of new anticancer treatments whose actions will be highly specific for particular genes or gene products. Exciting areas that may be exploited include oncogenes such as the HER-2/neu oncogene in breast cancer, suppressor genes, signal transduction, cell cycle regulation, growth factors/receptors, metastasis, and angiogenesis. Several approaches will be necessary to take advantage of these new opportunities. Additional topics include, but are not limited to, drug discovery of new anticancer agents, biochemical and molecular mechanisms of antitumor drug action, and pharmacology and toxicology of antitumor agents. Studies to circumvent individual and multiple drug resistance and prevent metastasis of these cancers to other organs are included. Clinical research opportunities exist in the areas of high-dose chemotherapy followed by autologous bone marrow rescue, multidrug resistance, radiosensitizers, adjuvant chemotherapy, innovative surgical or multimodality approaches, particle beam irradiation, novel immune therapies and genetic manipulations of host or malignant tissues, therapy with biological products, such as interleukins, monoclonal antibodies, and/or retinoic acid. Applications that address these opportunities and these particular tumors are specifically solicited.

STUDY POPULATIONS

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

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E. Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups must be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

APPLICATION PROCEDURES

Applications must be submitted on the grant application form PHS 398 (rev. 10/88, reprinted 9/89) and will be accepted at the standard application deadlines as indicated in the application kit.

Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301/496-7441. The title and number of the announcement must be typed in line 2 on the face page of the application.

The completed original application and six legible copies must be sent or delivered to:

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

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by study sections of the Division of Research Grants, NIH, in accordance with the standard NIH peer review procedures. Following scientific-technical review, the applications will receive a second-level review by an appropriate national advisory council or board. Applications for supplements to ongoing awards will be reviewed according to procedures applicable to the mechanism of the ongoing award.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions:

o Quality of the proposed project as determined by peer review

o Availability of funds

o Program balance among research areas of the announcement

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this program announcement are encouraged and must be directed to the NCI Referral Office at the address below. The opportunity to clarify any issues or questions from potential applicants is welcome.

NCI Referral Office
Review Logistics Branch
Division of Extramural Activities
National Cancer Institute
Westwood Building, Room 850
Bethesda, MD 20892
Telephone: (301) 496-7173
FAX: (301) 402-0275

Inquiries will be referred to the appropriate NCI Program Director in one of the program Divisions noted above in the "Research Objectives" section of this announcement.

Direct inquiries regarding fiscal matters to:

Ms. Roslyn Bacon
Grants Administration Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 51
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance under one or more of the applicable sections: No. 93.393, No. 93.394, No. 93.395, No. 93.396, and No. 93.399. 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.

ACADEMIC RESEARCH ENHANCEMENT AWARD

PA: PA-92-28

P.T. 34; K.W. 0710030, 0404000, 1014006

National Institutes of Health

Application Receipt Date: June 19, 1991

PURPOSE

The National Institutes of Health (NIH) is making a special effort to stimulate research in educational institutions that provide baccalaureate training for a significant number of the Nation's research scientists but that historically have not been major recipients of NIH support. Since Fiscal Year (FY) 1985, Congressional appropriations for the NIH have included funds for this initiative, the Academic Research Enhancement Award (AREA) Program (R15).

The AREA funds are intended to support new research projects or expand ongoing research activities proposed by faculty members of eligible institutions in areas related to the health sciences. Applications received in June 1991 for AREA grants to be awarded in FY 1992 are currently undergoing review for scientific merit. Since it is anticipated that additional funds will be available next year, the NIH is inviting grant applications at this time for AREA grants to be awarded competitively in FY 1993.

ELIGIBILITY

Applicant Institutions

o All domestic institutions offering baccalaureate or advanced degrees in the sciences related to health are eligible, EXCEPT those that have received an NIH Biomedical Research Support Grant (BRSG) of $20,000 or more per year for four or more years during the period from FY 1985 through FY 1991.

o Health professional schools (e.g., schools of medicine, dentistry, nursing, osteopathy, pharmacy, veterinary medicine, public health, allied health, and optometry) as well as organizationally discrete campuses of a university system, are eligible if they meet the above criterion.

o Several applications proposing different research projects may be submitted by an applicant institution.

Proposed Principal Investigators

o Must not have active research grant support (including an AREA) from either NIH or the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) at the time of award of an AREA grant.

o May not submit a traditional NIH or ADAMHA research grant (R01) application for essentially the same project as a pending AREA application.

o Are expected to conduct the majority of their research at their own institution, although limited access to special facilities or equipment at another institution is permitted.

o May not be awarded more than one AREA grant at a time nor be awarded a second AREA grant to continue the research initiated under the first AREA grant.

Those in doubt about eligibility should consult the Office of Sponsored Programs at the institution. Questions regarding eligibility, policies, procedures, and other administrative aspects of the NIH AREA Program that remain AFTER CONSULTATION WITH THE INSTITUTIONAL OFFICE may be addressed to: Research Training and Special Programs Office, NIH, Building 31, Room 5B44, Bethesda, MD 20892, telephone (301) 496-1968.

APPLICATION PROCEDURES

Applications for the AREA Program will be accepted under the application submission procedures of the Division of Research Grants (DRG), NIH. The research grant application form PHS 398, Revised 9/91, must be used in applying for an AREA grant.

Applicants must obtain the AREA Program Guidelines containing supplemental instructions for AREA applications from the Office of Grants Inquiries, DRG, NIH (see address below). These instructions must be followed in preparing an application.

AREA grants are awarded on a competitive basis. Applicants may request support for up to $75,000 for direct costs (plus applicable indirect costs) for a period not to exceed 36 months. No more than $35,000 may be requested for direct costs for any one year. Although this award is non-renewable, it will enable qualified individual scientists within the eligible institutions to receive support for feasibility studies, pilot studies, and other small-scale research projects preparatory to seeking more substantial funding from the NIH research grant programs.

REVIEW PROCEDURES

Applications for the AREA Program will be subjected to the standard peer review process involving two sequential levels of review. The first level of review is performed by initial review groups composed primarily of non-Federal scientists selected for their competence in particular scientific fields. The second level of review is made by the National Advisory Council or Board of the NIH awarding component to which the grant application has been assigned by the DRG. These groups are composed of both scientific and lay representatives who are chosen for their expertise, interest, or activity in matters related to the mission of the individual awarding component. Council or Board recommendations are based on both scientific merit and relevance to awarding component program goals. In general, the NIH may award a grant only if the corresponding application has been recommended for funding by both levels of review.

AWARD DETERMINATION

Funding decisions will be based on the proposed research project's scientific merit and relevance to NIH programs and the institution's contribution to the undergraduate preparation of doctoral-level health professionals. Among projects of essentially equivalent scientific merit and program relevance, preference will be given to those submitted by institutions that have granted baccalaureate degrees to 25 or more individuals who have obtained academic or professional doctoral degrees in the health related sciences during the period 1982-1991.

SUPPLEMENTAL INSTRUCTIONS/APPLICATION FORMS

Those individuals and institutions meeting the eligibility requirements may contact the office named below to receive the AREA Program Guidelines and/or form PHS 398 application packages. (NOTE: Form PHS 398, Revised 9/91, is currently being printed. It should be available in institutional business offices and from the NIH by March 1992.)

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

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.390. Grants will be awarded under authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered in accordance with the PHS Grants Policy Statement and Federal Regulations at 42 CFR Part 52 and 42 CFR Part 74.

INTERACTIVE RESEARCH PROJECT GRANTS FOR CANCER

PA: PA-92-29

P.T. 34; K.W. 0715035, 0710070, 0760025, 0745027, 0755015, 0755025

National Cancer Institute

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

PURPOSE

Complex questions in cancer research often require investigative efforts that extend beyond the level practicable in a single project or that require a mixture of technical approaches beyond the means of a single investigator. The perceived merit of individual research project (R01) applications sometimes may be limited by the lack of a comprehensive, interdisciplinary approach, or by limitations in resident technical expertise. There also may be areas of investigation that are under-represented in applications because they cannot effectively be exploited without a collaborative effort, yet local opportunities for such interactions are not available.

The National Cancer Institute (NCI), under an Interactive Research Project Grant (IRPG) announcement, seeks to encourage the coordinated submission of related research project grant applications from investigators who want to collaborate on a common cancer research theme, but do not require extensive shared physical resources or core functions. A minimum of three independent investigators with related research objectives are encouraged to submit concurrent, collaborative, cross-referenced individual research project grant applications (R01) that share a common research focus. Applications may be from either a single institution or a consortium of

institutions. Applications will be reviewed independently for scientific merit. Meritorious applications will be considered for funding both as independent awards and in the context of the overall proposed collaboration.

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, Interactive Research Project Grants for Cancer, is related to the priority area of cancer. Potential applicants may obtain a copy of a "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).

BACKGROUND INFORMATION

Historically, the NCI has relied on multi-component awards, such as program projects (P01) and Cancer Center Support grants (P30), to encourage interdisciplinary collaborations in areas requiring integration and central direction of basic and clinical research components. A hallmark of such awards is the provision for extensive core facilities/resources and appointment of a program director to manage the overall effort.

For many research areas it may be more appropriate to consider an intermediate level of collaboration, less extensive than that described above, but beyond that practical for single projects. For such intellectually driven collaborative efforts, the exchange of data, materials, and ideas, rather than shared physical resources or central oversight, is the primary requirement. The concept of IRPGs set forth in this announcement is meant to address and facilitate this class of research activities. Typically, the IRPG approach will be suited to many basic research questions as well as research to develop, apply, and evaluate interventions for cancer prevention and control. The IRPG mechanism may also fit well with clinical applications that propose limited testable research questions or with focused phase I and II therapeutic and related correlative laboratory studies.

Applicants will benefit from use of the IRPG mechanism by establishing a larger framework of reference for the proposed work, by facilitating formal collaborations tailored to achieving research objectives, by providing a record of independently acquired awards credited to each funded investigator, and by allowing retention of research autonomy by the named Principal Investigator on each of the interactive grants. Each grantee will have the ability to submit on his/her own behalf competing supplements as appropriate to incorporate promising new directions of research as they evolve. The freedom to establish collaborations on an equal footing at separate sites (including foreign locations), and the improved transferability of awards made to individual Principal Investigators, also are significant benefits. In contrast, translational research programs that span a variety of disciplines and programs that require extensive co-located core resources, would continue to be served best by traditional multi-component program award mechanisms.

RESEARCH GOALS AND SCOPE

The NCI encourages qualified investigators to develop and submit concurrently coordinated research project applications that address areas of relevance to cancer in which the interactive research project concept may be applied. Applications submitted as a package should be tightly focused and the interactions and benefits of the proposed linkages should be made explicit as explained below.

IRPG applications will be accepted in any relevant area of cancer research where this mechanism may be constructively applied. Some typical (non-exhaustive) examples are cited below:

o Immunobiology of specific cancers, such as breast, ovarian, and prostate cancer. Since these cancers involve both immune and neuroendocrine responses, projects requiring expertise in various aspects of cancer biology, immunology, and/or endocrinology will be needed for a comprehensive approach for these questions.

o Hormones and signalling pathways. Basic science projects may be combined that integrate multiple aspects of hormonal regulation of cancer from growth factors to receptors to signal transduction to genetic regulation.

o Detection and intervention studies in breast and other cancers. New methods are needed to promote the use of detection methodologies in populations at risk and to measure the efficacy and compliance with recommendations. Studies to identify and overcome barriers to health promotion and to measure cost-effectiveness may also be linked to such a program.

o Focused studies on phase I and II clinical trials. Projects designed to investigate promising combined therapeutic approaches to a single type of cancer may be linked with correlative laboratory investigations to investigate further the mode of action and/or biological effects of treatments.

o Related basic studies focused on multiple facets of common viral or chemical carcinogenic agents such as HIV or human papilloma virus, that do not require extensive core resources.

o Basic drug discovery programs that focus on multiple aspects of a related class of compounds or on a single mechanism of action.

o Methodologically related applications that focus on development and/or application of specific methodologies to cancer research, where extensive shared physical resources are not required.

o Research on variations in control of the cell cycle that operate specifically in tumor cells. Projects might focus on unique enzymes or effector molecules, the role of protein modifications such as phosphorylation, activation of oncogenes, and interactions with suppressor genes.

Prospective applicants are encouraged to explore other areas of potential for the IRPG mechanism with NCI program directors.

MECHANISM OF SUPPORT AND SPECIAL INSTRUCTIONS

Support of this program will be by the research project (R01) grant. Applicants will be responsible for the planning, direction, and execution of the proposed projects. One Principal Investigator out of the group MUST be identified as the "Program Coordinator," and must be cited in all applications on page 2 of form PHS 398. Individual investigators may request funds for the time and effort contributed toward the coordination of the overall research and for collaborative resource activities.

Each application MUST be complete in itself, with all appropriate approvals, budgets, and signatures. Each application MUST be identified by checking "yes" on line 2 of the PHS 398 face page and citing this announcement, "Interactive Research Project Grants for Cancer, PA-92-XX."

The use of the IRPG mechanism must be mentioned briefly in form PHS 398, Sections A-D of the Research plan. The goal of the collaborative efforts MUST be identified in the specific aims of each application, with the major rationale and explanation for the use of the IRPG mechanism to be given in Section G, Consultants/Collaborators. A complete list of applications in the IRPG must be provided in Section G, as well as an indication of the specific collaborations to be established for the individual application under consideration.

Requests for limited shared resources, if any, must be proportionally budgeted in each application based on anticipated use, with a full explanation given in the budget. Personnel Time and Effort requests for management of shared resources are allowable. If consortium arrangements between independent institutions are proposed that would make transfer of funds for required new equipment impractical, the entire equipment request may be budgeted by the responsible laboratory. This should be clearly justified.

All PHS and NIH grants policies will apply to applications received in response to this announcement.

ELIGIBILITY REQUIREMENTS

Domestic and foreign non-profit and for-profit organizations and institutions, governments and their agencies, are eligible to apply. Applications may be submitted from a single institution or may include arrangements with multiple institutions if appropriate. Applications from or involving minority institutions, individuals, and women are encouraged.

Each application will be considered on its own merit as an individual research project. Therefore, applicants for IRPGs MAY NOT concurrently submit R01 applications that represent significant duplication of the efforts described in the applicant's IRPG. In this regard, it should be noted that the NCI will consider funding meritorious individual IRPG applications if it is not possible to fund the IRPG package as a whole. Concurrent submission of program project (P01) applications that request support for essentially similar work is also prohibited.

REVIEW PROCEDURES

Upon receipt, applications and supporting material will be reviewed by the Division of Research Grants for completeness. Incomplete applications will be returned without further consideration. Each application will be assigned to an institute on the basis of the scientific subject matter of the application. Therefore, to be eligible for the NCI IRPG program, an application MUST meet the PHS referral guidelines to receive assignment to the NCI. APPLICANTS ARE STRONGLY ENCOURAGED TO CONSULT WITH NCI PROGRAM STAFF PRIOR TO SUBMISSION TO ENSURE THAT THE APPLICATION CONFORMS TO THESE GUIDELINES, AND THAT THE IRPG MECHANISM IS AN APPROPRIATE CHOICE.

Complete applications will be reviewed for scientific and technical merit by an appropriate peer review group convened by the Division of Research Grants, NIH. Insofar as possible, assignment of each IRPG application will be to a standing DRG initial review group, that may be supplemented by consultants with additional expertise as required. Investigators should be aware that applications utilizing widely differing approaches will not necessarily be reviewed by the same initial review group. Attention in selecting clearly related applications for submission will aid the process of assignment for review.

Initial review groups will employ standard peer review criteria that pertain to all individual research project applications. Following peer review, the applications will receive a second-level review by the National Cancer Advisory Board or other appropriate national advisory council or board.

Although there is no fixed set-aside of funds committed to the IRPG mechanism, the NCI will consider for funding all IRPG applications in a cohort if all are rated by peer review as having significant and substantial scientific merit.

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

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study populations must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans including American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign populations groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants that do not comply with these policies.

METHOD OF APPLYING

The research grant application form PHS 398 (rev. 10/88) must be used in applying for these grants. Applications will be accepted on the February 1, June 1, and October 1 receipt dates. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, Bethesda, MD 20892; and from the NCI Program Director named below. The Program Announcement title and number must be typed on line 2 of the face page. Submit a signed, typewritten original of each application and six signed exact single-sided photocopies to:

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

**THE MAILING ADDRESS FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NIH. 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, Maryland 20816

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this Program Announcement and inquiries about whether or not specified proposed research would be appropriate for this mechanism are encouraged and may be directed to:

NCI Referral Officer
Review Logistics Branch
Division of Extramural Activities
National Cancer Institute
Westwood Building, Room 850
Bethesda, MD 20892
Telephone: (301) 496-7173
FAX: (301) 402-0275

Callers will be referred to the appropriate NCI Program Director.

Inquiries regarding fiscal matters may be directed to:

Ms. Roslyn Bacon
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Blvd.
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 51
FAX: (301) 496-8601

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance under one or more of the applicable sections: No. 93.393, No. 93.394, No. 93.395, No. 93.396, and No. 93.399. Awards are made under the authorization of the Public Health Service Act, Sections 301, 410, and 411 (Public Law 78-410, 42 USC 241 as amended, Public Law 99-158, 42 USC 285a) and administered under PHS grants policies 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.