

NIH GUIDE

For Grants and Contracts

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

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NOTICES

NATIONAL WORKSHOPS ON "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 the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

I. MIDEAST WORKSHOP

DATES: March 4-5, 1991

WORKSHOP SITE:
Friday Center
Laurel Hill Parkway
Chapel Hill, NC 27599-1020

SPONSORS:
University of North Carolina at Chapel Hill
300 Bynum Hall
Chapel Hill, NC 27599-4100

Shaw University
118 E. South Street
Raleigh, NC 27611

REGISTRATION CONTACT:
Mr. Al Dawson
Director
Friday Center
Laurel Hill Parkway
C. B. 1020
Chapel Hill, NC 27599-1020
Telephone: (919) 962-1106

TOPIC: "Interpreting the Federal Code for the Protection of Human Subjects"

II. MIDWEST WORKSHOP

DATES: April 11-12, 1991

WORKSHOP SITE:
Ramada Inn, Lakeshore
4900 South Lake Shore Drive
Chicago, IL 60615

SPONSORS:
University of Chicago
970 East 58th Street
Chicago, IL 60637

Chicago State University
95th Street at King Drive
Chicago, IL 60628

REGISTRATION CONTACT:
Mr. Arnold L. Aronoff
Associate Director
Faculty and Administrative Services
University Research Administration
University of Chicago
970 East 58th Street
Chicago, IL 60637
Telephone: (312) 702-8669

TOPIC: "Cultural Diversity, Ethics, and Research: A Workshop on Human Subject Protection"

NIH/FDA have planned national human subject protections workshops in other parts of the United States. For further information regarding these workshops contact:

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

BIOMEDICAL ASPECTS OF OBESITY--PREVENTION AND TREATMENT

P.T. 34; K.W. 0715145, 0745027, 0745070, 0765020, 0710095

National Institutes of Health

The purpose of this notice is to inform the scientific community of plans underway at the National Institutes of Health (NIH) to pursue various activities related to research on the prevention and treatment of obesity. A planning meeting on Biomedical Aspects of Obesity-- Prevention and Treatment was held at NIH on August 3, 1990. The meeting was sponsored by the NIH Nutrition Coordinating Committee (NCC) Obesity Work Group, which comprises representatives of the 11 institutes and centers at the NIH that currently support obesity-related research: the National Institute of Diabetes and Digestive and Kidney Diseases; the National Heart, Lung, and Blood Institute; the National Center for Research Resources; the National Institute of Child Health and Human Development; the National Cancer Institute; the National Institute on Aging; the National Center for Nursing Research; the National Institute of Neurological Disorders and Stroke; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Environmental Health Sciences; and the National Institute on Deafness and Other Communication Disorders. Other participants included extramural scientists who are conducting research into various aspects of obesity.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This notice is related to the priority area of nutrition.

The purposes of this preliminary meeting were to identify the major issues in obesity that should be addressed by the NIH, to make recommendations on activities to address these issues, and to prioritize topics and the mechanisms for NCC-and institute-sponsored activities to be initiated in 1991. The meeting discussions encompassed research questions, technology transfer activities, and public policy issues. Topics addressed included the current understanding of energy balance, issues in the prevention and treatment of obesity, special concerns regarding high-risk groups, risks associated with obesity, genetic and behavioral aspects of obesity, practices of weight loss programs, public awareness and information dissemination, and ways to stimulate basic and clinical obesity research. Activities recommended for NIH attention included investigating the clinical, molecular, and behavioral aspects of energy balance; working with other agencies towards providing the public with information on the prevention and treatment of obesity; targeting the prevention of obesity in childhood; improving understanding of special issues related to high-risk populations, such as women and certain ethnic groups; developing scientifically based weight standards, including considerations of age, gender, and ethnicity; increasing the emphasis on behavioral aspects of both energy intake and expenditure in obesity prevention and treatment; and applying the techniques of molecular genetics to an understanding of obesity. Various mechanisms, such as workshops, expert panels, technology assessment conferences, requests for applications, requests for proposals, and program announcements, to address some specific aspects of these topics were also discussed.

Currently, plans to pursue several of the recommended activities are in development. As details of these plans are developed further, participation of the scientific community will be invited and information on the activities to be conducted will be broadly disseminated.

For further information contact:

Darla Danford, D.Sc.
Chairman, NIH Nutrition Coordinating Committee
National Institutes of Health
Building 31, Room 4B63
Bethesda, MD 20892
Telephone: (301) 496-9281

NOTICES OF AVAILABILITY (RFPs AND RFAs)

INDUCTIVELY POWERED MICROSTIMULATOR

RFP AVAILABLE: NIH-NINDS-91-05

P.T. 34; K.W. 0745047, 0740050

National Institute of Neurological Disorders and Stroke

The Neural Prosthesis Program of the National Institute of Neurological Disorders and Stroke, NIH, is developing implantable neural stimulating systems for sensory and motor handicapped individuals. To overcome problems with interconnect cables between electrodes and stimulators, an effort has been initiated to develop an implantable microstimulator that integrates an inductively coupled, addressable stimulator with its stimulating electrodes. The Contractor will be required to exert its best efforts to further develop and enhance the reliability of implantable, micro-sized receiver-stimulators (microstimulators) that are powered and controlled by inductive coupling from an extracorporeal transmitter and coil. In-vivo testing is not required. It is anticipated that one award will be made in September of 1991 for a period of three years.

This is not a Request for Proposals (RFP). To receive a copy of the RFP, please submit a written request to the following address, and supply this office with two self-addressed mailing labels. All responsible sources shall be considered by the agency. The RFP will be issued on or about February 20, 1991, with proposals due on April 20, 1991.

Contracting Officer
Contracts Management Branch, DEA
National Institute of Neurological Disorders and Stroke, NIH
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
Attention: RFP No. NIH-NINDS-91-05

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH AND DEMONSTRATION GRANTS RELATING TO OCCUPATIONAL SAFETY AND HEALTH

PA: OH-91-923

P.T. 34; K.W. 0725020, 0403004, 0715027

Centers for Disease Control
National Institute for Occupational Safety and Health

The National Institute for Occupational Safety and Health (NIOSH) is soliciting grant applications for fiscal year (FY) 1991 for research and demonstration projects relating to occupational safety and health.

The purposes of this grant program are to develop knowledge on the underlying characteristics of occupational safety and health problems in industry and on effective solutions in dealing with them; to eliminate or control factors in the work environment that are harmful to the health and/or safety of workers; and to demonstrate technical feasibility or application of a new or improved occupational safety and health procedure, method, technique, or system.

In 1983, NIOSH published a suggested list of ten leading work-related diseases and injuries as part of a national goal to improve the health of the American people through prevention activities. To provide guidance on priorities for action, NIOSH sponsored the development of "Proposed National Strategies for the Prevention of Leading Work-Related Diseases and Injuries." Implementation of the prevention strategies requires commitment from a broad array of

organizations and scientific and professional disciplines. The extramural research program is an important means of facilitating progress in these preventive efforts.

Additional guidance is found in the document, "Healthy People 2000: National Health Promotion and Disease Prevention Objectives." The document contains measurable objectives and strategies for creating a healthier society over the next decade. The objectives and strategies are organized broadly into 3 major categories: Health Promotion, Health Protection, and Preventive Services. There are a total of 22 priority areas. The tenth priority area, "Occupational Safety and Health," is applicable to this program announcement. Overall objectives in this priority area are to reduce work-related deaths, injuries, and illnesses. Research is needed on the following: identification of new stressors affecting workers, new measurement tools for assessing worker exposures, biomarkers of workers' exposure and response, identification of populations and individuals at special risk of work-related disease and injury, mechanisms of insult and intoxication, hazard surveillance, disease and injury identification and surveillance, development of control approaches, and effective use of controls.

ELIGIBILITY

Eligible applicants include non-profit and for-profit organizations. Thus, universities, colleges, research institutions, and other public and private organizations, including State and local governments, and small, minority-and/or woman-owned businesses, are eligible for these research and demonstration grants.

MECHANISMS OF SUPPORT

The support mechanisms for this program are the individual research project grants (R01); demonstration project grants (R18); special emphasis research career award (SERCA) grants (K01); and small grants (R03). Approximately \$6,501,000 is available for FY 1991 to fund these grants: \$4,158,000 for non-competing continuation awards and \$2,343,000 for new and competing renewal awards. The estimated breakdown for the new and competing renewal awards is as follows: R01 and R18 grants - 13 awards for \$1,834,000 (total costs of these awards range from \$50,000 to \$250,000 with the average award being about \$130,000); K01 grants - 4 awards for \$216,000; and R03 grants - 14 awards for \$293,000.

Grants are usually funded for 12-month budget periods within project periods up to 5 years for research project grants and demonstration project grants, up to 3 years for SERCA grants, and up to 2 years for small grants.

Brief descriptions on the types of grants NIOSH supports are provided below. More detailed information is provided in the complete program announcement that may be obtained by calling or writing the contacts listed under "INQUIRIES."

R01s should be designed to establish, discover, develop, elucidate, or confirm information relating to occupational safety and health, including innovative methods, techniques, and approaches for dealing with occupational safety and health problems. These studies may generate information that is readily available to solve problems or contribute to a better understanding of underlying causes and mechanisms.

R18s should address, either on a pilot or full-scale basis, the technical or economic feasibility, or application of a new or improved procedure, method, technique, or system, or an innovative method, technique, or approach for preventing occupational safety or health problems.

K01s are intended to provide opportunities for individuals to acquire experience and skills essential to the study of work-related hazards, and in so doing create a pool of highly qualified investigators who can make future contributions to research in the area of occupational safety and health. Candidates must hold a doctoral degree, have research experience at or above the doctoral level, not be above the rank of associate professor, and be employed at domestic institutions. Candidates must be citizens or non-citizen nationals of the U.S. or its possessions or territories or must have been lawfully admitted to the U.S. for permanent residence at the time of application. A minimum of 60 percent time must be committed to research, although full-time is desirable. This non-renewable award provides support for a three-year project period for individuals engaged in full-time research and related activities. Awards will not exceed \$50,000 in direct costs per year. The indirect cost rate is limited to 8 percent or the actual indirect cost rate, whichever results in the lesser amount.

R03s are intended to provide financial support to carry out exploratory or pilot studies, to develop or test new techniques or methods, or to analyze data previously collected. This program is intended for predoctoral graduate students, post-doctoral researchers (within 3 years following completion of a doctoral degree or completion of a residency or public health training) and junior faculty members (no higher than assistant professor). If university policy requires that a more senior person be listed as Principal Investigator, the application should include appropriate justification for this arrangement. Salaries are allowed for necessary support staff, but are not allowed for the Principal Investigator as well as that of the junior investigator. Direct costs are limited to \$15,000 in direct costs per year, and project periods are limited to 2 years for this non-renewable award.

The NIOSH program priorities applicable to this program are as follows: occupational lung diseases, musculoskeletal injuries, occupational cancers, severe occupational traumatic injuries, cardiovascular diseases, disorders of reproduction, neurotoxic disorders, noise-induced loss of hearing, dermatologic conditions, psychological disorders, control techniques, and respirator research. Investigators may also apply in other areas related to occupational safety and health. These priority areas represent the leading diseases and injuries related to risks on the job, and NIOSH intends to support projects that facilitate progress in preventing such adverse effects among workers. Potential applicants with questions concerning the acceptability of their proposed work are strongly encouraged to call or write the technical information contact listed under "INQUIRIES."

INCLUSION OF MINORITIES AND WOMEN IN STUDY POPULATIONS

Applicants should include, where feasible and appropriate, women as well as men and minorities in the study of populations for all clinical and research efforts and to analyze, where appropriate, differences among these populations. If women and minorities are not to be included, a clear rationale for their exclusions should be provided.

APPLICATIONS AND REVIEW PROCEDURES

Applications must be prepared on form PHS 398 (revised 10/88). State and local government applicants may use Form PHS-5161-1 (revised 3/89); however, form PHS 398 is preferred. Forms and the complete program announcement are available from the NIOSH and CDC addresses cited below. Please refer to Announcement Number 923 when requesting information.

To identify responses to this announcement, check "yes" and type "NIOSH Announcement Number OH-91-923" under item 2 of page 1 of the PHS 398 or at the top of the face page of the PHS-5161-1.

Receipt dates for new R01s and R18s are February 1, June 1, and October 1 (competing continuation deadlines are 1 month later). Receipt dates for K01s and R03s are March 1, July 1, and November 1. This is a continuous announcement, consequently, these receipt dates will be ongoing until further notice.

Applications must be received by these receipt dates. However, an application received after the deadline may be acceptable if (1) it carries a legible proof-of-mailing date assigned by the carrier and (2) the proof-of-mailing date is no later than 1 week prior to the deadline date. The receipt date will be waived only in extenuating circumstances. To request such a waiver, an explanatory letter must be included with the signed completed application. No waiver will be granted prior to the receipt of the application.

The original and six copies of the PHS 398 or the original and two copies of the PHS 5161-1 application must be submitted to the address below on or before the specified receipt dates provided above:

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

Applications received under this announcement will be assigned to an Initial Review Group (IRG). The IRGs, 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. Awards will be made based on results of initial and secondary reviews, as well as availability of funds.

INQUIRIES

For Technical Information:

Roy M. Fleming, Sc.D.
Associate Director for Grants
CDC, NIOSH
1600 Clifton Road, NE
Building 1, Room 3053, MS-D30
Atlanta, GA 30333
Telephone: (404) 639-3343

For Business Information:

Ms. Carole J. Tully
Grants Mgmt. Specialist
CDC, PGO, GMB
Room 300, MS-E14
255 E. Paces Ferry Rd, NE
Atlanta, GA 30305
Telephone: (404) 842-6630

This program is described in the Catalog of Federal Domestic Assistance No. 93.262. This program is authorized under the Public Health Service Act, as amended, Section 301 (42 U.S.C. 241); the Occupational Safety and Health Act of 1970, Section 20(a)(29 U.S.C. 669(a)); the Federal Mine Safety and Health Amendments Act of 1977, as amended, Section 501(30 U.S.C. 951) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52. This program is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

DEVELOPMENT OF HIGH CONNECTIVITY NONMAMMALIAN MODELS

PA: PA-91-26

P.T. 34; K.W. 0755020, 1004005

National Center for Research Resources

Application Receipt Dates: June 1, October 1, February 1

PURPOSE

The Biological Models and Materials Research Program (BMMRP) of the National Center for Research Resources (NCRR) is issuing this announcement to encourage the submission of applications for the development of high connectivity nonmammalian models for biomedical research, including all poikilotherms, but not homeotherms. Appropriate model systems include: lower organisms (such as fishes, invertebrates, and microorganisms); in vitro systems (cell and tissue culture from both nonmammalian and mammalian sources); and nonbiological models (such as mathematical and computer simulations).

RESEARCH GOALS AND SCOPE

The overall objective of this announcement is to stimulate research in the development of nonmammalian models for biomedical research in the following areas:

- o Research on systems that are high connectivity models, including both organismic and symbolic models. Symbolic (theoretical) models include computer, mathematical, and physical models. High connectivity is defined in the following ways:
 - those models where the body of knowledge about the system is large and has resulted in extensive cross information, or connection, with other systems. Examples of organisms that have many characterized properties or functions include, but are not limited to, *Drosophila melanogaster*, *Caenorhabditis elegans*, *Aplysia*, *Xenopus*, *Arabidopsis*, *Escherichia coli*, and sea urchins.
 - a function or property that is broadly retained across many taxa. Examples include cytoskeleton structure, cell adhesion, cytochrome c, hormones, and hormone receptors.
- o Research involved with broad intertaxonomic projects.
- o Formulation of mathematical or computer models, in particular when closely coupled to biological experimentation involving nonmammalian systems. There are opportunities for mathematical modeling in many areas of biomedical research and at all levels of biological organization.

MECHANISM OF SUPPORT

The support mechanism for this program will be the individual investigator-initiated research grant (R01), or the FIRST Award (R29) as applicable. Under these mechanisms, the applicant will plan, direct, and

carry out the research program. The proposed project period during which the research will be conducted should adequately reflect the time required to accomplish the stated goals and be consistent with the policy for grant support.

APPLICATION AND REVIEW PROCEDURES

Deadline

Applications will be accepted in accordance with the usual receipt dates for new research grant applications, i.e., June 1, October 1 and February 1.

Method of Applying

Applications will be received by the National Institutes of Health (NIH), Division of Research Grants (DRG), and referred to an appropriate Initial Review Group (IRG) for scientific and technical review. Institute assignment decisions will be governed by normal programmatic considerations as specified in the NIH Referral Guidelines. Some applications may receive secondary assignments. Following the initial scientific review, the applications will be evaluated by the National Advisory Research Resources Council or another appropriate Institute council.

Applications must be submitted on form PHS 398 (rev. 10/88) that is available in the business or grants and contracts offices at most academic and research institutions and from the DRG.

To identify the applications as a response to this announcement, check "yes" in Item 2 on the face page of the application and enter the PA number and the title "HIGH CONNECTIVITY NONMAMMALIAN MODELS."

The original and six (6) copies of the application must be directed to:

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

Potential applicants are encouraged to request further information by contacting:

Louise E. Ramm, Ph.D.
Director, Biological Models and Materials Research Program
National Center for Research Resources
Westwood Building, Room 8A07
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 402-0630

This program is described in the Catalog of Federal Domestic Assistance, No. 93.198, Biological Models and Materials Resources. 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 42 CFR Part 52 and 45 CFR Part 74). This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

**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