

# NIH GUIDE

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

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**NOTICES**

**NIH/ADAMHA CHANGES IN THE PEER REVIEW SYSTEM**

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

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

The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), as part of their Financial Management Plans, have initiated several major changes in the peer review system. These changes, which are being implemented beginning with the current round of Initial Review Group meetings, will affect all applications submitted to the NIH and the research Institutes of ADAMHA for funding consideration.

Applications will no longer be "approved" or "disapproved." Instead, each application will receive a score unless the peer review group determines that an application should be deferred for additional information or that it should be "not recommended for further consideration" (NRFC). By definition, NRFC means that an application does not have "significant and substantial merit," and differs from the former term "disapproval" which meant "lacking sufficient merit to warrant funding."

Thus, the NRFC recommendations can be expected to include a greater number/percentage of applications than did "disapprovals."

Of equal importance is the new scale of adjectival descriptors for priority ratings, modified to reflect the new concept of "significant and substantial" merit. These descriptors now cover the following range of scores:

1.0 - 1.5	Outstanding
1.5 - 2.0	Excellent
2.0 - 2.5	Very Good
2.5 - 3.5	Good
3.5 - 5.0	Acceptable

Regardless of the recommendations that are accorded, all applications will be completely and thoroughly reviewed.

Applications that receive the NRFC designation, as well as those whose scores fall within the bottom tier (approximately the last third), usually will not be brought to the National Advisory Councils/Boards for consideration. Councils/Boards will, however, be provided with a complete listing of all applications reviewed, and they may single out any application for individual discussion.

Another new procedure that the NIH and ADAMHA will implement at this time is to inform applicant investigators of the outcome of the initial review of their applications as soon as possible following the meeting of the Initial Review Groups. NIH and ADAMHA will provide this information and the name and telephone number of the staff person responsible for that application. This communication will also inform the applicant that the Summary Statement, containing evaluative comments, will be mailed to the applicant in approximately six to eight weeks. Applicant investigators are requested refrain from communicating with staff concerning the specifics of the review or funding possibilities until after the Summary Statement has been received.

**NOTICE OF ANTICIPATED REQUEST FOR APPLICATIONS**

P.T. 34; K.W. 0785130, 0404000, 0785035

National Center for Nursing Research

The National Center for Nursing Research (NCNR) is considering the release of a Request for Applications (RFA) for P20 grant applications in January, 1992. The RFA would be for Exploratory Centers for Biobehavioral Symptom Management. Eligible institutions will be schools of nursing and departments of nursing within clinical settings. The expected receipt date is May 7, 1992.

Although details will not be available until publication in the NIH Guide, the program contact person is:

Dr. Laura James  
Acute and Chronic Illness Branch  
National Center for Nursing Research

Building 31, Room 5B03  
Bethesda, MD 20892  
Telephone: (301) 496-0523

**CONFERENCE: "AGING--THE QUALITY OF LIFE"**

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

National Institutes of Health

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

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

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

- o Searching for the Fountain of Youth: 500 Years of Research to Understand Aging; Dr. Robert N. Butler, Mt. Sinai Medical Center, New York;
- o Age Associated Changes in Cardiovascular Function in Response to Exercise; Dr. Myron Weisfeldt, Columbia University, New York;
- o Nutrition, Aging and Disease: The Metabolic Crossroads; Dr. Edwin L. Bierman, University of Washington;
- o Drug Metabolism/Pharmacology in the Aging; Dr. Grant R. Wilkenson, Vanderbilt University;
- o The Brain: Lighthouse of the Aging Years; Dr. Fred Plum, Cornell Medical Center;
- o Osteoporosis, Osteoarthritis, and Other Musculoskeletal Disorders in the Elderly; Dr. Lawrence E. Shulman, National Institutes of Health;
- o The Effect of Chronological Age on Cancer Biology and Therapy; Dr. Emil J. Freireich, M.D. Anderson Hospital;
- o Implications of Aging for the Individual and Society; Dr. Robert H. Binstock, Case Western Reserve; and
- o Medicare: What is Covered?/What is not Covered?; Dr. Gail Wilensky, Administrator, Health Care Financing Administration.

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

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

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

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

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

**NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS**

P.T. 42; K.W. 0783005

National Institutes of Health  
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest

in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

**WEST COAST WORKSHOP**

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

**WORKSHOP SITE:** Los Angeles, CA

**SPONSORS:**

University of Southern California  
Los Angeles, CA 90089-4014

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

**REGISTRATION CONTACT:**

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

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

**SOUTH MIDWESTERN WORKSHOP**

**DATES:** February 20 and 21, 1992

**WORKSHOP SITE:** San Antonio, TX

**SPONSORS:**

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

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

**REGISTRATION CONTACT:**

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

**TOPIC:** Identifying and Assessing Risks in Human Subject Research

**SOUTHWEST WORKSHOP**

**DATES:** March 24 and 25, 1992

**WORKSHOP SITE:**

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

**SPONSORS:**

University of New Mexico  
Albuquerque, NM 87131-5126

Navajo Community College  
Shiprock, NM 87420

**REGISTRATION CONTACT:**

University of New Mexico  
Office of Continuing Medical Education  
Health Sciences and Services Building (Room 140)

Box 713  
Albuquerque, NM 87131-5126  
Telephone: (505) 277-3942

TOPIC: Ethics, Justice, and Tribal Participation in Research with American Indians: Basic Training for IRB Members

NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

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

Lincoln University  
Lincoln University, PA 19352

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

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

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

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

**NOTICES OF AVAILABILITY (RFPs AND RFAs)**

**PATHOLOGY AND VETERINARY SUPPORT FOR PRECLINICAL TOXICOLOGY STUDIES**

RFP AVAILABLE: NCI-CM-27726-72

P.T. 34; K.W. 0785165, 0201058, 0740020, 1007009

National Cancer Institute

The Developmental Therapeutics Program (DTP) of the Division of Cancer Treatment of the National Cancer Institute (NCI) will issue a Request for Proposals (RFP) to seek an organization to perform a variety of pathology and veterinary services to support the DTP preclinical toxicology program for anticancer and anti-AIDS drug development. Organizations must have the facilities and staff to carry out these efforts and the management expertise to respond to the diverse needs of this contract. As a minimum requirement, organizations must comply with the FDA current Good Laboratory Practice Regulations. One contract will be awarded and will be administered on a task-managed basis. Task orders will be issued under the "funded cost-reimbursement level of effort" contract resulting from this solicitation. Specific task orders to be issued will involve the following: (1) operation of a repository to hold the pathology materials generated in past and future toxicology studies; (2) performance of an independent verification (quality assessment) of the pathological findings by the study pathologist, especially with respect to drug-relatedness, nomenclature, and slide quality; (3) provision of a pathology support program to prepare blocks and slides and conduct histopathological evaluation of tissues; and conduct site visits to perform necropsies, slide preparation, or to assist the Project Office in project evaluation; (4) storage, maintenance, and shipment of Government infusion equipment to other DTP contractors; (5) development and implementation of new surgical or other procedures for drug administration, instruction in these procedures, and performance of this procedures in actual animal studies; and (6) Performance of site visits to the DTP toxicology contractor laboratories to evaluate animal care programs or to investigate animal care problems. The Principal Investigator must be a board certified veterinary pathologist or veterinarian with at

least three years experience with similar programs.

This is a SMALL BUSINESS SET ASIDE. This effort is currently being performed by Pathology Associates, Inc. under contract N01-CM-87258.

The RFP No. NCI-CM-27726-72 will be available on or about October 31, 1991, with a deadline for receipt of proposals on December 15, 1991. A copy of the RFP may be obtained by written request to:

Ms. Jacqueline Ballard  
Contract Specialist  
National Cancer Institute  
9000 Rockville Pike  
Executive Plaza South, Room 603  
Bethesda, MD 20892

**PRECLINICAL TOXICOLOGY AND PHARMACOLOGY OF DRUGS DEVELOPED FOR CANCER, AIDS, AND AIDS-RELATED ILLNESSES**

RFP AVAILABLE: NCI-CM-27727-72

P.T. 34; K.W. 0710100, 1007009, 0715008, 0715035, 0740020

National Cancer Institute

The Development Therapeutics Program (DTP) of the Division of Cancer Treatment of the National Cancer Institute is seeking organizations to carry out Pharmacology and Toxicology studies, the data from which must be suitable for filing with the Food and Drug Administration as part of Investigational New Drug Applications. Organizations must have the facilities and staff to carry out such studies and the management expertise to analyze and evaluate the data. As a minimum mandatory requirement, the contractor must perform all toxicology studies in accord with the FDA's current Good Laboratory Practices Regulations. Organizations must also indicate their willingness to sign a confidentiality of information statement.

Multiple awards will be made under this solicitation and will be administered on a task-managed basis. Task orders will be issued under the "funded cost- reimbursement level of effort" contracts resulting from this solicitation. Assignments are estimated to involve two to four chemical agents annually per contract. Offerors are required to propose at both levels of effort (46,875 and 93,750 hours over a five-year period). The objectives of the task orders to be issued are: (1) validation of analytical methodology to quantitate drug plasma levels in laboratory animals and to measure levels in rodents and dogs treated with the agent under study; (2) determination of bioavailability of drug after parenteral and/or oral administration, if efficacious drug levels can be attained in plasma in vivo, and if the drug crosses the blood-brain barrier (AIDS drugs); (3) assessment of acute and subacute toxicity in rodents and dogs including determination of a maximum tolerated dose, of dose limiting toxicities, schedule-dependent toxicity, or the reversibility of adverse effects, and of a safe clinical starting dose; (4) the use of pharmacokinetic information to permit extrapolation of toxic effects across species by relating plasma drug levels to the time of appearance and severity of toxicity, and to establish the safety of potentially efficacious doses.

The Principal Investigator must have a doctoral degree in pharmacology/toxicology plus at least three years experience in directing, implementing, and evaluating drug toxicity studies in experimental animals. The pathologist and analytical chemist must likewise have credentials that illustrate their competence and accomplishments in serving as critical team members in the conduct of such studies.

This effort is currently being performed by Battelle Memorial Institute, contract No. N01-CM-97617, Southern Research Institute, contract No. N01-CM-97574, Midwest Research Institute, contract No. N01-CM-87202, and Southern Research Institute, contract No. N01-CM-87259. The Request for Proposals (RFP) No. NCI-CM-27727-72 will be available on about November 4, 1991, with a deadline for receipt of proposals on January 3, 1992. A copy of the RFP may be obtained by written request to:

Ms. Jacqueline Ballard,  
Contract Specialist  
National Cancer Institute  
9000 Rockville Pike  
Executive Plaza South, Room 603,  
Bethesda, MD 20892  
No collect calls will be accepted.

**SURVEILLANCE EPIDEMIOLOGY AND END RESULTS EXPANSION**

RFP AVAILABLE: NCI-CN-25403-41

P.T. 34; K.W. 0715035, 0785055, 0755018

National Cancer Institute

The National Cancer Institute, Division of Cancer Prevention and Control, is soliciting proposals for an expansion of the Surveillance, Epidemiology and End Results Program (SEER). The thrust of this proposed project

is to: (1) obtain within the geographic area of coverage, data on all newly diagnosed cases of cancer beginning January 1, 1991 forward; (2) obtain cancer patient survival data on all cases diagnosed in 1991 forward; (3) monitor trends in the incidence of specific forms of cancer, particularly with respect to demographic and social characteristics of the populations; and (4) assess the completeness and accuracy of all data collected. It is anticipated that offerors must provide documentation of authority to collect data for their identified coverage area and be required to have a Hispanic population of at least 300,000 in their coverage area.

Requests for this Requests for Proposals (RFP) must be in writing and reference RFP No. NCI-CN-25403-41. The RFP will be available approximately October 15, 1991, and proposals will be due approximately December 2, 1991.

Copies of the RFP may be obtained by sending a written request to:

Susan K. Hoffman, Contracting Officer  
National Cancer Institute  
Research Contracts Branch, PCCS  
Executive Plaza South, Room 635  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-8603

**PRECLINICAL TOXICOLOGY AND PHARMACOLOGY OF DRUGS DEVELOPED FOR CANCER, AIDS, AND AIDS-RELATED ILLNESSES (SMALL BUSINESS SET-ASIDE)**

RFP AVAILABLE: NCI-CM-27729-72

P.T. 34; K.W. 0710100, 1007009, 0715008, 0715035, 0740020

National Cancer Institute

The Developmental Therapeutics Program (DTP) of the Division of Cancer Treatment of the National Cancer Institute is seeking organizations to carry out pharmacology and toxicology studies, the data from which must be suitable for filing with the Food and Drug Administration as part of Investigational New Drug Applications. Organizations must have the facilities and staff to carry out such studies and the management expertise to analyze and evaluate the data. As a minimum mandatory requirement, the contractor must perform all toxicology studies in accord with the FDA current Good Laboratory Practice Regulations. Organizations must also indicate their willingness to sign a confidentiality of information statement. One contract will be awarded and will be administered on a task managed basis. Task orders will be issued under the "funded cost-reimbursement level of effort" contract resulting from this solicitation. Assignments are estimated to involve two to four chemical agents annually per contract. Offerors are required to propose at both levels of effort (46,875 and 93,750 hours over a five-year period). The objectives of the task orders to be issued are: (1) validation of analytical methodology to quantitate drug plasma level in laboratory animals and to measure levels in rodents and dogs treated with the agent under study; (2) determination of bioavailability of drugs after parenteral and/or oral administration, if efficacious drug levels can be attained in plasma in vivo, and if the drug crosses the blood-brain barrier (AIDS drugs); (3) assessment of acute and subacute toxicity in rodents and dogs including determination of a maximum tolerated dose, of dose limiting toxicities, schedule-dependent toxicity, or the reversibility of adverse effects and of a safe clinical starting dose; (4) the use of pharmacokinetic information to permit extrapolation of toxic effects across species by relating plasma drug levels to the time of appearance and severity of toxicity, and to establish the safety of potentially efficacious doses.

The Principal Investigator must have a doctoral degree in pharmacology/toxicology plus at least three years experience in directing, implementing, and evaluating drug toxicity studies in experimental animals. The pathologist and analytical chemist must likewise have credentials that illustrate their competence and accomplishments in serving as critical team members in the conduct of such studies.

This is a SMALL BUSINESS SETASIDE. This effort is currently being performed by Springborn Life Sciences, Inc. under contract No. N01-CM-87256.

The Request for Proposals (RFP) No. NCI-CM-27729-72 will be available on or about October 31, 1991, with a deadline for proposals on December 30, 1991. A copy of the RFP may be obtained by written request to:

Ms. Jacqueline Ballard, Contract Specialist  
National Cancer Institute  
9000 Rockville Pike  
Executive Plaza South, Room 603  
Bethesda, MD 20892

**REFERENCE LABORATORY FOR NON-TUBERCULOUS ATYPICAL MYCOBACTERIA ISOLATED FROM AIDS PATIENTS**

RFP AVAILABLE: NIH-NIAID-DAIDS-92-04

P.T. 34; K.W. 0780000, 0715008, 1002027

National Institute of Allergy and Infectious Diseases



The Clinical Research Program of the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID) has a requirement for a centralized facility for identification and susceptibility testing of clinically important non-tuberculous mycobacteria. Such a facility would also serve as a microbiologic repository, maintaining a collection of clinical isolates for future analysis. The contractor would perform quantitative cultures of clinical specimens obtained from studies sponsored by DAIDS, perform antibiotic susceptibility testing on clinical isolates, and provide support for epidemiological studies of mycobacterial infection and ecological distribution. This contract will be a significant resource for monitoring eligibility and outcomes of clinical trials sponsored by the AIDS Clinical Trials Group and the Community Program for Clinical Research on AIDS aimed at the treatment and prophylaxis of disease caused by non-tuberculous mycobacteria (primarily *M. avium* complex), as well as for natural history studies sponsored by DAIDS.

This NIAID-sponsored project will take approximately five years to complete. A cost-reimbursement contract is anticipated and one award will be made.

This is an announcement for an anticipated Request for Proposals (RFP). RFP-NIH-NIAID-DAIDS-92-04 shall be issued on or about November 1, 1991, with a closing date tentatively set for January 6, 1992. Requests for the RFP shall be directed in writing to:

Phillip Hastings  
Contract Management Branch,  
National Institute of Allergy and Infectious Diseases  
Control Data Corp. Building  
6003 Executive Blvd., Room 3C07  
Bethesda, MD 20892

To receive a copy of the RFP, please supply this office with two self-addressed labels. All responsible sources may submit a proposal that will be considered. This advertisement does not commit the Government to award a contract.

#### MASTER AGREEMENT FOR CHEMICAL SYNTHESIS

MASTER AGREEMENT ANNOUNCEMENT AVAILABLE: NCI-CM-27730-28

P.T. 34; K.W. 1003006, 1003012

National Cancer Institute

The Drug Synthesis and Chemistry Branch Developmental Therapeutics Program, Division of Cancer Treatment, National Cancer Institute (NCI), is interested in receiving proposals from, and establishing Master Agreements (MAs) with, offerors who have the capability to provide services for the synthesis of a variety of organic/inorganic compounds. This is a recompetition of the project, "Master Agreement for Chemical Synthesis." Current holders of Master Agreements are the University of Alabama, H.G. Pars Pharmaceutical Laboratories, Research Triangle Institute, Ricerca, Inc., Southern Research Institute, Starks Associates, SRI International, and the Department of Scientific and Industrial Research.

It is planned that agreements negotiated as a result of this solicitation will be awarded for a five-year period beginning September 30, 1992. A Master Agreement (MA) is the instrument issued to sources who respond to a Master Agreement Announcement (MAA), and who are judged to be qualified to compete for future orders issued under the general project area or areas described in the MA. MAs are competitively negotiated and awarded to more than one organization. The MAs will not be funded per se; however, MA holders will be invited to propose competitively on Master Agreement Orders (MAOs) as they are issued. Each MAO will be designed to accomplish a specific task as promptly as possible. An MAO is a bilateral award document issued to the MA holder who successfully competed for the requirements described in a MAA RFP. Individual MAOs will be issued on either a completion or term (level of effort) basis, whichever is deemed appropriate by the Contracting Officer.

The objective of this project is the resynthesis of known compounds of varying degrees of complexity for confirmatory testing, the synthesis of unique compounds with reported biological activity, the resynthesis of compounds identified by in vitro anti-cancer and anti-AIDS screens as candidates for secondary testing, and the synthesis of unique compounds in support of The NCI intramural program.

Master Agreement Announcement (MAA) No. NCI-CM-27730-28 will be available on or about October 30, 1991, and proposals will be due approximately six weeks thereafter.

Copies of the MAA may be obtained by sending a written request to:

Ms. Carolyn E. Barker, Contract Specialist  
Research Contracts Branch, TCS  
National Cancer Institute  
Executive Plaza South, Room 603  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-8620

## CLINICAL TRIALS OF CANCER THERAPY WITH BIOLOGICAL RESPONSE MODIFIERS

RFA AVAILABLE: CA-92-01

P.T. 34; K.W. 0740015, 0755015, 0715035

National Cancer Institute

Letter of Intent Receipt Date: November 20, 1991

Application Receipt Date: January 22, 1992

### PURPOSE

The Biological Response Modifiers Program (BRMP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI), announces the availability of a Request for Applications (RFA) to establish cooperative agreements for clinical trials of cancer therapy with biological response modifiers (BRMs). These cooperative agreements are designed to foster innovative clinical trials of BRMs by peer-reviewed groups of highly experienced clinical and preclinical investigators who have the unique technical capabilities necessary for such trials. The "Research Goals and Scope" of this RFA will require a novel plan for early clinical development of a given new agent or agents, adequately supported by the applicant's own prior preclinical and, if available, clinical results. The application must describe how its objectives are in accord with the applicant's own interests and experience. The applicant must provide evidence of access to the agent(s) proposed for study. A detailed protocol for an initial clinical trial must also be included. The NCI will facilitate the institution of a peer-reviewed, investigator-initiated trial, participating according to Terms of Cooperation outlined in the RFA.

Each Clinical Trials of Cancer Therapy with Biological Response Modifiers (CATBRM) study group will be composed of: a Principal Investigator; one or more laboratory programs, each headed by a Program Leader with the demonstrated expertise to design and carry out assays for the appropriate monitoring of patients on the study; one or more clinical programs, each headed by a Program Leader with demonstrated expertise in conducting clinical trials of BRMs; and the NCI Program Director. The application may include investigators from one or more academic, nonprofit, and/or commercial institutions. This RFA may provide an opportunity to develop agents identified in National Cooperative Drug Discovery Groups, program projects (PO1s), or individual research grants (RO1s).

### HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This RFA, Clinical Trials of Cancer Therapy with Biological Response Modifiers, 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).

### ELIGIBILITY REQUIREMENTS

Applying groups may include members from academic, non-profit, and for-profit institutions. Involvement of intramural NIH personnel is limited as described in the RFA. Domestic and foreign organizations and institutions (non-profit and for-profit) are eligible, and domestic applications may include components outside the United States. Governments and their agencies are also eligible. Applications from women and members of minority groups are encouraged.

### MECHANISM OF SUPPORT

Awards will be made as cooperative agreements (U01). In cooperative agreements, unlike traditional research grants, substantial NCI programmatic involvement with the recipient during performance of the planned activity is anticipated. The nature of NCI staff involvement is described in the RFA. Applicants will be responsible for the planning, direction, and execution of the proposed project. Specifically, the CATBRM study group is responsive to the requirements and conditions set forth in the RFA. The Principal Investigator defines the details for the project in accordance with the Terms of Cooperation, retains primary responsibility for the performance of the activity, and agrees to accept close coordination, cooperation, and assistance of NCI extramural staff (through the NCI Program Director) in all aspects of scientific and technical management of the project. However, there is no intent, real or implied, for NCI staff to direct CATBRM activities or to limit the freedom of investigators.

This RFA is a one-time solicitation. Future unsolicited competing renewal applications will compete as research project applications with all other investigator-initiated applications. However, if the NCI determines that there is sufficient continuing program need, the NCI will invite recipients of awards under this RFA to submit competitive continuation cooperative agreement applications for review.

Applicants may request no more than four years of support. The earliest possible starting date for the initial annual period will be July 1, 1992.

## FUNDS AVAILABLE

The NCI plans to make up to five awards for project periods up to four years, and has set aside one million dollars total costs for the initial year funding. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the National Cancer Institute, awards pursuant to this RFA are contingent upon continuing availability of funds.

## 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 RFA label available in the most recent revision of the application form PHS 398 (rev. 10/88 and reprinted 9/89) must be affixed to the bottom of the face page. The title and number of this announcement must be typed in Item 2 on the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

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

## LETTER OF INTENT

Prospective applicants are asked to submit, by November 20, 1991, a letter of intent that includes a descriptive title of the proposed research, and if possible, names and institutional affiliations of members of the proposed study group. The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed. The letter of intent does not commit the sender to submit an application, nor is it a requirement for submission of an application, and does not enter into the review of an application subsequently submitted.

## INQUIRIES

For additional technical information, to request a copy of the RFA, and to submit a letter of intent, contact:

Jon Holmlund, M.D.  
Program Director, Biological Resources Branch  
Biological Response Modifiers Program  
National Cancer Institute  
Building 1052, Room 253  
Frederick, MD 21702-1201  
Telephone: (301) 846-1098  
FAX: (301) 846-5429

For business information, contact:

Carolyn Mason  
Grants Management Specialist  
Grants Administration Branch  
National Cancer Institute  
Executive Plaza South, Room 242  
6120 Executive Boulevard  
Bethesda, MD 20892  
Telephone: (301) 496-7800, Extension 59  
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 made under authorization of the Public Health Service Act, Title IV Sections 301, 410, and 411, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285(a.)), 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.

## MECHANISMS UNDERLYING CORONARY HEART DISEASE IN BLACKS

RFA AVAILABLE: HL-92-01-H

P.T. 34, FC; K.W. 0715040, 0755030

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: April 1, 1991

Application Receipt Date: May 6, 1992

PURPOSE

The Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute (NHLBI), announces the availability of a Request for Applications (RFA) and invites grant applications for up to five years of support for research to elucidate mechanisms underlying the clinical presentation, course, and outcome of coronary heart disease (CHD) in black Americans. Ultimately, insights gained may refine current understanding of CHD and provide strategies for more precise preventive and therapeutic interventions for the population at risk.

The program is open to all investigators. All applicants must have access to black patients and fluids or tissues suitable for molecular and cellular studies. Animal studies must have clear justification in terms of significance for understanding the disease process in blacks.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Mechanisms Underlying Coronary Heart Disease in Blacks, is related to the priority area of heart disease and stroke. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-0074-0) 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 for-profit and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional, individual research project grant (R01). Although approximately \$1.5 million in total costs for this program is included in the financial plans for fiscal year 1992, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that five to six grants will be awarded under this program. The specific number to be funded, however, will depend on the merit and scope of applications received and the availability of funds.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to inclusion of women and minorities in study populations. This RFA focusses on one minority group, black Americans and men and women should be included. Where gender considerations are not attended to in a given study, a clear reason for their exclusion must be provided. Applications without such documentation will not be accepted for review.

REVIEW PROCEDURES

Upon receipt, applications will be reviewed for responsiveness to the objectives of this RFA. Applications judged to be responsive will be reviewed for scientific and technical merit by an initial review group that will be convened by the Division of Extramural Affairs, NHLBI, solely to review these applications.

METHOD OF APPLYING

Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes identification of any other participating investigators and institutions and a descriptive title. The National Heart, Lung, and Blood Institute requests such letters only for the purpose of providing an indication of the number and scope of applications to be received and, therefore, usually does not acknowledge their receipt. A letter of intent is not binding, and it will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for application. This letter of intent is to be received no later than April 1, 1992, and is to be sent to:

Dr. Charles Turbyfill  
Review Branch/Division of Extramural Affairs  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Westwood Building, Room 553  
Bethesda, MD 20892

## Format for Applications

Submit applications on form PHS 398 (revised 10/88) the application form for the traditional research project grant. This form is available in the applicant institution's office of sponsored research or business office and the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

## INQUIRIES

Inquiries regarding this program and requests for the RFA document may be addressed to:

Patrice Desvigne-Nickens, M.D.  
Cardiac Diseases Branch  
Division of Heart and Vascular Diseases  
National Heart, Lung, and Blood Institute  
Federal Building, Room 3C06  
Bethesda, MD 20892  
Telephone: (301) 496-1081  
FAX: (301) 480-6282

For fiscal and administrative matters, contact:

Marie Willett  
Chief, Heart and Vascular Grants Management Section  
Division of Extramural Affairs  
National Heart, Lung, and Blood Institute  
Westwood Building, Room 4A11C  
Bethesda, MD 20892  
Telephone: (301) 496-7536

## AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Number 93.837, Heart and Vascular Diseases. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal regulations, most specifically 42 CFR part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

## CELLULAR AND MOLECULAR MECHANISMS OF PLACENTAL NUTRIENT TRANSPORT

RFA AVAILABLE: HD-92-05

P.T. 34; K.W. 1002004, 1002008, 0705060, 0710095

National Institute of Child Health and Human Development

Application Receipt Date: March 17, 1992

## PURPOSE

The Endocrinology, Nutrition, and Growth Branch and the Pregnancy and Perinatology Branch of the Center for Research for Mothers and Children of the National Institute of Child Health and Human Development (NICHD) announce the availability of a Request for Applications (RFA) on cellular and molecular mechanisms of placental transport.

Maternal-fetal nutrition is one of the most important research programs of the NICHD, especially from a preventive point of view. By encouraging research grant applications that focus on the cellular and molecular mechanisms of the placenta that transport nutrients from the maternal compartment to the fetal compartment, the NICHD hopes to increase the understanding of the etiology of intrauterine growth retardation, an important clinical problem that is poorly understood.

## HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Cellular and Molecular Mechanisms of Placental Nutrient Transport, is related to the priority areas of nutrition and 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, D.C. 20402-9325 (telephone 202-783-3238).

## ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and nonprofit, public and private organizations, such as universities, colleges, hospitals, laboratories, units of State or local governments, and

eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

#### MECHANISM OF SUPPORT

Applications in response to this RFA will be funded through the traditional individual research award (R01) program of the NIH. This announcement is for a single competition with the application receipt deadline of March 17, 1992. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed by a Division of Research Grants study section. If the NICHD determines that there is a sufficient continuing program need, the NICHD may announce a request for competitive continuation applications. The total project period for applications submitted in response to the present RFA may not exceed five years. The earliest anticipated award date is December 1, 1992.

#### FUNDS AVAILABLE

It is anticipated that five grants will be awarded under this program, contingent upon receipt of a sufficient number of meritorious applications and the availability of funds. To fund these awards \$700,000 has been set aside for direct costs in the first year.

#### RESEARCH OBJECTIVES

Every year approximately 100,000 babies who are small for their gestational age are born in this country. A disproportionate number of these small, growth-retarded babies die of sudden infant death syndrome. Although intrauterine growth retardation (IUGR) is a heterogeneous condition, these babies have all experienced some degree of impaired placental nutrient transport. Placental infarction, circulatory defects, hypoxia, maternal hypertension, and hyperthermia all impair placental nutrient transport. However, little is known of the specific cellular and molecular mechanisms that govern the placental transport of nutrients and how these mechanisms are impacted by physiologic insults.

A number of investigators have described the intercompartmental fluxes and the net movements of glucose, amino acids, and other substrates across the placenta from maternal to fetal compartments, primarily in animal models. The field now needs to ascertain the cellular and subcellular mechanisms responsible for the placental transport of amino acids, glucose, lipids, electrolytes, and micronutrients. Ultimately this research may lead to identification of the genes governing these nutrient transport systems. The discovery of a set of genetic defects of placental transport systems can be envisioned, leading to an understanding of maternal and possibly also paternal contributions to the development of placental nutrient transport systems. From a preventive point of view, future studies may focus on genetic testing of couples who have had infants afflicted with IUGR in order to identify potential defects of nutrient transport in subsequent pregnancies.

The placental transport of vitamins and trace elements, in particular, is poorly understood. Trace elements that play important roles during fetal development include: iron, iodine, zinc, copper, selenium, manganese, molybdenum, chromium, fluoride, and cobalt. Other trace elements that may also act as essential micronutrients during pregnancy include nickel, vanadium, silicon, arsenic, boron, lithium, and possibly cadmium, lead, and tin. The central nervous system and the immune system are especially vulnerable to trace element deficiencies during fetal life. Studies of the transport of trace elements merit priority attention, especially studies that address the molecular mechanisms that determine changes in their fractional absorption and excretion. Recent advances in mass spectrometry have opened the door to the *in vivo* research that is necessary in order to achieve better estimates of micronutrient transfer across the placenta. Better understanding of the rate of accumulation of trace elements by the fetus *in utero* is an important prerequisite for the estimation of the special requirements of the premature infant.

Although clinical studies of nutrient transport in pregnant women are desirable, it is recognized that studies that can be performed in non-pregnant volunteers may not be permissible in pregnant women, and many nutritional studies in pregnancy can only be carried out in animal models. *In vitro* studies of the control of the genetic transcription of nutrient transport proteins are also encouraged.

#### STUDY POPULATIONS

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

#### REVIEW CONSIDERATIONS

Applications will be reviewed by NICHD staff for responsiveness to the RFA. Applications judged to be nonresponsive will be returned. Following review by an NICHD Initial Review Group, applications will be evaluated by the NICHD Advisory Council for program relevance and policy issues before awards for meritorious applications are made.

#### APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 10/88, reprinted 9/89) must be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda,

MD 20892, telephone (301) 496-7441.

Applications must be received by March 17, 1992. If an application is received after that date, it will be returned to the applicant.

#### INQUIRIES

The RFA contains important information for applicants and may be requested from the contacts listed below. Written and telephone inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcomed.

Direct inquiries regarding programmatic issues to:

Gilman D. Grave, M.D.  
Chief, Endocrinology, Nutrition and Growth Branch  
Center for Research for Mothers and Children  
National Institute of Child Health and Human Development  
Executive Plaza North, Room 637  
Bethesda, MD 20892  
Telephone: (301) 496-5593

OR

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

Direct inquiries regarding fiscal matters to:

Mr. E. Douglas Shawver  
Office of Grants and Contracts  
National Institute of Child Health and Human Development  
Executive Plaza North, Room 501  
Bethesda, MD 20892  
Telephone: (301) 496-1303

#### AUTHORITY AND REGULATIONS

This program is described in the catalog of Federal Domestic Assistance No. 93.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241), and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.

#### ONGOING PROGRAM ANNOUNCEMENTS

##### RESEARCH GRANTS ON ALCOHOL AND IMMUNOLOGY INCLUDING ACQUIRED IMMUNODEFICIENCY SYNDROME

PA AVAILABLE: PA-92-12

P.T. 34; K.W. 0404003, 0715008, 0710070, 0785055

National Institute on Alcohol Abuse and Alcoholism

#### PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) announces the availability of a Program Announcement (PA) to seek basic and applied research grant applications to study the mechanisms of immunologic dysfunction associated with alcohol consumption. Grant support is available to develop knowledge in a wide range of areas relevant to alcohol abuse and alcoholism. Clinical studies and studies in experimental animals have shown that chronic use of alcohol can result in impairment of cell mediated and humoral immunity. However, the mechanisms for ethanol-induced immunosuppression remain to be elucidated. NIAAA is interested in stimulating multifaceted research efforts to study the potential role of excessive and moderate alcohol consumption on increased susceptibility to infections, including the human immunodeficiency virus (HIV); impairments to host defense mechanisms; impairments in the development of offspring immunocompetence due to in utero and/or lactational exposure; autoimmune diseases; increased susceptibility to certain types of cancers; and neurologic disorders resulting from HIV infection. Epidemiologic studies include the ascertainment of reliable and valid general population estimates of alcohol-related medical consequences such as alcoholic liver disease and prevalence of HIV infection in special populations. The PA solicits the submission of applications from investigators in the clinical, epidemiological, and basic science fields to compete for funds for the study of

the relationship between alcohol and immunological dysfunction.

#### 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 is related to the priority area of alcohol abuse reduction. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-783-3238).

#### ELIGIBILITY

Applications may be submitted by non-profit and for-profit organizations, public and private, 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.

#### MECHANISM OF SUPPORT

Research support may be requested through applications for a traditional research grant (R01), small grant (R03), and First Independent Research Support and Transition (FIRST) award (R29). Specialized announcements for the FIRST Award program (R29) and the small grant program (R03) are available from the National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, MD 20852, telephone: (301) 468-2600.

Applicants may request support for up to five years except for small grants are limited to two years. FIRST awards and small grants are not renewable.

#### AVAILABILITY OF FUNDS

In FY 1992, the NIAAA estimates that approximately \$2,000,000 will be available to support approximately ten new grants under this announcement. However, the amount of funding available will depend on appropriated funds and program priorities at the time of the award.

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

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

#### APPLICATION PROCESS

Applicants must use the current version of grant application form PHS 398 (rev. 10/88). The number and title of this program announcement, PA-92-XX Research Grants on Alcohol and Immunology, Including AIDS, must be typed in item number 2 on the face page of the PHS 398 application form.

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:

National Clearinghouse for Alcohol and Drug Information  
P.O. Box 2345  
Rockville, MD 20852  
Telephone: (301) 468-2600

For AIDS-related applications, the signed original and 23 permanent, legible copies of the completed application must be sent to the address listed below. The number of copies of appendix materials to be sent is six. Applicants who do not submit 23 copies of the application will be requested to do so. If applicants do not submit the required copies by the specified date, their applications will be deferred until the next special AIDS review cycle.

For non-AIDS-related applications, the signed original and six permanent, legible copies of the completed application must be submitted.

All applications, AIDS-related and non-AIDS-related applications, must be sent to:

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

\*\* If an overnight carrier or Express Mail is used, the Zip Code is 20816.



## REVIEW PROCESS

Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Results of the review will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate national advisory council, whose review may be based on policy considerations as well as scientific merit. Only applications recommended by the Council may be considered for funding.

## AWARD CRITERIA

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

## TERMS AND CONDITIONS OF SUPPORT

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.

Grants must be administered in accordance with the PHS Grants Policy Statement (Rev. October 1990).

## CONSULTATION AND FURTHER INFORMATION

Potential applicants are encouraged to request a copy of the PA and seek preapplication consultation by contacting the individuals listed below. Direct inquiries relating to program issues to:

### Division of Basic Research

Leslie Isaki, Ph.D.  
Biomedical Research Branch  
Division of Basic Research  
National Institute on Alcohol Abuse and Alcoholism  
Parklawn Building, Room 16C-05  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-4223

Ellen Witt, Ph.D.  
Neurosciences and Behavioral Research Branch  
Division of Basic Research  
National Institute on Alcohol Abuse and Alcoholism  
Parklawn Building, Room 16C-05  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-4223

### Division of Biometry and Epidemiology

Mary C. Dufour, M.D., M.P.H.  
Chief, Epidemiology Branch  
Division of Biometry and Epidemiology  
National Institute on Alcohol Abuse and Alcoholism  
Parklawn Building, Room 14C-26  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-4897

### Division of Clinical and Prevention Research

Heather Miller, Ph.D.  
Prevention Research Branch  
Division of Clinical and Prevention Research  
National Institute on Alcohol Abuse and Alcoholism  
Parklawn Building, Room 13C-23  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-1677

Direct inquiries regarding fiscal matters to:

Elsie Fleming  
Grants Management Branch  
Office of Planning and Resource Management  
National Institute on Alcohol Abuse and Alcoholism  
Parklawn Building, Room 16-86  
5600 Fishers Lane  
Rockville, MD 20857

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.273. Awards are made under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb). Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

#### SMALL RESEARCH GRANTS FOR DATA ANALYSIS

PA: PA-92-13

P.T. 34; K.W. 0755018, 0755015, 0413000, 1002046

National Eye Institute

#### PURPOSE

The National Eye Institute (NEI) Small Research Grants for Data Analysis are intended to provide limited support for meritorious research projects that involve secondary analyses of research data generated from clinical trials, population research, and other applied clinical vision research projects supported by the NEI. Analysis of existing clinical vision research data derived from other sources can also be supported under this program, but secondary analysis of data derived from NEI supported studies are of higher programmatic interest.

#### ELIGIBILITY REQUIREMENTS

Domestic non-profit and for-profit organizations, public and private, and eligible agencies of the federal Government are eligible to apply. Foreign institutions are ineligible.

#### RESEARCH OBJECTIVES

The NEI supports an extensive portfolio of clinical trials and epidemiologic research projects that result in the gathering of large amounts of data essential to the specific aims of these projects. In addition to generating and analyzing the data required to answer the main hypothesis, these types of studies often present unique opportunities to look for unusual or unanticipated outcomes. In the past, there has been no mechanism specifically targeted for the support of secondary data analyses. The NEI is instituting this small research grants program to provide investigators the opportunity to conduct such secondary analyses using available clinical vision research data bases.

The proposed project may be related to, but must be distinctly different from, the specific aims of other funded research projects or pending applications or proposals. New data collection activities will not be supported by these awards. The award is limited to the processing and analysis of data that have already been collected.

Investigators must take special care to specify the hypotheses that are to be tested in the proposed research. General, non-hypothesis driven approaches to data analysis are discouraged; hypothesis generating research is appropriate, if carefully described and justified.

#### MECHANISM OF SUPPORT

The mechanism of support will be the NIH small research grant (R03). Applicants may request up to \$50,000 (direct costs) per year for a maximum two-year grant period for technical assistance, supplies, computer usage, and limited travel for collaborative effort required by the project. Salary support for the Principal Investigator may be requested only in unusual circumstances, and then only with very strong justification. Equipment purchases are not allowed. Requests for limited travel funds will be considered by staff when strong justification is provided. Examples of travel that may be permitted are for collaboration and consultation in the preparation of a manuscript for publication and to scientific meetings to present accepted abstracts and/or posters directly related to the research activity. These are one-time, non-renewable awards.

#### REVIEW PROCEDURES AND CRITERIA

##### Review Procedures

The Vision Research Review Committee, administered by the Review and Special Projects Officer, NEI, will conduct the initial scientific merit review of applications submitted in response to this announcement. Second-level

review will be provided by the National Advisory Eye Council.

#### Review Criteria

The factors to be considered in assessing the merit of applications will include:

- o The scientific merit of the proposed project, including the clarity, significance, and originality of the hypotheses to be tested; the feasibility of the proposed analytical methods; and the adequacy of the data set for testing the stated hypotheses;
- o The qualifications of the investigator(s) to accomplish the proposed research goals and the appropriateness of the effort each will devote to the project;
- o The adequacy of facilities and resources for performance of the proposed research;
- o Documentation that the Principal Investigator will have access to the data to be analyzed; and,
- o Demonstration that the investigator(s) has(ve) an understanding of the extent and limits of the data base and how these factors may affect the proposed research.

#### APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 10/88) following the instructions supplied with this form (pages 12-23) and the additional instructions that are given below.

These forms are available at most institutional business offices and may be obtained from the Office of Grant Inquiries, Division of Research Grants, Westwood Building Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301/496-7441.

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

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

In order to expedite the review of the application, at the same time, please mail or deliver TWO additional complete copies of the application to:

Janet M. Cuca, Ph.D.  
Review and Special Projects Officer  
National Eye Institute  
Building 31, Room 6A06  
9000 Rockville Pike  
Bethesda, MD 20892

#### ADDITIONAL APPLICATION INSTRUCTIONS

##### Section 1.

(Form Page 1)

Item 2: Check "YES" and enter: NEI Small Research Grants  
for Data Analysis, PA-92-13

Item 6: A maximum of two years of support may be requested.

(Form Pages 4 and 5) Provide a detailed budget for each year of support requested. Equipment purchases are not allowed. Salary for the Principal Investigator is allowed only in unusual circumstances and with substantial justification. The total award request for a two-year period may not exceed a maximum of \$100,000 direct costs, or \$50,000 direct costs per year.

Biographical Sketch: This section may not exceed one page for each key investigator.

##### Section 2.

##### Research Plan

A. Specific Aims: Not to exceed one-half page.

B. Background and Significance: Not to exceed one page.

C. Progress Report/Preliminary Studies: A progress report is not applicable. If data from preliminary studies are available, the report may not exceed one page.

D. Experimental Design and Methods: Not to exceed five pages, with a maximum of two pages devoted to a description of the data set(s) proposed for analysis to allow an evaluation of the quality and extent of the data available.

H. Consortium/Contractual Arrangements: Not to exceed one and one-half pages. Documentation of access to the data must be provided in this section.

I. Literature Cited: Not to exceed one page.

#### RECEIPT, REVIEW, AND AWARD SCHEDULE

Receipt dates are February 1, June 1, and October 1. The NEI will attempt to have these applications reviewed and awarded within five to seven months of the receipt date. However, this expedited schedule will be possible only if investigators, as requested above, submit the requested two additional complete copies of the application to Dr. Cuca.

#### INQUIRIES

Written and telephone inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcomed. For further information regarding the initial scientific review, prospective applicants may contact Dr. Janet Cuca at (301) 496-5561.

For inquiries about the programmatic aspects of this announcement, applicants may contact:

Richard L. Mowery, Ph.D.  
Chief, Collaborative Clinical Research Branch  
National Eye Institute  
Building 31, Room 6A49  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-5983

Natalie Kurinij, Ph.D.  
National Eye Institute  
Building 31, Room 6A49  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-5983

Donald Everett, M.A.  
National Eye Institute  
Building 31, Room 6A49  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-5983

For grants administration information, applicants may contact:

Ms. Gaye Lynch  
National Eye Institute  
Building 31, Room 6A48  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-5884

#### AUTHORITY AND REGULATIONS

Awards will be made under the authority 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, most specifically at 42 CFR Part 52 and CFR Part 74. This program is not subject to inter-governmental review requirements of Executive Order 12372 or Health Systems Agency review.

#### MODEL CANCER CONTROL DELIVERY SYSTEMS

PA: PA-92-14

P.T. 34; K.W. 0715035, 0795003, 0403004, 0745027

National Cancer Institute

#### PURPOSE

The National Cancer Institute invites applications for studies to develop, implement, and evaluate effective organizational models for integrating cancer prevention and early detection services into existing prevention

and primary care services being provided by health care systems such as community and migrant health centers, public health clinics, and public and university hospitals. Projects must focus on the organizational settings in which health care is delivered to low income, minority, and medically disadvantaged populations and how these settings can be adapted to enhance delivery of cancer prevention and control services.

#### 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, Model Cancer Control Delivery Systems for the Medically Disadvantaged, is related to the priority areas of cancer, nutrition, and tobacco. 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

The primary objectives of this research are:

- o To test the feasibility and effectiveness of modifying existing community and public health care delivery systems to increase delivery and utilization of counseling and early cancer detection screening regimens among persons who do not usually initiate contact with the health care system for purposes of receiving preventive care, or who are not likely to receive preventive care when it is present.

- o To test the effectiveness of these interventions in improving knowledge, attitudes, and practices of the clinic clientele with respect to cancer prevention and control.

Special consideration must be given to how the cancer prevention and control services can build upon existing medical or health promotion services and the interest and expertise of existing personnel.

#### MECHANISM OF SUPPORT

Support of this program will be the research project grants (R01) and program project grants (P01) funding mechanisms.

#### ELIGIBILITY

Applications may be submitted by public and private entities, such as universities, hospitals, community health centers, and units of State or local governments. Collaboration between official health service delivery organizations and public health and medical research scientists experienced in cancer prevention and control is encouraged.

#### GENERAL REQUIREMENTS

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

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

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

Applicants 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 or etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

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

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

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

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

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

#### REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by an appropriate review group, or in the case of P01s, by the review group of the relevant Institute in accordance with the usual NIH peer review procedures. Following review, the applications will receive a second-level review by the appropriate national advisory council.

#### AWARD CRITERIA

Applications will compete for available funds with all other approved applications. The following will be considered in making funding decisions: (1) quality of the proposed project as determined by peer review; (2) availability of funds; and (3) balance among research topics within the announcement.

#### METHOD OF APPLYING

Grant application kits (form PHS 398 (rev. 10/88) are available at most institutional business and grant or contract offices and may be obtained from the Office of Grant Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone 301/496-7447. The title and number of this announcement must be typed in Item 2 on the face page of the application.

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

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

#### INQUIRIES

Requests for further information should be addressed to the Program Director:

Helen I. Meissner, Sc.M., C.H.E.S.  
National Cancer Institute  
Division of Cancer Prevention and Control  
Executive Plaza North, Room 239G  
9000 Rockville Pike  
Bethesda, MD 20892-4200  
Telephone: (301) 496-0273

Written and telephone inquiries concerning the objectives and scope of this PA or inquiries about whether or not specific proposed research would be responsive, clarifying scientific content and objectives of an application, size and focus of a research program, organization of an application, and appropriate use of consultants are strongly encouraged and are to be directed to Helen I. Meissner at the above address and telephone number. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants. The business contact for this PA is:

Katherine Shulze  
Grants Management Specialist  
Grants Administration Branch  
National Cancer Institute  
Executive Plaza South, Room 243  
6120 Executive Blvd.  
Bethesda, MD 20853  
Telephone: (301) 496-7800, ext. 16

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Grants will be awarded under

the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

#### PSYCHOTHERAPEUTIC DRUG DISCOVERY AND DEVELOPMENT PROGRAM

PA AVAILABLE: PA-92-15

P.T. 34; K.W. 0740020, 0755025, 0715129

National Institute of Mental Health

#### PURPOSE

The National Institute of Mental Health (NIMH) is accepting applications in response to a new program announcement entitled "Psychotherapeutic Drug Discovery and Development Program." The objective of this announcement is to stimulate multicenter, multidisciplinary research in the design, development, and testing of potential psychotherapeutic agents. The goal is not to duplicate or compete with pharmaceutical companies, but to encourage, complement, and accelerate the process of discovering new, innovative, and efficacious treatments for mental disorders.

#### HEALTHY PEOPLE 2000

The Public Health Service (PHS) urges applicants to submit work plans that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock Number 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock Number 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 and private, non-profit and for-profit organizations such as universities, colleges, hospitals, laboratories, research institutions, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

#### MECHANISMS OF SUPPORT

Although all mechanisms will be considered, the funding mechanisms are research project grants (R01), program project grants (P01), Research Scientist Awards (K series), and small grants (R03).

#### 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.

#### REVIEW PROCEDURES

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

#### METHOD OF APPLYING

Applications will be received under the usual PHS receipt and review schedule. All applicants must use the grant application form PHS 398 (revised 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.

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 be used to establish, add a component to, or operate a treatment, rehabilitation, or prevention 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 a generalizable knowledge and/or make a significant contribution to theoretical concepts.

Support may be requested for a period of up to five years (renewable for subsequent periods, except for small grants (R03) which are limited to two years.

#### FUNDS AVAILABLE

Applications submitted in response to this announcement and assigned to the NIMH will compete for at least

\$1,000,000 (direct costs) in new grant money that has been made available for this purpose in fiscal year 1992 to support approximately eight to ten grants. Applications submitted in future years will compete with others submitted for NIMH funding.

#### INQUIRIES

The program announcement and additional information may be obtained by contacting:

Jerry Cott, Ph.D.  
Psychopharmacology Research Branch  
Division of Basic Brain and Behavioral Sciences  
National Institute of Mental Health  
5600 Fishers Lane, Room 11-105  
Rockville, MD 20857  
Telephone: (301) 443-1691  
FAX: (301) 443-4822

Information on grants management issues may be obtained from:

Stephen J. Hudak  
Grants Management Section  
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 authority of Sections 301, 487, and 518 of the Public Health Service Act (42 USC 241, 288, and 290cc-11) as amended, and subject to the availability of funds, the National Institute of Mental Health will accept applications in response this announcement, under the receipt dates listed herein. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.