

# NIH GUIDE

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## For Grants and Contracts

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The NIH Guide announces scientific  
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administrative information to indi-  
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NOTE: The final rule entitled, "Responsibilities of Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science," was published in the Federal Register on August 8, 1989, Vol. 54, No. 151, pp 32446-32451. It is anticipated that this final rule will be published in the NIH Guide for Grants and Contracts on September 1, 1989.

## NOTICES

### NOTICE OF MEETING - PROGRAMS FOR SUPPORT OF MINORITIES IN BIOMEDICAL RESEARCH

P.T. 42, FF; K.W. 0710030, 1014006

National Institutes of Health

The National Institutes of Health (NIH) will hold the fourth and fifth of a series of five regional public hearings to be conducted under the auspices of the Office of the Director, NIH, on "Programs for Support of Minorities in Biomedical Research." The purpose of the hearings is two-fold:

(1) to provide current information concerning the activities of the NIH by describing in broad terms existing programs offered by NIH, and

(2) to solicit through public testimony the views of biomedical researchers, university faculty and administrators, students, representatives of professional societies, and other interested parties regarding the nature and scope of programs to attract and support minorities in biomedical research.

The fourth hearing will be held on Sunday, September 24, 1989, from 10 a.m. to 4 p.m. in the Doubletree Suite Hotel, Phoenix Gateway Center, Phoenix, Arizona, preceding the annual meeting of the Hispanic Association of Colleges and Universities. The fifth hearing will be held on October 9, 1989, from 9 a.m. to 4 p.m. at the Anchorage Hilton Hotel, Anchorage, Alaska, in conjunction with the National Indian Education Association Annual Meeting.

Following presentations by senior NIH staff, a panel comprised of NIH program administrators will spend the remainder of each day receiving testimony from public witnesses. Each witness will be limited to a maximum of ten minutes. Attendance and the number of presentations will be limited to the time and space available. Consequently, all individuals wishing to attend or to present a statement at either of these public hearings should notify, in writing:

William H. Pitlick, Ph.D.  
Executive Secretary  
National Institutes of Health  
Shannon Building, Room 252  
Bethesda, Maryland 20892

Those planning to make a presentation should file a one-page summary of their remarks with Dr. Pitlick by September 15, 1989. A copy of the full text should be submitted for the record at the time of the meeting. Additional information may be obtained by calling:

Ms. Loretta Beuchert  
Office of Extramural Research  
National Institutes of Health  
Shannon Building, Room 252  
Bethesda, Maryland 20892  
Telephone: (301) 496-9743

### GUIDELINES FOR CLINICAL TRIAL PLANNING GRANT

P.T. 34; K.W. 0755015, 0755000, 0715100

National Eye Institute

The National Eye Institute has recently developed guidelines for a Clinical Trial Planning Grant (R21). The objective of the Clinical Trial Planning Grant is to support the development of a clinical trial research plan. The grant provides a mechanism for early peer review of the rationale and need for the trial as well as support for the development of a detailed Manual of Procedures. An approved application will be considered for one year of funding of up to \$50,000 in direct costs.

Applications may be submitted any time during the year. Copies of the new guidelines may be obtained by contacting:

Richard L. Mowery, Ph.D., Chief  
Collaborative Clinical Research Branch  
National Eye Institute  
Building 31, Room 6A48  
Bethesda, Maryland 20892  
Telephone: (301) 496-5983

#### AVAILABILITY OF FISH OIL TEST MATERIALS

P.T. 34; K.W. 0780000, 0780017

National Institutes of Health

This notice supercedes the previous announcement published in the NIH Guide for Grants and Contracts on July 14, 1989 (Vol. 18, No. 24).

#### SUMMARY AND PURPOSE

##### TEST MATERIALS CURRENTLY AVAILABLE

- o n-3 ethyl ester concentrate, prepared from menhaden oil, bulk packed or soft-gel encapsulated (80 percent n-3 fatty acids including EPA and DHA)
- o Ethyl esters of olive oil (70 percent oleic), bulk packed or soft-gel encapsulated
- o Deodorized menhaden oil, bulk packed or soft-gel encapsulated
- o Commercial preparations of corn, olive, or safflower oil, soft-gel encapsulated only

#### PROCESSING AND SPECIFICATIONS OF BIOMEDICAL TEST MATERIALS

##### o n-3 Ethyl Ester Concentrate

The n-3 ethyl ester concentrate is prepared from vacuum-deodorized menhaden oil using transesterification, urea adduction and short-path distillation. The concentrate contains approximately 80 percent n-3 fatty acid ethyl esters (44 percent EPA, 24 percent DHA, 10-12 percent other n-3 fatty acid ethyl esters), 3 percent C18 (other than n-3), 6 percent C16 and the remainder as other esters. It contains 0.2 mg/g TBHQ as antioxidant, 2 mg/g tocopherols and 2.0 mg/g cholesterol. The concentrate is available in 1 g soft-gel capsules (100 capsules/bottle) or packaged in bulk in quantities suitable to investigators' needs.

##### o Placebo Ethyl Esters

The ethyl esters of virgin olive oil are prepared by transesterification. The preparation contains approximately 70 percent oleic acid, 13 percent C16, and 15 percent C18 (<1 percent n-3) fatty acid ethyl esters. It contains 0.2 mg/g TBHQ as antioxidant and 2 mg/g tocopherols. The preparation is available in 1 g soft-gel capsules (100 capsules/bottle) or packaged in bulk in quantities suitable to investigators' needs.

##### o Deodorized Menhaden Oil

Deodorized menhaden oil is prepared from oil that has been winterized and alkali refined; it is processed through a two-stage wiped-film evaporator to remove cholesterol, volatile oxidation products and any traces of organic contaminants. The oil contains approximately 30 percent n-3 fatty acids in the triglyceride form; 14 percent EPA, 8 percent DHA, 8 percent other n-3. It contains 0.2 mg/g TBHQ as antioxidant, 2 mg/g tocopherols and 2.0 mg/g cholesterol. The deodorized oil is available in 1 g soft-gel capsules (100 capsules/bottle) or is packaged in bulk quantities suitable to investigators' needs. Special requests for antioxidant-free oil will be considered.

##### o Placebo Oils

Commercial preparations of corn, olive, and safflower oil have been soft-gel encapsulated to serve as placebos for studies involving encapsulated menhaden oil. These oils contain 0.2 mg/g TBHQ as antioxidant and 2 mg/g tocopherols. The major fatty acids for each oil are: corn (58 percent 18:2n-6, 26 percent 18:1n-9), olive (17 percent 18:2n-6, 57 percent 18:1n-9), safflower (80

percent 18:2n-6, 9 percent 18:1n-9). They are available in 1 g soft-gel capsules (100 capsules/bottle). Although vegetable oils will not be supplied in bulk form, investigators may request analysis of antioxidant and tocopherol levels in vegetable oils that they purchase.

#### FISH OIL TEST MATERIALS PROGRAM

The Fish Oil Test Materials Program is administered by the Division of Nutrition Research Coordination in the Office of Disease Prevention, NIH. It was established in 1986 through the cooperation of the National Institutes of Health (NIH), the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), and the National Oceanic and Atmospheric Administration/Department of Commerce (NOAA/DOC). This program has been designed to provide a long-term, consistent supply of quality-assured/quality-controlled test materials to researchers in order to facilitate the evaluation of the role that omega-3 fatty acids play in health and disease.

#### Fish Oil Test Materials Advisory Committee:

A Fish Oil Test Materials Advisory Committee (FOTMAC) is cochaired by scientific staff from ADAMHA and NIH and is composed of scientists representing the funding agencies (NIH, ADAMHA), the research community, Department of Commerce (DOC), and the Food and Drug Administration (FDA). The FOTMAC provides scientific advice to the DOC regarding the types of materials needed by research scientists, shipping procedures for the materials, and additional quality control and production issues. The committee is advisory to the Fish Oil Test Materials Program on general programmatic issues such as future directions and has produced a manual on Good Laboratory Practices for the handling of polyunsaturate materials. In addition, the committee provided guidance to DOC during the production of the Drug Master File submitted to the FDA by the FOTMAC. A manual on Analytical Methods for the Quality Assurance of Fish Oil was produced by the DOC.

#### Fish Oil Test Materials Distribution Committee:

A Fish Oil Test Materials Distribution Committee (FOTMDC) is composed of NIH and other Federal scientists that do not use these products. The Distribution committee processes the applications received from investigators and advises the DOC of applications that have fulfilled the application process and makes recommendations regarding the distribution of requested materials.

The awarded materials are provided to investigators free of charge. Availability of materials are contingent on DOC/NOAA production capabilities. When prioritization is necessary, the order will be: 1) NIH/ADAMHA funded, 2) other government funded, 3) peer-reviewed, privately funded, 4) NIH/ADAMHA approved, not funded, and 5) other.

To qualify to receive materials described in this announcement the applicant must: 1) have peer-reviewed research indicating the need for the requested materials, and 2) submit a correctly completed application form and a signed waiver of liability. The committee will not be responsible for assessing the scientific merit of the application. Regulations on human subjects and animal research apply. In accordance with federal regulations, an IND number will be required for the use of these materials in human studies. The FOTMAC has established a drug master file at the FDA which includes manufacturing, chemical composition and toxicological data relevant to these products. Investigators using DOC/NOAA materials may reference this file in order to expedite their IND requests.

Requests for materials of amounts greater than 500 kg of vacuum-deodorized menhaden oil and/or 50 kg of n-3 ethyl ester concentrate should not be submitted without prior discussion with the National Marine Fisheries Service - Charleston Laboratory. For further information contact Ms. Patricia Fair at (803) 762-1200.

#### Test Materials Available in the Future:

Test materials and the relevant application process will be announced in the NIH Guide for Grants and Contracts as new materials become available.

#### Other Information:

Additional information will be provided the investigator in the form of complete quality assurance data for each lot of test material shipped, general diet preparation information, and instructions for formulation of placebos containing antioxidants balanced to the level in the test material.

## INQUIRIES AND APPLICATIONS

Investigators may obtain further information and apply for available fish oil test materials for relevant studies by requesting an application form from:

Ms. Melissa Workman  
Program Assistant  
Fish Oil Test Materials Program  
Division of Nutrition Research Coordination  
Building 31, Room 4B63  
National Institutes of Health  
Bethesda, Maryland 20892  
Telephone: (301) 496-2323

## APPLIED RESEARCH ETHICS NATIONAL ASSOCIATION - ANNUAL MEETING

P.T. 42; K.W. 1014004, 0755018, 1014003, 0783005

### Applied Research Ethics National Association

On October 11, Applied Research Ethics National Association (ARENA) will host its fourth annual meeting at the Park Plaza Hotel in Boston, Massachusetts. This meeting will be held from 9 a.m. to 5 p.m., and will feature a variety of presentations addressing issues pertinent to both IRB and IACUC administrators, including: the problem of data sharing, including recent requirements by pharmaceutical firms for data sharing prior to completion of research; review and highlighting of the new FDA proposed regulations on animal welfare. All ARENA members are encouraged to submit abstracts of papers for presentation at this meeting. Deadline for consideration is August 31 and presentations will be limited to 10 minutes with 5 minutes for questions. Topics for papers should focus on issues of interest to other ARENA members such as human or animal research, IRB or IACUC policies or procedures, research office administration, etc. Please direct abstracts and questions to:

David Bernhardt  
330 Holmecrest Road  
Jenkintown, Pennsylvania 19046  
Telephone: (215) 456-7216

## NOTICE OF MEETINGS - PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

P.T. 42; K.W. 0783010, 1014004, 0715008

### Public Responsibility in Medicine and Research

Public Responsibility in Medicine and Research (PRIM&R), a national organization concerned with ethical issues in research and medicine, is sponsoring two meetings in the Fall of 1989. Both meetings will be held at the Boston Park Plaza Hotel and Towers in Boston, Massachusetts.

The first conference, "The History and Current Status of IRBs: A Retrospective and Planner," will consider a range of regulatory, policy and operational issues of concern to IRBs, including their regulation, AIDS research, subject payment for research and issues involving scientific misconduct. This meeting will be held on October 12-13, 1989.

The second meeting, co-sponsored by PRIM&R and Tufts University School of Medicine, is entitled, "People as Products: Legal, Ethical and Social Issues in Reproductive Technology and Other Procedures Involving the Commercialization of Bodily Products." This meeting will be held on November 6-7, 1989.

For complete programs or further information on both of these meetings, please contact:

PRIM&R  
132 Boylston Street  
4th Floor  
Boston, Massachusetts 02116  
Telephone: (617) 423-4112 or  
423-1099

DATED ANNOUNCEMENTS (RFPs AND RFAs)

MASTER AGREEMENT FOR BIRTH DEFECTS STUDIES

MASTER AGREEMENT ANNOUNCEMENT AVAILABLE: MAA-NICHD-PRP-89-27

P.T. 34; K.W. 0775020, 0715006, 0775025, 0755030

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) is planning to investigate the causes of adverse pregnancy outcomes which would include congenital malformations and related problems by establishing a pool of prequalified contractors to collaborate in these studies. The Master Agreement Holders must be capable of identifying malformed children and appropriate control subjects within a defined geographical area. This would include being able to locate and interview families of these children and to obtain other pertinent medical information from other sources.

The projects to be performed under this Master Agreement are not yet defined. They will be primarily etiologic investigations in the area of birth defects. It is anticipated that in general a case-control approach will be used to evaluate the importance of potential etiologic factors. When blood samples are available, the case and control subjects will be compared on levels of substances of interest.

This announcement is a new solicitation. The issuance of the Master Agreement Announcement (MAA) will be on or about August 31, 1989, and the proposals are due by 4:00 pm (local time), October 30, 1989. Those organizations desiring a copy of the above MAA may send their written request with two self-addressed mailing labels to:

Mrs. Lynn Salo  
NICHD, OGC, CMS  
Executive Plaza North Building, Room 515  
9000 Rockville Pike  
Bethesda, Maryland 20892

All responsible sources may submit a proposal which will be considered.

This advertisement does not commit the Government to award a contract.

DATA CENTER FOR EPIDEMIOLOGICAL INVESTIGATIONS OF HIV

RFP AVAILABLE: RFP-NIH-NIAID-DAIDS-90-09

P.T. 34, AA, II; K.W. 0715008, 0785055, 0413001, 0755018

National Institute of Allergy and Infectious Diseases

The Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, is soliciting proposals from organizations having the capabilities and facilities to operate a data center with data management and analysis capability for the multicenter cohort study of the vertical transmission of human immunodeficiency virus in women and the natural history of the disease in a cohort of children. Clinical, laboratory, demographic and behavioral data collected in studies supported by the Epidemiology Branch and in other clinical studies supported by the Division of AIDS are essential to the mission of the Division of AIDS by providing natural history data for the design and conduct of vaccine and clinical trials. Hence, there is the further need that the data center possess the scientific/technical resources to provide assistance and resources to the staffs of the Epidemiology Branch and Biostatistics Research Branch in their efforts to integrate the findings from various DAIDS-sponsored contracts to meet needs in forecasting the epidemic and assessing the appropriateness of proposed study designs for vaccine and clinical trials.

Specifically, the selected Contractor shall be responsible for the operation and maintenance of a data center that services four clinical study sites. This includes coordination and supervision of all aspects of data collection activities, forms design, software development and modification, primary and secondary analysis of data. In addition, the selected Contractor shall provide scientific/technical assistance to Program staff in the monitoring of Program activities.

This is an announcement for an anticipated Request for Proposal (RFP). RFP-NIH-NIAID-DAIDS-90-09 will be issued on or about August 28, 1989, with a closing date tentatively set for October 17, 1989.

Requests for the RFP should be directed in writing to:

Jacqueline C. Holden  
Contract Management Branch  
Control Data Corp. Bldg., Room 214P, 6003 Executive Blvd.  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
Bethesda, Maryland 20892  
Telephone: (301) 496-7119

To receive a copy of the RFP, please supply this office with two self-addressed mailing labels. All responsible sources may submit a proposal which will be considered.

This advertisement does not commit the Government to award a contract.

#### BASIC CHEMISTRY IN SUPPORT OF AIDS-RELATED STUDIES

RFA AVAILABLE: 89-GM-01

P.T. 34; K.W. 0715008, 1003006, 1003012, 0760035, 0760053, 0760060

National Institute of General Medical Sciences

Application Receipt Date: December 1, 1989

The National Institute of General Medical Sciences announces that new funds are available to support the development of chemical design strategies and chemistry methodology with the potential to facilitate more targeted AIDS-related studies. This announcement is not intended to support studies of biological efficacy or in vivo evaluation of any products derived from these studies in basic chemistry.

The intent of this Request for Applications (RFA) is to support studies whose focus is basic chemistry, but which have the potential to contribute to AIDS-targeted studies. The new knowledge to be gained should advance the state-of-the-art for chemical design and methodology in support of targeted anti-AIDS drug development and enable researchers to more quickly and precisely intervene as new targets emerge.

Advances are sought in, but not limited to, the following areas:

- o Linkage chemistry for the tethering of small molecules and prosthetics to natural macromolecules.
- o Chiral synthesis of nucleosides, nucleotides, and oligonucleotides.
- o Synthetic methodology for the construction of novel or difficultly accessible isosteres and transition-state analogs.
- o Design and synthesis of new, selective DNA cleaving moieties.
- o Novel approaches to achieving enzyme inhibition and to the design of protein probes.
- o Peptide and oligonucleotide mimics.

Other areas with promise for innovation in chemical design and synthesis may be considered where potential to contribute to the preparation of molecular probes or drugs for AIDS-related studies can be established. The intent of this request is to elicit proposals to investigate original ideas and novel concepts for research in areas of basic chemistry which can be applied to anti-AIDS drug development. It is anticipated that any biological testing supported under this announcement will be limited to that necessary to establish the chemical principles being investigated.

Support for this program will be through traditional research grants, including regular project grants (R01) and FIRST awards (R29). Collaborations between groups strong in organic synthesis and those strong in molecular design are welcomed, and applications submitted by collaborating investigators from more than one institution can be supported by consortium arrangements.



Investigators from any institution, foreign or domestic, are eligible to apply for this funding.

The total amount of support of grants under this RFA is contingent upon the appropriation of funds for this purpose. The number of awards will be determined by the merit of the proposals and by their relevance to the program goals, as well as by the availability of funds. It is anticipated that in fiscal year 1990 seven to ten grant awards will be allocated to the research initiatives described in this RFA.

To receive the full RFA send two address labels to:

Dr. Michael Rogers  
Program Administrator  
Pharmacological Sciences Program  
National Institute of General Medical Sciences  
National Institutes of Health  
Westwood Building, Room 919  
Bethesda, Maryland 20892  
Telephone: (301) 496-7181

#### THE BIOCHEMISTRY OF FIBRINOLYSIS

RFA AVAILABLE: 89-HL-16-B

P.T. 34; K.W. 1003002, 0760035, 0790000

National Heart, Lung, and Blood Institute

Application Receipt Date: March 15, 1990

The Blood Diseases Branch of the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute (NHLBI), announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI. Awards will be made to foreign institutions only for research of very unusual merit, need, and promise.

This program will support basic research on the biochemical mechanisms that result in fibrinolysis and thrombolysis with particular emphasis on the thromboselectivity of plasminogen activators and their regulation by plasminogen activator inhibitors. Research elucidating the biochemical basis of resistance of old thrombi towards thrombolytic agents and those thrombi forming after thrombolytic therapy is also relevant to the goals and objectives of this RFA. This announcement may be of particular interest to investigators with expertise in physical and structural biochemistry.

Support for this program will be through traditional research grants, including regular project grants (R01) and FIRST awards (R29). Collaborations between groups strong in organic synthesis and those strong in molecular design are welcomed, and applications submitted by collaborating investigators from more than one institution can be supported by consortium arrangements. Policies that govern research grant programs of the NIH apply to this program.

The total amount of support of grants under this RFA is contingent upon the appropriation of funds for this purpose. The number of awards will be determined by the merit of the proposals and by their relevance to the program goals, as well as by the availability of funds. It is anticipated that in fiscal year 1990 seven to ten grant awards will be allocated to the research initiatives described in this RFA.

Requests for copies of the RFA should be addressed to:

Diane L. Lucas, Ph.D.  
Division of Blood Diseases and Resources  
National Heart, Lung, and Blood Institute  
Federal Building, Room 5A12  
Bethesda, Maryland 20892  
Telephone: (301) 496-5911

## PUBLIC HEALTH APPROACHES TO BREAST AND CERVIX SCREENING

RFA AVAILABLE: 89-CA-16

P.T. 34, II; K.W. 0715035, 0745020, 0730070

National Cancer Institute

Letter of Intent Receipt Date: October 1, 1989

Application Receipt Date: December 11, 1989

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites grant applications from a consortium of public health agencies or institutions to develop, implement, and evaluate programs designed to increase breast and cervical cancer screening of older, low income, low education level and minority women.

### RESEARCH GOALS AND SCOPE

The goal of this project is to develop, implement, and evaluate programs designed to increase breast and cervical cancer screening of older, low income, low education level and minority women.

The primary objectives of this research are to demonstrate how a consortium of community agencies can:

1. Characterize utilization patterns for mammography, clinical breast examination, breast self-examination and cervical cytology screening in the target population through baseline surveys. These data will establish frequency of screening, as well as assess barriers to utilization.
2. Design and pilot test interventions to recruit women in need of breast and cervical cancer screening regimens that can:
  - o be integrated with other health services used by these women
  - o affect the behavior of non-health agency clients.
3. Evaluate the effectiveness of specific interventions to reach the target population for breast and cervical cancer screening.
4. Assure compliance with follow-up recommendations for women with anything but completely normal mammograms (i.e., indeterminate or suspicious findings) and smears (i.e., further action recommended).
5. Describe prospectively the screening behavior of the targeted women in view of current NCI recommendations (i.e., establish that women are coming back at recommended intervals for screening).

### ELIGIBILITY REQUIREMENTS

Grants-in-Aid may be awarded to profit and nonprofit organizations and institutions, and governments and their agencies within the United States. However, it should be noted that this Request for Applications (RFA) is primarily targeted at demonstrating a consortium approach, involving public agencies or institutions, such as health departments, community health centers or public hospitals with established linkages to the target population (e.g., The Health Department may have experience with providing or contracting for the health services, an Area Agency on Aging may have established networks with elderly women, and the American Cancer Society may have experience with providing public education campaigns). This approach seeks to address the problem in a coordinated fashion while taking advantage of the public agency's role as noncompetitive collaborator, stimulator, convenor, and facilitator of existing resources to increase mammography and Pap smear utilization in women least likely to be screened. The lead agency must demonstrate experience with disease control, but does not necessarily have to be the direct provider of the screening services. In many communities, the lead agency is likely to be the health department; however, other public agencies could fill this role. Among the team of applicants or consortium, one institution must be proposed as the lead institution to serve as the applicant and assume responsibility for the conduct of the award.

## MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health (NIH) grant-in-aid. Applicants will be responsible for the planning, direction, and execution of the proposed project. Allowable direct costs for the intervention will not include funds to pay for mammograms or Pap smears. However, expenses incurred in developing and promoting the utilization of these services, such as baseline and follow-up surveys, design of materials, and public and professional education are considered allowable costs. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000, revised January 1, 1987.

This RFA is a one-time solicitation. Approximately \$1,000,000 in total costs per year for five years will be committed to specifically fund applications that are submitted in response to this RFA. The total project period for applications submitted in response to the present RFA should not exceed five years. The earliest feasible start date for the initial awards will be August 1, 1990. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA also is contingent upon the availability of funds for this purpose.

## INQUIRIES

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

Lawrence Bergner, MD, MPH  
Program Director  
Cancer Control Applications Branch  
National Cancer Institute  
EPN Room 233C  
Bethesda, Maryland 20892  
Telephone: (301) 496-8584