

NIH GUIDE

For Grants and Contracts

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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.

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NOTICES

NOTICE OF REGIONAL MEETINGS

P.T. 42; K.W. 1014006, 1014002

National Institutes of Health

The National Institutes of Health (NIH) has been engaged in a strategic planning process aimed at developing the Agency's first corporate long-range Strategic Plan. The purpose of the NIH Strategic Plan is to: (1) identify areas of research that promise extraordinary dividends for the Nation's future health, (2) nurture the intellectual base of biomedical research and the conditions that lead to breakthroughs on the cutting edge of science, and (3) provide approaches for addressing broad administrative and science policy issues that affect the ability of the NIH to carry out its mandate. The Strategic Plan incorporates the ideas of all the organizational components of the NIH as well as the research components of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

The NIH will convene two regional meetings to provide a forum for the extramural community to comment on the draft Strategic Plan before it is finalized. The first meeting will take place on February 12, 1992, at Occidental College, Los Angeles, California, and will be co-hosted by Occidental College and the Charles R. Drew University of Medicine and Science. The second meeting will be held on February 25, at the University of Connecticut Health Center, Farmington, Connecticut.

Each of the regional meetings will be of one day duration, beginning at 9 a.m. and ending at 3 p.m. The meetings will begin with the NIH Director presenting an overview of the NIH Strategic Plan. Immediately afterwards, representatives of concerned organizations and institutions will be invited to present testimony before a panel of senior NIH officials, to be chaired by the Director, NIH. Due to time constraints, it would

be appreciated if only one representative from each organization would present testimony; oral presentations will be limited to five minutes. Written testimony may be any length and should include a brief description of the organization presenting. Testimony will be scheduled based upon when notification of intent to present testimony is received. If the number of organizations that want to present oral testimony exceeds the time available on the agenda, the individual written statements will serve as testimony presented. All testimony, whether oral or written, will form a part of the official record of the NIH Strategic Plan.

If you or others from your organization who plan to attend one of these regional meetings have any special needs that require assistance, please inform the office listed below. If you have questions concerning either of the two regional meetings, please contact Ms. Mary Demory (301) 496-1454.

If you will be attending one of the regional meetings or if your organization would like to testify before the NIH panel, please provide the name, title, institution, telephone number, and mailing address of the individual attending. Indicate which regional meeting and whether or not testimony will be presented. The requested information is to be sent by mail or facsimile no later than December 16, 1991 to:

NIH Strategic Plan Regional Meetings
c/o Dr. Jay Moskowitz
NIH, Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892
FAX: (301) 402-1759

A copy of the Draft NIH Strategic Plan and additional information will be sent prior to the regional meetings to participants attending and/or testifying.

NATIONAL WORKSHOPS ON THE 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 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:

WEST COAST WORKSHOP

DATES: January 23 and 24, 1992 (REVISED DATES)

WORKSHOP SITE: Los Angeles, CA

SPONSORS:
University of Southern California
Los Angeles, CA 90089-4014

California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202

REGISTRATION CONTACT:
Ms. Lily Patterson
Assistant to the Director
Research and Sponsored Programs
California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202
Telephone: (213) 343-3820

TOPIC: Whose Research is it Anyway? A Workshop on the Protection of Human Subjects in Research

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78284-7972

St. Mary's University
One Camino Santa Maria
San Antonio, TX 78228-8572

REGISTRATION CONTACT:

Ms. Angie Khan
Institutional Coordinator of Research Review
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive (Room 402L)
San Antonio, TX 78284-7972
Telephone: (512) 567-2351

TOPIC: Identifying and Assessing Risks in Human Subject Research

For further information regarding these workshops and future NIH/FDA National Protection of Human Subjects Workshops, please contact:

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

NOTICES OF AVAILABILITY (RFPs AND RFAs)

UNITED STATES RENAL DATA SYSTEM

RFP AVAILABLE: NIH-NIDDK-92-2

P.T. 34; K.W. 0755018, 0780030, 1010013, 0785055

National Institute of Diabetes and Digestive and Kidney Diseases

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Division of Kidney, Hematology and Urology (DKUH) has a requirement to continue the Coordinating Center (CC) for the United States Renal Data System (USRDS). The CC, in coordination with the NIDDK and the Health Care Financing Administration (HCFA), shall provide the medical, biostatistical, epidemiological, data management, and analytical expertise to maintain and update the database. Equally important functions of the CC will be the coordination, scientific management, development, and expansion of the database, data analysis, preparation, and release of subset(s) of the database to support investigator-initiated research, and publications of papers and reports of scientific findings based on USRDS data. This program will be undertaken through the joint efforts of the NIDDK/DKUH and the HCFA Bureau of Data Management and Strategy, Health Standards and Quality Bureau, and the ESRD Networks or equivalent system in close collaboration with the United States nephrology and renal transplant communities and the major specialty organizations.

The Request for Proposals (RFP) NIH-NIDDK-92-2 will be released on or about November 29, 1991, with a closing date on or about March 31, 1992. To receive a copy of this RFP, supply this office with two self addressed mailing labels and cite the RFP number referenced above. Requests must be in writing and addressed to:

Patrick M. Sullivan
Contracting Officer, Contracts Management Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 602
Bethesda, MD 20892

This advertisement does not commit the Government to make an award.

RESEARCH ON PHARMACOLOGIC TREATMENTS FOR ALCOHOLISM

RFA AVAILABLE: AA-92-01

P.T. 34; K.W. 0404003, 0710100, 0740020

National Institute on Alcohol Abuse and Alcoholism

Application Receipt Date: April 3, 1992

PURPOSE

Development of new medications for the treatment of brain and behavior disorders is a priority of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). As part of this initiative, the National Institute on

Alcohol Abuse and Alcoholism (NIAAA) is seeking applications for grants in the area of clinical pharmacological treatments for alcoholism. The Request for Applications (RFA), available from the program administrators listed below, briefly discusses current knowledge on pharmacologic therapies, some specific research questions under each topic, broader issues that "cut across" pharmacotherapy in the treatment of alcoholism, key study design considerations, procedures for submission and review of grant applications, and terms and conditions for grant support. The RFA deals with a range of pharmacological agents at various stages of research development, ranging from preclinical research and development to Food and Drug Administration (FDA) approval.

HEALTHY PEOPLE 2000

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, Research on Pharmacologic Treatments for Alcoholism, is related to the priority area of alcohol abuse reduction. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY

Applications may be submitted by domestic and foreign, nonprofit and for-profit public and private organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISMS OF SUPPORT

Research support may be requested through applications for an individual research grant (R01), small grant (R03), First Independent Research Support and Transition (FIRST) Award (R29), and exploratory/developmental grants (R21). Applicants who are interested in applying for a FIRST Award (R29), Exploratory/Developmental Grant (R21), or Small Grant (R03) may request additional information about these funding mechanisms from the National Clearinghouse for Alcohol and Drug Information, P.O. Box 2345, Rockville, MD 20852, telephone (301) 468-2600.

AVAILABILITY OF FUNDS

In FY 1992, it is anticipated that approximately \$2,300,000 will be available to support approximately 10 to 20 new grants, depending on the mechanism of support, under this RFA. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NIAAA, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

BACKGROUND AND AREAS OF RESEARCH

Over the past decade, research activity on the pharmacological treatment of alcohol dependency has burgeoned (Litten and Allen, 1991). As a result, many types of pharmacological agents have been employed in the various situations encountered in clinical practice. The pharmacological agents for managing the clinical events can be divided into the following categories (Liskow and Goodwin, 1987):

- Anticraving agents
- Aversive agents
- Agents to treat acute alcohol withdrawal
- Agents to treat the protracted withdrawal syndrome
- Agents to diminish drinking by treating associated psychiatric pathology
- Agents to decrease drinking by treating associated drug abuse
- Agents to induce sobriety in intoxicated individuals (amethystic agents)

Research is needed to resolve questions within each of these classes of pharmacological agents. Research is also needed to address general questions that transcend specific pharmacological classes. The following provides a background on each of the classes of pharmacological agents listed, describes general, cross-cutting research issues in the area of pharmacotherapy, and identifies some specific research questions. The discussion of any agent within this announcement is not to be considered a comprehensive appraisal of its effectiveness nor an endorsement of its suitability for clinical trial.

GENERAL RESEARCH QUESTIONS IN PHARMACOTHERAPY

Even though research efforts on alcoholism treatment have expanded over the past decade, a wide range of general research questions remain in developing effective alcoholism treatments that employ pharmacotherapeutic agents. These include:

- o What are the precise conditions that are amenable to pharmacological interventions? How can psychosocial and behavioral interventions be integrated with pharmacotherapy to enhance treatment outcome? What should be the short- and long-term goals of these interventions?
- o What psychological and biomedical variables are associated with responsiveness to alcoholism medications in general and specific agents or classes of agents?

- o Is the concept of matching specific treatments to different aspects of alcoholism (e.g., alcohol subtypes, comorbid psychopathology, and primary versus secondary alcoholism) more efficacious than a more generalized medication approach to treatment?
- o Does collateral pharmacological treatment enhance or detract from participation in traditional alcoholism treatment and sobriety support groups?
- o What are the most effective research/statistical methodologies for conducting pharmacologic research on alcoholism treatment?
- o How can alcohol abuse phenomena be quantified to assess more precisely the impact of psychopharmacological agents?
- o How can treatment compliance be measured during pharmacotherapy?
- o What are the long-range effects of pharmacotherapy?

STUDY DESIGN CONSIDERATIONS

Well-designed studies need to be conducted to answer research questions such as those listed above. These studies must include the use of appropriate control groups (i.e., double blind studies) with adequate sample sizes and employment of proper statistical analyses. In addition, all treatment interventions must be specified. Although developmental projects may employ highly homogeneous samples in a single setting, it is desirable in later-stage research to include greater heterogeneity in samples and sites. Finally, efficacy studies need to measure compliance and adequately verify self-reports.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

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

APPLICATION PROCESS

Applicants must use the grant application form PHS 398 (rev. 10/88). The number and title of this RFA, "AA-92-01, Research on Pharmacologic Treatments for Alcoholism," must be typed in item 2 on the face page of the PHS 398 application form.

When using the PHS 398 application form to respond to an RFA, applicants must staple the RFA label, printed in the application kit, 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 signed original and five permanent legible copies of the completed application should be sent to:

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

In addition, one copy must be sent directly to:

Office of Scientific Affairs
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 16C-20
Rockville, MD 20857
Telephone: (301) 443-4375

INQUIRIES

Potential applicants are encouraged to request a copy of the RFA and may contact the individuals listed below for consultation in preparing an application under this RFA. Direct inquiries regarding to program issues to:

Division of Clinical and Prevention Research

Raye Z. Litten, Ph.D.
Treatment Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 14C-20
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-0796

Division of Basic Research

Walter Hunt, Ph.D.
Chief, Neuroscience and Behavioral Research Branch
Division of Basic Research
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 16C-03
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4223

Direct inquiries regarding fiscal matters to:

Ms. Elsie Fleming
Grants Management Branch
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 16-86
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4703

REVIEW PROCESS

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 RFA will be assigned to an Initial Review Group (IRG) convened by the NIAAA in accordance with established PHS Referral Guidelines. The IRG, 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 Alcohol Abuse and Alcoholism, whose review may be based on policy considerations as well as scientific merit. Only applications recommended for consideration by the Council will be considered for funding.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.273. Awards are made under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb). Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH ON HAIR TESTING FOR DRUGS OF ABUSE

PA AVAILABLE: PA-92-18

P.T. 34; K.W. 1003008, 0404009, 0710100

National Institute on Drug Abuse

PURPOSE

The goals of this program for which a program announcement is now available from the contact named below, are to encourage systematic research on the use of hair testing to detect drugs of abuse in an accurate and reliable manner and to develop the necessary procedures and safeguards. The purpose is to provide the scientific basis to enable the routine use of such testing in workplace situations, epidemiological studies, studies of the behavioral effects and medical consequences of chronic drug use, maternal and fetal studies, and other applications. Specific areas of interest discussed are: pharmacological studies, analytical studies, and cost/benefit studies.

RESEARCH OBJECTIVES

The National Institute on Drug Abuse (NIDA) is interested in exploring the pharmacokinetics of drugs in hair and some of the factors that would influence variability in these processes. Studies are encouraged that will identify the mechanisms by which drugs of abuse are incorporated into hair; the relationship between the amount of drug used and the concentration of the drug or its metabolites in hair; the relationship of hair incorporation to urine elimination; the minimum dose required to produce a positive result; the time interval between drug use and appearance of drug in the hair shaft; the in situ stability, chemical and positional, of drugs; the variability of drug incorporation and retention in hair according to race, age, sex, and other individual differences; the extent to which externally applied drugs (whether by sweat, glandular secretions or environmental exposure) are retained in hair; the effect of various washing and hair treatment procedures on the removal of externally applied drugs and internally incorporated/bound drugs.

This program encourages research aimed at evaluating existing methods or the development of new methodologies for the detection of drugs of abuse in hair specimens. Validation of these analytical techniques by assessing their accuracy, precision, sensitivity, and specificity and identifying ways to establish appropriate cutoffs that define potentially false-positive or false-negative results for either screening or confirmation procedures is strongly encouraged through this initiative. Research endeavors aimed at the development of reference materials for hair testing are also of interest to NIDA. Studies are encouraged that deal with sample preparation including those that relate to the effectiveness of various washing procedures in removing externally and/or internally bound drug and the effectiveness of various sample preparation techniques.

The biggest costs of hair analysis are labor intensive preparation, handling, and analysis techniques. Instrumentation is an additional factor. Cost/benefit studies that compare drug testing using hair specimens with those using body fluids, such as urine or blood, would be extremely useful. Benefits of hair testing, including its non-invasiveness and the historical information it may provide, must be weighed against potential costs.

HEALTHY PEOPLE 2000

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 program announcement, Research on Hair Testing for Drugs of Abuse, is related to the priority area of alcohol and other drugs. 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, DC 20402-9325 (telephone: 202-783-3238).

MECHANISM OF SUPPORT

Mechanisms of support included under this announcement are limited to Research Project Grants (R01). Annual awards will be made subject to continued availability of funds and progress achieved.

ELIGIBILITY

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

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.

APPLICATION PROCEDURES

Applicants must use the research grant application form PHS 398 (rev. 10/88). Support may be requested for a period of up to five years (renewable for subsequent periods). A competing supplemental application may be submitted during an approved period of support to expand the scope of protocol of a project during the approved period. A competing continuation (i.e., renewal) application may be submitted before the end of an approved period of support to continue a project.

RECEIPT AND REVIEW SCHEDULE

Receipt Dates New/Renewal	Initial Review	Advisory Council Review	Earliest Start Date
Jun 1/Jul 1*	Oct/Nov	Jan/Feb	Apr
Oct 1/Nov 1*	Feb/Mar	May/Jun	Jul
Feb 1/Mar 1*	May/Jun	Sep/Oct	Dec

* Competing continuation, supplemental, and revised applications are to be submitted by these dates.

REVIEW PROCESS AND CRITERIA

Applications received under this announcement will be assigned to an Initial Review Group (IRG) consisting primarily of non-Federal scientific and technical experts. Applications will receive a second-level review by the appropriate National Advisory Council. Criteria for scientific/technical merit review of applications will include the following: 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 and research experience of the Principal Investigator and other key research personnel; and adequacy of provisions for the protection of human subjects and the welfare of animal subjects, as applicable.

AWARDS

Applications recommended for approval by the 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, Institute program needs and balance, and availability of funds.

INQUIRIES

Further information and consultation on this program announcement may be obtained from:

Robert L. Stephenson II, M.P.H.
Division of Applied Research
National Institute on Drug Abuse
Parklawn Building, Room 9A-53
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-6780

A copy of the complete program announcement may be obtained from:

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

Questions on fiscal or grant management issues may also be directed to this office.

AUTHORITY AND REGULATIONS

This program is described in Catalog of Federal Domestic Assistance No. 93.279. 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.

SMALL INSTRUMENTATION GRANTS PROGRAM

PA: PA-92-19

P.T. 34; K.W. 0735000, 1002024, 0735015, 1014001

National Institutes of Health

Application Receipt Date: February 12, 1992

BACKGROUND

The appropriations for the National Institutes of Health (NIH) for Fiscal Year (FY) 1987 included, for the first time funds for grants to purchase small instruments costing between \$5,000 and \$60,000. This action was in response to several studies of the problem of obsolete biomedical research instrumentation that indicate that the state of biomedical research instrumentation had seriously eroded over the previous ten years and that this situation was retarding the progress of biomedical research.

Approximately \$5 million will be available from the NIH in FY 1992 for small instrumentation grants.

ELIGIBILITY AND TERMS OF AWARD

Each institution that received \$21,608 or less in support under the Biomedical Research Support Grant (BRSG) Program in FY 1991 and currently has active NIH research grant support is eligible to apply. Only one application may be submitted from each eligible institution or organizational component. Each institution may establish its own procedures for identifying equipment requests to be included.

The small instrumentation award will be restricted to the purchase of equipment costing between \$5,000 and \$60,000. Awards will be made on or before September 30, 1992. The amount of the award will be based upon a percentage of the institution's research grants base for FY 1991 or \$5,000, whichever is greater.

Specific funding decisions will depend on available funds and the appropriateness of the request to the active projects. Institutions will be notified of the maximum amount for which they may apply.

METHOD OF APPLYING

Letters of instructions to eligible institutions will be mailed on or about November 28, 1991.

Completed applications must be received by February 12, 1992.

Investigators interested in participating in their institution's application must contact the institution's BRSG Program Director. Institutional officials who expect to be involved in preparing an application are requested to review the letter of instructions prior to contacting the NIH.

For additional information contact:

Office of Research Training and Special Programs
Office of Extramural Programs
National Institutes of Health
Building 31, Room 5B44
Bethesda, MD 20892
Telephone: (301) 496-1968

AUTHORITY AND REGULATIONS

Grants will be available under the authority of and administered in accordance with the PHS Grants Policy Statement and Federal regulations at 42 CFR 52 and 42 USC 241.

CENTERS FOR RESEARCH ON MENTAL HEALTH SERVICES FOR CHILDREN AND ADOLESCENTS

PA AVAILABLE: PA-92-20

P.T. 04, AA; K.W. 0715095, 0730050, 0403001

National Institute of Mental Health

PURPOSE

The National Institute of Mental Health (NIMH) announces the availability of support for Centers on Research on Mental Health Services for Children and Adolescents to develop multidisciplinary research to improve the organization, financing, delivery, effectiveness, and outcomes of mental health services for children and adolescents.

This announcement addresses one of the major goals set forth in The National Plan for Research on Child and Adolescent Mental Disorders. It also complements the NIMH program announcement, Implementation of the National Plan for Research on Child and Adolescent Mental Disorders, available from NIMH, Room 9-95, 5600 Fishers Lane, Rockville, MD 20857; telephone: (301) 443-4673.

HEALTHY PEOPLE 2000

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. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017- 001-00473-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20042-9325 (telephone: 202-783-3238). This announcement is responsive to the Healthy People 2000 Objectives in the areas of suicide attempts among adolescents (6.2), mental disorders among children and adolescents (6.3), and assessment by primary care providers of children's and adolescents' cognitive, emotional, and parent-child functioning with appropriate counseling, referral, and followup (6.4).

ELIGIBILITY

Applications may be submitted by any public and private, nonprofit and for-profit organizations such as universities, colleges hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

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

Applicants should also be aware that the Department of Health and Human Services has regulations for the protection of human subjects and has developed additional regulations for the protection of children. A copy of these regulations, 45 CFR 46, Protection of Human Subjects, is available from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 5B59, Bethesda, MD 20892.

METHOD OF APPLYING

Applications will be received under the usual PHS receipt and review schedule. To be considered for fiscal year 1992 funding, applications must be complete and must be submitted by February 1, 1992.

All research applicants must use the grant application form PHS 398 (rev. 10/88). Support may be requested for a period of up to five years. Annual awards will be made subject to continued availability of funds and progress achieved. A competing supplemental application may be submitted during an approved period of support

to expand the scope or protocol of a project during the approved period. A competing continuation (i.e., renewal) application may be submitted before the end of an approved period of support to continue a project.

Grant funds may be used for expenses clearly related and necessary to conduct research projects, including direct costs that can be specifically identified with the project and allowable indirect costs of the institution. Funds may not be used to establish, add a component to, or operate a treatment, rehabilitation, or prevention intervention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for costs required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield generalizable knowledge and/or make significant contribution to theoretical concepts.

REVIEW PROCEDURES

Applications will be reviewed by an initial review group (IRG) primarily consisting of non-Federal scientific and technical experts. Applications will receive a second-level review by the appropriate Advisory Council based on policy considerations and scientific merit. Only applications recommended for approval by Council may be considered for funding.

Preference will be given to projects consistent with the NIMH Public-Academic Liaison initiative (bringing together public sector service providers and academic researchers), projects involving high-risk populations (e.g., homeless children and adolescents, and those with severe mental disorders), and projects that include females and minorities in study groups.

INQUIRIES

Applicants are strongly encouraged to contact the office listed below. Copies of the full program announcement and additional information may be obtained by contacting:

Thomas L. Lalley, M.A., Chief
Kathryn M. Magruder, Ph.D., M.P.H., Assistant Chief
Kimberly Hoagwood, Ph.D.
Services Research Branch
Division of Applied and Services Research
National Institute of Mental Health
5600 Fishers Lane, Room 18-105
Rockville, MD 20857
Telephone: (301) 443-372

Information on grants management issues can be obtained from:

Steven J. Hudak
Grants Management Section
National Institute of Mental Health
5600 Fishers Lane, Room 7C-26
Rockville, MD 20857
Telephone: (301) 443-4596

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.242. Under the authority of Section 301 of the Public Health Service Act (42 U.S.C. 241), as amended, NIMH will accept applications in response to this announcement. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or review by a Health Systems Agency.

ERRATUM

NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS FOR THE TREATMENT OF HUMAN IMMUNODEFICIENCY VIRUS INFECTION

RFA: AI-91-13

P.T. 34; K.W. 0715008, 0740020, 0755025

National Institute of Allergy and Infectious Diseases

The National Cooperative Drug Discovery Groups for the Treatment of Human Immunodeficiency Virus Infection (NCDDG-HIV) Request for Applications (RFA) (NIH Guide for Grants and Contracts, Vol. 20, No. 41, November 1, 1991) has been amended. This amendment applies only to copies of the RFA that are obtained from the Division of AIDS, National Institute of Allergy and Infectious Diseases. The amendment is to clarify the purpose of the letter of intent (p.2), to state that an NIAID peer review group will determine the competitiveness of the application in triage (p. 22), to include acknowledgement of the recent approval of didanosine by the Food and Drug Administration (p. 2), and to modify the wording of the section on the Inclusion of Women and Minorities in Basic Research Studies (pp. 21-22).

Copies of the modification may be obtained from:

Ms. Besita Wyche
Targeted Drug Discovery Section
Developmental Therapeutics Branch, Division of AIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Room 2C11
Bethesda, MD 20892
Telephone: (301) 496-8197

ORPHAN RECEPTORS IN ENDOCRINOLOGY

RFA: DK-92-03

P.T. 34: K.W. 0785050, 0760075, 1002004, 1002008, 0710100, 1002061

National Institutes of Diabetes and Digestive and Kidney Disease

Letter of Intent Receipt Date: December 15, 1991
Application Receipt Date: January 24, 1992

This Request for Applications was published in the NIH Guide for Grants and Contracts on October 4, 1991, Vol. 20, No. 37. The applications will be reviewed for scientific and technical merit by an Initial Review Group convened by the Division of Research Grants. The other review procedures remain unchanged.

For further information, contact:

Ronald N. Margolis, Ph.D.
Director, Endocrinology Research Program
Division of Diabetes, Endocrinology and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 605
Bethesda, MD 20892
Telephone: (301) 496-7504

****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, MD 20816

NOTE: The NIH Guide for Grants and Contracts will not be published on December 6. The next issue will be December 13.