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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. 4
January 26, 1990

Vol. 19, No. 4, January 26, 1990

NOTICES

DATED ANNOUNCEMENTS (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

NATIONAL CANCER INSTITUTE-DESIGNATED COMPREHENSIVE CANCER CENTER GUIDELINES

P.T. 04; K.W. 0715035, 0710030, 1014006

National Cancer Institute

The National Cancer Institute (NCI) announces the availability of Cancer Center Support Guidelines for NCI-Designated Comprehensive Cancer Centers. Copies of the Guidelines have been distributed to the Directors of all current NCI-Supported Cancer Centers. Copies for general distribution are now available and may be obtained by contacting:

Margaret E. Holmes, Ph.D.
Acting Chief, Cancer Centers Branch
Division of Cancer Biology and Diagnosis
National Cancer Institute
Executive Plaza North, Room 308
6130 Executive Boulevard
Bethesda, Maryland 20892
Telephone: (301) 496-8531

UPDATE ON THE NIH POLICY REGARDING PROGRAM PROJECT, AND OTHER COMPLEX MULTIFACETED, UNSOLICITED GRANT APPLICATIONS

P.T. 34; K.W. 0710030, 1014006

National Institutes of Health

The Institutes, Centers, and Divisions (ICDs) of the National Institutes of Health (NIH) accept a variety of large unsolicited grant applications, such as those for program projects and other large, complex coordinated research grants. However, guidelines and policies governing preparation, review, and funding of these applications are not uniform across the NIH and may differ because of a variety of factors such as legislative mandates, fiscal constraints and programmatic management.

In order to serve the extramural community better, the National Institutes of Health advise that prior to submission of any application for an unsolicited, multifaceted grant, applicants communicate with appropriate ICD staff. This action will allow the applicant to be apprised of the guidelines and policies that govern the preparation, review and funding of such applications for a particular ICD. Of special concern is the fact that the different ICDs have different dollar limits for such multifaceted applications, and applications that exceed these limits will be returned without review.

The assignment of an application to a potential funding source within the NIH is based on scientific guidelines developed for each ICD in conjunction with the Division of Research Grants (DRG) and is the responsibility of the DRG, not of the individual ICDs. Thus, when the potential applicant discusses plans for a complex program grant application with the initial ICD contact, he/she is strongly advised to inquire whether other ICDs may also have relevant scientific interests so that additional staff contacts can be made if appropriate.

The following individuals may be contacted for specific questions related to such applications:

National Institute on Aging
9000 Rockville Pike
Bldg. 31, Room 5C06
Bethesda, Maryland 20892
Att.: Dr. Miriam Kelty
Telephone: (301) 496-9322

National Institute of Allergy and Infectious Diseases
5333 Westbard Avenue
Westwood Bldg., Room 703
Bethesda, Maryland 20892
Att.: Dr. John Diggs
Telephone: (301) 496-7291

National Institute of Arthritis and Musculoskeletal and Skin Diseases
9000 Rockville Pike
Bldg. 31, Room 4C32
Bethesda, Maryland 20892
Att.: Dr. Michael Lockshin
Telephone: (301) 496-0802

National Cancer Institute
9000 Rockville Pike
Bldg. 31, Room 10A03
Bethesda, Maryland 20892
Att.: Ms. Barbara Bynum
Telephone: (301) 496-5147

National Institute of Child Health and Human Development
9000 Rockville Pike
Bldg. 31, Room 2A03
Bethesda, Maryland 20892
Att.: Dr. Antonio Novello
Telephone: (301) 496-1848

National Institute of Deafness and Other Communication Disorders
7550 Wisconsin Avenue
Federal Bldg., Room 1C11
Bethesda, Maryland 20892
Att.: Dr. Ralph Naunton
Telephone: (301) 496-1804

National Institute of Dental Research
5333 Westbard Avenue
Westwood Bldg., Room 503
Bethesda, Maryland 20892
Att.: Dr. Lois Cohen
Telephone: (301) 496-7723

National Institute of Diabetes and Digestive and Kidney Diseases
5333 Westbard Avenue
Westwood Bldg., Room 657
Bethesda, Maryland 20892
Att.: Dr. Walter Stolz
Telephone: (301) 496-7277

National Eye Institute
9000 Rockville Pike
Bldg. 31, Room 6A08
Bethesda, Maryland 20892
Att.: Dr. Ralph J. Helmsen
Telephone: (301) 496-5884

National Institute of Environmental Health Sciences
P.O. Box 12233
Bldg. 3, Room 301
Research Triangle Park, North Carolina
Att.: Dr. Anne Sassaman
Telephone: (919) 541-7723
FTS 8-629-7723

National Institute of General Medical Sciences
5333 Westbard Avenue
Westwood Bldg., Room 953
Bethesda, Maryland 20892
Att.: Dr. W. Sue Shafer
Telephone: (301) 496-7061

National Heart, Lung and Blood Institute
5333 Westbard Avenue
Westwood Bldg., Room 7A17
Bethesda, Maryland 20892
Att.: Dr. Ronald Geller
Telephone: (301) 496-7416

National Institute of Neurological Disorders and Stroke
7550 Wisconsin Avenue
Federal Bldg., Room 1016
Bethesda, Maryland 20892
Att.: Dr. John Dalton
Telephone: (301) 496-9248

National Center for Human Genome Research
9000 Rockville Pike
Bldg. 1, Room 203
Bethesda, Maryland 20892
Att.: Dr. Mark Guyer
Telephone: (301) 496-0844

National Center for Nursing Research
9000 Rockville Pike
Bldg. 31, Room 5B09
Bethesda, Maryland 20892
Att.: Dr. Janet Heinrich
Telephone: (301) 496-0523

Division of Research Resources
9000 Rockville Pike
Bldg. 31, Room 1B63
Bethesda, Maryland 20892
Att: Dr. Judith Vaitukaitis
Telephone: (301) 496-6023

DATED ANNOUNCEMENTS (RFPs AND RFAs)

MAGNETIC RESONANCE IMAGING STUDIES IN MULTIPLE SCLEROSIS

RFP AVAILABLE: NIH-NINDS-90-03 (Broad Agency Announcement)

P.T. 34; K.W. 0706030, 0715140, 0710070, 0785035

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke, NIH, has a requirement to determine the optimal frequency for performing magnetic resonance imaging (MRI) in multiple sclerosis (MS) patients. Offerors must have expertise in clinical, immunological, and MRI investigations of MS patients.

It is anticipated that one or more awards will be made for a period of two years each, depending upon the nature and complexity of the research projects proposed.

This is not a Request for Proposals (RFP). The RFP will be issued on or about January 23, 1990, as a Broad Agency Announcement (BAA) as defined in FAR Subparts 6.102 (d) (2) and 35.016. A tentative date for receipt of proposals is set for March 23, 1990.

To receive a copy of the RFP, please submit a written request and two self-addressed mailing labels to the following address:

Contracting Officer
Contracts Management Branch, DEA
National Institute of Neurological Disorders and Stroke, NIH
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, Maryland 20892

Attn: BAA/RFP No.NIH-NINDS-90-03

NATIONAL COLLABORATIVE DIAGNOSTIC IMAGING TRIAL PROJECTS

RFA AVAILABLE: 90-CA-05

P.T. 34; K.W. 0706030, 0715035, 0745020

National Cancer Institute

Letter of Intent Receipt Date: March 25, 1990
Application Receipt Date: April 25, 1990

The Radiation Research Program (RRP), Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites applications for Cooperative Agreement for NATIONAL COLLABORATIVE DIAGNOSTIC IMAGING TRIAL PROJECTS. The objectives of the present proposal are to conceive new approaches for the development and implementation of national cooperative trials carried out by multiple institutions to develop new algorithms for the appropriate sequential

use of the most advanced imaging procedures to diagnose, stage and monitor malignant disease.

The decades of the 1970's and 1980's have been characterized by spectacular technical advances in medical imaging, particularly those applied to tumor definition and characterization. These technologies have now developed to the stage where a clear identification of the relative roles of each diagnostic modality in the diagnosis and staging of cancer is warranted. To date, most comparative studies evaluating imaging technologies have been based on limited studies and have involved small numbers of cases making their results often equivocal and not applicable in large scale patient care settings.

Multi-institutional trials (collaborative group) have been established by NCI to assess the relative role of each imaging modality in cancer management of carcinomas of the prostate, lung, colorectal and pancreas.

The objective of this Request for Applications (RFA) is to support multicenter cooperative clinical trials to determine the most effective imaging procedures required to stage and monitor head and neck and musculoskeletal carcinomas. The successful applicants will join the on-going cooperative agreement; (86-CA-10) an re-issuance, (88-CA-02). Sufficient numbers of patients including minorities and women must be available and committed to meaningful imaging trials.

Approximately $900,000 in total costs per year for four years will be committed specifically to fund applications that are submitted in response to this RFA. It is anticipated that approximately six or possibly eight scientifically meritorious applications can be funded.

The RFA label available with the 10/88 revision of application 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review.

Request for copies of the complete RFA should be addressed to:

Dr. Matti Al-Aish, Acting Chief,
Diagnostic Imaging Research Branch
Radiation Research Program
National Cancer Institute
Executive Plaza North, Suite 800
Bethesda, Maryland 20892

RESEARCH DEMONSTRATIONS PROGRAM TO ENHANCE DRUG ABUSE TREATMENT

RFA AVAILABLE: DA-90-05

P.T. 34; K.W. 0404009, 0403004

National Institute on Drug Abuse

Application Receipt Date: April 9, 1990

PURPOSE

The purpose of this announcement is to request applications for research demonstration projects to improve the effectiveness of drug abuse treatment and expand treatment capacity. An additional aim of the announcement is to provide support for expanded treatment or the improved provision of treatment services within the context of a research program.

RESEARCH DEMONSTRATION OBJECTIVES

The aim of the grant program is to demonstrate improvements in drug abuse and dependence treatment, with results that enable treatment systems to operate with greater effectiveness and efficiency. Applicants are expected to design carefully controlled studies to demonstrate the effectiveness of improvements in existing treatment strategies or the efficacy of new therapeutic interventions. Funding will be available for the treatment of opioid, cocaine, and polydrug abuse, as well as treatment of abused "gateway" drugs that may lead to more serious drug abuse. Enhancing client recruitment and retention, making treatment more effective, and reducing relapse after treatment are appropriate areas of investigation under this announcement. Outcomes must be tailored toward reducing drug use, improving retention in treatment, improving client compliance with program expectations, and reducing relapse to abused drugs. Interventions can be pharmacological or nonpharmacological and may be based in a variety of settings. Investigation

into all types of treatment modalities, including those seeking to mainstream drug treatment, is encouraged. Reports describing the expanded treatment or the improved provision of treatment services will be required.

INCLUSION OF MINORITIES IN STUDY POPULATIONS

Applicants are urged to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in a given study, a clear rationale for their exclusion should be provided.

INCLUSION OF WOMEN IN STUDY POPULATIONS

Applicants are urged to consider the inclusion of women in the study populations for all clinical research efforts. Exceptions would be studies of diseases which exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If women are not to be included, a clear rationale should be provided for their exclusion.

AVAILABILITY OF FUNDS

Money has been made available to fund up to 10 new research demonstration grants at an approximate first year cost of up to $1 million each.

APPLICATION PROCEDURES

Applicants must use the standard PHS 398 (rev. 10/88) grant application form. When applying, the name of this RFA, "Research Demonstration Program to Improve Treatment for Drug Abuse, RFA 90-05", should be typed in item 2 of the face page of PHS 398. Application kits are available from university grant offices or from the Grants Management Branch, National Institute on Drug Abuse, Room 8A-54, 5600 Fishers Lane, Rockville, Maryland 29875, Telephone (301) 443-6710. Applicants must affix the RFA label available in the 398 to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. The original and six (6) copies of each application must be submitted to:

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

REVIEW PROCESS AND CRITERIA

Applications received under this announcement will be assigned to an initial review group (IRG) in accordance with established PHS Referral Guidelines. 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. Applications will receive a second-level review by an appropriate National Advisory Council, whose review may be based on policy considerations as well as scientific merit. Only applications recommended for approval by the Council may be considered for funding.

AWARD CRITERIA

Applications recommended for approval by an appropriate National Advisory Council will be considered for funding on the basis of overall scientific, clinical, and technical merit of the proposal as determined by peer review, appropriateness of budget estimates, the agency's program needs and balance, policy considerations, adequacy of provisions for the protection of human subjects, and availability of funds.

INQUIRIES

Further information and consultation on program requirements can be obtained from:

Frank M. Tims, Ph.D.
Deputy Chief, Treatment Research Branch
Division of Clinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-30
Rockville, Maryland 20857
Telephone: (301) 443-4060

This program is described in the Catalog of Federal Domestic Assistance No. 13.279. Grants will be awarded under the authority of Sections 301 and 515 of the Public Health Service Act, as amended (42 USC 241 and 42 USC 290), and administered in accordance with the PHS Grants Policy Statement and Federal Regulations at 42 CFR Part 52, and 45 CFR Part 74. This program is subject to the intergovernmental review requirements of Executive Order 12372.

DRUG ABUSE TREATMENT EVALUATION RESEARCH CENTER GRANT

RFA AVAILABLE: DA-90-04

P.T. 04; K.W. 0404009, 0710030, 0795005, 0404000

National Institute on Drug Abuse

Application Receipt Date: March 30, 1990

PURPOSE

The purpose of this announcement is to establish and support a Center to conduct interdisciplinary research on the effectiveness of drug abuse treatment.

RESEARCH OBJECTIVES

The Abuse Treatment Evaluation Research Center Grant Program is designed to complement the regular research grants program of the National Institute on Drug Abuse (NIDA) by providing long-term support for interdisciplinary evaluative research on drug abuse treatment. The program is intended to attract investigators in the behavioral, social, and biomedical sciences to conduct evaluative research on the treatment of drug abuse, and to provide a stable environment for such persons to engage in treatment research. A Center is expected to become a significant regional or national research resource. The Center funded under this announcement will not only conduct treatment evaluation research but also will participate actively in and cooperate with NIDA's programmatic efforts to systematically review, coordinate, and integrate research on treatment populations, process, and outcome.

A variety of designs and research strategies may be employed to evaluate existing treatment programming and related interventions. Both field studies and controlled (randomized) studies may be used, as well as secondary analyses to investigate issues of interest to treatment evaluation. Areas for investigation potentially include comparative effectiveness of treatment program types for well-defined client groups, treatment process, the structure of treatment, studies of specific modalities, outreach, differential attractiveness of treatment, client-treatment matching, the role of non-treatment factors, correctional treatment, treatment of drug abuse in primary health care delivery systems, effectiveness of alternative (i.e., not designed primarily for drug abusers) treatments, treatment improvement, treatment for specific drugs of abuse, aftercare and relapse prevention, treatment careers, and cohort-based studies of long-term outcomes. Methodologically oriented studies may also be appropriate activities for the Center under this program.

INCLUSION OF MINORITIES IN STUDY POPULATIONS

Applicants are urged to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in a given study, a clear rationale for their exclusion should be provided.

INCLUSION OF WOMEN IN STUDY POPULATIONS

Applicants are urged to consider the inclusion of women in the study populations for all clinical efforts. Exceptions would be studies of diseases

which exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If women are not to be included, a clear rationale should be provided for their exclusion.

In order to provide more precise information to the treatment community, it is recommended that publications resulting from research supported by the Alcohol, Drug Abuse, and Mental Health Administration in which the study population was limited to one sex for any reason other than that the disease or condition studied exclusively affects that sex, should state, in the abstract summary, the gender of the population studied, e.g., "male patients," "male volunteers," "female patients," and "female volunteers."

APPLICATION PROCEDURES

Applicants must use the standard PHS 398 (rev. 10/88) grant application form. When applying, type in item 2 of face page of PHS 398, the name of this announcement, "Drug Abuse Treatment Research Center Program, RFA DA-90-04." Application kits are available from university grant offices or from the Grants Management Branch, National Institute on Drug Abuse, Room 8A-54, 5600 Fishers Lane, Rockville, Maryland 20857; Telephone (301) 443-6710.

Applicants must affix the RFA label available in the 398 to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

The original and six (6) copies of applications must be submitted to:

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

REVIEW PROCESS AND CRITERIA

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary HHS grant programs. Applications received under this announcement will be assigned to an initial review group (IRG) in accordance with established PHS Referral Guidelines. 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. Applications will receive a second-level review by the National Advisory Council on Drug Abuse, whose review may be based on policy considerations as well as scientific merit. Only applications recommended for approval by the Council may be considered for funding.

AWARD CRITERIA

Applications recommended for approval by the National Advisory Council on Drug Abuse will be considered for funding on the basis of overall scientific and technical merit of the Center proposal as determined by peer review, appropriateness of budget estimates, NIDA program needs and balance, NIDA policy considerations, adequacy of provisions for the protection of human subjects, and availability of funds.

AVAILABILITY OF FUNDS

In fiscal year 1990, an estimated $1 million will be available to support one new grant under this announcement. The actual amount of funding available will depend on appropriated funds and program priorities at the time of award.

INQUIRIES

Prospective applicants may obtain additional information regarding the development of Drug Abuse Treatment Evaluation Research Center grant applications and advice regarding the feasibility/appropriateness of such applications by contacting:

Frank M. Tims, Ph.D.
Deputy Chief, Treatment Research Branch
Division of Clinical Research
National Institute on Drug Abuse
Parklawn Building, Room 10A-30
5600 Fishers Lane
Rockville, Maryland 20857
Telephone: (301) 443-4060

This program is described in the Catalog of Federal Domestic Assistance No. 13.279. Grants will be awarded under the authority of Sections 301 and 515 of the Public Health Service Act, as amended (42 USC 241 and 42 USC 290), and administered in accordance with the PHS Grants Policy Statement and Federal Regulations at 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.

COOPERATIVE AGREEMENTS FOR RESEARCH DEMONSTRATION PROJECTS ON ALCOHOL AND OTHER DRUG ABUSE TREATMENT FOR HOMELESS PERSONS

RFA AVAILABLE: AA-90-01

P.T. 34; K.W. 0404003, 0403004, 0404009

National Institute on Alcohol Abuse and Alcoholism and
National Institute on Drug Abuse

Application Receipt Date: April 9, 1990

PURPOSE

The purpose of this research demonstration program is to assess the effectiveness of interventions for homeless individuals with alcohol and/or other drug problems. In FY 1990, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), in consultation with the National Institute on Drug Abuse (NIDA), will award approximately $14 million to support the first year costs of up to 18 new research demonstration projects. Non-competing continuation awards will be made for a total of three years, subject to continued availability of funds and progress achieved.

RESEARCH OBJECTIVES

The general purpose of this research demonstration program is to contribute to scientific knowledge regarding effective interventions for homeless individuals with alcohol and/or other drug problems. Hypotheses should be tested in terms of the following primary objectives:

- o reduction of the consumption of alcohol and/or other drugs;
- o increase in levels of shelter and residential stability;
- o enhancement of economic and/or employment status.

FUNDING MECHANISM

The funding mechanism to be used to support these research demonstration projects will be a cooperative agreement. The major difference between cooperative agreements and other grants is the substantial programmatic involvement of Institute staff above and beyond the levels regularly required for traditional program management of grants. While individual investigators will propose the hypotheses and key questions to be tested and will develop the methods and research designs to accomplish this, the cooperative agreement enables the Institutes to obtain specific data across sites and to report findings at the national level.

ACTIVITIES FOR WHICH SUPPORT IS AVAILABLE

Interventions for homeless persons with alcohol and other drug problems are divided into two broad categories: initial interventions and extended interventions. Examples of initial interventions include outreach, engagement and the provision of shelter, sobering, or detoxification services. Extended interventions include comprehensive treatment, self-help group involvement, case management, transitional and permanent housing, and vocational training. Support is available for the development, implementation and evaluation of new treatment interventions only; funds may not be used solely for the evaluation of existing interventions. Applicants may choose from, but are not limited to, the interventions listed above.

EVALUATION RESEARCH DESIGN

NIAAA and NIDA will support applications whose evaluation research designs provide a rigorous test of the individual project's proposed intervention(s) and are capable of contributing data that is comparable across sites for the purposes of the national evaluation. Therefore, applicants are required to design an individual project evaluation that includes, at minimum, a comparison group and a core set of standardized instruments (described below).

While the primary activities supported under this Request for Applications (RFA) will be the evaluation research projects designed and implemented by the awardees, a national evaluation will be conducted by NIAAA in collaboration with the awardees. As participants in the national evaluation, all sites will collect individual-level, outcome evaluation data on all study participants in extended interventions using, at a minimum, the following instruments: the Addiction Severity Index, the Alcohol Dependence Scale, the Global Assessment Scale, and the housing section of the Personal History Form.

INCLUSION OF MINORITIES IN THE RESEARCH DEMONSTRATION

The Institutes urge applicants to give added attention (where feasible and appropriate) to the inclusion of minorities in the research demonstration. If minorities are not included, a clear rationale for their exclusion should be provided. Applicants are also urged to consider the inclusion of women in the research demonstration. Gender differences should be noted and evaluated. If women are not to be included, a clear rationale should be provided for their exclusion. In addition, the Institutes would like to encourage applications which address the special needs of other homeless subpopulations, such as women with children, adolescents, young adult males, chronic public inebriants, and individuals with alcohol and/or other drug problems concomitant with a mental illness.

APPLICATION PROCEDURES

Applicants should use Form PHS 398 (revised 10/88). Important additional materials are enclosed with the PHS 398 in a Supplemental Materials Package for this RFA. These materials should be requested from:

NIAAA Homeless Demonstration Program RFA
National Clearinghouse for Alcohol and Drug Information
Post Office Box 2345
Rockville, Maryland 20857
Telephone: (301) 468-2600

A technical assistance workshop will be sponsored to assist those interested in responding to this announcement. The workshop will be offered on two occasions: February 20-21, 1990 in Phoenix, Arizona, and March 13-14, 1990 in Bethesda, Maryland. Attendance at the workshop is not required but is encouraged for those who intend to complete an application for this announcement.

INQUIRIES

All inquiries and requests for the full text of the RFA should be directed to:

Barbara G. Lubran, M.P.H.
Chief, Homeless Demonstration and Evaluation Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 16C-02
Rockville, Maryland 20857
Telephone: (301) 443-0786

ONGOING PROGRAM ANNOUNCEMENTS

DRUG ABUSE ASPECTS OF THE ACQUIRED IMMUNODEFICIENCY SYNDROME

P.T. 34; K.W. 0715008, 0404009, 0414015, 0411005, 0785055

National Institute on Drug Abuse

PURPOSE

The purpose of this announcement is to stimulate research on the interrelationships between acquired immunodeficiency syndrome (AIDS) and drug abuse. This announcement is a revision that addresses the progress in this research area since December 1986.

RESEARCH OBJECTIVES

There are a number of partially overlapping foci for this research that cannot be ranked in order of importance in dealing with the complexities of these problems, but that must be addressed. One focus is research on implications for AIDS risk behaviors of poly- and multiple-drug abuse, opiate drug use (e.g., cocaine [including crack], methamphetamine [including ice]), and non-IV

routes of administration. A second focus is prevention/intervention issues and strategies including the overall study of the behavioral implications of serostatus and concentrating on: (1) behavior change and resistances to such change in drug-abusing populations at risk, covering issues and strategies involving communities, community-based training, workplace-based initiatives, special populations, sexual behavior, basic research on risk-taking and drug treatment programs; and (2) the development of technology. A third focus is the clinical epidemiology/natural history of: (a) initiation to drug abuse, including the progression from experimentation to dependence and the relationships between drug use and sexual behavior; and (b) HIV infection and associated medical diseases in IV drug abusers and their sexual partners with an emphasis on heterosexual transmission. A fourth focus is the study of the role of drug abuse in vertical (mother-to-child) transmission with emphasis on the acquisition of data that is potentially relevant to prevention/intervention strategies. A fifth focus is the identification and study of cofactors that, together with factors related to exposure to HIV, affect vulnerability, transmissability, and disease course. A sixth focus is preclinical research using animal models and isolated human and animal tissues to look at interrelationships among HIV infection and effects of drugs of abuse on the immune, neuroendocrine and central nervous systems. A seventh focus is the clinical immunology of AIDS/HIV infection in drug-abusing populations with an emphasis on joint effects of medical, drug abuse and stress-related factors. An eighth focus is the study of central nervous system (neuropsychological and neuropsychiatric) impairments due to HIV in drug abusers. A ninth focus is the mathematical modeling of AIDS risk and transmission among special vulnerable populations and the general population. A tenth focus is on the acquisition of data from other countries that are not available in the U.S. but have implications for U.S. AIDS programs and policies. Finally, an eleventh focus is on the ethical and legal issues relevant to drug abuse and AIDS.

MECHANISMS OF SUPPORT

Support mechanisms include: Research Projects (R01), Small Grants (R03), First Independent Research Support and Transition Awards (R29), and Program Projects (P01). In addition, the National Institute on Drug Abuse (NIDA) employs a variety of support mechanisms that undergird the research training and professional development of the clinicians and scientists upon whom future drug-abuse research will depend and may have different application requirements. For this announcement, these include: Research Scientist Development Awards (K02, K05) as well as Scientist Development Awards (K21), and Scientist Development Awards for Clinicians (K20). For details on a particular support mechanism or program, please contact staff members listed at the end of this announcement.

ELIGIBILITY

Application for research grants may be submitted by any public or private non-profit or for-profit institution such as universities, colleges, hospitals, laboratories, units of State or local government, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

INCLUSION OF WOMEN IN STUDY POPULATIONS

Applicants are urged to consider the inclusion of women in the study populations for all clinical research efforts. Exceptions would be studies of diseases which exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If women are not to be included, a clear rationale should be provided for their exclusion.

In order to provide more precise information to the treatment community, it is recommended that publications resulting from NIDA-supported research in which the study population was limited to one sex for any reason other than that the disease or condition studies exclusively affects that sex, should state, in the abstract summary, the gender of the population studied, e.g., "male patients," "male volunteers," "female patients," "female volunteers."

INCLUSION OF MINORITIES IN STUDY POPULATIONS

Applicants are urged to give added attention (where feasible and appropriate to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in a given study, a clear rationale for their exclusion should be provided.

APPLICATION PROCEDURES

Applicants should use the grant application form PHS 398 (Rev. 10/88). The title of this Progam Announcement, DRUG ABUSE ASPECTS OF AIDS, should be typed in item number 2 on the face page of the PHS-398 application form. The specific section(s) of the full program announcement to which the application responds should be noted in parenthesis following this title (e.g. [section II. A.]). Names of NIDA Staff consulted should also be noted in a cover letter.

Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

Grants Management Branch
National Institute on Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, Maryland 20857
Telephone: (301) 443-6710

The narrative portion of the application (sections A-D of the PHS-398), including tables and charts, should not exceed 20 pages. Type density may not exceed 15 characters per inch. Those exceeding this page limitation may be rejected by the Division of Research Grants, NIH. The signed original and 24 permanent legible copies of the complete application should be sent to:

Division of Research Grants, NIH
Westwood Building, Room 240
Bethesda, Maryland 20892**

RECEIPT AND REVIEW SCHEDULE

Receipt Dates	Initial Review	Advisory Council Review	Earliest Start Date
Jan. 2*	Feb./March	May/June	June
May 1*	June/July	Sept./Oct.	November
Sept. 1*	Oct./Nov.	Jan./Feb.	February

* These schedules apply to all new, competing, revised, and supplemental AIDS applications (only R01 and R29). See application kit PHS 398 for information on receipt dates for other mechanisms.

REVIEW PROCESS AND REVIEW CRITERIA

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. 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. Applications will receive a second-level review by an appropriate National Advisory Council whose review may be based on policy as well as scientific merit considerations.

Only applications recommended for approval by the Council may be considered for funding. Criteria for scientific/technical merit review of applications will include the following: relevance of the proposed research to improving understanding of drug abuse aspects of AIDS; significance and originality from a scientific or technical standpoint of the goals of the proposed research; adequacy of the methodology proposed to carry out the research; feasibility of the proposed research; qualifications of the principal investigator and other key research personnel; availability of adequate facilities, other resources and collaborative arrangements necessary for the research; appropriateness of budget estimates for the proposed research activities; and adequacy of provisions for the protection of human subjects and welfare of animal subjects, as applicable.

Applications submitted in response to this announcement are not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through Department of Health and Human Services regulations at 45 CFR Part 100 and are not subject to Health Systems Agency review.

AWARD CRITERIA

Applications recommended for approval by an appropriate National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, program needs and balance, relevance to national need as reflected by research priorities, potential contribution to the areas identified in the announcement, and availability of funds.

INQUIRIES

Further information, general consultation on program requirements and referral to specific staff representatives for specific sections of this announcement can be obtained from:

Sander G. Genser, M.D., M.P.H.
Clinical Medicine Branch, DCR
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-12
Rockville, Maryland 20857
Telephone: (301) 443-1801

FOOTNOTE This program is described in the Catalog of Federal Domestic Assistance No. 13.279. Grants will be awarded under the authority of sections 301 and 515 of the Public Health Service Act, as amended (42 USC 241 and 290cc) and administered in accordance with the PHS Grants Policy Statement and Federal regulations at 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.

ETHICAL, LEGAL AND SOCIAL IMPLICATIONS OF THE HUMAN GENOME INITIATIVE

P.T. 34; K.W. 1215018, 1014004, 0404000, 1002019, 0783005, 0720005

National Center for Human Genome Research

This Program Announcement supercedes the one that appeared in the March 3, 1989 issue of the NIH Guide to Grants and Contracts, (Vol. 18, No. 7) and restates the interest of the National Center for Human Genome Research (NCHGR), National Institutes of Health (NIH), in receiving applications for research grants and conference grants addressing ethical, legal, and social issues that may arise from the application of knowledge gained as a result of the Human Genome Initiative. Applications for cross-disciplinary postdoctoral training are also being sought.

BACKGROUND

The NIH is currently engaged, along with several other federal, private, and international organizations, in a research program known as the Human Genome Initiative. This program is designed to characterize the human genome and the genomes of selected model organisms. It has several interrelated goals: the construction of high resolution genetic linkage maps; the development of physical maps of the human genome and the genomes of selected model organisms; the determination of the complete nucleotide sequence of human DNA and the DNA of several model organisms; the development of the capability for collecting, storing, distributing, and analyzing the data and materials produced; and the development of appropriate new technologies necessary to achieve these objectives. The information that will be obtained as a result of the genome project will be a resource for studies of gene structure and function and will promote research into the genetic aspects of human disease.

The capabilities that arise out of the Human Genome Initiative also are expected to have a profound impact on individuals and society. Over 4,000 known inherited disorders have been identified. Some cause disease before or shortly after birth, while others are observed only in adulthood. Mapping the human genome will increase our ability to predict, understand, and eventually prevent or cure human diseases. However, knowing the entire sequence of the human genome also will raise questions about how this information should be used. There are numerous social, legal, and ethical implications of this endeavor. To anticipate the impact of the Human Genome Initiative, the NIH will give high priority to studies that address these issues and develop options for policies or programs that minimize the possibilities of adverse impact. The NIH also is interested in improving public understanding of the issues and stimulating broad discussion among the general public, professionals, and policy makers with the goal that the information generated be of maximum benefit to individuals and society.

RESEARCH SCOPE

This program announcement emphasizes the ongoing commitment of the NIH to support activities that focus on anticipating issues arising from the application of the results of the Human Genome Initiative and on proposing solutions that will forestall adverse effects. In order to accomplish this objective, support will be provided through research grants, conference grants and individual postdoctoral fellowships for projects designed to address a range of ethical, social and legal issues. Areas of special interest include, but are not limited to, the following topics:

1. Questions of fairness in the use of genetic information with respect to: insurance, employment, the criminal justice system, the educational system, adoptions, the military, and other areas to be identified.

2. The impact of knowledge of relevant genetic information on the individual, including questions of: stigmatization, ostracism, labelling, and individual psychological responses.

3. The privacy and confidentiality of genetic information, including questions of ownership and control of genetic information and consent to disclosure and use of genetic information.

4. Issues raised by the impact of the Human Genome Initiative on genetic counseling in the following areas: prenatal testing, presymptomatic testing, carrier status testing, testing when there is no therapeutic remedy, counseling and testing for polygenic disorders, and population screening versus testing.

5. Issues raised by reproductive decisions influenced by genetic information, including questions of the effect of genetic information on options available and the use of genetic information in the decision-making process.

6. Issues raised by the introduction of increased genetic information into mainstream medical practice, including questions of: professional standards of care and quality control in acquiring and using genetic information, the qualifications and training of health professionals involved in genetic testing and counseling, the impact on the physician-patient relationship, standards of appropriate patient education, and education of the general public with respect to availability and accessibility of genetic services.

7. The uses and misuses of genetics in the past and their relevance to the current situation, e.g., the eugenics movement in the U.S. and abroad, problems arising from screening for sickle cell trait, and other recent examples in which screening or testing sometimes achieved unintended and unwanted outcomes, and the misuse of behavioral genetics to advance eugenics or prejudicial stereotypes.

8. Questions raised by the commercialization of the products from the Human Genome Initiative in the following areas: intellectual property rights (patents, copyrights, and trade secrets), property rights, impact on scientific collaboration and candor, and accessibility of data and materials.

9. Conceptual and philosophical questions raised by the Human Genome Initiative, such as its implications for: the concepts of personal identity and responsibility, the problems of determinism and reductionism, and the concepts of health and disease (particularly in view of the high rate of human genetic variability and the large numbers of people who will be found to have genetic vulnerabilities).

Most of these topics can best be addressed through scholarly research or conferences. Support for conferences will be limited to those that are highly focussed and produce a specific product, such as recommendations or policy options. Research methods should be appropriate to the nature of the projects proposed and the disciplines involved, but priority will be given to studies that address normative problems of social policy, professional ethics, and jurisprudence raised by the topics above. Thus, projects that use the interpretive methods traditional to humanities, law, and the social sciences are particularly encouraged. General surveys for purposes of information gathering will not be supported at this time. Until a plan for international activities has been developed, priority will be given to projects that focus on issues relevant to the U.S. population.

It is essential that applicants address the full range of views on each issue they select to investigate in a responsible, scholarly, and balanced manner, with the goal of advancing scholarship, achieving better understanding, or working towards consensus or useful recommendations. Collaborative projects

between geneticists and ethicists, legal scholars, educators, or social scientists are encouraged.

INDIVIDUAL POSTDOCTORAL FELLOWSHIPS

An important aspect of the program is to train individuals who have the knowledge and skills to address the research topics listed above in a comprehensive and thorough manner. For this reason, postdoctoral fellowships will be provided to scientists trained in biomedical disciplines relevant to the human genome project to receive training in ethics, law or other topics that will enable these scientists to contribute to studies of the ethical, legal or social implications of the genome project. Conversely, individuals with doctoral degrees in disciplines traditional to the humanities and the social sciences can receive support for postdoctoral training in genomics research in order to enhance their abilities to study problems related to the Human Genome Initiative. Support for fellowships will be provided through National Research Service Awards. The training to be supported must be research-oriented training. Studies leading to a professional degree will not be eligible for funding under this mechanism. Additional details about the policies and procedures governing these postdoctoral fellowships can be found in the NIH Guide to Grants and Contracts, Vol. 13, No. 1, January 6, 1984. Single copies are available from this office.

MECHANISM OF SUPPORT

Support for this program will be through research grants (R01), conference grants (R13), and individual postdoctoral fellowships (F32).

APPLICATION REVIEW

Applications received in response to this announcement will be reviewed by an initial review group with appropriate expertise in ethics, law, medicine, genetics, social science, and public education. Criteria for evaluating the applications will include: potential for producing new knowledge or understanding; potential impact of the proposed project to provide solutions to critical issues; balance and breadth of approach; originality of the project; potential of the proposed project in terms of scholarly or lay audience reached; experience and expertise of the applicants; and relevance to the Human Genome Initiative.

NCHGR is interested in attracting individuals with varied backgrounds to consider studies in this area. However, individuals must show that they either have or will obtain a sound working knowledge of the underlying biology so that relevance to the human genome program can be assured. Applicants are strongly urged to contact NIH staff to discuss their plans before submitting an application.

Although there is no set-aside of funds for this area of research, the human genome program is prepared to spend at least 3 percent of its resources addressing these issues, provided a sufficient number of high quality applications is received.

METHOD OF APPLYING

Applications should be submitted on the new form PHS 398 (Rev. 10/88). The conventional presentation for grant applications should be utilized (see instructions in the application kit). Application kits are available at most institutional business offices and from: Office of Grants Inquiries; Division of Research Grants; Westwood Building, Room 449; National Institutes of Health, Bethesda, Maryland 20892.

Applications for research grants and conference grants will be accepted in accordance with the usual NIH receipt dates for new applications -- October 1, February 1, and June 1; funding decisions will be made approximately 9 months after receipt of applications. Applications for individual postdoctoral fellowships will be accepted September 10, January 10, and May 10; funding decisions will be made approximately 6 months after receipt of applications. It is essential that applicants type, "Ethical, Legal and Social Implications of the Human Genome Initiative," in item 2 on the face page of the application form. The original and six copies of the application should be submitted to:

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

Applications that deal with a specific medical condition may be assigned to the NIH Institute responsible for that condition with secondary assignment to NCHGR. Funding decisions will be based on recommendations of the initial review group and a National Advisory Council regarding scientific merit and program relevance, respectively, and on the availability of funds.

For additional information, please contact:

Bettie J. Graham, Ph.D.
Chief, Research Grants Branch
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, Maryland 20892
Telephone: (301) 496-7531

**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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