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. 19, No. 15
April 13, 1990

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

NUCLEIC ACID AND PROTEIN SEQUENCE ANALYSIS WORKSHOP FOR BIOMEDICAL RESEARCHERS

P.T. 42; K.W. 0755045, 0760070, 1004000

National Center for Research Resources

The Pittsburgh Supercomputing Center (PSC) is conducting a three-day workshop on "Nucleic Acid and Protein Sequence Analysis," August 6-8, 1990. This workshop is funded by a cooperative agreement award from the Biomedical Research Technology (BRT) Program, National Center for Research Resources (NCRR), National Institutes of Health.

The workshop will familiarize biomedical researchers with computational methods and provide practice in applying supercomputing resources to problems of concern in macromolecular sequence analysis. The workshop will emphasize alignment of and pattern extraction from multiple sequences. Participants will gain practical experience on Pittsburgh Supercomputing Center's Cray Y-MP/832 in (1) comparing and aligning sequences, (2) identifying informative patterns in a set of sequences, and (3) using extracted informative patterns to identify related sequences. Participants will gain experience with rigorous dynamic programming approaches to multiple sequence alignment as well as with consensus word approaches; they will also learn how to use profile analysis effectively on their own problems. Participants are encouraged to bring sequence analysis problems from their current research.

Workshop Leaders: Stephen Altschul and Greg Schuler from the National Library of Medicine and Michael Gribskov from the National Cancer Institute-Frederick Cancer Research Facility.

This three-day workshop will include an optional half-day session on the afternoon of Sunday, August 5. This session will introduce participants to VAX VMS and Unicos, the Cray version of the AT&T System V Unix operating system.

Travel, meals and hotel accommodations are covered for U. S. academic participants under the cooperative agreement award. A limited number of openings for industry-based biomedical researchers may be available for a fee of $1000. Enrollment is limited to 20 participants. The deadline for the submission of applications is June 4, 1990.

Grants of computing time are also available through this cooperative agreement award program funded by the Biomedical Research Technology Program, NCRR, NIH.

For application forms and further information, call or write to:

Nancy Kiser
Biomedical Coordinator
Pittsburgh Supercomputing Center
4400 Fifth Avenue
Pittsburgh, PA 15213
Telephone: (412) 268-5206 or 1-800-222-9310 (PA)
1-800-221-1641 (outside PA)
E-mail: kiser@a.psc.edu or
kiser@cpwpsca.bitnet

NIH REGIONAL CONFERENCE IN GRANTS ADMINISTRATION

P.T. 42; K.W. 1014006

National Institutes of Health

A regional conference covering topics related to grants administration at the National Institutes of Health (NIH) is planned for June 2-3, 1990, at the Virginia Beach Resort and Conference Center, Virginia Beach, Virginia. The NIH conference will precede the Society of Research Administrators' Northeast Section meeting scheduled for this same location from June 4-6, 1990.

The conference is located to attract administrators and faculty from Delaware, Maryland, Pennsylvania, Virginia, West Virginia, and Washington, D.C. Those interested from other states are also encouraged to attend. Investigators and staff from small and minority colleges, for-profit research organizations, hospitals, universities, and research institutes are also invited.

This two-day conference has a dual focus of interest to both researchers and grants administrators. Discussions of current issues that affect NIH funding and grants administration are included to give conference participants a comprehensive, up-to-date view of NIH-sponsored research. The first day of the conference will be devoted to discussions of budget issues affecting NIH funding decisions. Preparation of an NIH grant application and the NIH review process are the agenda topics for Sunday morning's program. The afternoon will be devoted to policy and procedural issues affecting NIH grants administration. The format for this conference will include case studies, group discussions, and formal presentations. Time will be available for conference participants to meet informally with the NIH representatives and discuss topics of special interest.

Mr. Geoffrey Grant, Grants Policy Officer in the Office of Extramural Research at NIH, representatives from the Division of Research Grants, and program and grants management staff of several awarding components are featured speakers.

Conference schedule and fee information will be mailed early April 1990. For more information contact:

Mr. Joe Flaherty
Massachusetts Eye and Ear Infirmary
243 Charles Street
Boston, MA 02114
Telephone: (617) 573-3009

or

Ms. Janis Gottlieb
Laurie Imaging Center
141 French Street
New Brunswick, NJ 08901
Telephone: (201) 247-9191

THE NATIONAL DISEASE RESEARCH INTERCHANGE

P.T. 34; K.W. 0780000, 0780005, 0780020, 0755050

National Center for Research Resources

The National Disease Research Interchange (NDRI) is a center for the procurement, preservation and distribution of normal and diseased human tissues and organs available for biomedical researchers. NDRI currently provides 165 different types of human tissue procured from autopsies, eye banks, surgical procedures, and organ retrieval programs. NDRI tailors the procurement and preservation of human tissue to the individual researcher's scientific protocol. Donor information accompanies all distributed tissue samples. To obtain human tissue for research, investigators must submit a formal brief application for specific types of tissue. The requests are reviewed by a committee of advisors for scientific merit and feasibility. Once approved, a procurement proposal is developed with the investigator for each specific tissue, outlining the constraints with regard to donor criteria, tissue size, processing needs, and time/delivery limitations. Investigators may request to have tissue delivered fresh with or without tissue culture media, fixed, or frozen. A modest service fee for the retrieval, preservation, and delivery of tissue is paid by the investigator. To receive an application or make inquiries, write or call:

The National Disease Research Interchange
2401 Walnut Street, Suite 408
Philadelphia, PA 19103
Telephone: (800) 222-NDRI or (215) 557-7361.

NDRI is supported by a cooperative agreement award from the Biological Models and Materials Resources Program, National Center for Research Resources, NIH.

ASSESSMENT OF PDQ AS A MODEL SYSTEM TO DISSEMINATE INFORMATION ABOUT EFFECTIVE THERAPY

RFP AVAILABLE: NCI-CO-03886-59

P.T. 34; K.W. 0715035, 0745070, 1004017, 0730050

National Cancer Institute

The National Cancer Institute (NCI) and the new Agency for Health Care Policy and Research (AHCPR) are collaborating on a project to evaluate PDQ [Physician Data Query - an NCI clinical cancer treatment information resource] as a model system to disseminate information about effective therapy. The purpose of this project is to determine if the use of explicit standards of care and guidelines, as represented by PDQ, by physicians will modify their behavior and increase the delivery of what is judged as treatment(s) most likely to be effective. The areas of examination should include the characteristics of the physicians and their practice settings. The contractor shall identify a way or ways to provide PDQ information to physicians in community practice settings, i.e., communities outside an academic medical center or major teaching hospital, and shall examine physicians' behavior when PDQ is implemented in the different community practice settings (office, clinic, hospital, etc.) at the point of decision making. The central question to be answered by this study is whether physician treatment plans become more congruent with treatment options in PDQ after physicians are presented with treatment information from PDQ. Success will thus be measured by modification in physician behavior and patient enrollment in clinical trials.

It is anticipated that a cost-reimbursement type contract will be awarded for a period of three years beginning September 30, 1990. This is a full and open competition and all responsible sources may submit a proposal which shall be considered by the agency. RFP No. NCI-CO-03886-59 will be issued on or about April 16, 1990, with proposals due approximately 45 days thereafter.

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

A. Christine Virts
Contracting Officer,
Research Contracts Branch
National Cancer Institute
9000 Rockville Pike
Executive Plaza South, Room 608
Bethesda, MD 20892

NOTICE: AIDS CLINICAL TRIAL INFRASTRUCTURE COOPERATIVE AGREEMENT FOR MINORITY INSTITUTIONS

RFA: 90-AI-04

P.T. 34, FF; K.W. 0715008, 0755015, 0404000, 0403004

National Institute of Allergy and Infectious Diseases

Revised Application Receipt Date: June 12, 1990

A National Institute of Allergy and Infectious Diseases (NIAID)-sponsored Request for Applications (RFA) entitled "AIDS Clinical Trial Infrastructure Cooperative Agreement for Minority Institutions" was published in the March 2, 1990 (Vol. 19, No. 9, page 6) issue of the NIH Guide for Grants and Contracts. It stated that receipt of application is April 26, 1990. However, the receipt date has been changed to June 12, 1990.

A one day Pre-Application Meeting will be held in Bethesda, Maryland, on April 24 for representatives from eligible institutions to discuss elements of, and clarify issues in, the RFA 90-AI-04 entitled "AIDS Clinical Trial Infrastructure Cooperative Agreement for Minority Institutions." NIAID representatives from Review, Grants Management and Division of AIDS staff will be available at this meeting to answer questions regarding the RFA, preparation and review of the application, and grants management and administrative aspects.

For more information please contact:

Ms. Tina Johnson
Clinical Research Management Branch
Treatment Research Program
Division of AIDS
National Institute of Allergy and Infectious Diseases
Control Data Bldg., Room 207P
6003 Executive Bldg.
Bethesda, MD 20892
Telephone: (301) 496-8214

CLINICAL STUDIES OF SAFETY AND EFFECTIVENESS OF ORPHAN PRODUCTS

RFA AVAILABLE: FDA-OP-90-01

P.T. 34; K.W. 0715149, 0755015, 0740000

Food and Drug Administration

Application Receipt Date: May 15, 1990

The Food and Drug Administration (FDA) is announcing the availability of funds for Fiscal Year 1990 to support clinical trials on the safety and effectiveness of orphan products.

BACKGROUND

The Office of Orphan Products Development (OPD) was established to identify and facilitate the availability of orphan products. These orphan products include drugs, biologics, medical devices, and foods for medical purposes which are indicated for a rare disease or condition (i.e., one affecting fewer than 200,000 people in the United States). Such products usually lack adequate commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are marketed products for which there is evidence suggesting usefulness in a rare disease or condition but which are not labeled for that disease or condition because substantial evidence of safety and effectiveness for that use is lacking.

All funded studies are subject to the requirement of the requirements of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

The goal of the FDA's Orphan Products Development grants program is to encourage the investigation of new products and new uses for already approved products, for use in rare diseases or conditions. In support of this goal, the FDA provides grants to conduct clinical studies intended to provide data acceptable to the agency which will either result in or substantially contribute to approval of these new products or new uses. Applicants should keep this goal in mind and must include in the application a discussion of how their proposed study will either facilitate product approval or provide essential data needed for product development. The application will be returned without review if such information is not included. This requires the applicant to have had discussions with the responsible FDA reviewing division regarding the submission of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) before submitting the grant application. Application for an IND or IDE must be submitted to FDA and approval to proceed must be received before a grant or cooperative agreement will be awarded. (Medical foods may possibly be exempt from this requirement.)

FDA will consider awarding grants and cooperative agreements to support clinical studies for determining whether the products are safe and effective for premarket approval under the act (21 U.S.C. 301 et seq.) or under section 351 of the Public Health Service Act (42 U.S.C. 262). Ordinarily, at least some preliminary clinical research suggesting effectiveness and relative safety should already be available.

Applications should be for one discrete clinical trial. The applicant must provide evidence that the product to be investigated is available to the applicant in the form needed for the clinical trial. The applicant must also provide evidence that the patient population has been surveyed and that there is reasonable assurance that the necessary number of eligible patients are available for the study.

MECHANISM OF SUPPORT

Support will be in the form of grant or cooperative agreement awards which will be subject to all policies and requirements that govern the research grant programs of the Public Health Service.

REVIEW PROCEDURES

All applications submitted in response to this request for applications will be reviewed and evaluated for scientific and technical merit by experts in the subject field of the specific application and will also be subject to a second level of review by a National Advisory Council for concurrence of the recommendations made by the first-level reviewers.

METHOD OF APPLYING

Potential applicants should write or phone the individual listed below for the full RFA document, which includes instructions for the submission of applications:

Carol A. Wetmore
Food and Drug Administration
Office of Orphan Products Development, HF-35
5600 Fishers Lane, Room 15-61
Rockville, MD 20857
Telephone: (301) 443-4903

Applications must be submitted to the Food and Drug Administration using PHS Form 398. The outside of the mailing package and line 2 of the application face page should be labeled "Response to RFA-FDA-OP-90-1."

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH GRANTS ON NARCOLEPSY

PA: PA-90-03

P.T. 34; K.W. 0715138, 0715187, 0765035, 1002058, 0745020, 0745070

National Institute of Neurological Disorders and Stroke

I. INTRODUCTION

The National Institute of Neurological Disorders and Stroke (NINDS) encourages the submission of research project grant applications (R01) related to narcolepsy.

II. BACKGROUND

Narcolepsy is a neurological condition characterized by irresistible episodes of sleep. The classic symptoms of narcolepsy are: 1) sleep attacks - sudden urges to sleep; 2) cataplexy - sudden generalized or partial flaccid paralysis; 3) hypnagogic hallucinations - sleep onset hallucinations; and 4) sleep paralysis - generalized paralysis before or at the time of falling asleep or on awaking. Narcolepsy usually appears during the teen or early adult years. The natural history of this condition has not been well described.

The prevalence of narcolepsy in the United States has been estimated to be as high as one per 1,000. It is a major reason for patient visits to sleep disorder centers. Cognitive impairment does occur, but may be secondary to excessive daytime somnolence.

The neural control of sleep states and the relationship to narcolepsy are only partially understood. In humans, narcolepsy sleep is characterized by a tendency to go from a waking state to rapid eye movement (REM) sleep with little or no intervening nonREM sleep. The changes in the motor and proprioceptive systems during REM sleep have been studied in both human and animal models. During normal REM sleep, spinal and brainstem alpha motor neuron hypopolarization produces almost complete atonia of skeletal muscles via an inhibitory descending reticulospinal pathway. Acetylcholine may be one of the neurotransmitters involved in this pathway. In narcolepsy, the reflex inhibition of catalepsy is believed identical to that seen in normal REM sleep. Modern neuroanatomical, neurophysiological and neurochemical techniques need to be further applied to increase the understanding of the pathophysiology of narcolepsy.

Studies in narcoleptic dogs, a naturally occurring model, suggest an autosomal recessive mode of transmission in that animal. However, despite the experimental evidence in human narcolepsy that there may be an inherited basis for at least some forms of narcolepsy, the mode of inheritance is unknown. Genetic analysis of cohorts of narcoleptic patients and identification of informative families are needed to define the mode of inheritance and to facilitate the search for gene markers.

In clinical practice, the differentiation between narcolepsy and other conditions characterized by excessive somonolence may be difficult. Objective methods for improving diagnosis are needed.

Treatment options are currently limited. There is a paucity of controlled double-blind studies of possibly effective drugs or other forms of therapy in the literature. Mechanisms of action of some of the few available therapeutic modalities have been explored but detailed studies of mechanism of action are needed.

III. RESEARCH GOALS

The goal of this announcement is to stimulate research in both basic and clinical aspects of narcolepsy. The scope of this program encompasses both animal and human studies, which, would utilize a variety of experimental approaches and methods. If experimental studies on human subjects are proposed, the protocols should contain recruitment procedures to encourage the participation of women and minorities.

Examples of areas of potential research include studies on the pathophysiology of narcolepsy; abnormalities of circadian rhythms, particularly anatomical and biochemical; the molecular genetics of narcolepsy; and the rational development of new therapy. Objective diagnostic procedures need to be developed and validated.

IV. MECHANISM OF SUPPORT

Support for this program will be through the traditional research grant-in-aid (R01) and First Awards (R29). Successful applicants will direct and carry out the individual research projects.

V. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on Form PHS 398 (revised 10/88) according to instructions contained in the application kit. Application kits are available from most institutional business offices or may be obtained from the Division of Research Grants at the address given below. Check "yes" in item two on the face sheet of the application and type "NINDS Grant Related to Narcolepsy, PA-90-03" in the space provided.

Applications must be responsive to the program announcement and the goals of the NINDS. They will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. An initial review will be by an appropriate study section of the Division of Research Grants. A second level of review will be by an appropriate National Advisory Council.

Receipt dates for applications are February 1, June 1, and October 1.

The original and six copies of the application should be mailed to the following address:

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

For further information, applicants may contact:

Charlotte B. McCutchen, M.D.
NIH, NINDS, DCDND, EB
Federal Building, Room 114
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1917

This program is described in the Catalog of Federal Domestic Assistance No. 13.853, Clinical Basis Research, NINDS. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and

Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject 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

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