NIH GUIDE

For Grants and Contracts

NOTICE OF MAILING CHANGE

☐ Check here if you wish to discontinue receiving this publication

☐ Check here if your address has changed and you wish to continue receiving this publication. Make corrections below and mail this page to:

NIH Guide
Printing & Reproduction Branch
National Institutes of Health
Room B4BN08, Building 31
Bethesda, Maryland 20892

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICIAL BUSINESS
Penalty for Private Use, $300

First Class Mail
Postages & Fees Paid
PHS/NIH/OD
Permit No. G-291

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. 18, No. 42
November 24, 1989

Vol. 18, No. 42, November 24, 1989

NOTICES

SALARY LIMITATION ON GRANTS AND CONTRACTS 1
National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration
Index: NATIONAL INSTITUTES OF HEALTH
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

NIH/FDA REGIONAL WORKSHOPS - PROTECTION OF HUMAN SUBJECTS 1
National Institutes of Health
Food and Drug Administration
Index: NATIONAL INSTITUTES OF HEALTH
FOOD AND DRUG ADMINISTRATION

DATED ANNOUNCEMENTS (RFPs AND RFAs)

DEVELOPMENT AND TESTING A DISPOSABLE (SINGLE USE), SPERMICIDE RELEASING VAGINAL CONTRACEPTIVE (RFP) 2
National Institute of Child Health and Human Development
Index: CHILD HEALTH, HUMAN DEVELOPMENT

PROSPECTIVE OBSERVATIONAL STUDY OF BARRIER CONTRACEPTION FOR THE PREVENTION OF STDs IN A HIGH-RISK POPULATION (RFP) 3
National Institute of Child Health and Human Development
Index: CHILD HEALTH, HUMAN DEVELOPMENT

DESIGN, ESTABLISHMENT AND ADMINISTRATION OF A SYSTEM FOR MONITORING OF DAIDS CLINICAL TRIALS SITES (RFP) 3
National Institute of Allergy and Infectious Diseases
Index: ALLERGY, INFECTIOUS DISEASES

ONGOING PROGRAM ANNOUNCEMENTS

BIOMEDICAL RESEARCH SUPPORT GRANT APPLICATIONS FOR FISCAL YEAR 1990 4
Division of Research Resources
Index: RESEARCH RESOURCES

ERRATUM

NEUROSCIENCE RESEARCH ON DRUG ABUSE (PA) 6
National Institute on Drug Abuse
Index: DRUG ABUSE

NOTICES

SALARY LIMITATION ON GRANTS AND CONTRACTS

P.T. 04, 34; K.W. 1014006

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

As reported from the Committee of Conference, the Department of Health and Human Services Appropriation Bill for fiscal year (FY) 1990 (October 1, 1989-September 30, 1990) contains a provision that restricts the amount of salary of an individual under a grant or contract award to a rate of $120,000 per year. That restriction would apply to amounts INCLUDED in grant and contract awards as well as amounts allowed to be CHARGED to those grants and contracts.

Should this provision be enacted in law, the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) will apply the restriction to all grant and contract awards and to all funding amendments to existing grants and contracts made during FY 1990 and with FY 1990 funds.

In the meantime, NIH and ADAMHA grant and contract awards that indicate salaries of individuals in excess of a rate of $120,000 per year will include the following notification:

> A final appropriation bill may prohibit reimbursement of direct salary for individuals at a rate greater than $120,000 a year as determined in the original award. This award contains (specific $ amount for direct salary plus fringe benefits and associated indirect costs) above the level which will be reduced by revised award should this provision be enacted in law. The language contained in the proposed appropriation bill follows:
>
> > "None of the funds appropriated in this title for the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of $120,000 per year."

Grant applications and contract proposals submitted to NIH and ADAMHA should continue to request funding at the regular rates of pay of all individuals for whom reimbursement is requested. However, SHOULD THE ABOVE PROVISION BE ENACTED IN LAW, NIH and ADAMHA will make downward adjustments of salary amounts in excess of the ceiling rate and fringe benefits based upon the budget approved as part of the original award. Corresponding indirect costs will also be adjusted.

Finally, the salary ceiling is intended to apply to those subawards for substantive work under an NIH or ADAMAHA grant or contract.

Further guidance will be provided in the NIH GUIDE FOR GRANTS AND CONTRACTS upon disposition of the salary limitation provision.

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 sponsoring a continuing 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:

Dates: January 11-12, 1990

Location: Houston, Texas

Title of Workshop: "1990 IRB Challenges"

Contact: Ms. Laurie Flowers
Conference Coordinator
Affiliated Systems Corporation
1200 Post Oak Blvd., Suite 540
Houston, Texas 77056-3104
Telephone: (713) 439-0210

Dates: March 8-9, 1990

Title: "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

Dates: May 14-15, 1990

Title: "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

Dates: July 19-20, 1990

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

Contact: Ms. Leigh Tenkku
Assistant Director of Research Administration
Jewish Hospital of St. Louis
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
Education Program Coordinator
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B62
9000 Rockville Pike
Bethesda, Maryland 20892
Telephone: (301) 496-8101

DATED ANNOUNCEMENTS (RFPs AND RFAs)

DEVELOPMENT AND TESTING A DISPOSABLE (SINGLE USE), SPERMICIDE RELEASING VAGINAL CONTRACEPTIVE

RFP AVAILABLE: NICHD-CD-90-10

P.T. 34; K.W. 0750020, 1009008

National Institute of Child Health and Human Development

The Contraceptive Development Branch of the Center for Population Research, National Institute of Child Health and Human Development, has a requirement to develop, design and fabricate a spermicide-releasing, disposable, diaphragm and/or device, for female use as a vaginal barrier contraceptive, utilizing polymers, excipients and spermicides that are currently accepted as medically safe. The goal of this program is to develop a disposable diaphragm and/or a similar contraceptive device in order to increase the potential for higher efficacy and acceptability. It is not the intent of the Request for Proposals (RFP) to solicit research in controlled release of different spermicides from various polymers or to solicit research for the initial development of new spermicides, polymeric materials or excipients. The offeror must be able to

perform in-vitro studies, determine physical properties (ASTM procedures) and spermicide release characteristics, and conduct, if necessary, the animal, pre-clinical safety, and Phase I clinical studies on the diaphragm/device as required by the Food and Drug Administration. The offeror will also be required to supply diaphragms/devices for Phase II clinical studies. It is estimated that two contract awards will be made for a period of up to 36 months.

This is not a Request for Proposals. RFP-NICHD-CD-90-10 will be issued on or about December 1, 1989. Proposals will be due approximately 75 days thereafter. Copies of the RFP may be obtained by sending written requests to Mr. Paul J. Duska at the address listed below.

Paul J. Duska, Contracting Officer
Contracts Management Section, OGC
National Institute of Child Health and Human Development
Executive Plaza North, Room 610
9000 Rockville Pike
Bethesda, Maryland 20892

PROSPECTIVE OBSERVATIONAL STUDY OF BARRIER CONTRACEPTION FOR THE PREVENTION OF STDs IN A HIGH-RISK POPULATION

RFP AVAILABLE: NICHD-CE-90-3

P.T. 34; K.W. 0750020, 0715182, 0503018

National Institute of Child Health and Human Development

The Contraceptive Evaluation Branch of the Center for Population Research, National Institute of Child Health and Human Development, requires information on the maximal efficacy of barrier contraceptive methods for protection from sexually transmitted disease. An observational study is requested; it must include an educational/motivational component in order to maximize the number of consistent and correct users of barrier methods during the course of follow-up. The observation will cover four groups of women, each using a different barrier contraceptive regimen, plus a comparison group not using a barrier. Offerors should have expertise in the treatment of sexually transmitted diseases, the conduct of cohort studies, and in research involving contraception. Emphasis will be placed on the ability of the offeror to recruit and follow adequate numbers of subjects during the course of the study.

The Government estimates the total required effort to be approximately 21 technical staff years; it is estimated that one cost-reimbursement, incrementally-funded type contract will be awarded for a period of forty-two (42) months. This announcement is not a request for proposals (RFP). RFP-NICHD-CE-90-3 will be issued on or about November 28, 1989. Proposals will be due 90 days thereafter. Copies of the RFP may be obtained by sending a written request to the address listed below. Please enclose a self-addressed label.

Paul J. Duska, Contracting Officer
Contracts Management Section, OGC
National Institute of Child Health and Human Development
Executive Plaza North, Room 610
9000 Rockville Pike
Bethesda, Maryland 20892

DESIGN, ESTABLISHMENT AND ADMINISTRATION OF A SYSTEM FOR MONITORING OF DAIDS CLINICAL TRIALS SITES

RFP AVAILABLE: RFP-NIH-NIAID-DAIDS-90-22

P.T. 34, FF, II; K.W. 0755015, 0785035, 0715008, 0502000, 0785130, 0404009

National Institute of Allergy and Infectious Diseases

The Divisions of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases, intends to issue a request for proposals (RFP) for the Clinical Site Monitoring contract. The purpose of the contract is to provide site monitoring for protocols being conducted at DAIDS clinical sites and training for the staff who are conducting those protocols.

One of DAIDS responsibilities is the clinical development of effective therapies for HIV infection and its sequelae. In order to meet this goal, two

systems of clinical sites have been created: the AIDS Clinical Trials Group (ACTG) and Community Programs for Clinical Research on AIDS (CPCRA). The ACTG is a cooperative clinical trials program among investigators in other research settings, NIAID personnel officials and contractors. The CPCRA supports community-based health organizations by providing primary care personnel working in community settings with technical resources and assistance. This allows scientifically sound research to be conducted for persons who are currently underrepresented in the ACTG system, such as minorities, women at risk for HIV infections, and intravenous drug users.

As of September 1989, the DAIDS had funded 47 AIDS Clinical Trials Units (ACTUs) and 66 subunits in the ACTG system. Approximately 8000 patients had been enrolled in 74 protocols. It is anticipated that 3500 patients per year will enter ACTG studies. By early FY 1990, seven CPCRA sites were funded for the immediate initiation of protocols and eleven others were identified for training in order that there will be between 30 and 60 and be located throughout the United States with a patient enrollment around 3000. Beginning in FY 1993, the number of CPCRAs is expected to be relatively stable.

The Clinical Site Monitoring contractor will be expected to design, establish and administer a system for monitoring of DAIDS clinical trials sites. This will include conducting visits to DAIDS sites to determine compliance with federal requirements and DAIDS standards and procedures pertaining to the collection of data, Institutional Review Board and informed consent procedures, drug accountability and the clinical management of the sites and to report its findings. The contractor will also be expected to play a key role in the design and conduct of educational and training activities for DAIDS staff and several of the DAIDS contractors.

In order to perform the required work, the Contractor must be able to provide: experience in managing the monitoring of multi-center and/or multi-protocol clinical trials; and monitors with clinical health training at the level of a Bachelor's degree in nursing (BSN), nurse practitioner (NP) or physician's assistant (PA) and experience in hospital and clinic settings, preferably working with minority and disadvantaged populations and intravenous drug users. Monitors' experience in research trials is essential. This NIAID-sponsored project will take approximately five years to complete. It is anticipated that one cost-plus-fixed-fee contract will be made. This is an announcement for an anticipated RFP. RFP-NIH-NIAID-AIDSP-90-22 will be issued on or about November 24, 1989, with a closing date tentatively set for January 11, 1990. This is a 100 percent small business set-aside.

Requests for the RFP shall be directed in writing to:

William Roberts
Contract Management Branch
Control Data Corp. Building
6003 Executive Boulevard, Room 214P
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-0349

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

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

ONGOING PROGRAM ANNOUNCEMENTS

BIOMEDICAL RESEARCH SUPPORT GRANT APPLICATIONS FOR FISCAL YEAR 1990

P.T. 34; K.W. 0710030, 0720005

Division of Research Resources

Application Receipt Date: December 29, 1989

BACKGROUND AND OBJECTIVES

The Biomedical Research Support Grant (BRSG) Program is designed to provide funds to eligible institutions (i.e., those heavily engaged in health-related research) to strengthen their programs by allowing flexibility to meet emerging opportunities in research; to explore new and unorthodox ideas; and

to use these research funds in ways and for purposes which, in the judgment of the grantee institution, would contribute most effectively to the furtherance of their research program.

ELIGIBILITY

Awards are made to non-profit institutions, not directly to individual investigators. Health professional schools, other academic institutions, hospitals, state and municipal health agencies, and research organizations may apply if, during FY 1989 (October 1, 1988 through September 30, 1989), the institution was awarded a minimum of three allowable Public Health Service (PHS) biomedical or health-related behavioral research grants and/or cooperative agreements, totaling $200,000 (including direct and indirect costs). Individuals, Federal institutions, foreign institutions, and profit-making institutions are not eligible.

NOTE: "Other academic institutions" include, as a single eligible component, all other schools, departments, colleges, and free-standing institutes of the institution other than the health professional schools of a university.

AWARD CONDITIONS

Awards are contingent upon the availability of funds. With eligibility determined annually, the BRSG award is for one year beginning April 1. The BRSG award provides funds only for direct costs, and is based upon a formula that is applied to the total costs awarded to an institution in the preceding fiscal year for allowable PHS research grants. No indirect costs will be awarded. Final progress and financial status reports as well as a final invention statement will be required by June 30, 1991.

METHOD OF APPLYING

Applicants should note that the Form PHS 398 (Rev. 10/88) is to be used in lieu of forms previously used to apply for BRSG support. Form PHS 398 (Rev. 10/88) is available in grantee business offices or may be requested from:

Office of Grants Inquiries
Division of Research Grants, NIH
Westwood Building, Room 449
5333 Westbard Avenue
Bethesda, Maryland 20892

On or about November 27, a listing of eligible Fiscal Year 1989 grants, together with program application guidelines, will be mailed to institutions that, according to NIH records, are eligible to apply for a BRSG. If an institution believes that it is eligible and has not received application materials, please submit a letter of request to the address noted below.

Completed applications must be mailed to the following address in sufficient time to be received by the firm deadline date of December 29, 1989:

Office of Grants and Contracts Management
Division of Research Resources
National Institutes of Health
Room 849, Westwood Building
Bethesda, Maryland 20892**

This program is described in the Catalog of Federal Domestic Assistance, No. 13.337, Biomedical Research Support. Grants will be awarded under the authority of the Public Health Service Act, Section 301 (a)(3); Public Law 86-798, (42 USC 241) and administered under PHS grant policies and Federal Regulations 45 CFR Part 74 and the Biomedical Research Support Grant Information Statement and Administrative Guidelines. This program is not subject to the intergovernmental review requirements of the Executive Order 12372 or Health Systems Agency review.

ERRATUM

NEUROSCIENCE RESEARCH ON DRUG ABUSE

P.T. 34; K.W. 1002030, 0404009, 0705055, 0760075, 0414005, 0404000, 0785115

National Institute on Drug Abuse

PURPOSE

The following is a correction notice to reflect two changes in the Program Announcement entitled, "Neuroscience Research on Drug Abuse," published in the NIH Guide for Grants and Contracts in Volume 18, No. 37, on October 20 and Volume 18, No. 38, on October 27, 1989. Both changes are in the in the Research Objective Section; therefore, only this section is being published below. The changes are: (1) addition of National Institute on Alcohol and Alcohol Abuse (NIAAA) to the Institutes having specific programs in the neurosciences, and (2) missing words in the first sentence. The corrected section follows:

RESEARCH OBJECTIVES

The neuroscience program of the National Institute on Drug Abuse, Division of Preclinical Research, encourages investigations into the basic mechanisms underlying the action of abused drugs and substances on the central nervous system as well as research leading to the development of drugs that potentially may be used in the treatment or amelioration of drug abuse. Research that focuses on the relationship between drug-receptor interactions or neurochemical alterations and consequences of drug usage in terms of behavioral processes is specifically encouraged. Areas of particular interest include the following:

(1) Brain Reward Mechanisms in Drug Abuse
(2) Neuropsychopharmacology of Abused Drugs
(3) Anabolic Steroid Abuse
(4) Drug-Induced Neurotoxicity
(6) Developmental Neurobiology
(7) Drug Effects on Cognitive Processes
(8) Drug Effects on Sensory Processes
(9) Blood-Brain Barrier Studies
(10) Clinical Neuroscience

Support can be obtained in the form of R01 (Research Project Grants), R03 (Small Grants), R13 (Research Conference Grants), and R29 (First Independent Research Support and Transition Awards).

NIAAA, National Institute of Mental Health and various NIH Institutes have specific programs in the neurosciences. Grant applications will be assigned to the appropriate Institute based upon existing programmatic guidelines.

*U.S. GOVERNMENT PRINTING OFFICE:1989-261-138:00025