

# NIH GUIDE

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**For Grants  
and  
Contracts**

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

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HEALTH AND SAFETY GUIDELINES FOR GRANTEES AND CONTRACTORS

P.T. 34; K.W. 1014002, 0725010, 0725020

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

This notice is a republication, with modifications, of previous issuances on this subject. It is being reissued to emphasize its continuing importance.

Organizations receiving grant or contract awards are responsible for protecting their personnel from hazardous conditions, while the Government, generally is not legally liable for accidents, illnesses, or liability claims arising out of research performed under its awards. The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are nonetheless concerned that a variety of hazards may threaten the safety and health of both laboratory and clinical research personnel. Accordingly, the publications listed below are designed to help identify potential hazards and inform awardee organizations and investigators of certain guidelines and standards that should be considered in addressing particular health and/or safety concerns. It should be noted that significant concerns about potentially hazardous conditions could result in grant or contract funding delays until those concerns have been resolved to the satisfaction of the awarding component.

1. Types of potential hazards to research personnel include the following:

- a. Biohazards (e.g., Human Immunodeficiency Virus, HIV; other infectious agents; oncogenic viruses).
- b. Chemical hazards (e.g., carcinogens; chemotherapeutic agents; other toxic chemicals; flammable or explosive materials).
- c. Radioactive materials.

2. The following guidelines and standards contain information designed to assist grantees and contractors in assessing potential hazards and providing a safe work environment for research personnel. Therefore, depending upon the particular safety hazard at issue, one or more of these documents should be consulted by grantees or contractors. (Items a through h).

- a. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Centers for Disease Control and the National Institutes of Health, HHS Publication No. (CDC) 88-8395.
- b. Recommendations for Prevention of HIV Transmission in Health-Care Settings. Morbidity and Mortality Report, August 21, 1987, Vol. 35, No. 25.
- c. Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings. Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.
- d. NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication No. 81-2385.

Single copies of the above documents (Items a through d) may be obtained from:

Division of Safety (9/91)  
Office of Research Services  
National Institutes of Health  
Building 31, Room 1C02  
Bethesda, MD 20892

Additional copies to be purchased at a cost of \$3.75/copy through:

Government Printing Office  
Superintendent of Documents  
Washington, DC 20402  
Stock # 17-40-508-3

e. Guidelines for Research Involving Recombinant DNA Molecules (49 FR 46266 or latest revision) and Administrative Practices Supplement. These guidelines may be obtained from: Office of Recombinant DNA Activities, National Institutes of Health, Building 31, Room 4B11, Bethesda, MD 20892.

f. Procedures for the Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents, National Committee for Clinical Laboratory Standards, July 17, 1985, Vol. 5, No. 1. These procedures may be obtained from: National Committee for Clinical Laboratory Standards, 771 East Lancaster Avenue, Villanova, PA 19085.

g. Standards issued pursuant to the National Occupational Safety and Health Act of 1970 (29 CFR Part 1910).

Copies may be obtained from:

Occupational Safety and Health Administration  
National Training Institute Building  
1555 Times Drive  
Des Plaines, IL 60018

h. Standards issued pursuant to the Atomic Energy Act of 1954 (42 USC 2021). Contact Regional Office of Nuclear Regulatory Commission.

The following materials also are recommended and may be purchased from:

National Academy Press  
2102 Constitution Avenue, N.W.  
Washington, DC 20418

A. Prudent Practices for Handling Hazardous Chemicals in the Laboratory. Price \$19.95

B. Prudent Practices for the Disposal of Chemicals from the Laboratory. Price \$19.95

C. Biosafety in the Laboratory: Prudent Practices for Handling and Disposal of Infectious Materials. Price \$29.95

### 3. Identification of Hazards

#### a. Preaward

Grant and cooperative agreement (hereafter will be referred to grant(s)) applications and contract proposals posing special hazards typically are identified in the review process, but such concerns can formally be expressed by agency staff or consultants at any time prior to award. If these hazards are not addressed, the awarding component must ascertain how the special hazards will be handled or the grant/contract funding could be delayed until the matter has been resolved to the satisfaction of the awarding component.

#### b. Postaward

Grant Mechanism: The grantee must inform the awarding component of the nature and extent of the hazard, as well as the corrective action(s) taken or planned to prevent future occurrence. If the hazard is not adequately controlled, it may create a danger and adversely impact the activities being funded so that it impinges upon progress, efficient and effective management of resources, and research findings. The adverse impact may cause the grantee to materially fail to comply with the terms of the grant. This may lead the awarding office to take postaward action, including suspension or termination of the grant, in order to resolve the situation. (See 45 CFR 74.113 et seq. and the appeal rights set forth in 42 CFR Part 50, subpart D and 45 CFR Part 16) Postaward action also may be necessary if the application had addressed the issue of special hazards but the grantee does not adequately control the special hazards as was indicated in the application.

Contract Mechanism: Special hazards that are identified after an award is made may lead to suspension or termination of work under the contract pending corrective action by the contractor. (See 48 CFR 12.5 concerning contract "stop work" orders and the Clause at 48 CFR Part PHS 352.223-70, Safety and Health (APR 1984).

### 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:

#### NORTH MIDWESTERN WORKSHOP

DATES: October 17 and 18, 1991

WORKSHOP SITE:  
Westin Hotel  
Renaissance Center  
Detroit, MI  
Telephone: (313) 568-8000

SPONSORS:  
Children's Hospital of Michigan  
3901 Beaubien Blvd.  
Detroit, MI 48201

Wayne State University  
4237 Scott Hall  
Detroit, MI 48201

REGISTRATION CONTACT:  
Mr. Jerome Wilczynski  
Vice President for Operations  
Children's Hospital of Michigan  
3901 Beaubien Blvd.  
Detroit, MI 48201  
Telephone: (313) 745-5450

TGPIC: Protection of Human Subjects in Research: The Vulnerable Patient

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)

BREAST CANCER AND THE BIRTH CONTROL PILL: CASE-CONTROL STUDY OF PERIMENOPAUSAL AND PAST ORAL CONTRACEPTIVE USE (FIELD CENTERS)

RFP AVAILABLE: NICHD-CRE-91-13

P.T. 34; K.W. 0715035, 0750020, 0785140, 0785055

National Institute of Child Health and Human Development

The Contraceptive and Reproductive Evaluation Branch of the Center for Population Research, National Institute of Child Health and Human Development (NICHD), requires information on the relationship between oral contraceptives and breast cancer among women in the age range of 40-64 years. The NICHD is seeking organizations capable of serving as Field Centers for a population-based, multi-center, concurrent case-control study of breast cancer and oral contraceptives. Each Field Center (five to seven awards are anticipated) must be capable of designing and conducting an epidemiologic study that will recruit a minimum of 750 cases of breast cancer among women in the age range of 40-64 years, obtain reproductive, medical and family histories, and retrieve pathology material. There will be an opportunity for biological specimen collection and in-depth pathology review.

Offerors must have expertise in contraceptive epidemiology and large collaborative case-control studies. Emphasis will be placed on the ability of the offeror to recruit adequate numbers of subjects. Additional consideration will be given to Field Center offerors having expertise in clinical pathology and laboratory management. The Government estimates the effort at each Field Center to be approximately 22 technical staff-years over a performance period of six years.

This announcement is not a Request for Proposals (RFP). The RFP will be issued on or about October 1, 1991. Proposals will be due approximately 120 days thereafter. Copies of the RFP may be obtained by sending a written request to the address listed below. Please enclose a self-addressed label. Requests may also be made by FAX Telephone on (301) 402-0915.

Paul J. Duska, Contracting Officer  
Contracts Management Branch, OGC  
National Institute of Child Health and Human Development  
Executive Plaza North, Room 610  
9000 Rockville Pike  
Bethesda, MD 20892-9903

STUDIES TO EVALUATE THE TOXIC AND CARCINOGENIC POTENTIAL OF RETROVIRAL VECTORS IN LABORATORY ANIMALS

RFP AVAILABLE: NIH-ES-92-14

P.T. 34; K.W. 1007009, 0715035, 1002045, 1002002, 0755010, 0760053

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), is soliciting proposals from offerors having the capability to conduct studies to evaluate the toxic and carcinogenic potential of retroviral vectors in laboratory animals for the National Toxicology Program (NTP). This project will be separated into two phases: In Phase 1 the resources of the contractor will be used to demonstrate proficiency in the preparation of frozen histological sections and in the performance of the X-gal assay prior to beginning the prechronic studies. The prechronic studies will determine what exposure regimen maximizes the probability of vector insertion and evaluate methods of monitoring for the presence of vector-derived DNA in selected tissues. The Phase 2 project is optional and will only be conducted after results from Phase 1 have been evaluated and approval to proceed has been granted by the NTP. The chronic study will evaluate the carcinogenic potential associated with random insertion of a retroviral vector into cellular DNA of organs and tissues of F344 rats and B6C3F1 mice. The Government will determine at the end of Phase 1 whether Phase 2 studies will use weanlings or will require the breeding of neonates. The Government estimates that the Phase 1 portion of the project will last approximately 21 months, including review time, and will require approximately 2,841 senior professional manhours, 3,041 professional manhours, and 13,480 technical manhours. Phase 2, if approved, will have a duration of approximately 37 1/2 months and will require approximately 2,700 senior professional manhours, 3,000 professional manhours, and 24,650 technical manhours.

If breeding neonates is required, the Government estimates that Phase 2 will require one additional month and 130 senior professional manhours, 130 professional manhours, and 850 technical manhours in addition to the Phase 2 estimates cited above. An option for Phase 2 will be included in the contract. It is expected that one contract will be awarded for a 21 month period, with an option for 38 1/2 months.

The Request for Proposals (RFP) will be released on or about October 8, 1991, and proposals due to be received December 3, 1991. All responsible sources may submit a proposal that shall be considered by the Agency.

Requests for the RFP must reference RFP NIH-ES-92-14 and must be forwarded to:

National Institute of Environmental Health Sciences  
Contracts and Procurement Management Branch, OM  
ATTN: Mr. Donald Gula, Contract Specialist  
79 T.W. Alexander Drive, 4401 Research Commons Building  
P.O. Box 12874  
Research Triangle Park, NC 27709  
Telephone: (919) 541-7893

CLAUDE D. PEPPER OLDER AMERICANS INDEPENDENCE CENTERS

RFA AVAILABLE: AG-91-13

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

National Institute On Aging

Letter of Intent Receipt Date: February 1, 1992  
Application Receipt Date: April 1, 1992

**PURPOSE**

Millions of older Americans suffer from loss of abilities needed to live fully independently. Loss of independence imposes enormous personal and financial burdens on older persons and their families. Dependence is not inevitable in old age. It results from disabling conditions that are potentially, if not currently, preventable or reversible. The development and testing of interventions to reduce disability and increase independence thus offers immense benefits and potential savings in health care costs. In response to this need, Congress amended the Public Health Service Act in 1990 to authorize the establishment of Claude D. Pepper Older Americans Independence Centers (OAICs). The overall goals of the OAIC program are: to develop and test interventions to increase or maintain abilities needed for independence of older persons and to train researchers capable of leading and conducting research programs in the above activities.

**ELIGIBILITY REQUIREMENTS**

Only U.S. organizations are eligible to apply. Applications may be submitted by for-profit or nonprofit organizations, public or 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**

Older Americans Independence Centers will be supported through comprehensive center grants (P60).

**FUNDS AVAILABLE**

The total costs (direct plus indirect) requested per application for the first year may not exceed \$1,100,000. Plans are to make up to two awards depending upon availability of funds. Up to \$2.0 million (total cost) for first-year expenses will be committed in Fiscal Year 1992 to fund applications submitted in response to this Request for Applications (RFA), subject to receipt of high-quality applications, and availability of funds.

Additional approved expenses for up to five years may be requested.

**RESEARCH OBJECTIVES**

OAICs will support:

**INTERVENTION STUDIES:** These studies are the major research components of OAICs. At least one approved intervention research project is required for approval of an OAIC. Proposed intervention studies must test efficacy of interventions to prevent or ameliorate functional impairments contributing to loss of independence. **CENTRAL IN THE EVALUATION OF THESE STUDIES WILL BE THE ADEQUACY AND APPROPRIATENESS OF THE PLANS FOR MEASUREMENT OF CHANGES IN FUNCTIONAL STATUS.** Each proposed intervention study must also include planned investigations of mechanisms underlying effects (or lack of effects) of the intervention on functional status, factors affecting recruitment into the study and participants' compliance once enrolled, and cost-effectiveness and effects on health care utilization of the intervention(s) tested.

Examples of study topics include: interventions to prevent or reduce frailty and physical performance disabilities, cognitive disability, affective disorders, and sensory disabilities, and/or comorbidity associated with these conditions; to reduce risk of disabling events such as hip fractures and strokes, and impairments following these events; to prevent or reduce disabilities in complex functions involving combined motor,

sensory, and cognitive performance; disabling side effects from medication use; temporary disability from exacerbation or complications of chronic diseases of older persons; disabling sequelae of menopause and associated estrogen deficiency; and combined intervention strategies to prevent or ameliorate disabilities in older persons with multiple impairments.

**INTERVENTION DEVELOPMENT STUDIES:** OAICs will also support intervention development studies to identify, develop, or refine potential interventions to preserve or increase independence. Types of such studies include preliminary tests of therapies to test their effects on physiologic and/or behavioral factors known to affect functional status and studies to identify or confirm reversible or preventable risk factors for disability and/or disabling events. Large-scale epidemiologic studies are outside the scope of this RFA.

**RESEARCH RESOURCES CORES:** Applicants may request core resource support to enhance the quality of OAIC research projects, i.e., Intervention Studies, intervention development studies and pilot research projects.

**RESEARCH DEVELOPMENT CORE:** This core will provide salary and other support for junior faculty and research associates to acquire abilities in all phases of research to develop interventions to enhance independence, including clinical trials, studies of mechanisms of treatment response, and cost-effectiveness/health care utilization studies. The Research Development Core will also support pilot research projects on topics related to the activities of the OAIC.

**DEMONSTRATION AND INFORMATION DISSEMINATION PROJECTS:** OAICs must include activities to translate findings from their research into health care practice.

**LEADERSHIP/ADMINISTRATIVE CORE:** Applicants may request funds for the OAIC Director, OAIC Administrator, and support staff. The OAIC Director must be a scientist who can provide effective administrative and scientific leadership and coordination with OAIC Intervention Studies. An OAIC Administrator who will assist the Director in managing the Center, addressing issues of fiscal management and compliance with institutional, PHS, NIH, and NIA policies, must be identified.

#### STUDY POPULATIONS

It is NIH policy that women and minorities must be included in clinical study populations unless there is a good reason to exclude them, and the study design must seek to identify any pertinent gender or minority.

#### 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 that fail to comply with this policy will be returned without review. 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 summarized in Section 2 E, Human Subjects.

#### APPLICATION PROCEDURES

The applicant must submit the application using PHS 398 (revised 10/88), following the OAIC (P60) Guidelines that are available by contacting Dr. Slater at the address below. Application kits containing this form and the necessary general instructions are available in most institutional business offices and may be obtained from the Office of Grants Inquiries, Division of Research Grants, NIH (telephone (301) 496-7441).

#### LETTER OF INTENT

If an investigator is satisfied that his/her institution is eligible and elects to apply for an OAIC grant, a letter of intent is requested (but not required) to be submitted to the Geriatrics Program at the address given below. The letter of intent consists of the name of the OAIC Director and Principal Investigators and the titles of the major research projects and cores proposed. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it provides an indication of the number and scope of the applications to be reviewed. The letter of intent is to be submitted by February 1, 1992.

#### INQUIRIES

The RFA may be requested in writing and by telephone. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Stanley L. Slater, M.D.  
Geriatrics Program  
National Institutes of Health  
National Institute on Aging  
Building 31, Room 5C27  
Bethesda, MD 20892  
Telephone: (301) 496-6761

Direct inquiries regarding fiscal matters to:

Barbara Cunningham  
Grants and Contracts Management Office  
National Institutes of Health  
National Institute on Aging  
Building 31, Room 5C07  
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.

#### ORPHAN RECEPTORS IN ENDOCRINOLOGY

RFA AVAILABLE: DK-92-03

P.T. 34; K.W. 0785050, 0760075, 1002004, 1002008, 0710100, 1002061

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: December 15, 1991

Application Receipt Date: January 24, 1992

#### PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announces the availability of a Request for Applications (RFA) for investigator-initiated research grant applications to elucidate ligands and mechanisms of action for previously unclassified (orphan) receptors.

#### BACKGROUND

The advent and general applicability of molecular cloning strategies and technologies has enabled the identification and sequencing of numerous receptors for hormones, growth factors, and cytokines. The ability to use "consensus" sequences derived from known receptor sequences in Polymerase Chain Reaction (PCR)-based cloning protocols has resulted in the isolation of an additional large pool of putative receptors for which no known ligand(s) has as yet been identified. The high degree of conservation of many of these putative receptor sequences through evolution suggests the continued function of these molecules in some aspect of signal transduction or cell communication in higher organisms. Further investigation of receptor structure, including domain organization may serve to elucidate potential mechanisms of action and help to reveal ligand specificities and serve to increase our understanding of the diversity in structural and cellular responses that result from hormonal action in cells and tissues.

#### OBJECTIVES

This solicitation is intended to address a key new issue in molecular endocrinology that has resulted from the application of emerging new gene cloning technologies. It is anticipated that this research will result in identification of potentially important biologic effector molecules and new understandings of signal transduction through hormone/ligand receptors with subsequent impact on knowledge of mechanisms of cell regulation.

#### 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.

#### ELIGIBILITY

Applications for research grants may be made by public and private, foreign and domestic, for-profit and non-profit organizations, such as universities, colleges, hospitals and laboratories, units of State or local governments, and authorized units of the Federal Government. Women and minority investigators are encouraged to apply.

#### MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid via the research project grant (R01). The regulations and policies that govern the research grant programs of the National Institutes of Health will prevail. Up to \$1 million for first-year expenses, and additional approved expenses for up to five years, will be committed to fund applications submitted in response to this RFA. It is anticipated that approximately five to six awards may be made. In order for the NIDDK to adhere to prudent principles of cost-containment, requested direct costs may not exceed \$135,000.



## METHOD OF APPLYING

Applications must be submitted on form PHS 398 (rev. 10/88), that is available from an applicant institution's Office of Sponsored Research and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. Use the conventional format for research project grant applications.

### Letter of Intent

Applicants are requested to submit by December 15, 1991, a letter of intent that includes the name and address of the Principal Investigator, the name and address of any other key investigator(s), and other participating institutions. Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it provides an indication of the number and scope of the applications to be reviewed. The letter of intent is to be sent to:

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

## REVIEW PROCEDURES AND CRITERIA

### Assignment of applications

Applications will be received by the NIH, Division of Research Grants (DRG). Responsive applications will be assigned to a special peer review group by the NIDDK. Following review by the initial review group, the applications will be considered by the National Diabetes and Digestive and Kidney Diseases Advisory Council. Since it has been postulated that 'orphan receptors' play a key role in mediating the toxic effects of some environmental chemicals, specifically those for which no direct biochemical mechanisms can be found to explain the toxicities, applications proposing to study these agents and their interactions in this context could possibly be assigned to the NIEHS as research grant applications responsive to Program Announcement PA-91-85, "Role of Xenobiotic Receptors in Toxicology," NIH Guide for Grants and Contracts (Vol. 20, No. 31), August 16, 1991. The Referral Branch, DRG, will apply standard referral guidelines in determining final disposition of such grants.

### Review criteria

Applications in response to this solicitation will be reviewed using the NIH peer review procedures and criteria as applied to investigator-initiated research grant applications.

## INQUIRIES

It is essential that prospective applicants study the text of this RFA before developing an application. The RFA may be obtained from:

Ronald N. Margolis, Ph.D.  
Director, Endocrinology Research Program  
Division of Diabetes, Endocrinology and Metabolic Diseases  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 605  
Bethesda, MD 20892  
Telephone: (301) 496-7504

Questions concerning the proposed budgets of applications are to be directed to:

Bruce Butrum  
Grants Management Specialist  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 649D  
Bethesda, MD 20892  
Telephone: (301) 496-7467

## AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.847, Diabetes, Endocrinology, and Metabolic Diseases. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulation 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.

PERINATAL EMPHASIS RESEARCH CENTER

RFA AVAILABLE: HD-92-04

P.T. 04; K.W. 0710030, 0775020, 0775025, 0411005, 0755030, 1002061

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: November 10, 1991

Application Receipt Date: February 10, 1992

PURPOSE

The National Institute of Child Health and Human Development (NICHD) announces the availability of a Request for Applications (RFA) from current members of the Perinatal Emphasis Research Centers (PERC) program (competitive continuation applications) and from prospective members (new applications) with the objective of encouraging investigators to develop multidisciplinary research efforts that will advance knowledge about diseases and disorders of pregnancy and infancy. These grants are for the support of hypothesis-testing research efforts; they are not intended to support service, survey, or demonstration projects. PERCs are organized around problem/need themes and are established where research can be coordinated with existing programs of health care to ensure the rapid assimilation of new scientific knowledge into health care delivery. Active PERCs are addressing issues in high-risk pregnancies (diabetes, hypertension), prevention of prematurity, fetal hypoxia, and intrauterine growth retardation.

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 Request For Applications (RFA), Perinatal Emphasis Research Centers, 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 "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

A PERC grant promotes and supports multidisciplinary research efforts with the aim of improving pregnancy outcome and ensuring infant survival and well-being. Clinical studies may include etiologic mechanisms, improvement of diagnostic techniques, and various aspects of prevention and management. All investigative approaches may be used, from molecular biology to cellular, organ, or whole organism physiology and clinical evaluations. Supported research may be carried out in experimental animals. A minimum of one subproject must address issues in patients. Some of the research areas are: high-risk pregnancies, intrauterine growth retardation, perinatal toxicology and pharmacology, initiation of labor, neonatal disorders, and infant sleep as it relates to sudden infant death syndrome.

MECHANISM OF SUPPORT

PERC grants (P-50) will be supported through the customary grant-in-aid mechanism. Review of applications and management of grants will be subject to applicable policies for NIH research center P-50 grants. The P-50 is an institutional award, made in the name of a Principal Investigator, and awarded competitively. It provides support for both research projects and the core services used by those projects. It is expected that up to five awards will be made as the result of this announcement (three awards in the area of perinatology and two in the area of infant sleep). Awards will be made initially for a five-year period with an option for renewal.

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.

METHOD OF APPLYING

Letter of Intent: Potential applicants are strongly encouraged (but not required) to submit a letter of intent to the Chief of the Pregnancy and Perinatology Branch. The letter of intent, includes a descriptive title, names and institutions of the Principal Investigators of the individual projects. Such letters are requested 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 does not enter into the review of the application.

An application must be prepared using research grant application form PHS 398 (rev. 10/88) following both the form PHS 398 instructions and the NICHD Center Guidelines. Appropriate human subject and animal welfare documentation must be submitted before the review.

This announcement indicates plans by NICHD to make five awards in fiscal year 1993 (three in perinatal medicine, and two in infant sleep). The original and four copies of the application are due in the Division of Research Grants on or before February 10, 1992. Late or incomplete applications will be returned. Instructions in the PHS 398 (rev. 10/88) grant application kit must be followed, and the RFA label (supplied in the application kit) must be attached to the bottom of the face page of the original grant application and placed on top of the entire package. Applications must be identified by checking the "Yes" box in Item 1 and typing in the words

"RFA-HD-92-04 PERINATAL EMPHASIS RESEARCH CENTER" in Item 2 on the front page of the grant application form. The original and four copies of the application must be mailed or delivered to:

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

Two copies of the application also must be sent to:

Laurance S. Johnston, Ph.D.  
Acting Director  
Division of Scientific Review, NICHD  
Executive Plaza North Bldg., Room 520  
6130 Executive Boulevard  
Rockville, MD 20892

#### INQUIRIES

Applicants may request a copy of the NICHD Center Guidelines and the full RFA from:

Dr. Charlotte Catz, Chief  
Pregnancy and Perinatology Branch  
Center for Research for Mothers and Children  
National Institute of Child Health and Human Development  
National Institutes of Health  
Executive Plaza North Building, Room 643  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-5575

The full RFA is also available on the electronic version of the NIH Guide, the E-Guide.

Inquiries regarding grants management and administrative policy may be directed to:

Mr. Douglas Shawver  
Supervisory Grants Management Specialist  
Office of Grants and Contracts  
National Institute of Child Health and Human Development  
Executive Plaza North Building, Room 505  
Bethesda, MD 20892  
Telephone: (301) 496-1303

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.965, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Sections 1004, 301, and 444, and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

#### MINORITY DISSERTATION RESEARCH GRANTS IN AGING, 1992

RFA AVAILABLE: RFA AG-91-14

P.T. 34, FF; K.W. 0710010, 0720005

National Institute on Aging

Application Receipt Date: December 20, 1991

Small grants (R03) to support doctoral dissertation research will be available in 1992 for underrepresented minorities. Grant support is designed to aid the research of new minority investigators and to encourage individuals from a variety of academic disciplines and programs to study problems in aging. Specific research topics should be discussed with the National Institute on Aging (NIA). The interests of the programs are given in the full RFA. Dissertation research grants will be administered in accordance with the U.S. Code Annotated, Title 42, Part B, Section 284.

Underrepresented minority investigators are defined as individuals belonging to a particular ethnic or racial group that has been determined by the grantee institution to be underrepresented in biomedical and behavioral research. NIA will give priority to projects from African-Americans, Native Americans, Hispanics, Pacific Islanders and other ethnic or racial group members who have been found to be underrepresented in geriatric and gerontology research nationally.

#### ELIGIBILITY

The applicant investigator applying for a dissertation research grant must be a minority individual enrolled in an accredited doctoral degree program in the biomedical, social, or behavioral sciences and must have

approval of the dissertation proposal by a named committee. All requirements for the doctoral degree other than the dissertation must be completed by the time of the award.

The applicant institution must be a domestic one and it will administer the grant on behalf of the proposed investigator. Individuals must at the time of application be citizens or non-citizen nationals or have been lawfully admitted to the United States for permanent residence and have in their possession an Alien Registration Receipt Card (I-151 or I-551). Individuals with temporary visas or student visas are not eligible.

#### MECHANISM OF SUPPORT

This RFA will use the NIH small grant (R03) mechanism.

#### FUNDS AVAILABLE

Awards will depend on the availability of funds. NIA expects to fund up to 20 dissertation research projects in Fiscal Year 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 for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

#### APPLICATION PROCEDURES

The full RFA and special guidelines for dissertation grant applications must be requested from the Office of Extramural Affairs, (see address below). The application must be submitted on form PHS-398 (revised 10/88) available from the university research office and the Division of Research Grants, 5333 Westbard Avenue, Bethesda, MD 20892, Telephone: (301) 496-7441. The special instructions described in the RFA and the application kit must be followed. Applications will be assigned to the NIA for review and possible funding.

Applicant investigators should request support for the amount of time necessary to complete the dissertation. However, a dissertation research grant usually is awarded for a period of 12 months or less but may be awarded for up to 24 months. The direct costs of the entire project may not exceed \$25,000. An application that exceeds this amount will be returned. Indirect costs are limited to 8 percent of direct costs.

The applicant must submit the original and four copies of the completed application, which includes a detailed narrative project description (not to exceed 10 pages) and required letters.

Applications must be received by December 20, 1991 and must be sent directly to:

Division of Research Grants  
National Institutes of Health  
5333 Westbard Avenue  
Westwood Building, Room 240  
Bethesda, MD 20892

An additional two copies of the application must be sent to:

Chief, Scientific Review Office  
National Institute on Aging  
Building 31, Room 5C12  
Bethesda, MD 20892  
Attn: Minority Dissertation

A letter from the faculty committee or university official directly responsible for supervising the development and progress of the dissertation research must be submitted with the application. Detailed requirements for the letter are given in the full RFA.

#### REVIEW CONSIDERATIONS

Dissertation research grants are competitive. Review will be conducted by a special committee convened by NIA. Review results and funding decisions will be announced within six months after the submission date. Final funding decisions are based on the recommendations of the reviewers, the relevance of the project to NIA priorities, and the availability of funds.

#### INQUIRIES

Interested applicants are encouraged to request the full RFA and additional guidelines for preparing the application and to discuss the suitability of the mechanism to their needs by letter or by telephone with the

person named below. The applicant also will be referred to the relevant NIA program director to discuss the suitability of the research topic.

Phyllis B. Eveleth, Ph.D.  
Deputy Associate Director and Training Officer  
Office of Extramural Affairs  
National Institute on Aging  
Building 31, Room 5C02  
Bethesda, MD 20892  
Telephone: (301) 496-9322

Direct inquiries relating to fiscal matters should be made to:

Mr. Joseph Ellis  
Grants Management Officer  
National Institute on Aging  
Building 31, Room 5C07  
Bethesda, MD 20892  
Telephone: (301) 496-1472

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.366. 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 DSC 241 and 285) and administered under PHS grant policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74.

#### ONGOING PROGRAM ANNOUNCEMENTS

##### RESEARCH ON LAW AND MENTAL HEALTH

PA AVAILABLE: PA-92-01

P.T. 34; K.W. 0715094, 0715129

National Institute of Mental Health

Under authority of Section 301 of the Public Health Service Act PL 78-410, as amended, and subject to availability of funds, the National Institute of Mental Health (NIMH) announces a new program announcement, Research on Law and Mental Health. The aim of the announcement is to stimulate investigator-initiated research on a range of clinical, programmatic, and policy issues associated with the processing of mentally disordered adult and juvenile offenders in the criminal and juvenile justice systems, and with mentally ill persons subject to involuntary hospitalization through the civil commitment system. Studies supported under this announcement are expected to improve scientific knowledge on the clinical assessment, treatment, and management of the seriously mentally ill in the legal system.

##### HEALTHY PEOPLE 2000

This announcement will also support objectives 7.1 and 7.6 (reduction of homicides and assault injuries, respectively) of Healthy People 2000: National Health Promotion and Disease Prevention Objectives. 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 "Health 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

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

##### 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.

Grants funded under this announcement are subject to the requirements of 45 CFR 46, Protection of Human Subjects. These regulations are available from the Office of Protection from Research Risks, National Institutes of Health, Bethesda, MD 20892. Telephone: (301) 496-7041.

## MECHANISMS OF SUPPORT

The pending mechanisms for this announcement are the traditional research grant (R06), the small grant (R03), and the First Independent Research Support and Transition (FIRST) Award (R29).

## REVIEW PROCEDURES

Applications will be received under the usual PHS receipt and review schedule. Applications will be reviewed by an initial review group (IRG) consisting primarily of non-Federal scientific and technical experts.

Applications will receive a second-level review by the appropriate advisory council based on policy considerations as well as scientific merit. Only applications recommended for approval by Council may be considered for funding. Applications recommended for approval by the national advisory council will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, public health significance, and availability of funds.

## APPLICATION PROCEDURES

All research applicants must use the current version of the grant application form PHS 398 (rev. 10/88). Support may be requested for a period of up to five years. Annual awards will be made subject to continued availability of funds and progress achieved. A competing supplemental application may be submitted during an approved period of support to expand the scope or protocol of a project during the approved period. Except for small grants (R03) and FIRST awards (R29), a competing continuation (i.e., renewal) application may be submitted before the end of an a period of support to continue a project.

Grant funds may be used for expenses clearly related and necessary to conduct research projects including direct costs that can be specifically identified with the project and allowable indirect costs of the institution. Funds may not be used to establish, add a component to, or operate a treatment, rehabilitation, or prevention intervention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for costs required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield generalizable knowledge and/or make a significant contribution to theoretical concepts.

## INQUIRIES

Copies of this full announcement and additional information may be obtained by contacting:

Ecford S. Voit, Jr., Ph.D.  
Assistant Chief  
Violence and Traumatic Stress Research Branch  
National Institute of Mental Health  
5600 Fishers Lane, Room 18-105  
Rockville, MD 29857  
Telephone: (301) 443-3728

Information on grants management issues may be obtained from:

Steven J. Hudak  
Grants Management Branch  
National Institute of Mental Health  
5600 Fishers Lane, Room 7C-26  
Rockville, MD 20857  
Telephone: (301) 443-4596

## AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.242. Under the authority of Section 301 of the Public Health Service Act, P.L. 78-410, as amended, 42 U.S.C. 241 (42 CFR part 52), and subject to availability of funds, NIMH will accept research grant applications in response to this announcement, under the receipt dates listed herein.

## RESEARCH ON VICTIMS OF TRAUMATIC STRESS

PA AVAILABLE: PA-92-02

P.T. 34; K.W. 0715195, 0414000, 0710105, 0411005

National Institute of Mental Health

Under authority of Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended, and subject to availability of funds, the National Institute of Mental Health (NIMH) announces a new Program Announcement (PA), Research on Victims of Traumatic Stress, that encourages research on traumatic life crises and catastrophic events. NIMH expects to promote the understanding of victims' psychological responses to traumatic events and to encourage the development of interventions to assist victims with mental health problems resulting from this exposure.

## HEALTHY PEOPLE 2000

This announcement will also support objectives 6.3, 6.4, 6.5, 7.12, and 7.14 of Healthy People 2000: National Health Promotion and Disease Prevention Objectives. 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 "Health 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 supported in this program includes studies of the immediate and long-term psychopathological and stress reactions in victims, families, service workers, and community members; individual and environmental risk factors associated with the development and perpetuation of mental and physical disorders; informal support networks and coping mechanisms as mediators of trauma; and design, implementation, and effectiveness of formal programs to prevent and treat mental health problems.

### ELIGIBILITY

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

### 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.

Grants funded under this announcement are subject to the requirements of 45 CFR 46, Protection of Human Subjects. These regulations are available from the Office of Protection from Research Risks, National Institutes of Health, Bethesda, MD 20892. Telephone: (301) 496-7041.

### REVIEW PROCEDURES

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

Applications recommended for approval will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, and availability of funds.

### MECHANISM OF SUPPORT

The funding mechanisms for this announcement are the traditional research grant (R01), the small grant (R03), and the First Independent Research Support and Transition (FIRST) award (R29).

### APPLICATION PROCEDURES

All research applicants must use the grant application form PHS 398 (rev. 10/88). Support may be requested for a period of up to five years. Annual awards will be made subject to continued availability of funds and progress achieved. Except for small grants (R03) and (FIRST) awards (R29), a competing supplemental application may be submitted during a period of support to expand the scope or protocol of a project during the approved period. A competing continuation (i.e., renewal) application may be submitted before the end of an approved period of support to continue a project.

Grant funds may be used for expenses clearly related and necessary to conduct research projects including direct costs that can be specifically identified with the project and allowable indirect costs of the institution. Funds may not be used to establish, add a component to, or operate a treatment, rehabilitation, or prevention intervention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for costs required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield generalizable knowledge and/or make a significant contribution to theoretical concepts.

Unless clearly relevant to mental illness and mental health, the Traumatic Stress Research Program does not support basic studies of social organizations affected by emergency conditions or basic studies of social policy in the area of crisis management. Furthermore, the program does not support studies of psychiatric emergencies due to substance abuse or major mental disorders, or research that more appropriately falls within the mission of other Federal programs (e.g., National Institute of Justice, National Science Foundation).

## INQUIRIES

Prospective investigators are encouraged to contact program staff for program information, a copy of the Program Announcement, and consultation:

Susan D. Solomon, Ph.D., Chief  
Violence and Traumatic Stress Research Branch  
National Institute of Mental Health  
5600 Fishers Lane, Room 18-105  
Rockville, MD 20857  
Telephone: (301) 443-3728

Information on grants management issues may be obtained from:

Steven J. Hudak  
Grants Management Branch  
National Institute of Mental Health  
5600 Fishers Lane, Room 7C-26  
Rockville, MD 20857  
Telephone: (301) 443-4596

## AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.242. Under the authority of Section 301 of the Public Health Service Act, (42 U.S.C. 241), and subject to availability of funds, NIMH will accept research grant applications in response to this announcement, under the receipt dates listed herein.

## RESEARCH ON PERPETRATORS OF VIOLENCE

PA AVAILABLE: PA-92-03

P.T. 34; K.W. 0404023, 0404000, 0755030, 0403001, 0415001, 0745027

National Institute of Mental Health

Under the authority of Section 301 of the Public Health Service Act, P.L., 78-410, 42 U.S.C. 241, as amended, the National Institute of Mental Health (NIMH) announces the availability of a Program Announcement for applications for investigator-initiated research on the etiology, course, and correlates of aggressive and violent behaviors in children, adolescents, and adults. Through this announcement, NIMH expects to support research that will improve the scientific base for more effective and cost-efficient approaches to clinical assessment, treatment, management, and prevention.

## 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, RESEARCH ON PERPETRATORS OF VIOLENCE, is related to the priority areas of reducing homicides, reducing abuse of women by male partners, reducing assaults, reducing rapes, and reducing fights among adolescents. 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

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

## 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.

Applicants must also be aware that the Department of Health and Human Services has regulations for the protection of human subjects and has developed additional regulations for the protection of children. A copy of these regulations, 45 CFR 46, Protection of Human Subjects, is available from the Office for Protection from Research Risks, National Institutes of Health, Bethesda, Maryland 20892.

## REVIEW PROCEDURES

Applications will be received under the usual PHS receipt and review schedule. Applications will be reviewed by an initial review group (IRG) consisting primarily of non-Federal scientific and technical experts. Secondary review is by the appropriate national advisory council. Only applications recommended for consideration for funding by the Council may be supported.



Initial review criteria include the following: significance and originality from a scientific or technical standpoint of the goals of the proposed research; adequacy of the methodology proposed to carry out the research; 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 planning for including women and minorities, as applicable.

General award criteria include overall scientific and technical merit of the research as determined by IRG, Council recommendations, program priorities and needs, and availability of funds.

#### MECHANISM OF SUPPORT

The funding mechanisms for this announcement are the traditional research grant (R01), the small grant (R03), and the First Independent Research Support and Transition (FIRST) award (K29). Support may be requested for a period of up to five years. Annual awards will be made subject to continued availability of funds and progress achieved. This announcement does not address applications that fall more appropriately within the mission of other Federal programs (e.g., the National Institute of Justice, the Office of Juvenile Justice and Delinquency Prevention, or the National Science Foundation).

#### APPLICATION PROCEDURES

All research applicants must use the current version of the grant application form PHS 398 (rev. 10/88). Support may be requested for a period of up to five years. Annual awards will be made subject to continued availability of funds and progress achieved. A competing supplemental application may be submitted during an approved period of support to expand the scope or protocol of a project during the approved period. Except for small grants (R03) and First Independent Research Support and Transition awards (R29), a competing continuation (i.e., renewal) application may be submitted before the end of an approved period of support to continue a project.

#### INQUIRIES

For a copy of the Program Announcement, further information, and consultation in preparing research applications, prospective applicants are encouraged to contact:

James Breiling, Ph.D.  
Interpersonal Violence Research Program  
Violence and Traumatic Stress Research Branch  
National Institute of Mental Health  
5600 Fishers Lane, Room 18-105  
Rockville, MD 20857  
Telephone: (301) 443-3728

Further information on grants management issues may be obtained from:

Stephen J. Hudak, Chief  
Grants Management Section  
National Institute of Mental Health  
5600 Fishers Lane, Room 7C-23  
Rockville, MD 20857  
Telephone: (301) 443-4596

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance 93.242. Under the authority of Section 301 of the Public Health Service Act, P.L. 78-410, as amended, 42 U.S.C. 241 (42 CFR part 52), and subject to availability of funds, NIMH will accept research grant applications in response to this announcement, under the receipt dates listed herein.

#### DRUG ABUSE PREVENTION RESEARCH CENTERS

PA: PA-92-04

P.T. 04; K.W. 0404009, 0745027

National Institute on Drug Abuse

#### PURPOSE

The purpose of this announcement by the National Institute on Drug Abuse (NIDA) is to encourage the development of multidisciplinary prevention research centers that will improve our ability to prevent drug abuse through the design and testing under controlled research conditions of promising, theory-based drug preventive interventions.

#### RESEARCH OBJECTIVES

The proposed Centers are designed to: formulate theories of drug use onset and progression and test them through the design and evaluation of theory-based preventive interventions; design preventive interventions appropriate to general populations and sub-populations at risk of drug abuse and test these interventions through controlled randomized studies established in relevant settings to include schools, family homes, institutions, the work

place, and neighborhood organizations; integrate and disseminate the prevention research knowledge base through national leadership in programming and evaluation, research training, and coordination of research planning with other prevention research centers; increase the capacity of the field to conduct prevention research and evaluation; and facilitate the diffusion of research findings and innovative preventive practices to drug abuse researchers, practitioners, and policy makers.

#### MECHANISM OF SUPPORT

Center grants (P50).

#### ELIGIBILITY

Applications may be submitted by public or private, nonprofit or profit-making organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

#### APPLICATION PROCEDURES

Applicants must use the form PHS-398 (rev. 10/88). Drug Abuse Prevention Research Centers (PA-92-04) must be typed in item #2 on the face page of the application form.

Center applications must adhere to the following special page limitations: The overall description of the center, each core, and the research plan for each major research component are limited to 20 pages each. Applications exceeding these page limits will not be accepted.

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  
National Institutes of Health  
Administrative Services  
Westwood Building, Room 436  
5333 Westbard Avenue  
Bethesda, MD 20982  
Telephone: (301) 496-9797

The signed original and six permanent legible copies of the completed application must be sent to:

Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 240  
5333 Westbard Avenue  
Bethesda, MD 20892\*  
Telephone: (301) 496-7441

\*If an overnight courier is used, the zip code is 20816.

#### RECEIPT AND REVIEW SCHEDULE

The receipt and review schedule for applications under this announcement is as follows:

Receipt Dates New/Renewal Date	Initial Review	Advisory Council Review	Earliest Start
Jun 1/Jul 1*	Oct/Nov	Jan/Feb	Apr
Oct 1/Nov 1*	Feb/Mar	May/Jun	Jul
Feb 1/Mar 1*	May/Jun	Sep/Oct	Dec

\*Amended applications (new or renewal) are to be submitted on these dates.

#### 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. Applications must be completed in accordance with the page limitations noted in the APPLICATION PROCEDURES.

Criteria for scientific/technical merit review of applications will include the following: the overall quality, scientific merit, and innovativeness of the research to be done; the likelihood that the work will lead to fundamental advances within the field, to new discoveries, and/or to new technological developments. In addition, the research conducted must center around a highly focused and well-defined hypotheses; the need for and suitability of the Center approach; whether a multidisciplinary Center approach will add significantly to

what could be accomplished through other modes of research support. In this respect, the integration of component projects is of utmost significance and should be explicitly described; the qualifications and scientific credentials of the Center director and constituent project directors will be considered. It is expected that these individuals will be regarded by their peers as leaders in their respective fields; the nature and level of resource commitments from the home institution and from other participant institutions; and plans for interactions with the rest of the sponsoring institution; the feasibility and adequacy of the organizational and administrative plans; the appropriateness of each budget; and the mechanisms to evaluate the Center's progress; the attract and involve young investigators and students who show potential for significant contributions and independent research careers; adequacy of the Center's plans for the protection of human and animal subjects; involvement of minority populations and minority researchers; responsiveness to NIH/ADAMHA policy on the inclusion of women and minorities in study populations.

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

Applications for ADAMHA grants and cooperative agreements are required to include both women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including either women or minorities is provided. This requirement is intended to ensure that research findings will be of benefit to all persons at risk of the disease, disorder, or condition under study. For the purpose of these policies, clinical research involves human studies of etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders or conditions, including but not limited to clinical trials; and minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics).

ADAMHA recognizes that it may not be feasible or appropriate in all clinical research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

Applications should include a description of the composition of the proposed study population by gender and racial/ethnic group, and the rationale for the numbers and kinds of people selected to participate. 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.

Applications should incorporate in their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities in sufficient numbers to permit assessment of differential effects is not feasible or is not appropriate, the reasons for this must be explained and justified. The rationale may relate to the purpose of the research, the health of the subjects, or other compelling circumstances (e.g., if in the only study population available there is a disproportionate representation in terms of age distribution, risk factors, incidence/prevalence, etc. of one gender or minority/majority group). 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 gender and/or minority representation/justification are judged to be inadequate, reviewers will consider this as a deficiency in assigning the priority score to the application. All applications for clinical research submitted to ADAMHA are required to address these policies. ADAMHA funding components will not award grants that do not comply with these policies.

#### AWARD CRITERIA

Applications recommended for approval by the appropriate Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the application as determined by peer review, Institute's program needs, and availability of funds.

#### INQUIRIES

Further information and consultation on Research Center requirements may be obtained from:

Dr. Zili Amsel  
Acting Director, Division of Epidemiology and Prevention Research  
National Institute on Drug Abuse  
Rockville, MD 20857  
Telephone: (301) 443-1514

Additional research program information can be obtained from:

Dr. William Bukoski  
Acting Chief, Prevention Research Branch  
National Institute on Drug Abuse  
Rockville, MD 20857  
Telephone: (301) 443-1514

#### 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 section 310 and 515 of the Public Health Service Act, as amended (42 USC 241 and 290 cc) 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 as implemented through Department of Health and Human Services regulations at 45 CFR Part 100.

MINORITY HIGH SCHOOL STUDENT RESEARCH APPRENTICE PROGRAM

PA: PA-92-05

P.T. 34, FF; K.W. 0502000, 0710030

National Center for Research Resources

Application Receipt Date: December 2, 1991

**BACKGROUND AND OBJECTIVES**

The National Center for Research Resources (NCRR), National Institutes of Health (NIH), currently plans to continue and expand the Minority High School Student Research Apprentice Program (MHSSRAP) in 1992. The purpose of the program is to provide minority high school students with a meaningful experience in various aspects of health-related research in order to stimulate their interest in careers in science.

In FY 1992, the program is expanding the science teacher initiative to include elementary, middle, and junior high school teachers in addition to senior high school teachers. Eligible teachers will still be those who are members of a minority group or who teach a significant number of minority students. Teachers may participate in the program for a second year. The hands-on summer research project must be structured to update the teachers' knowledge and skills in modern research tools and techniques as well as to strengthen their teaching skills.

The experience should provide teachers the opportunity to bring back to the classroom a sense of the excitement of research that would stimulate students to pursue scientific careers. A longer range goal is to establish year round linkages between science teachers, elementary and secondary school students, and biomedical researchers.

Please note, however, that expansion of the program in FY 1992 is contingent on the availability of appropriated funds. Thus, allocations may be reduced below the requested amount. Upon recommendation of the National Advisory Research Resources Council, the NCRR will give preference in making awards to those institutions that can support a summer program having a "critical mass" of at least five or six students.

**ELIGIBILITY**

Eligible institutions are those that were awarded grants during the Federal fiscal year 1991 from either the Biomedical Research Support Grant (BRSRG) Program or the Minority Biomedical Research Support (MBRS) Program. ALL ELIGIBLE INSTITUTIONS, INCLUDING THOSE NOT CURRENTLY OR PREVIOUSLY FUNDED UNDER THE MHSSRAP, ARE STRONGLY ENCOURAGED TO APPLY. Only one application for the Apprentice Program may be submitted by a component of an institution that is the recipient of both the BRSRG and MBRS awards.

Students eligible for support under this program are those who (1) identify themselves as a member of a minority group (i.e., Black, Hispanic, American Indian, Alaskan Native, Pacific Islander, or Asian) that is under represented in biomedical research; (2) are U.S. citizens or have a permanent visa; and (3) are enrolled in high school during the 1991-92 academic year. (Students who will graduate from high school in 1992 are eligible, as is a student who participated in a previous year provided he/she is still enrolled at the high school level.)

**MECHANISM OF SUPPORT**

The mechanism of support for this program will be the NIH grant-in-aid (S03).

Awards will be for one year beginning March 1, 1992, contingent upon availability of appropriated funds. Support will be provided at a level of \$2,000 for each student apprentice and \$5,000 for each science teacher. Applications may request both students and teachers or students only. No indirect costs will be paid. Direct support must be as salary; stipends are not allowed. Funds allocated may also be utilized for supplies, extending the research experience, or if adequate funds exist, for the addition of a student apprentice. However, funds from these grants may only be used for the costs of the apprentice program. The Program Director is responsible for the recruitment and selection of the apprentices, and science teachers and assignment of each to an appropriate investigator.

**Students:**

Recruitment and selection of students must emphasize factors including the student's motivation, ability, scholastic aptitude, and accomplishments. In addition, consideration must be given to science teachers' recommendations and, whenever possible, the degree of parental commitment. Assignments must be made to investigators involved in health-related research who are committed to increasing the high school student's understanding of research and the technical skills needed.

**Teachers:**

Recruitment and selection criteria must include: experience and teaching responsibilities, level of interest in participating in a research program, expected impact on their teaching programs, ability to stimulate minority students to pursue scientific careers, and future plans for continued interaction with the research institution.

## METHOD OF APPLYING

The application consists of (a) a letter stating the justification for the number of student and teacher positions requested (preference will be given to those institutions with a demonstrated commitment and a documented history of encouraging students to pursue scientific careers); (b) the original and one signed and completed copy of the face page, page 4 "Detailed Budget for First 12-Month Budget Period Direct Costs Only," and checklist page of the grant application form PHS 398 (rev. 10/88). The required pages of the PHS 398 application form must be completed according to instructions provided in the PHS 398 (rev. 10/88) kit except for the following:

### Face Page:

Item 1 - Leave blank.

Item 2 - Check the box marked "YES" and indicate the announcement title as "Minority High School Student Research Apprentice Program, PA-92-05."

Items 4, 5, 7b, 8, and 10 - Not applicable; do not complete.

Item 6, Dates of entire proposed project period - Enter 92-03-01 through 93-02-28.

Item 7a - Insert the total dollar amount of the request, which is the sum, from application page 4, of the number of student positions requested times \$2,000 per student and \$5,000 per teacher.

Item 14, Organizational component to receive credit towards a Biomedical Research Support Grant - Use this space to enter the code and the BRSG and/or MBRS grant number(s) on which eligibility for this Minority High School Student Research Apprentice Program application are based (no credit will be given for the S03 application).

Page 4, "Detailed Budget for First 12-Month Budget Period Direct Costs Only" - Using ONLY the Other Expenses category, enter on separate lines the number of students requested at \$2,000 per student and the number of science teachers requested at \$5,000 per teacher. Enter the sum of the amounts requested for each under the "TOTALS" column for the Other Expenses category and under "Total Direct Costs for First 12-Month Budget Period" at the bottom of the page.

The original and one copy of the student and teacher report(s), signed by the Program Director, must be submitted with the renewal application by December 2 so that the data contained in these reports can be used by NCCR to decide about policies and future funding for the Minority High School Student Research Apprentice Program.

These reports must also be submitted at the same time even if renewal support is not requested. All reports, including the Financial Status Report, must be submitted to the NIH by the grantee institution no later than May 31, 1992, unless an extension of the budget period end date has been authorized in writing.

Applications must be received by December 2, 1991 by:

Office of Grants and Contracts Management  
National Center for Research Resources  
National Institutes of Health  
Westwood Building, Room 849  
5333 Westbard Avenue  
Bethesda, MD 20892\*\*

### INQUIRIES

Inquiries can be made of Dr. Marjorie A. Tingle at the above address or by calling (301) 496-6743.

### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.337, Biomedical Research Support. Grants will be awarded under the authority of the Public Health Service Act, Section 301 (a)(3); Public Law 78-410 (42 USC 241) as amended, and administered under PHS grants policies and Federal Regulations 45 CFR 74 and the Guidelines for Minority High School Student Research Apprentice Program. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

### SMALL GRANTS FOR LUNG, BREAST, AND OVARIAN CANCER CLINICAL TRIALS

PA: PA-92-06

P.T. 34, II; K.W. 0715035, 0755015, 0705075

National Cancer Institute

Application Receipt Date: January 23, 1992

### PURPOSE

The National Cancer Institute (NCI) announces the availability of a Program Announcement (PA) to encourage the submission of grant applications for new pilot, phase I, or phase II therapeutic clinical trials that take

advantage of recent laboratory developments in the treatment of lung, breast, and ovarian cancers. New and experienced investigators in relevant fields and disciplines (clinical and surgical oncology) may apply for small grants to test new treatment strategies or do pilot studies.

A PA for solicitation of grant applications is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the NCI. The small grants research program provides limited funds (maximum of \$48,000 direct costs per year) for short-term (up to two years) research projects. They are non-renewable. The present PA is for a single solicitation with a specified deadline (January 23, 1992) for receipt of applications.

#### 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, Small Grants for Lung, Breast, and Ovarian Cancer Clinical Trials, 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 20402-9325 (telephone 202/783-3238).

#### BACKGROUND INFORMATION

While therapeutic advances have been made in the treatment of hematologic malignancies and certain solid tumors, other cancers have not yet yielded to effective treatment and are the focus of continuing research. Carcinomas of the lung, breast, and ovary have been targeted because they are among the leading causes of cancer deaths, accounting for an estimated 200,300 fatalities in 1991. The respiratory system is the most prevalent cancer site accounting for 178,000 estimated new cases in 1991. While the incidence of lung cancer in men has begun to decline, the incidence rate in women continues to increase with lung cancer surpassing breast cancer as the major cause of cancer death in women. The incidence of breast cancer has increased three percent per year since 1980 accounting for 175,900 new cases per year. Ovarian cancer accounts for an estimated 20,700 new cases a year with a five-year survival rate of only 38 percent.

Recent discoveries concerning the role of growth factors, genes that promote and suppress neoplasia, mechanisms of treatment sensitivity and resistance, and the biology of the immune systems have provided the basis for the development of novel and improved cancer treatments. At present there is no mechanism targeted to stimulate the communication of promising and potentially relevant innovative developments between the laboratory and the clinical setting. There is a need for a rapid mechanism to fund short-term studies and obtain preliminary clinical data. These studies may serve as a basis for future clinical grant applications (R01) or NCI cooperative group studies.

#### RESEARCH GOALS AND SCOPE

The aim of this initiative is to stimulate pilot, Phase I, or Phase II therapeutic clinical trials to move new treatment strategies more rapidly from the laboratory into the clinic in the areas of breast, lung, and ovarian cancer.

Clinical studies must involve human subjects and be designed to ultimately improve cancer treatment. New clinical trials dealing with treatment using drugs, biologics, radiation, or surgery, whether used as a single agent/modality or in combination, are appropriate. The clinical studies must be based on a strong rationale and preclinical data should support the underlying hypothesis.

Some examples of categorical areas for R03 studies include: (1) biochemical modulation studies; (2) immunotherapy (e.g., monoclonal antibodies, cytotoxins, vaccines); (3) biological response modifiers in combination with chemotherapy; (4) studies of drug- or hormone- or radiation-resistance and reversal; (5) therapies aimed at interfering with growth factor action; (6) therapies with novel mechanisms of action; and (7) innovative surgically based multimodality studies. Investigators are not limited to the above areas of potential studies.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

#### MECHANISM OF SUPPORT

Support of the program will be through the National Institutes of Health (NIH) grant-in-aid small grants mechanism (R03). Applicants will be responsible for the planning, direction, and execution of the proposed project. All PHS and NIH grants policies will apply to applications received in response to this announcement.

Applications submitted in response to this PA will compete for funds with all other R03 grant applications assigned to the NCI. The award of grants in response to this PA is also contingent upon the availability of funds. The direct costs must not exceed \$48,000 per year. The total project period for applications submitted in response to the present PA may not exceed two years. The earliest feasible start date for the initial award will be September 1992.

#### ELIGIBILITY

Non-profit and for-profit organizations, governments and their agencies, and occasionally individuals are eligible to apply. Applications may be from a single institution or may include arrangements with multiple institutions (e.g., consortia, clinical cooperative group) if appropriate. Both domestic and foreign

institutions may apply. Applications from new and experienced investigators, minority individuals, and women are encouraged.

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

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

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants 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 preventative strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

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

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

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

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

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

#### REVIEW PROCEDURES AND CRITERIA

##### A. REVIEW PROCEDURE

Upon receipt, applications will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Evaluation for responsiveness to the PA is an NCI program staff function. Applications will be judged to determine how well they meet the goals and objectives of the program as described in the PA. Applications that are judged non-responsive or do not meet the minimal mandatory requirements (see Review Criteria) will be returned to the applicant. Applications will be reviewed for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review by NCI program staff considers the application in light of the special needs of the Institute and the priorities of the National Cancer Program. Foreign grant applications will also be reviewed by the National Cancer Advisory Board.

##### B. REVIEW CRITERIA

The customary peer review criteria will be applied for this announcement.

The review group will critically examine the submitted budget and will recommend an appropriate budget and period of support for each approved application.

#### APPLICATION REQUIREMENTS

The application must include the following:

1. Submission of the clinical protocol in the Appendix.
2. Human subjects and animal use approval before an application can be reviewed.
3. Letter of agreement from either the GCRC program director or Principal Investigator if the GCRC is identified as a resource for conducting research.

4. A listing of sources of existing and supplemental financial support. The latter information is to be provided if requested funds will only partially fund the clinical trial.

5. Documentation for the composition of the proposed study population in terms of gender and racial/ethnic group together with a rationale for its choice.

Incomplete applications will be returned to the applicant without review.

#### METHOD OF APPLYING

The research grant application form PHS 398 (revised 10/88) must be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grant Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892; and from the NCI Program Director named below. The title and number of this announcement must be typed in line 2 on the face page of the application.

Submit a signed, typewritten original of the application, including the Checklist, and four signed, exact photocopies, in one package to the Division of Research Grants at the address below. The photocopies must be clear and single sided.

DIVISION OF RESEARCH GRANTS  
National Institutes of Health  
Westwood Building, Room 240  
Bethesda, MD 20892\*\*

At the time of submission, two additional copies of the application should also be sent to:

REFERRAL OFFICER  
Division of Extramural Activities  
National Cancer Institute  
Westwood Building, Room 848  
5333 Westbard Avenue  
Bethesda, MD 20892

Applications must be received by January 23, 1992.

If the application submitted in response to this announcement is substantially similar to a grant application already submitted to the NIH for review, but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. Therefore, an application cannot be submitted in response to this announcement that is essentially identical to one that has already been reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an Introduction addressing the previous critique.

#### INQUIRIES

To obtain a copy of the PA and supplemental instructions, contact the program director, Ms. Diane Bronzert, at the address below. Written and telephone inquiries concerning the objectives and scope of this PA and inquiries about whether or not specific proposed research would be responsive are strongly encouraged and are to be directed to Ms. Bronzert. The program director welcomes the opportunity to clarify any issues or questions from potential applicants.

Ms. Diane Bronzert, Program Director  
Cancer Therapy Evaluation Program  
Division of Cancer Treatment  
National Cancer Institute  
Executive Plaza North, Room 734  
Bethesda, MD 20892  
Telephone: (301) 496-8866  
FAX: (301) 496-9384

Written and telephone inquiries of a budgetary, administrative, and/or policy nature are to be directed to:

Ms. Sara Stone, 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 66  
FAX: (301) 496-8601

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.395, Cancer Treatment Research. Awards are under authorization of the Public Health Service Act, Title IV, Sections 301, 410, and 411, Part A (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.