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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:

MIDWEST WORKSHOP

DATES: April 11-12, 1991

PLACE:
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 workshops on human subject protections 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 (Bldg. 31, Room 5B59)
Bethesda, MD 20892
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

WOMEN'S HEALTH TRIAL: FEASIBILITY STUDY IN MINORITY POPULATIONS - CLINICAL CENTERS

RFP AVAILABLE: NCI-CN-15344-20

P.T. 34, FF, II; K.W. 0755015, 0710095

National Cancer Institute

The National Cancer Institute, Division of Cancer Prevention and Control, is soliciting proposals to establish three Clinical Centers for the Women's
Health Trial: Feasibility Study in Minority Populations. This dietary intervention study is a randomized, controlled multicenter trial that will enroll a total of 2,250 post-menopausal women. One of the Clinical Centers shall enroll 50 percent or greater representation of Black women, one shall enroll 50 percent or greater representation of Hispanic women, and one shall enroll women as they are represented in the U.S. population, including all minorities. Women representing all economic levels will be enrolled at each Clinical Center. The main focus of the three-year feasibility study is to assess the ability of Black, Hispanic, and low-income populations to change their current eating habits to a low-fat eating pattern (20 percent of calories as fat). Responsibilities of each Clinical Center include: (a) enrollment of 750 eligible study participants over an 18-month period and the capability to enroll an additional 1,250 eligible women; (b) implementation of the trial protocol for baseline and follow-up data collection; and (c) delivery of the standardized nutrition intervention program through group counselling and instruction.

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 RFP, "Women's Health Trial: Feasibility Study in Minority Populations - Clinical Centers," is related to the priority area of nutrition. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

Date of issuance of the RFP will be approximately April 5, 1991, with a closing date for receipt of proposals to be 60 days later. Copies of this RFP may be obtained by sending a written request citing the RFP No. NCI-CN-15344-20 to:

Mr. Charles E. Lerner, Contract Specialist
National Institutes of Health
National Cancer Institute
Research Contracts Branch, PCCS
Executive Plaza South, Room 635
Bethesda, MD 20892
Telephone: (301) 496-8603

No collect calls will be accepted.

WOMEN'S HEALTH TRIAL: FEASIBILTY STUDY IN MINORITY POPULATIONS - STATISTICAL AND NUTRITION COORDINATING CENTER

RFP AVAILABLE: NCI-CN-15343-20

P.T. 34, FF, II; K.W. 0755015, 0710095, 0755018

National Cancer Institute

The National Cancer Institute, Division of Cancer Prevention and Control, is soliciting proposals to establish a Statistical and Nutrition Coordinating Center for the Women's Health Trial: Feasibility Study in Minority Populations. This dietary intervention study is a randomized, controlled, multicenter trial that will enroll 2,250 post-menopausal women at three clinical centers. The Coordinating Center will play a central role in the overall coordination of the trial, data management and analysis, blood specimen storage, dietary assessment and monitoring, and development and coordination of the nutrition intervention program.

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 RFP, "Women's Health Trial: Feasibility Study in Minority Populations - Statistical and Nutrition Coordinating Center," is related to the priority area of nutrition. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

Date of issuance of the RFP was March 15, 1991, with the proposals due 45 days later. Copies of this RFP may be obtained by sending a written request citing the RFP No. NCI-CN-15343-20 to:
NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL TRAINING GRANTS IN MEDICAL REHABILITATION RESEARCH

RFA AVAILABLE: HD-91-11

P.T. 44; K.W. 0720005, 0745070, 0785180

National Institute of Child Health and Human Development

Application Receipt Date: June 17, 1991

The National Center for Medical Rehabilitation Research of the National Institute of Child Health and Human Development is implementing an institutional National Research Service Award (NRSA) pre- and postdoctoral research training program in medical rehabilitation research.

Applications will be accepted from domestic, nonprofit public and private schools of medicine, osteopathy, and accredited medical rehabilitation facilities with departments of physical medicine or the equivalent thereof, with this training program based in that department.

This is a one-time request with plans to make five or six awards in fiscal year 1991. The direct cost request for the first year may not exceed $125,000. The initial period of support requested may be five years. Funding beyond that time period will be subject to competitive renewal.

For a detailed copy of the Request for Applications (RFA), specifying eligibility and the characteristics of the training program, applicants must contact:

David B. Gray, Ph. D.
Health Scientist Administrator
National Institute of Child Health and Human Development
Executive Plaza North, Room 631
Bethesda, MD 20892
Telephone: (301) 496-1383

For fiscal and administrative matters, contact:

Mr. Don C. Clark
Grants Management Officer
National Institute of Child Health and Human Development
Executive Plaza North, Room 501
6130 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-5001

HUMAN GENOME PROGRAM DEVELOPMENTAL GRANTS

RFA AVAILABLE: HG-91-04

P.T. 44; K.W. 1215018, 0790010, 0755045

National Center for Human Genome Research

Letter of Intent Receipt Dates: May 9, 1991; September 14, 1991
Application Receipt Dates: July 9, 1991; November 14, 1991

The National Center for Human Genome Research (NCHGR) announces the availability of developmental grants (P20) to provide support to groups of outstanding investigators who wish to develop interdisciplinary research programs on genome problems.
BACKGROUND

The National Institutes of Health is currently engaged in a research program to characterize the genomes of selected model organisms, including that of the human. The five-year scientific goals for the NCHGR research program include: expanding the human genetic map to a resolution of two to five centimorgans; constructing complete physical maps of the DNA of certain model organisms and the human; and developing new technology to increase the efficiency and accuracy and to lower the cost of physical mapping and DNA sequencing.

Attaining these goals may require the establishment of interdisciplinary collaborations and/or large research projects that are usually supported by program project or center grants. Planning such a project requires considerable effort and may also require significant funding. To encourage investigators to undertake the effort of planning for such complex projects and acquiring the necessary preliminary data and key biological reagents, the NCHGR offers non-renewable developmental grants (P20) of limited size and duration.

OBJECTIVES OF HUMAN GENOME PROGRAM (HGP) DEVELOPMENTAL GRANTS

The primary purpose of the HGP developmental grant will be to provide support for a group of investigators to develop interdisciplinary collaborations and strategies, to obtain preliminary results that demonstrate feasibility, and to develop a research plan addressing a major research goal of the Human Genome Project to be used as the basis for an application for an HGP program project or center grant.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDIES

NIH policies concerning research on human subjects apply to this program. For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded from this requirement. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this must be addressed by applicants.

TERM OF SUPPORT

HGP developmental grants will be limited to $750,000 total costs per year for a maximum of three years. It is anticipated that up to five developmental grants will be awarded depending upon the quality of the applications received. Up to $3,750,000 may be awarded as HGP Developmental Grants. The awards are not renewable and supplements are not usually allowed.

REVIEW PROCEDURES

There will be two receipt dates for this Request for Applications (RFA): July 9, 1991 and November 14, 1991. Future RFAs for HGP developmental grants will be published if there is a continuing need to stimulate interdisciplinary genome research. Applications will be evaluated for scientific merit by the Genome Research Review Committee and will receive a second-level review by the National Advisory Council for Human Genome Research.

LETTER OF INTENT

Applicants are strongly urged to contact the individual listed below by telephone and with a letter of intent (due two months prior to the receipt date), to indicate that they plan to submit an application for an HGP developmental grant. The letter should include the name of the Principal Investigator and key co-investigators as well as the title and subject of the planned research.

INQUIRIES

Before preparing an application, applicants must obtain the full RFA and instructions for HGP Developmental Grants from:

Jane L. Peterson, Ph.D.
Chief, Research Centers Branch
National Center for Human Genome Research
National Institutes of Health
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
For information regarding NIH grants policy, contact:

Ms. Alice Thomas
Grants Management Officer
National Center for Human Genome Research
National Institutes of Health
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards will be made under the authority of the Public Health Service Act, Sections 301 (Public Law 78-410, as amended by 42 U.S.C. 241) and administered under PHS grants 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 to Health System Agency review.

KAPOSI'S SARCOMA: CELL CYCLE STUDIES OF VASCULAR CELLS

RFA AVAILABLE:  HL-91-06-H
P.T. 34; K.W. 0715040, 0715035, 1002004

National Heart, Lung, and Blood Institute
Application Receipt Date: September 16, 1991

The Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI), announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA are available from staff of the NHLBI. Awards will be made to foreign institutions only for research of very unusual merit, need, and promise.

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 RFA 'Kaposi's Sarcoma: Cell Cycle Studies of Vascular Cells' is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

This special program will support research into the basic mechanisms involved in the proliferative patterns of vascular cells in Kaposi's sarcoma (KS). One goal of these studies is to acquire knowledge that could be utilized to develop new approaches to the treatment of KS. A second and more general goal is to acquire knowledge that would have broad application for understanding the aberrations of vascular cell proliferation in a variety of diseases in which capillary cell dysfunction plays a key role.

The support mechanism for this program will be the traditional, individual research project grant (RO1). Although the financial plans for fiscal year 1992 include $1,000,000 for the total costs of this program, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that up to five grants will be awarded under this program.

ELIGIBILITY

All domestic public and private, for-profit and non-profit, institutions or organizations are eligible to apply in response to this RFA. Awards in connection with this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

Upon receipt, applications will be reviewed for their responsiveness to the objectives of this RFA. If an application is judged unresponsive, the
applicant will be contacted and given an opportunity to withdraw the application or to have it considered for the regular, investigator-initiated grant program of the NIH. Applications judged to be responsive will be reviewed for scientific and technical merit by an initial review group, which will be convened by the Division of Extramural Affairs, NHLBI, solely to review these applications.

Application Procedure

Send or deliver the completed application and four (4) signed, exact photocopies to the following, making sure that the original application with the RFA label attached is on top:

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

SEND AN ADDITIONAL NINETEEN (19) COPIES OF THE APPLICATION TO:

Dr. Charles Turbyfill
Review Branch/Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 553
Bethesda, MD 20892

IT IS IMPORTANT TO SEND THESE NINETEEN COPIES AT THE SAME TIME AS THE ORIGINAL AND FOUR COPIES ARE SENT TO THE DIVISION OF RESEARCH GRANTS. OTHERWISE THE NHLBI CANNOT GUARANTEE THAT THE APPLICATION WILL BE REVIEWED IN COMPETITION FOR THIS RFA.

Applications must be received by September 16, 1991. An application not received by this date will be considered ineligible.

Requests for copies of the RFA should be addressed to:

Constance Weinstein, Ph.D.
Chief, CDB, DHVD
National Heart, Lung, and Blood Institute
Federal Building, Room 3C06
Bethesda, MD 20892
Telephone: (301) 496-1081
FAX: (301) 480-6282

For fiscal and administrative matters, contact:

Linda Shaw
Grants Operation Branch
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11-D
Bethesda, MD 20892
Telephone: (301) 496-7536

INTERSTITIAL CYSTITIS DATA BASE: CLINICAL CENTERS AND DATA COORDINATING CENTER

RFA AVAILABLE: DK-91-10

P.T. 34; K.W. 0755018, 0785220, 0413001, 0780005

National Institute of Diabetes and Digestive and Kidney Diseases

Application Receipt Date: June 14, 1991

The National Institute of Diabetes and Digestive and Kidney Disease (NIDDK) through the Division of Kidney, Urologic and Hematologic Diseases (DKUHD) invites cooperative agreement applications to establish Clinical Centers and a Data Coordinating Center directed at determining the natural history of interstitial cystitis (IC).

BACKGROUND

Interstitial cystitis is a chronic, painful, and variably incapacitating disorder that manifests a symptom complex consisting of pain in the region of the urinary bladder and associated pelvic musculature, and variable motor and sensory dysfunctions of the urinary bladder. It affects a significant percentage of the adult population, predominately women. Although the symptom
complex was described nearly a century ago, there has been little research into this disorder until recently, and the existing data contain many conflicting and incongruous findings. The factors that have inhibited advances in the understanding of this disorder include: the lack of specific diagnostic criteria, the lack of specific tissue changes at the histological level, and the unpredictable and variable remission and recrudescence of symptoms.

OBJECTIVES AND SCOPE

The purpose of this Request for Applications (RFA) is to establish three Clinical Centers and one Data Coordinating Center to study the natural history of IC. The Clinical Centers will recruit and follow patients with IC and collect demographic, symptom information, and patient specimens, including bladder biopsy material, in a standardized manner. The Data Coordinating Center will collect, store, and analyze data and specimens that are obtained.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

The support mechanism for this program will be the cooperative agreement, which is similar to the traditional NIH research grant. It differs from a research grant in the extent and nature of NIH staff involvement.

As a result of this announcement, it is anticipated that four awards (three Clinical Centers and one Data Coordinating Center) will be made under this RFA, at a funding level of approximately $200,000 - $250,000 in total costs for the Data Coordinating Center and approximately $125,000 in total costs for each Clinical Center. However, the funding of such applications is contingent on the actual availability of funds and the receipt of applications of sufficient scientific merit. Support for successful applications will begin on September 30, 1991; total support for the project will be for approximately 5 years. The current policies and requirements that govern the review, funding, and performance of cooperative agreement programs of the NIH will prevail. Additional requirements for performance in this program are also set forth by NIDDK and are outlined in the full RFA.

APPLICATIONS AND REVIEW PROCEDURES

Applications will be reviewed initially by the Division of Research Grants (DRG) for completeness and will be assigned to a special NIDDK review group. Evaluation for responsiveness to the RFA is an NIDDK program staff responsibility. Applications that are judged non-responsive will be returned to the applicant. Those applications judged to be both responsive and competitive will be evaluated for scientific/technical merit by an appropriate initial review group convened by the NIDDK Review Branch. The second level of review by the National Diabetes, Digestive and Kidney Disease Advisory Council will make recommendations regarding funding.

METHOD OF APPLYING

Applications must be submitted on form PHS 398 (revised 10/88) available in the business or research grant offices of most academic or research institutions, and from the Office of Grants Inquiries, Division of Research Grants, Room 449, Westwood Building, 5333 Westbard Avenue, National Institutes of Health, Bethesda, Maryland 20892. Applications will be accepted until close of business on June 14, 1991. No extensions will be granted on the application deadline.
INQUIRIES

Copies of the full RFA may be obtained from:

John W. Kusek, Ph.D.
Director, Clinical Trials Program
Division of Kidney, Urologic and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 621
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7133

For fiscal and administrative matters, contact:

Thomas Turley
Grants Management Office
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 653B
Bethesda, MD 20892
Telephone: (301) 496-7467

ONGOING PROGRAM ANNOUNCEMENTS

PSYCHOPATHOLOGY AND MENTAL RETARDATION

PA: PA-91-37
P.T. 34; K.W. 0710105, 0715130, 0715095, 0745020, 0415001

National Institute of Mental Health

The National Institute of Mental Health (NIMH) announces support of research to elucidate the epidemiology, etiology, treatment, and prevention of behavioral and emotional mental disorders in persons of any age with mental retardation. Of special interest is basic research into the pathogenesis of emotional disorders among individuals with mental retardation and studies of those emotional disorders that appear to be etiologically related to mental retardation. In addition, NIMH encourages clinical and applied investigations that lead to the development of diagnostic research methodology and instrumentation, treatment, and intervention strategies. Research methodologies may range from laboratory experimental studies to observational field studies.

Applications may be submitted by any public or nonprofit institution such as a university, college, hospital, or community agency, units of State and local government, and authorized units of the Federal government, and for-profit institutions and entities. Women and minorities are encouraged to apply.

Applicants must give special attention to the inclusion of minorities and women in study populations for research. The lack of appropriate attention to these issues on the part of the applicant will be seen as weakening the application. If women and minorities are not included in a given study, a clear rationale for their exclusion must be provided.

Support mechanisms for this program include the individual research project grant (R01), the First Independent Research and Transition (FIRST) award (R29), program projects (PO1), small grants (R03), and appropriate research training mechanisms. Criteria for these various mechanisms should be requested from the contact listed below.

Support may be requested for a period of up to 5 years. Annual awards will be made subject to continued availability of funds. For fiscal year 1991, it is estimated that approximately $500,000 will be available for this purpose. Applications will be accepted on the regular receipt dates and assigned by the standing referral guidelines.
For further information, prospective applicants should contact:

Eleanor Dibble, DSW
Child and Adolescent Disorders Branch
Division of Clinical Research
National Institute of Mental Health
Parklawn Building, Room 10-104
5600 Fishers Lane
Rockville, MD 10857
Telephone: (301) 443-5944

For fiscal and administrative matters, contact:

Diana S. Trunnell
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane
Parklawn Building, Room 7C15
Rockville, MD 20857
Telephone: (301) 443-3065

CLINICAL MENTAL HEALTH ACADEMIC AWARD

PA: PA-91-38
P.T. 34; K.W. 0715095, 0715129, 0715177, 0414004

National Institute of Mental Health

The National Institute of Mental Health (NIMH) announces the Clinical Mental Health Academic Award to assist in the development of academic scholars oriented toward clinical research in the areas designated as high priority by NIMH: disorders of children and adolescents, geriatric mental health, and schizophrenia. A secondary purpose is to assist in the development of a greater number of departments/institutions with a strong academic and research base in these high priority areas. Upon completion of the award, the nominee is expected to function as a researcher, as a resource person to help foster development of other researchers, and as a teacher to introduce new research findings in the academic setting.

Eligible institutions are limited to accredited U.S. colleges and universities offering post-baccalaureate degrees. Nominees must be U.S. citizens or must have been lawfully admitted to the United States for permanent residence. Women and members of minority groups are encouraged to apply. Applications for this award are required to include both women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including them is provided.

The Clinical Mental Health Academic Award is limited to a period of 5 years. Candidates may request up to $25,000 each year of the award. In Fiscal Year 1990, approximately $2,000,000 was allocated to this program. NIMH anticipates awarding as many as 10 new awards per year, but applications submitted in response to this announcement will compete with others assigned to NIMH for funding.

Potential applicants seeking further information should direct inquiries to:

Leonard Lash, Ph.D.
Associate Director for Research Training and Research Resources
Room 10-99
Telephone: (301) 443-3264

Peter S. Jensen, M.D.
Chief, Child and Adolescent Disorders Research Branch
Room 10-104
Telephone: (301) 443-5944

Enid Light, Ph.D.
Head, Research Resources
Mental Disorders of the Aging Research Branch
Room 7-103
Telephone: (301) 443-1185

David Shore, M.D.
Acting Chief, Schizophrenia Research Branch
Room 10C-06
Telephone: (301) 443-3524
The mailing address for all of the above is:

Division of Clinical Research  
National Institute of Mental Health  
5600 Fishers Lane  
Rockville, MD 20857

For fiscal and administrative matters, contact:

Diana S. Trunnell  
Grants Management Branch  
National Institute of Mental Health  
5600 Fishers Lane  
Parklawn Building, Room 7C15  
Rockville, MD 20857  
Telephone: (301) 443-3065