

NIH GUIDE

**For Grants
and
Contracts**

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**U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES**

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

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NOTICES

ELECTRONIC TRANSMISSION OF THE NIH GUIDE FOR GRANTS AND CONTRACTS

P.T. 16; K.W. 1004017

National Institutes of Health

In September 1989, the National Institutes of Health began transmitting the NIH Guide for Grants and Contracts electronically via the computer communications network BITNET. Those institutions that have been receiving the electronic Guide are asked to let us know about their experience with this electronic system. We would appreciate comments concerning the advantages, disadvantages, and any problems encountered in using the electronic Guide. This information will be very helpful to us in improving our service to you. Please send your letters to:

M. Janet Newburgh, Ph.D.
Institutional Liaison Officer
Office of Extramural Programs
National Institutes of Health
Building 31, Room 5B31
Bethesda, Maryland 20892
Telephone: (301) 496-5366

Comments also can be sent to Dr. Newburgh electronically by using the BITNET address Q2C@NIHCU.

AAMC/NIH REGIONAL WORKSHOPS

P.T. 42; K.W. 1014004

National Institutes of Health

On April 20-21, the George Washington University will host the first of four regional workshops sponsored by the Association of American Medical Colleges (AAMC), under contract with the National Institutes of Health (NIH), to address issues in the promotion of integrity and responsibility in biomedical research. These regional workshops are designed to serve as a forum for discussing recent developments within the Public Health Service that include the establishment of the Office of Scientific Integrity and the new regulation requiring awardee institutions to assure that policies and procedures are in place for investigating possible misconduct in science. The workshop will address special topics such as training and mentoring, peer review and authorship practices, and data ownership as well as dissemination of the information developed by the Institute of Medicine study, "Promotion of Responsibility in Research in the Health Sciences" supported by the NIH. The workshop is expected to be of interest to program directors, investigators, and academic administrators involved in behavioral and biomedical research. CME credits will be available for the workshop through the George Washington University Office of Continuing Medical Education.

Title: PROMOTION OF INTEGRITY AND RESPONSIBLE PRACTICE IN BIOMEDICAL RESEARCH

Location: Holiday Inn Crowne Plaza, Arlington Virginia

Contact:

Leah C. Valadez
The George Washington University Medical Center
Office of the Dean for Research
2300 Eye Street, N.W., Suite 514
Washington, DC 20037
Telephone: (202) 994-2801

Similar workshops are planned for Boston, Massachusetts; St. Louis, Missouri; and San Diego, California. Dates will be announced in future notices.

INVENTIONS: IMPORTANT NOTICE FOR RESEARCH GRANTEES AND RESEARCH CONTRACTORS

P.T. 34; K.W. 1014016

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

The following comments provide a brief review of current regulations affecting inventions made with support from the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) research grants or related awards (G, H, K, M, P, R, S, and U awards); research and development contracts (N01 awards); and grants and contracts (N43, N44, R43, and R44 awards) made under the Small Business Innovation Research Program. Inventions made solely by trainees or fellows (assisted only by a T or F award) are not subject to these guidelines.

Congress has long encouraged the use of the patent system by universities, non-profit organizations, and small business firms. The principal concern is to protect the public interest in inventions developed with the aid of Federal funds, while giving due recognition to the legitimate interests of those who have contributed to the invention. The key provisions of patent law as they apply to inventions made with NIH and ADAMHA support are contained in several references cited at the end of this notice under "Citations." The following comments are based on those sources and describe procedures for the reporting and subsequent disposition of such inventions.

DISCLOSURE: Federal law requires that any invention arising from experimental, developmental, or research activities funded by Government grants and contracts be promptly and fully reported (disclosed) by the inventor to his or her employer, i.e., the contractor or grantee organization (non-profit or for-profit, public or private). In turn, the organization must fully disclose the invention to the NIH or ADAMHA at the address shown immediately below. This disclosure must be submitted within 60 days of the inventor's initial report to the organization and it shall be sufficiently complete in technical detail to convey a clear understanding of the invention. The disclosure also will identify the inventor, the grant or contract under which the invention was made, and any publication or manuscript submitted for publication that describes the invention. NOTE: Many organizations disclose inventions by providing a single copy of any report form the inventor submits for the organization's internal use. However, reporting an invention to the NIH or ADAMHA by merely submitting its title or summary description is NOT an acceptable disclosure. Since these disclosure reports contain proprietary information they are not released to the public without the organization's specific permission.

MAILING ADDRESS: The following office serves as the receipt point for any of the documents described in this Notice, as well as for any invention-related inquiries:

Extramural Inventions Reports Office National Institutes of Health ATT: Dr.
Howard Jenerick Building 31, Room 5B-41 Bethesda, Maryland 20892 Telephone:
(301) 402-0850

INVENTION RIGHTS: Most Government grant and contract awards for the performance of experimental, developmental, or research work incorporate standard patent rights clauses which state that, subject to certain limitations, the ownership of rights to any invention is usually left with the contractor or grantee organization. However, the organization must elect in writing whether or not to retain title to the invention during the next one or two years (see below) after the required disclosure to the Extramural Invention Reports Office. Any organization that elects to retain the title is thereafter obligated to file an initial patent application within a reasonable period of time, i.e., one year or prior to any statutory bar date. Thus, the NIH and ADAMHA strongly discourage organizations from attempting to protect or license inventions as "trade secrets" without filing for patent protection. If the organization elects not to file for a patent, it must so inform the NIH or ADAMHA which then have the right to take title. (The title does not flow to the inventor by default.) Agency staff will promptly evaluate the invention and will file a patent application for the Government if this seems in the public interest and it is practical to do so. If the Government obtains a patent, the organization may retain a nonexclusive, royalty-free license and the inventor may receive royalty payments according to a standard formula. If the agency elects not to exercise the Government's rights in the invention, these rights may be granted back to the inventor, who may then file for a patent.

PATENT APPLICATION and ACKNOWLEDGEMENT: At the time the organization or the inventor submits the formal application to the U. S. Patent Office, a copy

also should be sent to the Extramural Invention Reports Office along with the obligatory license (see below.) The patent application must include the following statement:

"This invention was made with Government support under (identify the grant/contract) awarded by the (cite the awarding agency, National Institutes of Health or Alcohol, Drug Abuse, and Mental Health Administration). The Government has certain rights in the invention."

TIMELINESS for ELECTION OF RIGHTS and FILING of PATENT APPLICATIONS: Timing is critical in patent law because there are statutory deadlines that must be met to avoid loss of valuable patent rights. The laws distinguish between inventions that are "disclosed" by confidential reporting to the Government and inventions that are "disclosed" to the public through speeches or publications. NOTE: Abstracts and posters presented at scientific meetings are considered as publications, and if abstracts for society meetings are mailed in early, the POST MARK DATE is considered the publication date.

If the invention has NOT been disclosed to the public, i.e., it has only been reported to the Government on a confidential basis, there is a two-year open period for filing a patent application.

Timing for United States Patent Applications after Public Disclosure: Under U. S. patent law a valid patent application may be filed only within a one-year grace period after the publication date of a printed article that discloses the invention.

Timing for Foreign Patent Applications after Public Disclosure: Other countries usually do not allow a one-year grace period after publication, unless a U. S. patent application has been filed prior to the publication date.

NOTE: If no application is filed during these open periods, the invention is considered to have been dedicated to the public and can no longer be patented. Since the Government and the inventor have certain rights to the invention as outlined above, the limited open periods for seeking patent protection makes it important for the organization to proceed promptly in its evaluation of the invention and inform the Extramural Invention Reports Office of its decision in timely fashion.

LICENSE: Every patent applicant (individual or institutional) is required to provide the Government with a nonexclusive, irrevocable, paid-up license in the invention. (A sample license form is provided at the end of this Notice.) A single copy of this license should be sent to the Extramural Invention Reports Office at the time the patent application is filed.

PATENT: The successful applicant will furnish a copy of the issued patent to the Extramural Invention Reports Office.

PREFERENCE FOR UNITED STATES INDUSTRY: The patent holder or its assignee will not license or grant any person the exclusive right to use or sell the invention in the United States unless the products are manufactured substantially in the United States.

INVENTION UTILIZATION REPORTS: Periodic utilization reports for each invention must be filed with the Extramural Invention Reports Office. Such reports shall be submitted every two years and shall include information regarding the status of development, date of first sale or use, and gross royalties received by the organization. These utilization reports are not releasable to persons outside the Government without permission of the grantee or contractor, or within the Government except on a need-to-know basis.

SPECIAL NOTE: Chemical compounds having potential medicinal or other utilities are often synthesized or identified during research financed by Federal funds. Such a compound is not patentable until a use can be described. Although the compound need not be tested, the patent application must "teach" the reader how to use the substance. It is NIH and ADAMHA policy that such compounds should be screened adequately so that all possible uses may be ascertained and any promising compounds be developed for widest possible use. The screening services of the Cancer Chemotherapy National Service Center and the Walter Reed Army Institute of Research should be utilized for this purpose, whenever appropriate.

LEGAL CONTACT: It is expected that institutions will rely primarily on their own legal counsel for advice and interpretation of relevant Governmental laws and regulations. However, if a technical question arises that requires an answer from a Government patent attorney please contact:

PATENT BRANCH
DHHS Office of the General Counsel
Public Health Division
National Institutes of Health
Building 31, Room 2B-62
Bethesda, Maryland 20892
Telephone: (301) 496-7056

INVENTION REPORTS in GRANT APPLICATIONS and FINAL REPORTS: Please note that inventions arising out of NIH and ADAMHA supported projects are customarily reported to the awarding component in competing and non-competing applications for continuation awards. To insure confidentiality, inventions reported through this channel should be described by title or summary paragraph only. It may be wise to discuss these descriptions with the organization's patent counsel before submission.

At the expiration or termination of each project, the Final Invention Statement and Certification (Form HHS 568) is sent to the Grants Management Officer of the awarding component. In the case of terminated contracts any inventions are identified in the contract close-out letter. (NOTE: Grantees are reminded that the Statement is required within 90 days following the expiration or termination of support for the project.) Because of brevity, these latter reports do not meet the requirements for full disclosure.

CITATIONS: Important changes in public laws in recent years have led to substantial revisions of the Agency regulations affecting inventions made with Federal support. The requirements of Public Laws 96-517 and 98-620 have been implemented in the regulations published in Title 37 Code of Federal Regulations (CFR) Part 401 and 45 CFR Part 8. The standard patent rights clauses that are incorporated into all NIH and ADAMHA grants and research contracts appear in 37 CFR Section 401.14.

SAMPLE License form for use by Institutional Official or individual inventor:
LICENSE TO THE UNITED STATES GOVERNMENT

This instrument confers to the United States Government, as represented by the Department of Health and Human Services, a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced on its behalf throughout the world the following subject invention:

Invention Title :
Inventor(s) :
Patent Application
Serial No. :
Filing Date :
Title :
Country, if other than
United States :

This subject invention was conceived or first actually reduced to practice in performance of a government-funded project, (National Institutes of Health or Alcohol, Drug Abuse, and Mental Health Administration grant/contract) No. _____.

Principal rights to this subject invention have been left with the Licensor: _____, subject to the provisions of 37 CFR 401 and 45 CFR 8.

Signed: _____ Date: _____

Typed Name: _____ Title: _____

NIH/FDA REGIONAL WORKSHOPS - 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 continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. The current schedule includes:

o Dates: March 8-9, 1990

Location: Denver, Colorado

Title of Workshop: "IRB Issues"

Contact:

Ms. Mary Jane Peratt
Secretary, IRB
University of Colorado Health Sciences Center
4200 East 9th Avenue (Box C290)
Denver, Colorado 80262
Telephone: (303) 270-7960

o Dates: June 22-23, 1990

Location: Seattle, Washington

Title of Workshop: "NIH/FDA Regional Human Subjects Protections Workshop"

Contact:

University of Washington
Continuing Medical Education
Washington Building (Suite 2000)
1325 4th Avenue
Seattle, Washington 98101
Telephone: (206) 543-1050

o Dates: July 19-20, 1990

Location: St. Louis, Missouri

Title of Workshop: "NIH/FDA Regional Human Subjects Protections workshop"

Contact:

Ms. Leigh Tenkku
Assistant Director of Research Administration
Jewish Hospital of St. Louis
at Washington University Medical Center
216 South Kings Highway
St. Louis, Missouri 63110
Telephone: (314) 454-8322

NIH/FDA have planned human subjects regional workshops in other parts of the United States. For further information regarding these workshops, contact:

Darlene Marie Ross
Human Subjects Education Program Coordinator
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B43
9000 Rockville Pike
Bethesda, Maryland 20892
Telephone: (301) 496-8101

DATED ANNOUNCEMENTS (RFPs AND RFAs)

EVALUATION OF CHEMOPREVENTIVE AGENTS BY IN VITRO TECHNIQUES

RFP/MASTER AGREEMENT ANNOUNCEMENT AVAILABLE: NCI-CN-05253-33

P.T. 34; K.W. 0740018

National Cancer Institute

The National Cancer Institute (NCI), Division of Cancer Prevention and Control (DCPC), Chemoprevention Branch, wishes to award Master Agreement contracts for Evaluation of Chemopreventive Agents by In Vitro Techniques. The required services will be defined by Master Agreement Orders (MAOs) issued during the period of performance.

Pursuant to the MAOs, the contractor shall screen and evaluate the activity of chemopreventive agents in various in vitro assays of cell transformation.

Agents with potential chemopreventive activity are identified by epidemiologic surveys, initial laboratory (experimental) findings, observations in the clinical setting, or structural homology with agents having known chemopreventive activity. A rigorous and systematic evaluation of these candidate agents is necessary before their efficacy can be examined in clinical trials for cancer prevention. In vitro screening and evaluation techniques measuring the ability of these chemopreventive agents to inhibit transformation provides a relatively rapid and efficient means of qualifying these agents for further evaluation for the prevention of cancer in humans.

Agents to be investigated by this project are potentially hazardous. The in vitro systems may involve the use of carcinogens, tumor cells or tumor viruses. Laboratory practices shall be employed which will keep any element of risk to personnel at an absolute minimum. Where indicated, tissue and compound handling must be performed in (at least) Class I laminar flow cabinets that must meet NIH specifications for work with these agents. The offeror shall comply with NCI safety standards for research involving chemical carcinogens (DHHS Publication No. NIH 76-900 and the Food and Drug Administration Good Laboratory Practices Regulations).

It is estimated that approximately four (4) MAOs per year will be issued pursuant to the award(s) of the Master Agreement (MA) contracts. The MAs awarded as a result of this Request for Proposals (RFP) will remain in force for a period of two years.

The contractor must have or be able to obtain all the equipment necessary to accomplish the studies, including but not limited to laminar flow hoods, CO(2) incubators, equipment for sterility testing, isotope counters, spectrophotometer, hazardous chemical storage cabinets and refrigerators and equipment such as microscopes and miscellaneous laboratory equipment. The laboratory shall have or have access to appropriate terminal and computer facilities and equipment for data collection and storage.

The purpose of this acquisition is to qualify additional contractors for an existing pool of Master Agreement Holders. There are currently six (6) qualified contractors in this pool. The period of performance of the Master Agreement pool runs through May 30, 1992, which would be the expiration date for any new Master Agreement Holders added as a result of awards from this Master Agreement Announcement (MAA). It is estimated that up to four (4) MAOs per year will be issued pursuant to the MA contracts. The MAA will be available on approximately February 13, 1990. The proposal due date will be approximately March 30, 1990.

Copies of MAA/RFP NCI-CN-05253-33 may be obtained by sending a written request to:

Mr. Alan Kraft, Contract Specialist
National Cancer Institute
Research Contracts Branch, PCCS
Executive Plaza South, Room 635
Bethesda, Maryland 20892
Telephone: (301) 496-8603

PHASE I STUDIES OF NEW CHEMOPREVENTIVE AGENTS

RFP/MASTER AGREEMENT ANNOUNCEMENT AVAILABLE: NCI-CN-05254-33

P.T. 34; K.W. 0740018, 0710100, 0755015

National Cancer Institute

The National Cancer Institute (NCI), Division of Cancer Prevention and Control (DCPC), Chemoprevention Branch, wishes to award Master Agreement (MA) contracts for Phase I Studies of New Chemopreventive Agents and to perform pharmacokinetic studies during these Phase I Studies. The objective of these studies is to determine the parameters and characteristics of toxicity in humans, the safely delivered dose, and the basic clinical pharmacokinetics of agents emerging from the NCI chemoprevention agent development program so that subsequent Phase III risk-reduction trials can be appropriately designed.

The Master Agreement Holder shall develop and conduct the following Task I and Task II studies:

TASK I: Phase I Studies - Phase I studies shall provide the parameters and characteristics of drug toxicity, the safely delivered dose and a recommended Phase II/III dose. Phase I clinical studies with combinations of agents may

be performed if mutually agreed upon by the contractor and the Project Officer.

TASK II: Pharmacokinetic Studies - Pharmacokinetic studies shall provide the parameters of drug absorption, blood concentration--time profiles, distribution and excretion. Using classical and non-classical modeling, the pharmacokinetic data shall be used to determine probable patterns of distribution, and excretion, compartmentalization and enterohepatic recirculation, and to include identification as well as distribution and excretion of metabolites.

The MA shall certify a holder's qualification to compete for both Tasks I and II. For a given agent tested, qualifications to carry out both Tasks I and II must exist, although only Task II may be required.

It is estimated that investigators/institutions shall be deemed to be qualified via peer review to be included in the MA. A maximum of ten master agreement orders (including both Tasks I and II), requiring approximately 200 subjects, shall be issued annually for studies on specific agents.

The purpose of this acquisition is to qualify additional contractors for an existing pool of Master Agreement Holders. There are currently six (6) qualified contractors in the pool. The period of performance of the MA pool runs through July 26, 1993, which would be the expiration date for new Master Agreement Holders, too. The Master Agreement Announcement will be available on approximately February 13, 1990. The proposal due date will be approximately March 30, 1990.

Copies of MAA NCI-CN-05254-33 may be obtained by sending a written request to:

Mr. Alan Kraft, Contract Specialist
National Cancer Institute
Research Contracts Branch, PCCS
Executive Plaza South, Room 635
Bethesda, Maryland 20892
Telephone: (301) 496-8603

IN VITRO TRANSFORMATION OF ONCOGENE PRIMED CELLS BY GENOTOXIC CHEMICALS

RFP AVAILABLE: NIH-ES-90-05

P.T. 34; K.W. 0785140, 1002019, 0755035, 1007009

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), is soliciting proposals for a project to study in vitro transformation induced by chemicals in cells that are engineered to express cellular oncogenes or other genes likely to be involved in neoplastic processes. The conceptual framework for this project is the hypothesized cooperation between experimentally activated oncogenes and chemically induced genetic effects where neither event alone is sufficient to cause transformation. The genetic manipulation is directed to the activation of proto-oncogenes, inappropriate expression or transcriptional activation, rather than somatic mutation in coding sequences. Proto-oncogenes that are cloned into retroviral derived vectors and introduced into recipient cells will provide the method for generating target cell populations. The project will include the following tasks: Task 1 - Recombinant DNA cloning, construction of proto-oncogene recombinants and generation of retroviral vectors for nonmutated mouse proto-oncogenes; Task 2 - Introduction of vectored oncogenes into test cells and characterization of cellular phenotypes; and Task III - Characterization of vectored subclones exposed to selected chemicals. A three-year contract is anticipated. The Government estimates that the project will require approximately 1.5 professional person years, 1.5 technical person years, and .25 administrative person years of effort per year. The Request for Proposals (RFP) will be released on or about February 6, 1990, and responses will be due to be received by the Contracting Officer sixty (60) days thereafter. All responsible sources may submit a proposal that shall be considered by the agency.

Requests should reference RFP NIH-ES-90-05 and should be forwarded to:

National Institute of Environmental Health Sciences
Contracts and Procurement Management Branch, OM
ATTN: Mary B. Armstead, Contracting Officer
79 T.W. Alexander Drive, 4401 Building, P.O. Box 12874
Research Triangle Park, North Carolina 27709

A RANDOMIZED TRIAL OF SMOKING CESSATION INTERVENTION FOR PREGNANT WOMEN

RFP AVAILABLE: NICHD-PRP-90-12

P.T. 34, II; K.W. 0404019, 0755015, 0755020

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) is seeking a contractor to provide assistance in carrying out a randomized clinical trial to assist pregnant women to stop smoking during pregnancy. The clinical trial, Smoking Trial of Pregnancy Project (STOP), is evaluating the effectiveness of a smoking cessation intervention program to be incorporated as part of routine prenatal care. Private physicians' offices will be recruited to participate in this randomized controlled clinical trial. The intervention has been designed as a self-help smoking cessation intervention with physician endorsement. During the pilot pre-test phase, the incumbent, Westat, Inc. and their subcontractor, Porter/Novelli, helped to acquire, design and compile educational materials and protocols for the project. All materials developed or acquired under the pre-test pilot contract will be supplied by the government to the awardee of the contract for the STOP main trial.

The issuance of the RFP will be on or about February 5, 1990 and the proposals are due 2:00 pm (Local Time), March 15, 1990. Those organizations desiring a copy of the above RFP may send their written request with two self-addressed mailing labels to:

Mrs. Carletha Gates
Contract Specialist
NICHD, OGC, CMS
Executive Plaza North, Room 515
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.

MINORITY DRUG ABUSE PREVENTION RESEARCH CENTERS

RFA AVAILABLE: DA-90-08

P.T. 04, FF, II; K.W. 0404009, 0745027, 0411005, 0755030

National Institute on Drug Abuse

Application Receipt Date: May 17, 1990

PURPOSE

The purpose of this announcement is to encourage the development of multidisciplinary research centers that will improve our ability to prevent drug abuse among minority populations. Minority populations include American Indian/Alaskan Natives, Asian Americans, Blacks, Hispanics, and/or Native Hawaiians/Pacific Islanders. The proposed Centers are designed to: 1) improve our understanding of etiologic factors that predispose individuals from minority communities to initiate drug use; 2) identify factors involved in the progression from initial drug use to drug dependence; 3) develop criteria and early identification methodologies for use with children and adolescents at high risk for drug abuse; 4) design and test preventive interventions at the individual and small group level through controlled randomized studies; 5) assess the progression of drug use through prospective longitudinal studies of high-risk populations; 6) develop a series of conferences and workshops addressing prevention research issues of specific relevance to understanding etiologic factors and intervention strategies among minority populations; 7) train minority investigators to conduct drug abuse prevention research; and 8) involve the minority community in the development and implementation of a research program.

RESEARCH OBJECTIVES

Prevention and intervention strategies demonstrate differential effects within various ethnic groups and socioeconomic populations. Multiple intervention strategies are needed within any geographic location to block and delay the initiation of drug-use behavior and to impede progression to drug dependency and associated social, psychological, and physiological sequelae.

Etiological studies designed to specify deferential causes for initiating, continuing and discontinuing drug abuse within and among ethnic groups in urban, suburban and rural geographic areas are needed. For example, are there selective or other factors associated with blacks who remain in school compared to blacks who do not graduate that "protect" them from drug abuse? What is the role of the educational system in reducing, delaying or eliminating drug use? Given the same environment and equivalent level of being "vulnerable" to drug abuse, what family, social, environmental protectors exist to prevent the use of drugs?

Previous surveys of minorities rarely have included high-risk groups such as school dropouts, runaways, and prisoners, so the current estimates of drug abuse in minority populations may be inaccurate. Current research indicates that dropouts have higher rates of illicit drug use than minority youth in school. Such data suggest the need for community-wide drug abuse education, prevention and intervention programs in addition to the school-based programs. More research is needed to explore the relationship between poor school performance and acculturation-related stress with drug abuse among minority youth. Areas related to the putative crime/drug connection among blacks needs further examination to understand more fully the causes and extent of the relationship within minority populations.

Applications for Minority Drug Abuse Prevention Research Centers are encouraged but not restricted to any of the four content areas among minority groups: Families and Multi-Generational Factors; Environmental and Cultural Factors; High-Risk Children, Adolescents, and Young Adults; and Women and Drugs.

INCLUSION OF FEMALES IN THE STUDY POPULATION

Applicants are urged to consider the inclusion of females in the study populations for all clinical research efforts. Exceptions would be studies of diseases which exclusively affect males or where involvement with pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If females are not to be included, a clear rationale should be provided for their exclusion.

In order to provide more precise information to the research and practitioner community, it is recommended that publications resulting from research sponsored by the Alcohol, Drug Abuse, and Mental Health Administration in which the study population was limited to one sex for any reason other than that the disease or condition studied exclusively affects that sex, should state, in the abstract summary, the gender of the population studied, e.g., "male subjects," "female subjects".

MECHANISM OF SUPPORT

The mechanism of support for this announcement will be the specialized center (P50). Initial center awards are limited to \$600,000 (direct costs) for the first year of the grant and up to \$750,000 (direct costs) for each subsequent year. It is anticipated that approximately three grants will be awarded under this announcement.

REVIEW PROCEDURES

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary Public Health Service grant programs. Applications received under this announcement will be assigned to an initial review group (IRG) in accordance with established Public Health Service Referral Guidelines. The IRG, consisting primarily of non-federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by the National Advisory Council on Drug Abuse whose review may be based on policy as well as scientific merit considerations. Only applications recommended for approval by the Council may be considered for funding.

APPLICATION PROCEDURES

An application for a Minority Drug Abuse Prevention Research Center grant must provide the following information within the general proposal: research plan to include specific information on the Center's research theme, goals, and objectives; detailed descriptions of the specific research projects and their relationship to the core program; identification of key scientists and their roles and responsibilities on specific projects and research teams; and discussion of the management structure to be employed to organize and coordinate multidisciplinary scientific research initiatives; the research

program plan must be organized around a central research theme and address the research and administrative requirements established by this announcement. Furthermore, the proposal must include a description of training of research personnel; evidence of a strong community relationship with demonstrated experience of working in the target community; and descriptions of conferences, publications, and other methods for the dissemination of research findings.

Applicants should use the research grant application form PHS 398 (rev. 10/88). The RFA number [DA-90-08] and the title of this announcement, "Minority Drug Abuse Prevention Research Research", should be typed in item number 2 of the face page of the PHS 398 application form.

When using the PHS 398 application form to Applicants must affix the RFA label available in the 398 to the bottom of the face page. 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.

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:

Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A54
Rockville, Maryland 20857
Telephone: (301) 443-6710

The signed original and six (6) permanent legible copies of the completed application should be sent to:

Division of Research Grants, NIH
Westwood Building, Room 240
Bethesda, Maryland 20892**

INQUIRIES

Further information and consultation on program requirements relevant to prevention research can be obtained from:

Dr. Zili Amsel
Chief, Prevention Research Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A20
Rockville, Maryland 20857
Telephone: (301) 443-1514

ONGOING PROGRAM ANNOUNCEMENTS

PREVENTIVE PULMONARY ACADEMIC AWARD

P.T. 34; K.W. 0715065, 0745027, 0404000, 0404019

National Heart, Lung, and Blood Institute

Application Receipt Date: July 23, 1990

The Division of Lung Diseases (DLD), National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH), announces the fifth and final competition for the Preventive Pulmonary Academic Award. The dual objectives of this award are to encourage (1) the development and/or improvement in teaching prevention of respiratory diseases in both undergraduate and graduate medical training, and (2) research in methods for the prevention of lung diseases. It is anticipated that approximately four awards will be made.

ELIGIBILITY: A candidate for this award must be a physician with both clinical and academic skills who is an established faculty member in an accredited academic medical institution. The candidate must commit a minimum of 50 percent effort to the program. An institution sponsoring a candidate for the award must show commitment to developing and improving the teaching of prevention of lung diseases, identifying educational resources, allowing time for the awardee to acquire educational skills, and providing facilities for research.

Applications from faculty members at minority medical schools are especially encouraged.

PROVISION OF THE AWARD: This award will provide up to \$40,000 salary support for the awardee, plus appropriate fringe benefits and up to \$20,000 a year for related research support. In addition, each awardee may apply for up to \$10,000 for technical assistance (see pages 4-5 of the Guidelines for this award); the use of these funds will be coordinated among other awardees and must be approved by the DLD, NHLBI. Funds will be provided for the reimbursement of actual indirect costs at a rate up to, but not exceeding, eight percent of the total direct costs of each award, exclusive of tuition, fees, and expenditures for equipment.

CURRICULA DEVELOPMENT: Curricula topics which might be addressed include identification of and interventions with populations at risk for respiratory diseases, prevention of respiratory infections, methods for encouraging smoking cessation, and respiratory disturbances during sleep.

RESEARCH PLANS: Research topics might include methods of intervening with populations at risk, methods for teaching prevention, smoking cessation, self-management of chronic lung diseases, and cost effectiveness of preventive measures. Educational and/or behavioral approaches to the prevention of respiratory diseases and/or the promotion of lung health are encouraged.

Letter of intent: Prospective applicants are asked to submit a one-page letter of intent that includes a descriptive title, name of the principal investigator(s), and any other participating institutions. Such letters are requested for the purpose of obtaining an indication of the number of applications to be received, and therefore the NHLBI usually does not acknowledge their receipt. A letter of intent is not binding, nor is it a necessary requirement for application. This letter should be received no later than June 15, 1990, and sent to:

C. James Scheirer, Ph.D.
Contract, Clinical Trials, and
Training Review Section
Review Branch
Division of Extramural Affairs, NHLBI
Westwood Building, Room 548
Bethesda, Maryland 20892

TIMETABLE:

Letter of Intent	June 15, 1990
Application Receipt Date	July 23, 1990
Technical Review (which may include interviews conducted by the Division of Extramural Affairs in Bethesda, MD with applicants)	October/November 1990
Advisory Council Review	February 14-15, 1991
Award Date	June 1, 1991

Requests for Guidelines for the Preventive Pulmonary Academic Award (Revised 1/90) should be directed to:

Joan M. Wolle, Ph.D., M.P.H.
Health Scientist Administrator
Prevention, Education, and Research Training Branch
Division of Lung Diseases, NHLBI
Westwood Building, Room 640
Bethesda, Maryland 20892
Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance number 13.838. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency Review.

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

**5333 Westbard Avenue
Bethesda, Maryland 20816**