

# NIH GUIDE

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## For Grants and Contracts

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## NOTICES

### NIH/ADAMHA POLICY CONCERNING INCLUSION OF WOMEN IN STUDY POPULATIONS

P.T. 34, II; K.W. 1014002, 1014006

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

The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) recognize that most researchers adequately and appropriately consider gender representation in clinical research design. Nevertheless, the following statement is published as a reiteration and further interpretation of the existing NIH/ADAMHA policy concerning inclusion of women in study populations. Clinical research findings should be of benefit to all persons at risk of the disease, regardless of gender. This policy was previously published in the NIH Guide for Grants and Contracts on October 24, 1986; January 23, 1987; March 27, 1987; January 15, 1988; and June 16, 1989. For the purpose of this policy, clinical research includes human studies of etiology, treatment, diagnosis, prevention, and epidemiology of disease, including but not limited to clinical trials. While this policy statement refers to inclusion of women, applicants are strongly reminded that a similar policy exists regarding the inclusion of minorities (NIH Guide for Grants and Contracts - September 25, 1987; January 15, 1988; and June 16, 1989). Both policies must be considered when preparing clinical research applications/proposals for submission to the NIH/ADAMHA.

Public concern requires that clinical studies include both genders in such a way that results are applicable to the general population; exceptions would be those diseases or conditions that occur only in one gender. Therefore, applications/proposals for NIH/ADAMHA support of clinical research should employ a study design with gender representation appropriate to the known incidence/prevalence of the disease or condition being studied. If inclusion of women is impossible or inappropriate with respect to the purpose of the research, the health of the subjects, or other reasons, or if in the only study population available there is a disproportionate representation of one gender, these reasons for excluding women or men must be well explained and justified by the applicant. Similar justification is required if women will not be included in numbers appropriate to the incidence/prevalence of the disease.

In conducting peer review for scientific and technical merit, members of Initial Review Groups (IRGs)/Technical Evaluation Groups (TEGs) will be instructed to evaluate the proposed gender composition of the study population.

- 1) If there is an inadequate number of women in a study design AND this affects the potential to answer the scientific question(s) addressed, that will be considered a weakness or deficiency in the study design and should be reflected in the assigned score given to the application/proposal, and in the summary statement of the review.
- 2) If an applicant proposes that there is justification for conducting a study in men only, or in a study population in which the proportion of women does not reflect the gender prevalence of the disease or condition under study, a strong scientific rationale, an explanation of the need to protect the health of the subjects, or other well-supported justification must be provided. The IRG/TEG will be instructed to evaluate the merit of such justifications. Appropriate justification will not adversely affect the assigned score. The NIH/ADAMHA will not fund such applications/proposals unless the justification provided is compelling.
- 3) If the gender composition of the study population is not described, BUT the study otherwise has the potential to answer the scientific question(s) posed and translate the findings to all persons at risk of the disease, the omission will be documented by the Executive Secretary of the IRG/TEG in an administrative note, and will not adversely affect the scientific assessment and the assigned score. If there is inadequate information on the study population to allow evaluation of the scientific question(s), the review may be deferred. The NIH/ADAMHA funding components will not fund/award grants or contracts until the applicant provides sufficient information on the study population to assure compliance with the NIH/ADAMHA policy on inclusion of women in study populations.

Since the need to modify sample design could delay award and affect the costs of the study, applicants are strongly advised to address this issue in the initial submission. If costs or study designs are significantly affected by such modification, submission of an amended application/proposal for IRG/TEG review and/or reconsideration by the appropriate National Advisory Council or Board may be necessary.

Whenever there are scientific reasons to anticipate differences between men and women with regard to the hypothesis under investigation, applicants should consider the inclusion of an evaluation of gender differences in the proposed study. However, if men and women are enrolled in numbers that reflect the gender proportion of the disease under study, it is not an automatic requirement for the study design to include statistical power for men and women separately.

It is important to note that regardless of the program relevance of the proposed research, the NIH/ADAMHA funding components will not fund/award grants or contracts that do not comply with this policy.

#### ADAMHA/NIH POLICY CONCERNING INCLUSION OF MINORITIES IN STUDY POPULATIONS

P.T. 34, FF; K.W. 1014002, 1014006

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

There are clear scientific and public health reasons for specifically including members of minority groups in study populations. Accordingly, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) and the National Institutes of Health (NIH) require that applications/proposals for clinical research must give appropriate attention to inclusion of minorities in study populations, unless compelling scientific or other justification for not including minorities is provided. For the purpose of this policy, minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics), and clinical research includes human studies of etiology, treatment, diagnosis, prevention, and epidemiology of diseases, disorders and conditions, including but not limited to clinical trials and research on health service and its impact on disease. Grants, cooperative agreements, and contracts are covered by this policy.

This statement is published as a reiteration and further interpretation of the existing ADAMHA/NIH policy concerning inclusion of minorities in study populations. This policy was previously published in the NIH Guide for Grants and Contracts on September 25, 1987, Vol. 16, No. 32; January 15, 1988, Vol. 17, No. 2; and June 16, 1989, Vol. 18, No. 21. While the focus of this policy is on inclusion of minorities in general population studies, ADAMHA and NIH also encourage attention to gaps in knowledge about specific U.S. racial/ethnic minorities and health problems that significantly affect them. Examples of these problems include but are not limited to: cancer, substance abuse, heart disease and stroke, homicide and accidents, diabetes, infant mortality, and acquired immunodeficiency syndrome (AIDS). Addressing these gaps may be appropriate justification for focusing a particular study on a single racial/ethnic group.

While this policy statement refers to inclusion of minorities, applicants are strongly reminded that a similar policy exists regarding women (NIH Guide for Grants and Contracts - October 24, 1986, Vol. 15, No. 22; January 23, 1987, Vol. 16, No. 3; January 15, 1988, Vol. 17, No. 2; June 16, 1989, Vol. 18, No. 21; and August 24, 1990, Vol. 19, No. 31). Both policies must be considered when preparing research applicants/proposals for submission to ADAMHA/NIH.

Applicants for grants/cooperative agreements and offerors for contracts should be aware that in attempting to include minority groups in a particular study, attention must be paid to research design and sample size issues. ADAMHA and NIH recognize that it may not be feasible or appropriate in all research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

In all applications or proposals for clinical research, applicants must describe the anticipated race/ethnic composition of the study population. In conducting peer review for scientific and technical merit, members of Initial Review Groups (IRGs)/Technical Review Groups (TEGs) will be instructed to evaluate the appropriateness of the proposed minority composition:

- 1) If there is insufficient attention to inclusion of minorities in a study design AND this affects the potential to answer the scientific question(s) addressed, that will be considered a weakness or deficiency and must be reflected in the assigned score given to the application/proposal, and in the summary statement of the review.
- 2) However, if an applicant proposes that there is justification for conducting a study where there will be limited minority participation or inclusion of only one racial/ethnic group, a strong scientific rationale or other well-supported justification must be provided. The IRG/TEG will be instructed to evaluate the merit of such justifications. Appropriate justification will not adversely affect the assigned score. The ADAMHA/NIH will not fund/award such applications unless the justification is compelling.
- 3) For grant and cooperative agreement applications, if there is inadequate information on the study population to allow evaluation of the scientific question(s), the review will be deferred or the application returned.

It is important to note that the ADAMHA/NIH funding components will not fund/award grants, cooperative agreement, or contracts that do not comply with this policy.

CONFERENCE: FOSTERING SCIENTIFIC INTEGRITY IN BIOMEDICAL RESEARCH

P.T. 42; K.W. 1014004, 1014006

National Institutes of Health

The National Institutes of Health (NIH), the Association of American Medical Colleges, and Washington University School of Medicine are co-sponsoring an interactive conference for biomedical investigators, research administrators, and university attorneys with an interest in fostering the integrity of scientists. The goals of the workshop are to discuss the scope of the problem of scientific misconduct; to identify perceived or real factors contributing to misconduct; to discuss the roles of Congress, NIH, and institutions in managing allegations of scientific misconduct; to examine how well specific institutions have dealt with allegations of fraud, plagiarism or other unacceptable scientific practices; to discuss any special ethical considerations associated with Industry/University ties; and to discuss the responsibilities of authors and collaborators in maintaining scientific integrity in research. Several break-out sessions will address focussed topics of particular concern.

This conference is approved for credit in AMA Category 1.

DATES: April 25-26, 1990

SITE: The Adams Mark Hotel, St. Louis, MO

PROGRAM AND REGISTRATION INFORMATION: Telephone: (800) 325-9862, interstate  
(314) 362-6893, in Missouri

NOTICES OF AVAILABILITY (RFPs AND RFAs)

CEREBRAL MAGNETIC RESONANCE IMAGING FOR EVALUATION OF STROKE RISK FACTORS IN THE CARDIOVASCULAR HEALTH STUDY

RFP AVAILABLE: NIH-NHLBI-HC-91-06

P.T. 34; K.W. 0706030, 0715200, 0715042, 0411005

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) requires a reading center for cerebral magnetic resonance imaging (MRI) to be performed on approximately 4,000 participants in the multicenter longitudinal study of risk factors for heart disease and stroke in the elderly entitled, "The Cardiovascular Health Study" (CHS). The MRI Reading Center will assist in protocol development for the performance of cerebral MRI in the four CHS Field Centers and will perform measurements and interpretations of these images in a standardized and reproducible manner. The period of performance is

anticipated to be September 1991 through June 1995. The NHLBI plans to make one award from this solicitation.

This is an announcement for a Request for Proposals (RFP). RFP NHLBI-HC-91-06 will be available on or about February 15, 1991. Responses will be due by close of business on April 5, 1991. One (1) award is anticipated to be made during September 1991. All requests should be submitted in writing and include three (3) mailing labels, self-addressed, and must cite RFP No. NHLBI-HC-91-06.

Requests for copies of the RFP should be sent to the following address:

Donna J. Neal  
Contracts Specialist  
ECA Section, Contracts Operations Branch, DEA  
National Heart, Lung, and Blood Institute  
Federal Building, Room 3C16  
National Institutes of Health  
Bethesda, MD 20892

#### HUMAN LIVER CELL CULTURE FACILITY

RFP AVAILABLE: NIH-NIDDK-91-3

P.T. 34; K.W. 0780015, 0780005, 0755050

National Institute of Diabetes and Digestive and Kidney Diseases

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is seeking an organization to provide a facility where: (1) the science of culturing human primary hepatocytes in long-term culture would be highly developed; (2) such cells would be available for use by other investigators in the culture facility; (3) such cultures would be shipped to investigators in the United States; and (4) cryopreserved hepatocytes from which cultures could be developed would be shipped to investigators in the United States. Stringent characterization and quality control of the cultures would be required. Requests for cells would be reviewed and prioritized by a committee advisory to the contractor.

The NIDDK expects to make one award from this solicitation.

This Request for Proposals (RFP), RFP No. NIH-NIDDK-91-3, will be available on or about February 18, 1991, with a closing date set for April 8, 1991. To receive a copy of the RFP, please supply this office with two (2) self-addressed mailing labels. Since a limited number of copies will be printed, requests shall be filled on a first come, first served basis until the supply is exhausted. Requests for the RFP should be sent to the following address:

Patrick M. Sullivan, Chief  
Contracts Management Branch  
National Institute of Diabetes, and Digestive and Kidney Diseases  
National Institutes of Health  
Westwood Building, Room 602  
5333 Westbard Avenue  
Bethesda, MD 20892

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

#### IMPROVED STRATEGIES FOR DIAGNOSIS OF LYME DISEASE

RFA AVAILABLE: AI-91-03

P.T. 34; K.W. 0745020, 0715125, 0710070, 0785035, 0710030, 0755010

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: March 15, 1991  
Application Receipt Date: May 3, 1991

The National Institute of Allergy and Infectious Diseases (NIAID) invites grant applications for research that applies an understanding of the biology of *Borrelia burgdorferi* and host responses to infection by this organism to studies that will lead to the development of reliable and sensitive diagnostic tests for the detection of Lyme disease.



## RESEARCH GOALS AND SCOPE

The goal of this Request for Applications (RFA) is to stimulate programs of multidisciplinary basic and clinical research focused upon determining the most effective approach(es) for diagnosis of Lyme disease. Applications submitted in response to this RFA are expected to focus upon developing and testing new diagnostic strategies that should result in a more reliable and sensitive approach to the detection of Lyme disease in patients.

Applications should include innovative approaches to the following:

- o Identification and characterization of antigens, antibodies, and DNA sequences that are good candidates as reagents, probes, or targets for use as a basis for a Lyme disease diagnostic test.
- o Identification and recruitment of three patient populations (patients that have a firm diagnosis of Lyme disease, patients that have no history or signs of Lyme disease, and patients that have symptoms of Lyme disease but test negative using a defined set of diagnostic tests currently available).
- o Evaluation of the sensitivity and specificity of candidate diagnostic assays relative to one another and to selected commercially available diagnostic kits using a standard panel of clinical specimens from each of the individuals in the recruited patient populations described above.

However, alternative approaches or additional components may be included in applications providing they are directly related to the overall objective of this RFA which is the development of improved strategies for the diagnosis of Lyme disease.

## 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 traditional individual research grant (R01). Responsibility for planning, direction, and execution of the proposed project will be solely that of the applicant.

This is a one-time solicitation. NIAID anticipates making two awards as a result of this request. However, the number of awards to be made is dependent upon receipt of a sufficient number of applications of high scientific merit and upon the availability of funds. If appropriate, collaboration with other investigators or institutions is encouraged. NIAID staff anticipates that each application would be a comprehensive single project (i.e., not a multiproject application). It is expected that the initial year's awards for successful applications will average \$500,000 in total (direct plus indirect) costs for each award, although individual awards may be slightly higher or lower. Awards will be made for a project period of up to five years. (Awards to applicant institutions outside the United States will be limited to three years). The earliest possible award date is September 30, 1991. NIAID has no plans to reissue this announcement. At the end of the award period, awardees may apply for continuation through the usual competing renewal process for R01 grants. Universities, medical colleges, hospitals, and laboratories or other public, private, or for-profit institutions are eligible.

## INQUIRIES

Investigators seeking information relevant to this RFA should contact Dr. Robert L. Quackenbush at the address below.

Dr. Robert L. Quackenbush  
Chief, Bacteriology and Mycology Branch  
Division of Microbiology and Infectious Diseases  
National Institute of Allergy and Infectious Diseases  
Westwood Building, Room 738  
Bethesda, MD 20892  
Telephone: (301) 496-7728

Questions regarding review procedures should be addressed to Dr. Preble at the address below.

Dr. Olivia Preble  
Chief, Microbiology and Immunology Review Section  
Program and Project Review Branch  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health Westwood Building, Room 3A10  
Bethesda, MD 20892  
Telephone: (301) 496-8208

SMALL GRANTS TO STIMULATE CORRELATIVE LABORATORY STUDIES AND CLINICAL TRIALS  
IN RADIATION THERAPY

RFA AVAILABLE: CA-91-04

P.T. 34; K.W. 0745062, 0715035, 0755015

National Cancer Institute

Letter of Intent Receipt Date: March 4, 1991 Application Receipt Date: May 22, 1991

Introduction

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) announces the availability of a Request for Applications (RFA) for tightly focused, basic science laboratory studies that interface with radiation therapy clinical trials or for radiation therapy clinical trials that attempt to correlate new and/or unique developments in the laboratory.

Background Information

Using the small grants (R03) mechanism, the NCI hopes to stimulate the communication of promising and potentially relevant new developments between the basic science laboratory and the clinical setting. The R03 mechanism provides complementary research support for short-term, pilot, radiation therapy clinical trials that test and verify basic laboratory findings.

Research Goals and Scope

The aims of this RFA are two-fold: (1) to provide a mechanism for accelerated funding of correlative studies relevant to radiation therapy clinical trials and (2) to stimulate pilot clinical studies with or without relevant laboratory correlations so as to foster the development of interactions between basic science laboratories and clinicians performing radiotherapy clinical trials. Laboratory correlates should be designed to ultimately lead to improved radiation therapy.

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 or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

Mechanism of Support

This small grant (R03) RFA is a non-renewable, one-time solicitation. The NCI plans to make multiple awards for project periods up to two years. All awards will be limited to a \$50,000 direct-cost ceiling for a period of up to two (2) years. The total project period for applications submitted in response to the present RFA should not exceed two (2) years. The earliest feasible start date for the initial awards will be December 2, 1991.

Eligibility Requirements

Only domestic non-profit and for-profit organizations, institutions, governments and their agencies are eligible to apply. Although NCI-funded Cooperative Groups are ineligible to apply, individual institutions or consortia of the Cooperative Groups may apply through their own institutions. Awards will be made only to institutions with either a funded clinical or laboratory component of the proposed study. These awards are to complement a



previously existing source of support. These pre-existing resources need not be at a single institution but may exist within a consortium.

#### Inquiries

Written or telephone inquiries concerning the objectives and scope of this RFA, or inquiries about whether or not specific proposed research would be responsive, are encouraged and should be directed to the program director at the address given below. The program director welcomes the opportunity to clarify any issues or questions from potential applicants.

Thomas A. Strike, Ph.D.  
Radiation Research Program  
Division of Cancer Treatment  
National Cancer Institute  
6130 Executive Boulevard, Suite 800  
Rockville, MD 20852  
Telephone: (301) 496-9360

#### COOPERATIVE AGREEMENT RESEARCH PROGRAM: MAXIMIZING THE EFFICACY OF PSYCHOTHERAPY AND DRUG ABUSE COUNSELING STRATEGIES IN THE TREATMENT OF COCAINE ABUSERS

RFA AVAILABLE: DA-91-04

P.T. 34; K.W. 0404009, 0745060

National Institute on Drug Abuse

Application Receipt Date: April 24, 1991

**PURPOSE:** The purpose of this announcement is to support collaborative multi-site research on the comparative efficacy of psychodynamic psychotherapy, cognitive-behavioral therapy, and drug counseling in the treatment of cocaine abusers in outpatient drug-free settings. The interaction of patient characteristics with type of treatment will also be investigated. Collaborators from a Coordinating Center, a Collaborative Treatment Site (CTS), and the National Institute on Drug Abuse (NIDA) are currently developing the protocol and piloting subjects for this study. Funds will be available under this announcement for supporting additional CTSs to collaboratively finalize and carry out this protocol. Applicants for additional CTSs must agree to abide by this protocol. Applicants must also propose sub-studies to be carried out within this protocol. Final protocols for sub-studies will be collaboratively developed by a Steering Committee (SC) after awards are made.

**RESEARCH OBJECTIVES:** One research objective is to conduct a comparative psychotherapy/drug counseling treatment efficacy study, using a common protocol at multiple CTSs, in order to compare the efficacy of different therapy approaches. An equally important goal is to specify the nature of any interactions between patient characteristics (e.g., sociopathy) and therapy type as reflected in treatment outcome.

**MECHANISM OF SUPPORT:** The mechanism to support these clinical trials will be a Cooperative Agreement (CA) between the awardees and NIDA. Researchers agree to accept close coordination and guidance by the SC in all aspects of the scientific and technical management of the common project, and retain primary responsibility for performance of the research, in accordance with terms formally negotiated and mutually agreed on prior to the award. CAs are subject to the same administrative requirements as grants. All pertinent DHHS, PHS, and ADAMHA grant regulations, policies, and procedures are applicable. Business management aspects of these awards will be administered in accordance with DHHS and PHS grant administrative requirements.

#### **SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF ADAMHA POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS**

Applications/proposals for Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) grants and cooperative agreements are required to include both women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including either women or minorities is provided. This requirement is intended to ensure that research findings will be of benefit to all persons at risk of the disease, disorder, or condition under study. For the purpose of these policies, clinical research involves human studies of etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders or conditions, including

but not limited to clinical trials; and minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics).

ADAMHA recognizes that it may not be feasible or appropriate in all clinical research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

Applications should include a description of the composition of the proposed study population by gender and racial/ethnic group and the rationale for the numbers and kinds of people selected to participate. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applications should incorporate in their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities in sufficient numbers to permit assessment of differential effects is not feasible or is not appropriate, the reasons for this must be explained and justified. The rationale may relate to the purpose of the research, the health of the subjects, or other compelling circumstances (e.g., if in the only study population available, there is a disproportionate representation in terms of age distribution, risk factors, incidence/prevalence of one gender or minority/majority group).

If the required information is not contained within the application, the applications will be returned to the applicant. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If gender and/or minority representation/justification are judged to be inadequate, reviewers will consider this as a deficiency in assigning the priority score to the application.

All applications/proposals for clinical research submitted to ADAMHA are required to address these policies. ADAMHA funding components will not award grants that do not comply with these policies.

**REVIEW PROCEDURES:** The Division of Research Grants, NIH, serves as a central point for receipt of applications. Applications received under this announcement will be assigned to a Special Review Committee (SRC) within the NIDA. The SRC will review the applications for scientific and technical merit during the summer of 1991. Notification of the review recommendations will be sent to the applicant after this initial review. Applications will receive a second-level review by the National Advisory Council on Drug Abuse in September 1991. Only applications recommended for approval by the Council may be considered for funding.

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 Service regulations at 45 CFR Part 100 and are not subject to Health Systems Agency review.

**APPLICATION PROCEDURES:** Applicants must use the research grant application form, PHS 398 (last revised 10/88). Application kits with the necessary forms and instructions (PHS 398) may be obtained from institutional business offices or offices of sponsored research at most universities, colleges and medical schools, and other major research facilities. Applications may also be obtained from: The National Institute on Drug Abuse (NIDA), Grants Management Branch, Room 8A-54, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857 (301-443-6710).

**INQUIRES:** Further information can be obtained from:

Dr. J. Boren  
National Institute on Drug Abuse  
5600 Fishers Lane, Room 10A-30  
Rockville, MD 20857  
Telephone: (301) 443-1263

## CHRONIC FATIGUE SYNDROME COOPERATIVE RESEARCH CENTERS

RFA AVAILABLE: AI-91-02

P.T. 04; K.W. 0715043, 0715026, 0715125, 0715150, 0710070, 1002045

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: March 1, 1991

Application Receipt Date: April 1, 1991

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for the establishment of Chronic Fatigue Syndrome Cooperative Research Centers (CFS CRCs) to augment the existing grant program for CFS research. The CRCs are intended to provide a sustained multidisciplinary approach to CFS research that will advance the field by bridging the basic science and clinical research arenas and facilitating confirmatory testing and follow-up of new hypotheses and observations.

### BACKGROUND

CFS is a multisystem syndrome thought to be triggered by viral infection and is characterized by months of debilitating fatigue frequently associated with sore throat, low grade fever, myalgia, headache, gastrointestinal symptoms, and tender lymph nodes. Cognitive deficits, symptoms of depression and sleep disorders have been reported and abnormal brain images derived by different techniques have been described. CFS patients are reported to have neuroendocrine response patterns that differ from those of controls. CFS is diagnosed more frequently in women than in men. There have been numerous reports of specific immune dysfunctions, but no single impairment has regularly been associated with the syndrome. Similarly, viruses from several taxonomic groups have been reported to be involved, but none as yet has been confirmed to be consistently associated with disease onset or progression. Patients have a high prevalence of allergies and recent reports indicate that a state of chronic immune activation may exist in a significant fraction of patients.

There have been many formidable obstacles to the effective study of this syndrome, the most serious of which has been the lack of objective diagnostic criteria. Progress has been made in case definition and a number of testable hypotheses recently have been proposed.

### 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.

### RESEARCH OBJECTIVES AND SCOPE

The purpose of this RFA is to stimulate the establishment of centers of CFS research excellence in which coordinated projects in the fields of immunology, virology, medicine, and clinical epidemiology are pursued in order to further our understanding of CFS leading to improved diagnosis and treatment. It is not expected that expertise in all these areas be available at a single institution. CRCs with well-designed research projects with adequate sample sizes are sought to confirm and extend preliminary findings and to test biologically rational hypotheses concerning the etiology or pathogenesis of CFS.

**CLINICAL FACILITIES:** CFS CRCs should be based at universities or at university-affiliated medical facilities that have a strong clinical facility with accessible well-defined CFS patient populations.

### MECHANISM OF SUPPORT

Awards will be made as cooperative agreements. This mechanism is used when an interactive assistance relationship exists between NIAID staff and the investigative team as outlined in the RFA under "TERMS OF AWARD: AWARDEE RIGHTS AND RESPONSIBILITIES; NATURE OF PARTICIPATION OF NIAID STAFF." Input from the NIAID Scientific Coordinator is intended to facilitate technology transfer, assist in the identification of expert consultants, collaborators and resources, enhance communication between awardees, and help to ensure that

new studies will complement and not unnecessarily duplicate existing or planned CFS research endeavors.

NIAID has set aside a total of \$488,000 (direct plus indirect costs) per year to support this RFA and anticipates making at least one (1) award in FY 1991, the final number being dependent upon the number, cost, and scientific merit of proposals received and the availability of funds. Awards will be made for a project period of up to four years. The earliest possible award date is September 30, 1991. NIAID intends to accept competitive renewal multi-project applications contingent upon the continued availability of funds for this purpose.

#### APPLICATION PROCEDURE

Investigators are urged to contact the NIAID staff listed below early in the development of the application. Additionally, before preparing an application, the applicant should carefully read the information brochure, "Program Project and Center Grants, NIAID." A letter of intent is requested by March 1, 1991. The deadline for receipt of applications is April 1, 1991.

#### INQUIRIES

Investigators seeking copies of the RFA and information relevant to this RFA should contact:

Ann Schluederberg, Sc.D.  
Chief, Virology Branch  
Division of Microbiology and Infectious Diseases  
National Institute of Allergy and Infectious Diseases  
Westwood Building, Room 736  
Bethesda, MD 20892  
Telephone: (301) 496-7453  
FAX: (301) 402-0804

#### RESEARCH PLANNING GRANT: DIABETES IN MINORITY POPULATIONS

RFA AVAILABLE: DK/NR-91-09

P.T. 34, FF; K.W. 0715075, 0755030, 0765033, 0745020, 0745027, 0745070

National Institute of Diabetes and Digestive and Kidney Diseases  
National Center for Nursing Research

Letter of Intent Receipt Date: May 16, 1991  
Application Receipt Date: July 16, 1991

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Center for Nursing Research (NCNR) have initiated a program for Research Planning Grants to support the development of plans for research projects that address critical questions related to the etiology, pathogenesis, diagnosis, treatment, cure, and prevention of diabetes mellitus and its complications in minority populations, including Blacks, Native Hawaiians, Hispanics, Pacific Islanders, and Asian Americans. American Indians and Alaskan Natives are not included in this Request for Applications (RFA), since a similar initiative limited to these populations was announced in Vol. 19, No. 40, November 9, 1990 issue of the NIH Guide for Grants and Contracts.

Research proposed in response to this RFA may involve basic, clinical, behavioral, or epidemiologic studies. Basic research may be designed to elucidate biochemical alterations responsible for increased susceptibility to diabetes mellitus or to the complications of diabetes. Clinical research may be oriented to the cellular, organ, or human level and may include metabolic studies and comparisons. Behavioral studies, particularly those focused on prevention of diabetes through weight control programs, are encouraged. Epidemiologic designs that might be considered include observational and natural history studies, case-control studies of racial/ethnic differences, studies of migrant populations in the U.S. versus in their country of origin, urban/rural comparisons, acculturation of the minorities to the U.S. lifestyle and environment, and longitudinal studies. Issues of obesity, aging, chronic disease, and multiple chronic diseases (such as diabetes and hypertension) are particularly encouraged. Research directed toward improving methodologies for population-based studies of minority ethnic/racial groups is also encouraged. Innovative approaches that involve new inter-disciplinary collaborations are particularly desirable. Whenever possible, applicants are urged to make cost-efficient use of current or recently terminated studies that contain large components of populations that are minorities in the U.S. Many of the

studies extant may have been conceived for reasons other than for research on U.S. minorities or for studies on diabetes mellitus.

This RFA is a one-time solicitation by NIDDK and NCNR for applications for Research Planning Grants (R21) to help support the unique short-term needs of investigators planning research studies related to diabetes in minority populations. It is anticipated that the award of these Research Planning Grants will be followed within approximately one year by an RFA for investigator-initiated research project grant applications (R01) related to this same program area.

Applicants are encouraged to submit and describe their own ideas on how best to meet the objectives of this RFA. Applications will be judged primarily on (1) the likelihood that the new knowledge that may be gained will subsequently help to reduce the burden of diabetes and its complications on the health status of minority populations; (2) the potential scientific and technical merit of the proposed project, including the significance of the scientific question(s), rationale, appropriateness of the proposed planning process, consideration of appropriate ethical issues, and availability of preliminary data; (3) the potential to establish collaborations with groups and other agencies involved in health care of the selected populations; and (4) the qualifications and experience of the proposed investigators.

#### 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 are not included in these study populations, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

Prospective applicants are requested to submit a letter of intent by May 16, 1991, that includes a descriptive title of the proposed research; the name, telephone number and mailing address of the Principal Investigator; the names of other key personnel; the name of the applicant institution and other collaborating entities; and the number and title of this RFA.

This letter of intent should be sent to:

Dr. Robert D. Hammond  
Chief, Review Branch Division of Extramural Activities  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 406  
Bethesda, MD 20892

Requests for the full text of this RFA and inquiries should be directed to the following NIDDK or NCNR program staff:

#### NIDDK

Dr. Lois F. Lipsett  
National Institute of Diabetes and Digestive and Kidney Diseases  
National Institutes of Health  
Westwood Building, Room 620  
Bethesda, MD 20892  
Telephone: (301) 496-7433

#### NCNR

Dr. Mary Lucas  
National Center for Nursing Research  
National Institutes of Health  
Building, 31, Room 5B03  
Bethesda, MD 20892  
Telephone: (301) 496-0523

#### MINORITY DRUG ABUSE PREVENTION RESEARCH CENTERS

RFA AVAILABLE: DA-91-02

P.T. 04; K.W. 0404009, 0710030, 0755030, 0411005, 0745027, 0404000

National Institute on Drug Abuse

Application Receipt Date: April 24, 1991

**PURPOSE:** The purpose of this announcement is to encourage the development of multidisciplinary research centers that will improve our ability to prevent drug abuse among minority populations. Minority populations include American Indian/Alaskan Natives, Asian Americans, Blacks, Hispanics, and/or Native Hawaiians/Pacific Islanders. The proposed Centers are designed to: 1) improve our understanding of etiologic factors that predispose individuals from minority communities to initiate drug use; 2) identify factors involved in the progression from initial drug use to drug dependence; 3) develop criteria and early identification methodologies for use with children and adolescents at high risk for drug abuse; 4) design and test preventive interventions at the individual and small group level through controlled randomized studies; 5) assess the progression of drug use through prospective longitudinal studies of high-risk populations; 6) develop a series of conferences and workshops addressing prevention research issues of specific relevance to understanding etiologic factors and intervention strategies among minority populations; 7) train minority investigators to conduct drug abuse prevention research; and 8) involve the minority community in the development and implementation of a research program.

**RESEARCH OBJECTIVES:** Prevention and intervention strategies demonstrate differential effects within various ethnic groups and socioeconomic populations. Multiple intervention strategies are needed within any geographic location to block and delay the initiation of drug use behavior and to impede progression to drug dependency and associated social, psychological, and physiological sequelae.

Etiological studies designed to specify differential causes for initiating, continuing, and discontinuing drug abuse within and among ethnic groups in urban, suburban, and rural geographic areas are needed. For example, are there selective factors associated with blacks who remain in school longer than other blacks and/or graduate? Are there factors that "protect" the students from drug abuse? What is the role of the educational system in reducing, delaying, or eliminating drug use? Furthermore, given the same environment and equivalent level of being "vulnerable" to drug abuse, what family, social, environmental protectors exist to prevent the use of drugs.

As our surveys of minorities rarely have included high-risk groups such as school dropouts, runaways, and prisoners, the current estimates of drug abuse in minority populations may underestimate the problem. Current research indicates that dropouts have higher rates of illicit drug use than minority youth in school. Such data suggest the need for community-wide drug abuse education, prevention, and intervention programs in addition to the school-based programs. More research is needed to explore the relationship between poor school performance and acculturation-related stress with drug abuse among minority youth. Areas related to the putative crime/drug connection among blacks needs further examination to more fully understand the causes and extent of the relationship within minority populations.

Applications for Minority Drug Abuse Prevention Research Centers are encouraged but not restricted to any of the four content areas among minority groups: Families and Multi-Generational Factors; Environmental and Cultural Factors; High-Risk Children, Adolescents, and Young Adults; and Women and Drugs.

#### **SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF ADAMHA POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS**

Applications/proposals for ADAMHA grants and cooperative agreements are required to include both women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including either women or minorities is provided. This requirement is intended to ensure that research findings will be of benefit to all persons at risk of the disease, disorder, or condition under study. For the purpose of these policies, clinical research involves human studies of etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders or conditions, including but not limited to clinical trials; and minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics).

ADAMHA recognizes that it may not be feasible or appropriate in all clinical research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

Applications should include a description of the composition of the proposed study population by gender and racial/ethnic group, and the rationale for the



numbers and kinds of people selected to participate. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applications should incorporate in their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities in sufficient numbers to permit assessment of differential effects is not feasible or is not appropriate, the reasons for this must be explained and justified. The rationale may relate to the purpose of the research, the health of the subjects, or other compelling circumstances (e.g., if in the only study population available there is a disproportionate representation in terms of age distribution, risk factors, incidence/prevalence, etc., of one gender or minority/majority group).

If the required information is not contained within the application, the application will be returned. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If gender and/or minority representation/justification are judged to be inadequate, reviewers will consider this as a deficiency in assigning the priority score to the application.

All applications/proposals for clinical research submitted to ADAMHA are required to address these policies. ADAMHA funding components will not award grants that do not comply with these policies.

MECHANISM OF SUPPORT: P50

#### ELIGIBILITY

Applications may be submitted by public or private nonprofit or profit-making 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.

REVIEW PROCEDURES: 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) within the National Institute on Drug Abuse. 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 Drug Abuse 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.

APPLICATION PROCEDURES: An application for a Minority Drug Abuse Prevention Research Center grant must provide the following information within the general proposal: research plan to include specific information on the Center's research theme, goals, and objectives; detailed descriptions of the specific research projects and their relationship to the core program; identification of key scientists and their roles and responsibilities on specific projects and research teams; and discussion of the management structure to be employed to organize and coordinate multidisciplinary scientific research initiatives; the research program plan must be organized around a central research theme and address the research and administrative requirements established by this announcement. Furthermore, the proposal must include a description of training of research personnel; evidence of a strong community relationship with demonstrated experience of working in the target community; and descriptions of conferences, publications, and other methods for the dissemination of research findings.

Applicants must use the research grant application form PHS 398 (rev. 10/88). The RFA number DA-91-02 and the title of this announcement, "Minority Drug Abuse Prevention Research Research", should be typed in item number 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 affix the RFA label available in the 398 to the bottom of the face page. Failure to use this label may result in delayed processing of the application such that it may not reach the review committee in time for review.

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: Division of Research Grants, NIH Westwood Building, Room 240, 5333 Westbard Avenue, Bethesda, MD 20892 (301) 496-9797.

The complete announcement may be obtained from:

Grants Management Branch  
National Institute on Drug Abuse  
Room 8A54, 5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-6710

The signed original and six (6) 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\*\*

#### INQUIRIES

Further information and consultation on program requirements relevant to prevention research can be obtained from:

Dr. Zili Amsel  
Acting Director  
Division of Epidemiology and Prevention Research  
National Institute on Drug Abuse  
Rockwall II Building, Suite 620  
c/o 5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-1514

### ONGOING PROGRAM ANNOUNCEMENTS

#### RURAL HEALTH CARE RESEARCH: IMPACTING VULNERABLE POPULATIONS

PA: PA-91-23

P.T. 34; K.W. 0730050, 0730000, 0785055, 0785035, 0403004

National Center for Nursing Research  
Agency for Health Care Policy and Research

#### PURPOSE

The National Center for Nursing Research (NCNR) and the Center for General Health Services Extramural Research, Agency for Health Care Policy and Research (AHCPR), invite applications for research grants to study ways of improving the health and well being of vulnerable populations living in rural areas. These vulnerable populations include: those who have a chronic disease or who are in jeopardy of becoming chronically ill; those who may become disabled due to health threatening behaviors; childbearing women; infants; children; adolescents; and persons over 65 years of age. Of particular importance are epidemiologic studies and clinical studies that focus on the health needs of residents of rural areas. It is anticipated that the clinical studies will focus on the development and validation of nursing interventions as well as the development and evaluation of innovative practice models aimed at facilitating improvements in the health and well being of vulnerable populations who reside in rural communities.

This new rural health care research program builds on a previous NCNR initiative focused on Community-Based Rural Health Care Models for Minority Populations, co-sponsored by AHCPR and the Division of Nursing, HRSA, and published in the NIH Guide for Grants and Contracts, Vol. 19, No. 10, March 9, 1990. The rural health research program of AHCPR is based on a research agenda published in Health Services Research, Vol. 23, No. 6, February, 1989.

#### SCIENTIFIC BACKGROUND

The rural population in the U.S. has been growing proportionately smaller, but at the same time their vulnerability to illness, disability, and poor pregnancy outcomes has increased. As of 1988, about 23 percent of the U.S. population lived in counties defined as nonmetropolitan and about 27 percent lived in rural areas defined by the Census Bureau as places where there are 2,500 or fewer residents. For the purposes of this research program either

definition of rural may be used. Rural residents are characterized as having higher rates of chronic illness, disability, and infant mortality, and their care has been characterized as representing a mixture of formal and informal approaches with variability in the quality of short- and long-term outcomes. With the changing availability of health care and long geographic distances between residents and health care services in most rural settings, rural residents are increasingly at risk for health problems that could be alleviated through scientifically based intervention strategies and health care models targeted to specific vulnerable rural populations.

Individuals residing in rural areas frequently live a considerable distance from health services. It is not unusual for families to care for those with chronic illness and disability at home with or without the advice and guidance of a health care practitioner. Older people, 25 percent of the overall rural population, have less education, a higher proportion of chronic illness, and higher mortality rates in comparison to urban residents. Most older persons live in the community and are not in need of institutional care, such as nursing homes; however, the longer a person survives, the more likely there will be a need for such care. Children comprise 33 percent of the total rural population. The health status of rural children has been difficult to determine, and to some extent it appears that nonrural child health data have been applied to rural populations. A high proportion of women who receive inadequate prenatal care reside in rural communities, and they are more likely to be minorities, teenagers, and single parents.

#### SCOPE

It is intended that the science that develops as an outcome of this announcement will build on existing epidemiological and clinical knowledge. In addition, it is anticipated that the theoretical and empirical base will be developed for understanding the health problems and health care requirements of vulnerable rural populations and for determining the most effective intervention strategies for improved patient outcomes. It should be noted that studies supported under this program need to show evidence of an interdisciplinary approach to the science and, when appropriate, the research team should be interdisciplinary in background. Applications from all regions of the nation and from investigators in rural areas are encouraged.

Some examples of important research topics for consideration might include, but should not be limited to:

- o Examination of factors related to health seeking, health promoting, or health threatening behaviors, including those that influence accessing health care resources;
- o Investigation of strategies for the prevention, intervention, and control of chronic disease and disability among vulnerable rural populations;
- o Evaluation of methods of primary care practice and the effect of primary care approaches and intervention strategies, and other community/public health-based care, on the health and outcomes of the health problems of vulnerable rural populations;
- o Investigation of the processes and outcomes of providing health care in the home to vulnerable populations;
- o Analysis of the continuity of care approaches used to support the transition of rural residents as they move among the various levels of health care services, particularly between acute care hospitals or nursing homes and the home;
- o Investigation of empirically derived nursing practice models targeted to one or more of the vulnerable populations residing in rural areas for the provision of community-based primary care or institutionally-based acute or long-term patient care.

#### SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If

women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognize that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of disease, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. 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 should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

#### MECHANISMS OF SUPPORT

All policies and requirements that normally govern the research grant programs of the Public Health Service apply. The particular research grant mechanisms for this announcement are the traditional research grant award (R01) and the First Independent Research Support and Transition (FIRST) award (R29). Applications for research training are encouraged and should be submitted under the usual requirements and receipt dates for the NIH Individual National Research Service Awards (F31, F32, & F33).

#### APPLICATION PROCEDURES AND REVIEW CRITERIA

Applications should be submitted on the standard PHS Form 398 (rev. 10/88). Application forms are available at most institutional business offices and from the Division of Research Grants, NIH, telephone (301) 496-7441. In order to expedite the application routing within NIH, please (1) check the box #2 on the face page indicating that your application is in response to this announcement and (2) print (next to the checked box) "Rural Health Care: Vulnerable Populations, PA-91-23." Mail the completed application and six copies to:

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

Receipt dates for applications are February 1, June 1, and October 1.

Applications will be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. Second level review will be conducted by an appropriate National Advisory Council.

Applications compete on the basis of scientific merit with all other applications. Researchers considering an application in response to this announcement are encouraged to discuss their project, and the range of the grant mechanisms available, with NCNR staff in advance of formal submission.

Correspondence and inquiries should be directed to:

Dr. Patricia Moritz, or  
Dr. Maureen Knippen  
Nursing Systems Branch  
National Center for Nursing Research  
Building 31, Room 5B09  
Bethesda, MD 20892  
Telephone: (301) 496-0523

Jean Carmody  
Center for General Health  
Services Research, AHCPR  
Maxima Building, Room 678  
Rockville, MD 20852-4993  
Telephone: (301) 443-2080

Another NIH component that has research programs on rural health separate from this announcement that potential applicants may wish to contact is the National Institute of Aging, Social and Behavioral Science Program, Dr. Ronald Ables, (301) 496-3136. In addition, the National Institute of Mental Health supports projects to study mental health issues in rural areas. This program was described in the NIMH Program Announcement, Research on Mental Disorders in Rural Populations, NIH Guide for Grants and Contracts, Vol. 19, No. 1, April 27, 1990. Contact Dr. Charles Windle, Services Research Branch, NIMH, (301) 443-4233, for information.

The research program of NCNR is described in the Catalog of Federal Domestic Assistance, No. 93-361, Nursing Research. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285; and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372, or to Health Systems Agency review, April 6, 1988.

#### THE UROLOGICAL COMPLICATIONS OF DIABETES MELLITUS

PA: PA-91-24

P.T. 34; K.W. 0715075, 0785220, 0715125

National Institute of Diabetes and Digestive and Kidney Diseases

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Division of Kidney, Urologic and Hematologic Diseases (DKUHD), and Division of Diabetes, Endocrinology, and Metabolic Diseases (DDEMD), announce interest in developing a research grants program in the urological disorders associated with diabetes mellitus (UDDM). Areas of research interest within this area include, but are not limited to, basic and clinical studies of diabetes related disorders of bladder function, including urinary retention and incontinence; male sexual function, especially erectile function; infections of the urinary tract including the kidneys; and the effect of diabetes mellitus, in general, on the innervation and musculature of the urinary tract.

#### INTRODUCTION

Diabetes mellitus produces significant deleterious effects on the lower urinary tract. Urinary bladder dysfunction, urinary tract infections and erectile impotence occur in a significant percentage of both insulin dependent and non-insulin dependent diabetics. These complications are rarely mentioned in studies of the disease and have been less frequently investigated. The morbidity and health care expenditures for these urologic disorders are extensive. If left untreated or undetected, these urological disorders can lead to progressive renal failure, urinary incontinence, urinary retention, drug-resistant urinary tract infections, and abscesses of the kidneys.

#### OBJECTIVES AND SCOPE

The objective of this announcement is to increase multidisciplinary research into the urological complications that result from both insulin dependent (IDDM) and non-insulin dependent (NIDDM) diabetes mellitus. Basic and clinical research studies utilizing both human and animal and cell culture models are encouraged. The comparison of the pathobiology of urological disorders with other known disorders of diabetes mellitus, to gain insight into the pathogenesis of urological disorders, is encouraged. Areas of

research that are applicable to this announcement include, but are not limited to:

- o the epidemiology of UDDM
- o diagnostic strategies for the early detection of clinical changes associated with UDDM
- o effect of IDDM and NIDDM on penile erectile tissue
- o effect of IDDM and NIDDM on the urinary bladder musculature, urothelium, and nervous innervation
- o genetic, molecular, cellular, and immunological abnormalities associated with diabetes mellitus as expressed in urological tissues
- o diabetes mellitus and urinary tract infections
- o sexual differences in the effect of diabetes mellitus on the bladder, including the role of hormones in these differences
- o racial differences in UDDM

**SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS**

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. 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 should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific



question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

#### MECHANISMS OF SUPPORT

Applications in any of the NIDDK mechanisms of support are accepted. Especially encouraged are the Research Project Grant (R01), First Independent Research Support and Transition Award (R29), National Research Service Award (NRSA) (F32), and Clinical Investigator Award (K08).

#### APPLICATION PROCEDURES

Applicants must use the standard research grant application form PHS 398 (revised 10/88) or the appropriate fellowship application forms PHS 416-1 (revised 7/88 or 4/89). These forms are available from the Office of Sponsored Research at most institutions and from the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 2082.

Receipt dates for the applications are listed on the forms. For new research projects (R01 and R29) the dates are February 1, June 1, and October 1 and for Clinical Investigator Award applications. Receipt dates for NRSA fellowship applications are January 10, May 10, and September 10.

To identify responses to this announcement, check "yes" and list the title and number of this announcement in item number 2 on the face page of the application form. Use the mailing label provided in the application kit and mail the signed original and six copies to:

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

Applications will be reviewed for scientific and technical merit by appropriate study sections comprised primarily of non-federal experts. Secondary review will be performed by the appropriate National Advisory Council.

Potential applicants are strongly advised to call or write for further information:

Ralph L. Bain, Ph.D.  
Acting Director, Urology Program  
DKUHD/NIDDK  
National Institutes of Health  
Federal Building, Room 102  
Bethesda, MD 20892  
Telephone: (301) 496-8248

or

Joan T. Harmon, Ph.D.  
Executive Director, Diabetes Research Program, DPB  
DDEMD, NIDDK  
National Institutes of Health  
Westwood Building, Room 622  
Bethesda, MD 20892  
Telephone: (301) 496-7731

These programs are described in the Catalog of Federal Domestic Assistance Nos. 93.849, 93.847. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

\*\*THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS: 5333 Westbard Avenue, Bethesda, MD 20816

NOTICE OF MEETING

NATIONAL WORKSHOPS ON "PROTECTION OF HUMAN SUBJECTS"

P.T. 42; K.W. 0783005

National Institutes of Health  
Food and Drug Administration

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

I. MIDEAST WORKSHOP

DATES: March 4-5, 1991

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

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

Shaw University  
118 E. South Street  
Raleigh, NC 27611

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

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

II. MIDWEST WORKSHOP

DATES: April 11-12, 1991

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

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

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

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

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

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

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

\*\*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