NIH GUIDE

For Grants and Contracts

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

Vol. 17, No. 34
October 21, 1988

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NOTICES

DATED ANNOUNCEMENTS (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

IMPLEMENTATION OF EXPANDED AUTHORITIES FOR GRANTEE ORGANIZATIONS

P.T. 34; K.W. 1014002

National Institutes of Health

INTRODUCTION/BACKGROUND

In March 1986 five Federal agencies, ten universities in the State of Florida, and the Government/University/Industry Research Roundtable of the National Academy of Sciences/National Research Council began a demonstration project designed to address ways in which unnecessary administrative burdens on sponsored research could be eliminated. Based on a review of the results of the Florida Demonstration Project, the Office of Management and Budget (OMB) has authorized Federal agencies to make routine use of the most successful features of the project which will reduce overhead costs and increase research productivity. Accordingly, the National Institutes of Health (NIH) plans to implement expanded authorities for grantee organizations. This announcement precedes a more comprehensive announcement of Public Health Service (PHS) policy guidance which will incorporate these features in routine grants administration. The PHS-wide changes will be incorporated in the PHS GRANTS POLICY STATEMENT and the PHS Grants Administration Manual.

APPLICABILITY

The expanded authorities described in this notice apply to all the "R" series grant award mechanisms, except:

--"R10" Cooperative Clinical Research Grants;

--"R18" Research Demonstration and Dissemination Projects; and

--"R43," "R44" Small Business Innovation Research Grants.

An awarding component may specifically exclude a grant award from these authorities when deemed necessary by programmatic and/or administrative considerations, for example, clinical trials supported by a regular research project (R01). In such cases, special conditions will be stated on the Notice of Grant Award.

The expanded authorities apply to all types of NIH grantees except awards to individuals and foreign organizations.

EXPANDED AUTHORITIES FOR GRANTEE ORGANIZATIONS

1. EXTENSIONS WITHOUT ADDITIONAL FUNDS

The grantee organization may extend the final budget period of a project one time for a period UP TO ONE YEAR beyond the original expiration date shown on the Notice of Grant Award. Such an extension may be made when any one of the following applies:

- o additional time beyond the established expiration date is required to assure completion of the original approved project scope or objectives; or
- o continuity of PHS grant support is required while a competing application is under review; or
- o the extension is necessary to permit an orderly phaseout of a project that will not receive continued support.

The fact that funds remain at the expiration date of the grant is not in itself sufficient justification for an extension without additional funds.

The grantee organization must notify the awarding component Grants Management Officer (GMO) in writing of the extension at least 10 days before the expiration date of the project period. Upon notification, a revised Notice of Grant Award will be issued to reflect the change of the expiration date.

Grantees may not extend project periods previously extended by the awarding component.

This authority is effective for awards active on or after October 1, 1988.

2. PREAWARD COSTS

A grantee organization may, at its own risk, incur obligations and expenditures to cover costs prior to the beginning date of an award provided the following criteria are met:

- o the costs concerned are considered necessary for the conduct of the project;
- o the costs are allowable under the potential award; and
- o when required for specific expenditures or activities, NIH prior approval is obtained.

For new and competing continuation awards, preaward costs no longer are contingent upon approval by a National Advisory Council or Board. However, such costs must be incurred within 90 days of the beginning date of the award. Preaward costs incurred more than 90 days before the beginning date of the award require the prior approval of the awarding component GMO.

The grantee organization must be fully aware that preaward costs must not impair its ability to accomplish project objectives or in any way adversely affect the conduct of the project. Additionally, the incurrence of costs prior to the award of a grant imposes no obligation on the Federal Government.

This authority is effective October 1, 1988.

3. CARRYOVER OF UNOBLIGATED BALANCES

Grantee organizations are authorized to carry over unobligated funds remaining at the end of a budget period, except for funds restricted on a Notice of Grant Award.

The grantee organization must notify the NIH of the amount of unobligated balance it has elected to carry over in item 12, "Remarks," of the Financial Status Report (FSR). A revised Notice of Grant Award will NOT be issued to reflect the carryover. Any unobligated balance not specified for carryover on the FSR shall be available for disposition by the NIH awarding component.

Grantee organizations are required to submit the FSR within 90 days after the expiration of a budget period. All FSRs should be mailed to:

Grants Section
Federal Assistance Accounting Branch
National Institutes of Health
Building 31, Room B1B11
Bethesda, Maryland 20892

This authority is effective for awards issued on or after October 1, 1988. To permit an orderly transition, awarding components will utilize actual balances which have been reported on a FSR for prior budget periods ("skip" year). However, grantees may automatically carry over any balance which is available from the budget period which is expiring after October 1, 1988.

The following example illustrates this feature.

(a) Grant No. 1 R01 CA12345-01, with a budget period of 1-1-87/12-31-87, has reported an unobligated balance of $5,000 on the FSR for that period.

(b) Grant No. 5 R01 CA12345-02, with a budget period of 1-1-88/12-31-88, is currently active; its FSR is due to be filed by 3-31-89.

(c) Grant No. 5 R01 CA12345-03, which is issued 12-10-88 for the budget period 1-1-89/12-31-89, contains an "offset" of $5,000 from the "01" year in arriving at the "Amount of this award." THIS IS THE CORRECT PROCEDURE AVAILABLE TO THE NIH AWARDING COMPONENTS.

(d) Any balance from the "02" year of support is available for AUTOMATIC carryover by the GRANTEE ORGANIZATION.

4. COST RELATED PRIOR APPROVALS

Cost related "prior approvals" required by OMB Circulars A-21 (Section J), A-87 (Attachment B), and A-122 (Attachment B) are waived. However,

requirements for allowability, reasonableness, allocability, and consistency of costs remain applicable.

This authority is effective for awards issued on or after October 1, 1988.

REMAINING COGNIZANT AWARDING AGENCY PRIOR APPROVAL AUTHORITIES

A list of the remaining actions requiring cognizant awarding agency prior approval is set forth below.

Consistent with the manner in which these authorities are expressed in the PHS GRANTS POLICY STATEMENT, the prior approval of the NIH awarding component GMO will continue to be required for these actions.

- o change in scope or objectives of the project;
- o change in principal investigator;
- o change in grantee organization;
- o preaward costs to be incurred more than 90 days before the beginning date of the award;
- o contracting for the performance of substantive programmatic work;
- o transferring amounts from trainee costs into another budget category;
- o retention of research grant funds when a Research Career Development Award is issued;
- o use of the additional costs or matching alternatives for program income;
- o any change that requires additional funding; and
- o any change specifically prohibited by the terms and conditions of the award.

METHOD OF OBTAINING AWARDING COMPONENT PRIOR APPROVAL

All requests that require prior approval must be submitted in writing to the GMO designated on the Notice of Grant Award. All requests must bear the signature of an authorized official of the business office of the grantee organization as well as the principal investigator. The GMO is responsible for informing the grantee, in writing, of the final disposition of the request. Grantees should ensure that the written approval or disapproval of such requests is signed by the GMO who signed the Notice of Grant Award, or his/her designee. Grantee organizations who take action on the basis of letters or telephone conversations from unauthorized officials do so at their own risk. Such responses will not be considered binding by the NIH.

NIH REGIONAL SEMINAR IN GRANTS ADMINISTRATION

P.T. 42; K.W. 1014002

National Institutes of Health

A two-day conference covering topics related to grants administration at the National Institutes of Health is planned for November 28-29 at the Miyako Hotel in San Francisco, California. The conference is hosted by The Medical Research Institute and the Society of Research Administrators and is targeted for an audience of researchers and research administrators at institutions in the Western region which includes Arizona, California, Hawaii and Nevada.

NIH staff will serve as faculty, representing several of the institutes, the Division of Research Grants, the Division of Research Resources, and the Office of the Director, NIH. Preparation of a proposal and the NIH review process are included as agenda topics, along with special concurrent sessions for less research-intensive institutions, case studies in grant applications, post-award grants administration, and current developments in Federal policy. Presentations will cover review trends, research facilities, manpower programs, financial management, the Federal Demonstration Project, and the revision to OMB Circular A-110. Policy and procedural issues affecting NIH grants administration form the core of the program, but this should be of interest to faculty, departmental administrators, sponsored programs staff,

and business management staff. NIH particularly encourages participation by four-year colleges and other less research-intensive institutions.

Conference materials have been mailed to institutions in the Western region. The deadline for conference registration is October 31, 1988. Lynne Day and Mary Torpey at The Medical Research Institute of San Francisco are in charge of conference arrangements. For more information, contact them on (415) 561-1680.

DATED ANNOUNCEMENTS (RFPs AND RFAs)

PREVENTIVE CARDIOLOGY ACADEMIC AWARD

P.T. 34; K.W. 0715040, 0745055

National Heart, Lung, and Blood Institute

Application Receipt Date: April 3, 1989

The Division of Epidemiology and Clinical Applications (DECA) of the National Heart, Lung, and Blood Institute (NHLBI), has initiated the Preventive Cardiology Academic Award (PCAA) to provide a stimulus for the development of a preventive cardiology curriculum in those schools of medicine and osteopathy that do not have one and to strengthen and improve the preventive cardiology curriculum in those schools that do. Each school of medicine or osteopathy in the United States and its possessions or territories is eligible to compete for one award for a project period that does not exceed five years. The number of awards made each year will depend upon the merit of the applications received and availability of funds.

For the purpose of the PCAA, the term preventive cardiology is used to define the area of cardiovascular medicine having a special concern with the development of knowledge and the application of knowledge directed at the prevention of heart and vascular diseases. This includes the area of primary prevention of cardiovascular diseases in infants, children, and adults who are at risk of developing such diseases and the reduction of preventable complications or disability in persons who have already developed cardiovascular disease.

This award is intended to:

- encourage the development of a high-quality preventive cardiology curriculum in schools of medicine and osteopathy that will significantly increase the opportunities for students, house staff, and fellows to learn both the principles and practice of preventive cardiology;
- develop promising faculty whose interest and training are in preventive cardiology teaching, research, and practice;
- develop established faculty who have a major commitment to and possess educational skills for teaching preventive cardiology;
- facilitate interchange of educational ideas and methods applicable to teaching preventive cardiology among awardees and institutions; and
- develop at the grantee institution the ability to strengthen continuously the improved preventive cardiology curriculum, with local funds, subsequent to the award.

Requests for copies of the Preventive Cardiology Academic Award Program Guidelines should be directed to :

Associate Director
Clinical Applications and Prevention Program
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building, Room 5C-01
Bethesda, Maryland 20892
Telephone: (301) 496-1706

This program of the NHLBI is identified in the Catalog of Federal Domestic Assistance No. 13.837. Awards will be made under the authority of the Public Health Service Act, Section 301 (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 Health Systems Agency review.

BLOOD CENTERS FOR EPIDEMIOLOGIC STUDIES OF HUMAN RETROVIRUSES IN VOLUNTEER BLOOD DONORS

RFP AVAILABLE: NHLBI-HB-89-01

P.T. 34; K.W. 0785055, 0411005, 1002045

National Heart, Lung, and Blood Institute

Four to six cost-reimbursement contracts are expected to be awarded to contractors with the capability to serve as blood centers for the epidemiologic studies of human retroviruses in volunteer blood donors. In performing these studies, the successful offerors shall: 1) determine the prevalence of retrovirus seropositivity in first-time blood donors; 2) determine the rate of retrovirus seroconversion in repeat blood donors as a measure of incidence of infection; 3) ascertain risk factors for antibody-positive donors; 4) characterize the blood donor population by geographic location, age, sex, race/ethnicity, and donation history to permit analysis on prevalence, incidence, and risk factors; 5) identify recipients of retrovirus-positive blood units and conduct clinical and laboratory follow-up of these recipients; and 6) establish a blood specimen repository for long-term storage of specimens from study donors and recipients for future testing.

RFP No. NHLBI-HB-89-01 will be issued, upon request to Patricia L. Shifflett, Contracting Officer, on or about October 17, 1988, and proposals will be due approximately three months thereafter. To expedite requests for solicitation, please furnish three self-addressed labels with your request. The contract period is to be six years, beginning approximately July 17, 1989.

Requests for copies of the RFP should be sent to:

Patricia L. Shifflett
Contracting Officer
BDR Contracts Section, COB
National Heart, Lung, & Blood Institute
National Institutes of Health
Federal Building, Room 5C-14
Bethesda, Maryland 20892

MEDICAL COORDINATING CENTER FOR EPIDEMIOLOGIC STUDIES OF HUMAN RETROVIRUSES IN VOLUNTEER BLOOD DONORS

P.T. 34; K.W. 1004008, 1004017

RFP AVAILABLE: NHLBI-HB-89-02

National Heart, Lung, and Blood Institute

One cost-reimbursement contract is expected to be awarded to a contractor with the capability to serve as the medical coordinating center for the epidemiologic studies of human retroviruses in volunteer blood donors. In performing these studies, the successful offeror shall: 1) coordinate the development of the protocol and the design of the study forms; 2) arrange for meetings of study investigators and take and distribute minutes of the meetings; 3) develop and maintain a manual of operations which describes in detail proper procedures for data collection; 4) develop data collection procedures for the epidemiologic studies and implement data collection procedures; 5) train the blood center staffs in entry of data and completion of study forms; 6) have primary responsibility to assure prompt accumulation, entry, and editing of study data; 7) communicate with the blood centers concerning missing, delayed, incomplete, or erroneous data; 8) establish a central laboratory; and 9) analyze data from the beginning of data collection through the end of the study.

RFP No. NHLBI-HB-89-02 will be issued, upon request to Patricia L. Shifflett, Contracting Officer, on or about October 17, 1988, and proposals will be due approximately three months thereafter. To expedite requests for solicitation, please furnish three self-addressed labels with your request. The contract period is to be six years, beginning approximately July 17, 1989.

Requests for copies of the RFP should be sent to:

Patricia L. Shifflett
Contracting Officer
BDR Contracts Section, COB
National Heart, Lung, & Blood Institute
National Institutes of Health
Federal Building, Room 5C-14
Bethesda, Maryland 20892

TROPICAL DISEASE RESEARCH UNITS

RFA AVAILABLE: 88-AI-16

P.T. 34; K.W. 0715125, 1002032, 0710070, 0745005

National Institute of Allergy and Infectious Diseases

Application Receipt Date: January 13, 1989

The National Institute of Allergy and Infectious Diseases invites the submission of Program Project Grant applications to establish a Tropical Disease Research Unit (TDRU). The primary goal of the TDRU is to apply recently developed innovative biomedical technologies to the problems of one or more of the following parasitic diseases of interest to NIAID: malaria, schistosomiasis, filariasis, trypanosomiasis, and leishmaniasis. The TDRU is expected to develop a multidisciplinary and cooperative program of basic and applied research in disease areas related to host-parasite relationships, pathogenesis, improved diagnostic procedures, immunotherapy and immunoprophylaxis, chemotherapy and chemoprophylaxis, vector biology and control, or other approaches to treatment and prevention. Since enhancement of tropical disease research capabilities in the United States is one of the objectives of the TDRU program, this invitation is being extended only to domestic institutions.

The RFA label available in the 9/86 revision of Application Form 398 must be affixed 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.

It is anticipated that up to three (3) awards will be made, although the number of grants awarded will depend upon the quality of the approved grant applications.

INQUIRIES

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

Stephanie L. James, Ph.D.
Parasitology Program Officer
Parasitology and Tropical Diseases Branch
Microbiology and Infectious Diseases Program
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 737
5333 Westbard Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-2544

This program is described in the Catalog of Federal Domestic Assistance, Microbiology and Infectious Diseases Program, Number 13. 856. (Grants or Cooperative Agreements) are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) (or other authority as pertinent) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

ONGOING PROGRAM ANNOUNCEMENTS

NATIONAL INSTITUTE ON DRUG ABUSE RESEARCH GRANTS PROGRAM ANNOUNCEMENT AND GUIDELINES

P.T. 34; K.W. 0404009, 0745055, 0785055, 0710030, 0715120

National Institute on Drug Abuse

The research programs of the National Institute on Drug Abuse (NIDA) are devoted to increasing our understanding of the causes and consequences of drug

abuse. NIDA supports extramural research projects that improve and refine our methods for the assessment, treatment and prevention of drug abuse, ranging from fundamental studies of the mechanisms of action of abused drugs to applied research and development, including studies of drug abuse as a contributing factor in the AIDS epidemic. Applications for research grant support will be considered in the areas of: basic biomedical and neuroscientific research at the genetic, molecular, organ, and system level; biochemistry, medicinal chemistry, and metabolic studies; epidemiology and natural history of drug abuse; prevention and treatment research; pharmacology and behavioral pharmacology research; and research on AIDS as it relates to drug abuse and on drug abuse in the workplace.

BASIC BIOMEDICAL AND NEUROSCIENCE RESEARCH

NIDA supports studies on the effects of abused drugs in biological systems, neurochemical processes, and anatomical substrates. Included are studies of long-term and short-term effects of drugs on CNS, transport systems, receptors, and ion channels; abuse liability of drugs, brain reinforcement and reward mechanisms, analgesia, mechanisms of tolerance and dependence, influence of pre- and post-natal drug exposure, neurotoxic, mutagenic, or neuroplastic effects, and the molecular biology of genes as related to vulnerability to drug abuse. Also included are effects of abused drugs on body systems such as endocrine or immune and studies of the consequences of drug abuse.

BIOCHEMISTRY, MEDICINAL CHEMISTRY, AND METABOLISM

The Institute supports studies on the development of analytical methods for the identification and quantification of drugs and their metabolites, the synthesis of new treatment drugs and analgesics, studies of the pharmacokinetics and metabolism of drugs, and those which characterize the structural specificities of compounds with their pharmacological activities.

EPIDEMIOLOGY

Research on the incidence/prevalence of non-medical use and abuse of drugs, including exploration of the patterns, trends, and extent of drug use and methodology and statistical techniques to determine drug use. Also included are studies of psychological, personality and behavioral factors which predispose to drug abuse and familial/peer factors which contribute to the acquisition, maintenance or extinction of drug behavior.

TREATMENT

Studies which reduce drug-related morbidity and mortality particularly the intravenous spread of AIDS. Included are trials to determine the efficacy and safety of psychotherapeutic, behavioral, and pharmacologic interventions as well as evaluation studies, counseling, treatment process, diagnosis and nosology, recruitment and retention in treatment, and co-morbidity.

PREVENTION

Research designed to lead to the understanding of the etiology of drug use and development and testing of strategies to prevent it, including programs which identify risk factors, (genetic, psychiatric, behavioral, and social vulnerabilities and prenatal exposure), develop and evaluate intervention strategies, and focus on the role of drug abuse in high risk behaviors such as delinquency or crime.

BEHAVIORAL AND CLINICAL PHARMACOLOGY

Studies of pharmacological characteristics (dose-response) using the behaving animal; effects of abused drugs on behavior, learning, conditioning, cognitive function, performance. Laboratory based abuse liability studies and studies of behavioral toxicity. Vulnerability studies of behavioral and environmental factors.

AIDS AND DRUG ABUSE

Studies of AIDS incidence and prevalence and that of other infectious diseases associated with drug abuse. Studies of factors contributing to IV drug use as a mode of transmission for AIDS, research and evaluation of programs for education, intervention, prevention, and treatment programs to halt the spread of AIDS through impacting on drug abusers and their sexual partners.

DRUG ABUSE IN THE WORKPLACE

Research to study the incidence and prevalence of drug abuse in the workplace and its correlation with performance and economic criteria. Development of performance batteries to study impairment. Design, development and implementation of substance abuse and EAP programs and measures of effectiveness.

The complete text of this announcement and application kits are available from:

Grants Management Branch
National Institute on Drug Abuse
Parklawn Building, Room 10-25
5600 Fishers Lane
Rockville, Maryland 20857
Telephone: (301) 443-6710

MEASUREMENT, COURSE, AND TREATMENT OF HIV-RELATED MENTAL DISORDERS

P.T. 34; K.W. 0715095, 0715120

National Institute of Mental Health

The National Institute of Mental Health (NIMH) seeks applications for research into the spectrum of neuropsychological and psychopathological risk factors and consequences associated with Human Immunodeficiency Virus (HIV) infection. NIMH hopes to stimulate clinical and epidemiological research in the measurement of HIV-related mental disorders, the nature and course of HIV-related mental disorders, and clinical treatment and prevention trials for HIV-related mental disorders. Applicants may request support for up to 5 years. NIMH will accept applications in response to this announcement under the Public Health Service receipt dates for AIDS applications, beginning January 2, 1989. Support is available through applications for a traditional research project, small grant, First Independent Research Support and Transition (FIRST) award, program project award, Research Scientist Development Award, Clinical Investigator Award, Physician Scientist Award, or research center grant. Potential applicants interested in obtaining further information should contact:

William E. Narrow, M.D., M.P.H.
Epidemiology and Psychopathology Research Branch
Parklawn Building, Room 10C-05
Division of Clinical Research
National Institute of Mental Health
5600 Fishers Lane
Rockville, Maryland 20857
Telephone: (301) 443-3373

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