# NIH GUIDE

## For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

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## NOTICES OF AVAILABILITY (RFPs AND RFAs)



## ONGOING PROGRAM ANNOUNCEMENTS



## NOTICES OF AVAILABILITY (RFPs AND RFAs)

### PERSPECTIVE STUDY OF PERSISTENT OR RECURRENT ARTHROPATHY AND OTHER POTENTIAL ADVERSE EVENTS FOLLOWING RUBELLA VACCINATION OF ADULT WOMEN

RFP AVAILABLE: 200-91-0931(P)

P.T. 34, II; K.W. 0715006, 0740075

Centers for Disease Control

The Centers for Disease Control contemplates award of a 48-month research contract to study persistent or recurrent arthropathy and other potential adverse events following rubella vaccination of adult women. The purpose of the contract is to compare the rate and severity of these events following rubella vaccination of seronegative and seropositive adult women to the rate in seropositive adult women not receiving rubella vaccine.

Written requests for copies of the solicitation will be honored if received within 45 days of the Request for Proposals (RFP) issue date, which will be on or about June 24, 1991. The date specified for the receipt of the offers will be approximately 90 days after the RFP issue date. Requests for the RFP must cite RFP No. 200-91-0931(P). Telephone requests will not be accepted. All responsible sources may submit a proposal that shall be considered by the Agency.

Requests for the RFP and questions about this announcement should be directed to:

Mark Federer
Centers for Disease Control
Procurement and Grants Office
Program Acquisitions Branch
255 East Paces Ferry Road, N.E.
Room 314
Atlanta, GA 30305

PEDIATRIC AND PERINATAL HIV CLINICAL TRIALS CENTERS

SOURCES SOUGHT FOR SUBCONTRACTING OPPORTUNITES

P.T. 34; K.W. 0715008, 0745027, 0785170, 0755015, 0403020

National Institute of Child Health and Human Development

Under Contract #NO1-HD-7-2925 with Westat, Inc., the National Institute of Child Health and Human Development sponsors a network of clinical centers that participate in clinical trials of therapies to prevent pediatric HIV infection or treat pediatric HIV disease. Clinical centers serve as subcontractors to Westat. NICHD and Westat intend to award additional subcontracts to expand patient access to trials. Preference will be given to clinical centers that can conduct both perinatal and pediatric protocols, have no other source of NIH funding for HIV-related clinical trials, and are located in areas where patients do not have reasonable access to existing clinical trials centers. Interested parties must submit three copies of a statement of capabilities, including a description of clinics for HIV-infected women and children, an estimated number of available patients, a description of staff qualifications, and a description of HIV-related research experience, to:

Mr. Stephen Durako
Vice President
Westat, Inc.
1650 Research Boulevard
Rockville, MD 20850

One additional copy of the response must also be sent to:

Dorothy McKelvin
OGC, CMB
National Institute of Child Health and Human Development
9000 Rockville Pike
EPN, Room 515
Rockville, MD 20892

The response must be received by 5:00 p.m. on July 15, 1991.

EXPANSION OF THE PEDIATRIC AIDS CLINICAL TRIAL UNITS

RFA AVAILABLE: AI-91-10

P.T. 34; K.W. 0715008, 0785170, 0755015

National Institute of Allergy and Infectious Diseases

Application Receipt Date: September 13, 1991

PURPOSE

The purpose of this Request for Applications (RFA) is to provide support for the expansion of the pediatric AIDS clinical trials program through the establishment of new pediatric clinical trial units. Pediatric components of adult AIDS Clinical Trial Units (ACTUs) that are currently enrolling patients, subunits of pediatric ACTUs currently enrolling patients, and new applicants are invited to apply. Upon funding, each new unit will be a free-standing pediatric unit; thus, the Principal Investigator is expected to be a pediatrician. This RFA specifically addresses and outlines requirements for ancillary services including outreach for pediatric and adolescent populations. While the inclusion of adolescents is encouraged, the main thrust of the RFA is on infants and children. We expect that applications will include obstetricians and their services as a part of the research team. Applications considered responsive to this RFA must demonstrate a capability to conduct pediatric clinical trials and provide the necessary ancillary services and outreach for HIV-infected infants, children, adolescents, and their families. The RFA focuses on these ancillary services because of the

critical link between provision of such services and the ability to recruit and maintain pediatric patients in clinical trials. Because of the increasing incidence of maternal-fetal transmission, applicants are required to describe the capability to conduct perinatal transmission studies or plans to develop such capability. Need for increased attention to studies of primary HIV infection, opportunistic infections, neurologic complications of HIV infection and enrollment of HIV-infected adolescents into clinical trials must be addressed. Strong emphasis will be placed on the enrollment of study participants from populations currently underrepresented in clinical trials (e.g., infants and children of minority women and substance abusers and disenfranchised youth).

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, Expansion of the Pediatric AIDS Clinical Trial Units, is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

Clinical Core Funding will provide the resources required to maintain an infrastructure sufficient to maintain an agreed-upon minimum number of new patients onto protocols each year. A portion of the total AIDS Clinical Trial Group (ACTG) pediatric budget may be set aside and designated as Incentive Funding. These funds will be awarded either as administrative supplements after review by the Treatment Research Program and Division of Extramural Activities staff or as competing supplements. Awards will be made consistent with National Institutes of Health (NIH) and National Institute of Allergy and Infectious Diseases (NIAID) policies and will support various activities including, but not limited to, the following: (1) augmenting awards to pediatric ACTUs able to accrue a greater than expected number of patients into high-priority protocols; (2) availability in mid-period of priority protocols established by the ACTG and the NIAID that require funding not included in the Clinical Core Funding budget; and (3) providing limited support to institutions whose investigators contribute a substantial amount of uncompensated time and effort to ACTG committees or other program activities.

RESEARCH OBJECTIVES

The aim of this initiative is to broaden the cooperative network of institutions and investigators with the capability to provide an effective and efficient system to evaluate the safety and efficacy of therapeutic interventions against HIV infection, AIDS, and its associated conditions in children and adolescents. Emphasis will be placed on the provision of ancillary services, the inclusion of obstetrical and perinatal research, and the inclusion of women and minorities. This goal will be accomplished through the accrual of pediatric patients into trials, analysis of the results of these trials, and publication of their findings. Throughout this process, the participation of awardee clinical investigators from individual clinical trial units, with substantive involvement of the NIAID under the cooperative agreement mechanism, is key in the overall ACTG efforts.

MECHANISM OF SUPPORT

Awards under this RFA will be made as cooperative agreements. Assistance provided through the cooperative agreement differs from the traditional research grant in that the Government component (NIAID) anticipates substantial programmatic involvement during performance of the award. It should be understood, however, that applicants must define their objectives in accord with individual interests and approaches to conducting the research. It is anticipated that approximately six to ten new pediatric ACTUs will be funded to supplement the current pediatric clinical trials group. Ongoing pediatric subunits or components of adult ACTUs that are successful in competing for these awards will cease to exist as such. The approximate total amount of this RFA will be $7.6 million. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit and availability of funds. Awards will be made for a 12-month budget period within a total project period of five years. Continuation awards for new budget periods within an approved project period will be made on the basis of satisfactory performance and availability of funds. The anticipated award date will be February 14, 1992. It is anticipated that the NIAID will continue this program after the initial project period through a competitive renewal of the cooperative agreements, however, continuation is contingent upon available funds and NIAID priorities.

SPECIAL INSTRUCTIONS FOR THE 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 population 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.

APPLICATION AND REVIEW PROCEDURES

The research grant application form PHS 398 (rev. 10/88) must be used in applying. Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. Failure to address all minimum requirements in the Specific Instructions, Section 2 of the RFA will result in the application being considered nonresponsive. If the application is not responsive to the RFA, NIH staff will return it to the applicant.

Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by the NIAID. Those applications may be subjected to triage by a Special Review Committee to determine their scientific merit relative to other applications received in response to this RFA. The NIH will administratively withdraw from competition those applications judged to be noncompetitive and notify the applicants and institutional business official. The second level review will be provided by the National Advisory Allergy and Infectious Diseases Council.

INQUIRIES

Copies of the complete RFA describing the research goals and scope, the cooperative agreement mechanism, the review criteria, and other application requirements may be obtained from:

Tina Johnson, M.A.
National Institute for Allergy and Infectious Diseases
6003 Executive Boulevard, Room 201W
Rockville, MD 20892
Telephone: (301) 496-8214

Written or telephone inquiries of a budgetary nature should be addressed to:

Ms. Jane Unsworth
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 706
Bethesda, MD 20892
Telephone: (301) 496-7075

## RESEARCH ON THE PREVENTION OF ALCOHOL-RELATED PROBLEMS AMONG ETHNIC MINORITIES

RFA AVAILABLE: AA-91-04

P.T. 34, FF; K.W. 0404003, 0745027, 0404000

National Institute on Alcohol Abuse and Alcoholism
Office for Substance Abuse Prevention

Application Receipt Date: November 15, 1991

PURPOSE

The primary purpose of this Request for Applications (RFA) is to encourage and facilitate alcohol abuse prevention research focused on Black Americans, Hispanic Americans, American Indians, Alaskan Natives, and Asian/Pacific Americans. The research envisioned will develop and test prevention strategies that are effective for these minority populations that are at elevated risks for specific types of alcohol problems and have diverse and distinctive sociocultural characteristics that must be considered in the development and implementation of prevention activities.

The 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 the Prevention of Alcohol-Related Problems among Ethnic Minorities," 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, D.C. 20402-9325 (telephone 202-783-3238).

RESEARCH OBJECTIVES

This RFA calls for diverse prevention and pre-intervention studies directed specifically to ethnic minority populations. Prevention research investigates ways of reducing the adverse personal and social consequences of alcohol abuse guided by the public health model that views alcohol-related problems as arising through a complex of individual, interpersonal, and social factors. The research may focus on entire communities, specific environments or high-risk groups, or individual behavior.

Studies of the effectiveness of environmental prevention strategies in minority settings may include national, state, or community-wide policies designed to control alcohol availability and reduce demand for such products including; (1) strengthening and/or enforcing alcohol beverage control laws regulating the hours of operation and the location and number of outlets for sales of alcoholic beverages; (2) enhancing enforcement of minimum drinking age laws; (3) implementing server training programs; and (4) raising taxes on alcoholic beverages.

Research strategies oriented to changing individual behavior, particularly that of youth, adolescents, and pregnant women, include further scrutiny of those programs that have been successfully tested in the general community but need adaptation to ethnic minorities and evaluation of their efficacy. Also needed is the systematic testing of prevention programs that appear to have been successfully implemented within ethnic communities but tested on only a limited scale and/or not systematically evaluated.

Applicants also may propose pre-intervention studies of sociocultural factors that may contribute to the occurrence or reduction of alcohol-related problems among ethnic minorities. Sociocultural factors related to the use of alcohol in ethnic minority communities of particular interest include: socialization processes and the role of the family; peer group influences on alcohol-related behavior; acculturation and the change process in response to immigration and migration; the effects of gender roles on alcohol consumption patterns; the effects of mass media messages; and the contributions of community institutions to alcohol use and abuse.

METHODOLOGICAL ISSUES

Research in the areas discussed above may be cast within any of the standard research traditions. If applicants do not have the full range of methodological and technical skills requisite to the design and analysis of the proposed research, they are strongly urged to consult with statisticians or other relevant specialists. Studies involving interventions must include comprehensive evaluation components that are conceptually and procedurally integrated with the overall research program. The three areas of evaluation (formative, procedural, and outcome) provide information relevant to the interpretation of the research findings.

Of central importance in the planning and execution of these studies is careful attention and sensitivity to the unique aspects of the culture of the group(s) under study.

MECHANISMS OF SUPPORT

Applicants may submit research project grants (R01s) requesting up to four years of support. Applications in response to this RFA will compete for $800,000 in new grant money that is expected to be made available for this purpose in fiscal year 1992. It is anticipated that three to five projects will be supported.

REVIEW PROCEDURES

Applications submitted in response to this RFA will be assigned to an Initial Review Group (IRG) in accordance with established Public Health Service Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review applications for scientific and technical merit. Applications will receive a second level review by the National Advisory Council on Alcohol Abuse and Alcoholism and the Advisory Committee on Substance Abuse Prevention, where reviews may be based on policy considerations as well as scientific merit considerations. Only applications recommended for approval by these advisory bodies may be considered for funding.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) requires applicants to give special attention to the inclusion of women in study populations. If women are not included in the study population 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 grant application form PHS 398 (revised 10/88). 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 and from:

National Clearinghouse for Alcohol and Drug Information
Post Office Box 2345
Rockville, Maryland 20852
Telephone: (301) 468-2600

INQUIRIES

For the complete RFA and pre-application consultation, contact:

Elsie Taylor or Susan E. Martin
Prevention Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 13C-23
Rockville, MD 20857
Telephone: (301) 443-1677

For fiscal and administrative matters, contact:

Elsie Fleming
Chief, Management Review and Assistance Section
Grants Management Branch
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 16-86
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4703

ALCOHOL RESEARCH CENTER GRANTS

RFA AVAILABLE: AA-91-02

P.T. 04; K.W. 0404003, 0745020, 0745027, 0755030, 0745070

National Institute on Alcohol Abuse and Alcoholism

Application Receipt Date: December 16, 1991

PURPOSE AND OBJECTIVES

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) provides grant support for Alcohol Research Centers to conduct interdisciplinary research on alcoholism and alcohol abuse. The Center grants program is interrelated with and complementary to all other research support mechanisms and scientific activities that comprise the NIAAA programs of research on the nature, causes, diagnosis, treatment, control, prevention, and consequences of alcohol abuse and alcoholism. The Alcohol Research Centers Grant program provides long-term (typically, for five years) support for interdisciplinary research programs with a distinct focus on a particular theme relating to alcoholism, alcohol abuse, and other alcohol-related problems. The program is intended to encourage outstanding scientists from biomedical, behavioral, social science, and other relevant disciplines to bring a full range of expertise, approaches, and advanced technologies to the study of problems related to alcohol abuse and alcoholism. Research to improve knowledge of other drug abuse and mental disorders that co-occur with alcohol abuse disorders is also encouraged.

A Center is expected to be a source of scientific excellence and, through sustained excellence, to become a significant regional or national research resource. In addition, the applicant institution is expected to afford

opportunities for research training to persons from various disciplines and professions.

MECHANISM OF SUPPORT

A Specialized Center Grant (P50) is a comprehensive, broad-based multidisciplinary, multi-investigator, long-term program of combined research and research support activity planned around a specific major research objective or research theme. In addition to providing support for shared resources, this type of Center supports a full range of basic, developmental, clinical, and/or applied research components; allows for growth and development through pilot projects; and is intended to provide state-of-the-art leadership in the alcohol field.

It is estimated that approximately $13-14 million will be available in FY 1993 to fund approximately eight Centers.

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

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 for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

APPLICATION SUBMISSION

Applicants must use the grant application form PHS 398 (rev. 10/88). The title and number of this Request for Applications, "Alcohol Research Center Grants, AA-91-02" must be typed in item number 2 on the face page of the PHS 398 application form.

REVIEW PROCEDURES

Each Center application will be reviewed by a group of experts to evaluate the scientific and technical merit of the proposal. Recommendations from this review will be presented to the National Advisory Council on Alcohol Abuse and Alcoholism that will make a final recommendation to the Director, NIAAA.

INQUIRIES

For a copy of the RFA and preapplication consultation contact:

Dr. Ernestine Vanderveen
Associate Director
Division of Basic Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 16C-06
Rockville, MD 20857
Telephone: (301) 443-1273

For fiscal and administrative matters, contact:

Ed Ellis
Grants Management Specialist
Management Review and Assistance Section
Grants Management Branch
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 16-86
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4703

## ONGOING PROGRAM ANNOUNCEMENTS

### RESEARCH ON MANAGED MENTAL HEALTH CARE

PA: PA-91-71

P.T. 34; K.W. 0715095, 0715129, 0730000, 0755018

National Institute of Mental Health

The National Institute of Mental Health (NIMH) expects to develop and expand scientific knowledge on the wide range of managed care programs. Researchers are encouraged to develop rigorous research designs for exploring the effect of managed mental health care. Such designs include natural experiments or quasi-experimental designs with comparison groups. Secondary data analysis of existing data sets may be adequate for some studies, as may other designs. Study populations should include subjects with primary mental disorders and/or those with co-occurring disorders such as alcohol or drug abuse.

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. The PHS urges applicants to submit work plans that address specific objectives of "Healthy People 2000." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20042-9325 (telephone 202-783-3238).

Applications may be submitted by any public or private, nonprofit or for-profit organization, including units of State or local governments. Women and minority investigators are encouraged to apply.

Research support may be requested through applications for a research grant (R01), small grant (R03), and First Independent Research and Transition (FIRST) award (R29). Applications must be prepared on the current version of the form PHS 398 (revised 10/88). All applications must clearly indicate the relevance of the proposed work to the stated purpose of this announcement.

Applications for this grant are encouraged to include both women and minorities in study populations, unless scientific evidence or other justification for not including them is provided. Applications should include in their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities is not feasible or appropriate, the reasons must be explained and justified.

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 5B39, Bethesda, Maryland 20892.

Applications will be reviewed according to the usual PHS receipt and review schedule. Applications will be reviewed for scientific merit by an initial review group (IRG) composed primarily of non-Federal scientific experts. Final review is by the appropriate National Advisory Council. Only applications recommended for approval by the Council may be considered for funding.

Review criteria include evidence of familiarity with relevant research literature; adequacy of the theoretical and conceptual framework of the proposed research and appropriateness of research methods; scientific quality of the project design and methodology; demonstrated research capability, experience, and commitment of the proposed research staff; demonstrated access to research subjects or data bases to conduct the research; adequacy of facilities, general environment, and core resources for the development and implementation of the proposed research; evidence of cooperation and commitment for persons and organizations whose support is essential for the conduct of the research; adequacy of the plan to protect research subjects; appropriateness of the budget requested; generalizability of the results; and applicability to minority populations and women.

Award criteria include IRG and Council recommendations, program needs and priorities, and availability of funds.

For a copy of the full announcement or for further information on research issues, applicants may contact:

Paul Widem, Chief, or Agnes Rupp, Ph.D.
Mental Health Economics Research Program
Services Research Branch
Division of Applied and Services Research
National Institute of Mental Health
Room 18C-14, 5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4233

Further information on grants management issues may be obtained from:

Stephen J. Hudak
Grants Management Branch
National Institute of Mental Health
Room 7C-26, 5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4456

Under authority of Section 301 of the Public Health Service Act as amended, PL 78-410, 42 U.S.C., 241 and the Catalog of Federal Domestic Assistance 93.242.

MOVEMENT DISORDERS

PA: PA-91-72

P.T. 34; K.W. 0715060, 0785035, 0785210, 0710100

National Institute of Neurological Disorders and Stroke

PURPOSE

An existing National Institute of Neurological Disorders and Stroke (NINDS) Program Announcement, published June 6, 1980, is being reissued to notify the scientific community of continuing NINDS interest in movement disorders with particular emphasis on dystonia, tremor, Parkinson's disease, and other basal ganglia degenerative disorders. The emphasis on dystonia is in response to the 1991 House and Senate Appropriations Reports. The NINDS invites grant applications to support neurological research leading to a better understanding of the etiology and pathogenesis of a variety of movement disorders, with the intent of improving the early diagnosis and the treatment of these nervous system dysfunctions and ultimately facilitating their prevention.

BACKGROUND INFORMATION

Neurological disorders of movement include dystonia, Parkinson's and Huntington's diseases, other basal ganglia degenerations (such as Progressive Supranuclear Palsy and Striatonigral Degeneration), and other diseases of varied causation characterized by tics, tremors, chorea, athetosis, and ballism. Most of these neurological disorders are progressive and may be associated with dementia, ataxia, and other neurological abnormalities, in addition to abnormal motor activity. In some cases, the symptoms reflect abnormal function of specific brain nuclei or classes of neurons; in others the abnormality is unknown. In no case is the pathophysiological process adequately understood.

Dystonic movements can result from a number of causes. Typical torsion spasms are twisting in nature and usually repetitive in occurrence. The symptom severity and natural history are variable, making treatment evaluation measures and prevalence estimates difficult. Essential tremor is among the most common of all neurological disorders. It is generally benign in course but may, at times, become a significant cause of disability.

The individual cost of medical care in these neurological disorders and the societal costs from lost or diminished function can be considerable.

RESEARCH GOALS AND SCOPE

Multidisciplinary and collaborative studies are encouraged. Experimental studies may focus on anatomical, pathological, biochemical, physiological, or pharmacological aspects of any of these diseases.

There is particular need for work in the following: (1) more precise definition of the anatomical and/or physiological lesion; (2) identification of characteristic abnormalities in non-neural tissues, such as blood, skin, or muscle, that are more amenable to biopsy or tissue culture; (3) development of animal models, experimental or genetic, that mimic significant aspects of a movement disorder; (4) molecular genetics; and (5) advanced neuroimaging research.

Existing therapies for the movement disorders are, in general, unsatisfactory. Many drugs currently used are either ineffective over long periods of time or associated with undesirable side effects. For this reason, experimental therapeutic studies on animal models of movement disorders and studies of appropriate in vivo systems are encouraged.

MECHANISMS OF SUPPORT

Applicants may apply for the research project grant (RO1), research program project (PO1), research center grant (P50), and First Independent Research Support and Transition Award (R29). Prospective applicants are encouraged to communicate with the Institute staff listed at the end of the announcement regarding the appropriate funding mechanism. Both basic science and clinical investigations are encouraged to address relevant research issues.

APPLICATION AND REVIEW PROCEDURES

Applications must be prepared on form PHS 398 (revised 10/88) according to instructions contained in the application kit. Application kits are available from most institutional business offices and may be obtained from the Division of Research Grants at the address given below:

Office of Grants Inquiries
National Institutes of Health
Division of Research Grants
Westwood Building, Room 449
5333 Westbard Avenue
Bethesda, MD 20892

Check "yes" in item two on the face sheet of the application and type "Movement Disorders, PA-91-72."

Applicants for the P01 or P50 should use the application format as described in the NINDS pamphlet, "Application Guidelines: Program Project and Clinical Research Center Grants" (revised 10/89), that may be obtained from the contacts listed under INQUIRIES.

Applications will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. An initial review will be made by an appropriate study section of the Division of Research Grants for research grants and FIRST awards, and by an appropriate institute committee for program projects and centers. A second level of review will be made by an appropriate national advisory council.

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 incuding 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.

Deadlines for the receipt of applications are February 1, June 1, and October 1.

The original and six copies of the application must be sent directly to:

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

INQUIRIES

For further information regarding this announcement, potential applicants should write or call:

Philip H. Sheridan, M.D., Chief
Developmental Neurology Branch
Division of Developmental, Convulsive, and Neuromuscular Disorders
NINDS
Federal Building, Room 8C10
Bethesda, MD 20892
Telephone: (301) 496-6701

or

Eugene J. Oliver, Ph.D.
Division of Demyelinating, Atrophic, and Dementing Disorders
NINDS
Federal Building, Room 806
Bethesda, MD 20892
Telephone: (301) 496-1431

The program to which the intended grants relate is described in the Catalog of Federal Domestic Assistance, entry number 93.853 - Clinical Research Related Neurological Disorders, and 93.854 - Biological Basis Research in the Neurosciences. Grants will be awarded under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 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 the intergovernmental review requirements of Executive Order 12372 or 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, Maryland 20816