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.

VOL. 16, NO. 28 - AUGUST 14, 1987

Vol. 16, No. 28, August 14, 1987

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NOTICES

APPLICATIONS INVOLVING HUMAN SUBJECTS - IRB Review "Pending"

P.T. 34; K.W. 0783005, 1014002

National Institutes of Health

The instructions for completing Form PHS-398 (revised 9/86) from an applicant organization which has an appropriate approved Multiple Project Assurance of Compliance on file with the Office of Protection from Research Risks, and which proposes non-exempt research involving human subjects, includes the following:

- o The "information in Items 4a and 4b and the signatures on the Face Page fulfill the requirement for certification of IRB approval. To insure against delays in the review of the application, IRB review is best completed prior to submission of the application. However, if the IRB review is unavoidably delayed beyond the submission of the application, enter 'pending' at Item 4a. A follow-up certification of IRB approval from an official signing for the applicant organization must then be sent to and received by the Executive Secretary of the initial review group within 60 days after the receipt date for which the application is submitted. Any modifications in the Research Plan section of the application required by the IRB must be submitted with the follow-up certification. Occasionally PHS initial review may be scheduled to occur before the end of the 60-day grace period. In these special cases of accelerated review, the follow-up certification will be requested earlier. Otherwise, it is the responsibility of the applicant organization to submit the follow-up certification. The PHS does not guarantee that it will remind the applicant organization or the principal investigator/program director to provide this missing information. If certification of IRB approval is not received prior to the scheduled PHS initial review date, the application will be considered incomplete and deferred to the next review cycle."

A clarification is necessary. If a follow-up certification of IRB approval has to be sent to the Executive Secretary of the initial review group, an appropriately completed and signed Form HHS 596 (available on request from DRG) continues to meet the requirements for certification. In lieu of this preferred form, a letter prepared on organizational letterhead stationery or a revised Face Page is acceptable provided that all of the following required information is included: title of project, application number, name of investigator and institution, Multiple Project Assurance number, date of IRB approval, and appropriate signatures. The form HHS 596, the organizational letter, or the revised Face Page with an attachment must contain any changes or modifications required by the IRB and if none, a statement to that effect.

The name and address of the Executive Secretary of the initial review group will be sent to the principal investigator/program director as soon as possible after the receipt date, usually within six weeks. To avoid delays in review, do not send the follow-up information to any other addressee.

APPLICATIONS INVOLVING LIVE VERTEBRATE ANIMALS - IACUC Review "Pending"

P.T. 34; K.W. 1014002, 1014003

National Institutes of Health

The instructions for completing Form PHS-398 (revised 9/86) from an applicant organization that has an approved Animal Welfare Assurance on file with the Office of Protection from Research Risks, and which proposes research involving vertebrate animals, includes the following:

- o The "information in Items 5a and 5b and the signatures on the Face Page fulfill the requirement for verification of IACUC approval. To insure against delays in the review of the application, IACUC review is best completed prior to submission of the application. However, if the IACUC review is unavoidably delayed beyond the submission of the application, enter 'pending' at Item 5a. A follow-up verification of IACUC approval from an official signing for the applicant organization must then be sent to and received by the Executive Secretary of the initial review group within 60 days

after the receipt date for which the application is submitted. Any modifications in the Research Plan section of the application required by the IACUC must be submitted with the follow-up verification. Occasionally PHS initial review may be scheduled to occur before the end of the 60-day grace period. In these special cases of accelerated review, the follow-up verification will be requested earlier. Otherwise, it is the responsibility of the applicant organization to submit the follow-up verification. The PHS does not guarantee that it will remind the applicant organization or the principal investigator/program director to provide this missing information. If verification of IACUC approval is not received prior to the scheduled PHS initial review date, the application will be considered incomplete and deferred to the next review cycle."

A clarification is necessary. If a follow-up verification of IACUC approval has to be sent to the Executive Secretary of the initial review group, an appropriately completed and signed letter, prepared according to the example found on page 16 of the PHS Policy on Humane Care and Use of Laboratory Animals (revised as of September 1986), continues to meet the requirements for verification. In lieu of this preferred method, a revised Face Page is acceptable, provided that all of the following information is included: application number, title of project, name of investigator and institution, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures. An attached page should contain any changes or modifications required by the IACUC, and if none, a statement to that effect.

The name and address of the Executive Secretary of the initial review group will be sent to the principal investigator/program director as soon as possible after the receipt date, usually within six weeks. To avoid delays in review, do not send the follow-up information to any other addressee.

DATED ANNOUNCEMENTS (RFPs AND RFAs AVAILABLE)

EPIDEMIOLOGIC SURVEYS FOR HUMAN RETROVIRUSES

RFP AVAILABLE: NCI-CP-EB-85603-57

P.T. 34; K.W. 0785055, 0404021, 1002045, 0715035

National Cancer Institute

The Family Studies Section (FSS), Environmental Epidemiology Branch (EEB), Epidemiology and Biostatistics Program (EBP), Division of Cancer Etiology (DCE), National Cancer Institute (NCI), is recompeting an ongoing project which is currently being performed by the Medical Research Council (Contract No. N01-CP:-N01-CP-51030). The objectives of this acquisition are: 1) to conduct surveys of the occurrence of human retroviruses in relationship to malignancy by collecting sera and other samples for serologic and virologic analysis from epidemiologically defined study populations; 2) to chart the distribution of HTLV-I in relationship to leukemia/lymphoma and other disease outcomes focusing in areas suspected to be HTLV-I endemic; 3) to explore the role of HIV as a cofactor for virally-associated cancer in Africa; and 4) to search for new human retroviruses suspected on the basis of epidemiologic or serologic evidence. Project sites will be targeted by the NCI and the Principal Investigator based on the potential for exploring or settling specific questions. Choice of study sites will be based on new data contacts with local scientists with access to study populations and through results of ongoing studies in a specific locale with unexpected findings.

Under this proposed acquisition the Contractor shall be responsible for: a) consultations and collaborations with NCI Project Officer(s), other investigators designated by the P.O. and officials of international health organizations as directed by the P.O.; b) surveys of existing and new sera; c) data and specimen collection; d) quality control and standardization; and e) laboratory resources of the Principal Investigator. It is anticipated that a single award will be made for a period of five years with the anticipated award scheduled for February 1988. There are no limitations on the geographic location of the Contractor. In order to be considered, the Contractor must meet three sets of requirements and specifications with regard to institutional (corporate) requirements, institutional experience and personnel requirements. These will be detailed in the solicitation package which will be forwarded upon request. A primary restriction will be the non-interchangeability of the key personnel (substitutions of key personnel after award or resignation of key personnel may be cause for termination and

recompetition of the contract). An RFP will be available on/about August 17, 1987, and proposals will be due within 45 calendar days after the date of issuance of the RFP. All responsible sources may submit a proposal which will be considered for award by the National Cancer Institute.

Copies of the RFP may be obtained by sending a written request to:

Trina M. Porter
Contract Specialist
National Cancer Institute
Blair Building, Room 114
9000 Rockville Pike
Bethesda, Maryland 20892

A CLINICAL TRIAL FOR THE USE OF MONOCLONAL ANTIBODIES IN THE PREVENTION OF KIDNEY GRAFT REJECTION

RFP AVAILABLE: NIAID-IAIDP-88-13

P.T. 34; K.W. 0760045, 0755015, 0745040, 0705075

National Institute of Allergy and Infectious Diseases

The National Institutes of Health (NIH) has a requirement for the acquisition of a Clinical Trial for the Use of Monoclonal Antibodies in the Prevention of Kidney Graft Rejection.

The Genetics and Transplantation Biology Branch of the Immunology, Allergy and Immunologic Diseases Program of the National Institute of Allergy and Infectious Diseases (NIAID) is soliciting contract proposals from organizations having the capabilities and facilities for conducting a clinical trial in the prevention of kidney graft rejection. Offerors should have demonstrated experience in kidney transplantation and immunotherapeutic technologies as well as experience in the conduct of clinical trials. The ability to collect and analyze data relating to the efficacy of therapeutic regimens is also required.

RFP-NIAID-IAIDP-88-13 will be available on or about August 31, 1987. Responses are due by November 20, 1987. This NIAID-sponsored project will take approximately four years to complete. Two awards are anticipated. Any responsible organization may submit a proposal which will be considered by the Government. To receive a copy of this RFP, please supply this office with two self-addressed mailing labels.

Telephone inquiries will not be honored and all inquiries must be written and addressed to the office listed below.

Your request should be mailed to:

Ms. Rosemary L. McCabe
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Westwood Building, Room 707
Bethesda, Maryland 20892

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

THE OPTIC NEURITIS TREATMENT TRIAL (ONTT): COOPERATING CLINICS

RFA AVAILABLE: 87-EY-01

P.T. 34; K.W. 0715100, 0755015, 0740025

National Eye Institute

Application Receipt Date: October 15, 1987

The National Eye Institute (NEI) invites applications for cooperative agreements to support individual clinics' participation in a multi-center clinical trial on the treatment of optic neuritis.

BACKGROUND INFORMATION

Optic neuritis is the most common acquired optic nerve disorder (excluding glaucoma) in the under 50 age group, especially individuals between the ages of 15 and 45. The annual incidence has been estimated at about three per

100,000 in high risk areas and one per 100,000 in lower risk areas. Even though from a clinical perspective this rate seems quite low, it still indicates that a substantial number of cases of optic neuritis occur each year. While the prognosis for visual recovery has generally been said to be good, significant visual disability may exist after resolution of the condition. Currently, there are no established guidelines to follow in deciding on a treatment for a patient with this condition. Thus, a treatment which would reduce the residual optic nerve damage produced by optic neuritis would be useful.

RESEARCH GOALS AND SCOPE

The goal of this initiative is to generate a multicenter, masked, randomized, controlled clinical trial designed to determine the value of corticosteroids in the treatment of optic neuritis. Specifically, the current trial has been developed to determine whether treatment with corticosteroids will decrease residual visual dysfunction following resolution of optic neuritis and whether it will speed recovery. A standard protocol will be followed in all clinics. Contrast sensitivity and perimetry will serve as the primary parameters for determination of ultimate outcome.

The complete design of the ONTT, background and rationale for the study, organization, patient eligibility and exclusion criteria, as well as all matters relating to the conduct of this study are detailed in the ONTT Manual of Procedures. A copy may be obtained by contacting the NEI program director (see below).

MECHANISM OF SUPPORT

Awards will be made as cooperative agreements. These awards reflect an assistance relationship in which substantial involvement with NEI staff during performance of the project is anticipated. Policies that govern research grant programs of the Public Health Service will prevail. The award of grants pursuant to this RFA is contingent upon receipt of grants of high scientific merit and the availability of appropriated funds. In fiscal year 1988, the NEI plans to fund approximately ten awards in response to this RFA.

METHOD OF APPLYING

All applications in response to this RFA must be submitted on Application Form PHS 398 (revised 9/86). Forms are available at most institutional business offices or offices of sponsored research. These forms may also be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 448
Bethesda, Maryland, 20892.

The RFA label available in the 9/86 revision of Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review.

Additional information and instructions for completing the application should be obtained from the NEI program director (see below).

INQUIRIES

A copy of the complete RFA, which decribes the research goals and scope, terms and conditions, review procedures and criteria, and method of applying may be obtained by contacting the Strabismus, Amblyopia, and Visual Processing Program, NEI:

Dr. Constance W. Atwell
Chief, Strabismus, Amblyopia, and
Visual Processing Branch
Building 31, Room 6A51
National Eye Institute
Bethesda, Maryland 20892
Telephone: (301) 496-5301

DEVELOPMENT, TESTING, AND VALIDATION OF A PROTOCOL TO ASSESS CARDIOVASCULAR REACTIVITY IN HUMAN POPULATIONS

RFA AVAILABLE: 87-HL-24-P

P.T. 34; K.W. 0715040, 0715195, 0785055, 0411005

National Heart, Lung, and Blood Institute (NHLBI)

Application Receipt Date: November 23, 1987

The Behavioral Medicine Branch of the Division of Epidemiology and Clinical Applications, NHLBI, announces the availability of an RFA for the development of a protocol for assessing cardiovascular reactivity to stressors, suitable for use in prospective epidemiological and clinical investigations of reactivity and cardiovascular diseases.

Several issues must be addressed in devising a valid reactivity measurement protocol. These issues include procedures to measure baseline values, design of the appropriate challenge tests, the choice of physiological responses to be measured, and demonstration of appropriateness of the tests and protocol for various population subgroups.

In order to take fully into consideration the numerous variables which influence such tests, development of the cardiovascular reactivity protocol in two phases should be considered. Phase I would utilize a battery of potentially useful tests and measures, while Phase II would continue more extensive development and validation of only the most promising elements from Phase I. Since a variety of circumstances might dictate the time available for test administration, a short and long form of the protocol would be desireable. Finally, variants, or different forms of the same protocol may be desireable to accommodate experimental designs which require frequently repeated testing.

Because of the complexities inherent in the development and reliability testing of such a protocol, and in order to bring to bear the full breadth of existing experience available in the scientific community, the grantee will be urged to convene an advisory board to assist with periodic review of the project.

The award will be made as a Cooperative Agreement. Under this mechanism, a negotiated partner relationship exists between the recipient of the award and the NHLBI, in which the performer of the activity is responsive to the requirements and conditions set forth in the RFA, and agrees to accept the assistance, advice, and involvement of a designated NHLBI staff member in the execution of the project. This involvement will be primarily through full participation of this staff member in the advisory board referred to above, and through periodic review of progress and procedures used in the implementation of the reactivity protocol. Applicants must, however, define their objectives in accord with their own interests and perceptions of approaches to cardiovascular reactivity assessment. It is anticipated that one or two awards will be made under this program.

The RFA label available in the 9/86 revision of Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review.

For further information and a copy of the RFA contact:

Dr. Peter G. Kaufmann
Behavioral Medicine Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 216
Bethesda, Maryland 20892
Telephone: (301) 496-9380

NUTRITION COORDINATING CENTER TO PARTICIPATE IN AN ONGOING MULTICENTER CLINICAL STUDY OF MODIFICATION OF DIET IN RENAL DISEASE (MDRD)

RFA AVAILABLE: 87-DK-11

P.T. 34; K.W. 0710095, 0705075, 1010013

National Institute of Diabetes and Digestive and Kidney Diseases

Application Receipt Date: November 13, 1987

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for a Nutrition Coordinating Center to participate in a multicenter clinical study entitled Modification of Diet in Renal Disease (MDRD) Study.

BACKGROUND INFORMATION

In 1983, the NIADDK (now NIDDK) issued Requests for Cooperative Agreement Applications inviting applications from Clinical Centers and a Data Coordinating Center to participate with the NIADDK in a multicenter collaborative clinical trial to study the effect of protein restriction on the progression of renal disease. Nine Clinical Centers and a Data Coordinating Center were selected on the basis of peer review and received awards to undertake the Planning (Phase I) and Feasibility Study (Phase II) of this multicenter clinical trial. A Nutrition Coordinating Center was funded as a subcontract to the Data Coordinating Center.

The MDRD Study is now at approximately the halfway mark of the Feasibility Study and is expected to proceed to Phase III in September 1988. The Nutrition Coordinating Center presently participating in the study is scheduled to be phased out on June 30, 1988. This solicitation is to invite applications from organizations with the requisite experience and resources to serve as the MDRD Nutrition Coordinating Center for Phases III and IV of the study.

RESEARCH GOALS AND SCOPE

The Nutrition Coordinating Center serving the MDRD Study will be responsible for overseeing the nutrition component of the study, including the development, evaluation and monitoring of clinical center nutritionists, compliance and counseling techniques and educational material; analysis of nutrient and compliance data; nutrient data base management; data collection and processing; internal and external quality control procedures; and documentation, handling and reporting of study data.

Access to a nutrient data base and adequate computer hardware capacity are fundamental requirements of a Nutrition Coordinating Center serving the study. The details of the MDRD Study, including study organization, the Phase II Protocol and other matters relating to the conduct of the study will be made available to respondents.

MECHANISM OF SUPPORT

The administrative and funding mechanism which will be used to support the MDRD Nutrition Coordinating Center for Phases III and IV of the study is the cooperative agreement.

Under the cooperative agreement, a negotiated partner relationship exists between the recipient of the award and the NIDDK in which the performer of the activity is responsive to the requirements and conditions set forth in the RFA and agrees to accept NIDDK staff advice and involvement in the execution of the project.

The specific terms, conditions, and arbitration procedures pertaining to the scope and nature of the interaction between the NIDDK and the Nutrition Coordinating Center are described in the RFA and will be incorporated in the Notice of Award.

Letter of Intent receipt date	October 2, 1987
Application receipt date	November 13, 1987
Scientific merit review	December 1987
NIDDK Advisory Council review	February 1988
Anticipated award date	March 1, 1988

INQUIRIES

Requests for the complete RFA and Phase II Protocol may be obtained from:

Anna M. Sandberg, Dr. P.H.
Clinical Trial Coordinator
Division of Kidney, Urologic and
Hematologic Diseases
National Institute of Diabetes and Digestive
and Kidney Diseases
National Institutes of Health
Westwood Building, Room 621
Bethesda, Maryland 20892
Telephone: (301) 496-7133

Applications must be submitted using Form 398 (Rev. 9/86). The RFA label contained in the application kit must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in a delayed processing and review of your application.

NATIONAL RESEARCH SERVICE AWARD INSTITUTIONAL RESEARCH TRAINING GRANTS IN PRIMARY MEDICAL AND DENTAL CARE

P.T. 44; K.W. 0720005, 0730000, 0785035, 0785040

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

Receipt Date: November 12, 1987

AUTHORITY AND PURPOSE

Public Law 99-158 authorized research training grants under the National Research Service Award (NRSA) Act to be made to individuals affiliated with entities which have received grants or contracts under Section 780, 784 or 786 of the Public Health Service Act and are for research in primary medical care. By virtue of this authority, the National Institutes of Health (NIH) and the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) are implementing an institutional NRSA postdoctoral research training program in primary care medicine to be administered by the National Institute of Child Health and Human Development (NICHD), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Dental Research (NIDR) and the National Institute of Mental Health (NIMH).

LEVELS OF TRAINING

Applications will be accepted from institutions and entities, as defined above, for the support of individuals holding the M.D., D.O., D.D.S. or equivalent degrees who wish to engage in research training preparatory to entering academic careers in primary medicine or dentistry.

ELIGIBILITY REQUIREMENTS

Domestic nonprofit public or private schools of medicine, osteopathy and dentistry, specifically departments of family medicine, general internal medicine, general pediatrics, obstetrics and gynecology or the general practice of dentistry may apply for grants to support research training programs.

The applicant institution must have, or be able to develop, the staff and facilities required for the proposed program. The training program director at the institution will be responsible for the selection and appointment of trainees and for the overall direction of the program.

CHARACTERISTICS OF THE PROGRAM

A primary care physician has been defined as one who establishes a relationship with an individual or a family and provides continuing surveillance of their health care needs, comprehensive care for acute and chronic disorders, including mental and/or emotional disorders or problems with alcohol or drug abuse. The physician or dentist in the primary care setting could also provide access to the health care delivery system for those disorders requiring the services of other specialists. A recent definition of primary care states that it generally refers to the routine medical care and services people receive on first contact with the health care system for a particular health incident, i.e., prevention, maintenance, diagnosis, limited treatment, management of chronic problems, and referral.

Owing to the diverse nature of primary care responsibilities, it is anticipated that the proposed postdoctoral research training will reflect a broad interdisciplinary approach to research preparation. To assure the acquisition of skills in research design for primary care research, some portion of the training should be devoted to biostatistics and epidemiology. The exact content of the research training program is the responsibility of the applicant's program director and advisors and should be designed to take optimum advantage of the resources available at the institution. Providing didactic experience and education is encouraged. Individuals may matriculate for a master's degree where deemed congruent with the purposes of the research training.

GENERAL PROVISIONS

NRSAs may not be used to support studies leading to the M.D., D.O., D.D.S., D.V.M. or other similar professional degrees or to support residency. Trainees are required to pursue their research training on a full time basis devoting at least 40 hours per week to the research training as specified by the sponsoring institution in accordance with its own policies.

TRAINEE ELIGIBILITY REQUIREMENTS

The individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residency. Individuals on temporary or student visas are not eligible.

RECRUITMENT AND APPOINTMENT OF TRAINEES

The primary objective of the NRSA program is the preparation of qualified individuals for careers in biomedical and behavioral research. Within the framework of the program's long-standing commitment to excellence and projected needs for investigators in particular areas of research, it is important that emphasis be placed on recruiting individuals from minority groups that are now underrepresented nationally in the biomedical and behavioral sciences.

PAYBACK PROVISIONS

Before trainees can be appointed to a training grant, they must sign an agreement that they will fulfill the NRSA payback requirements. Recipients agree to engage in biomedical or health related behavioral research and/or teaching for a period equal to the period of NRSA support in excess of 12 months.

STIPENDS AND OTHER TRAINING COSTS

For postdoctoral trainees, the stipend for the first year of support is determined by the number of years of relevant experience beyond receipt of the doctoral degree. Current postdoctoral stipends are as follows:

Years of Relevant Experience	Annual Stipend
0	$15,996
1	17,004
2	21,996
3	23,004
4	24,000
5	26,004
6	27,996
7 or more	30,000

Tuition and fees, including medical insurance, are allowable trainee costs provided such charges are required of all persons in a similar training status at the institution without regard to their source of support. Tuition at the postdoctoral level is limited to that required for specific courses in support of the approved training program.

Trainee travel, including attendance at scientific meetings, which the institution determines to be necessary to the individual's training, is an allowable trainee cost.

Institutional allowances of up to $2,500 per year per postdoctoral trainee may be requested to help defray the cost of other training related expenses, such as staff salaries, consultant costs, equipment, research supplies, and staff travel. An indirect cost allowance based on 8 percent of total allowable direct costs or actual indirect costs, whichever is less, may also be requested.

PERIOD OF SUPPORT

Institutional grants may be made for five years and are renewable upon successful recompetition.

REVIEW PROCESS

Applications will be reviewed for technical and scientific merit by an NIH or ADAMHA Initial Review Group convened especially for this purpose and evaluated according to the following critical components: the proposed research training objectives and the program design to achieve them, the qualifications of the participating faculty, the previous training record, the ability to attract high caliber trainees, the availability of research support, the extent of the institutional commitment, and the available resources. Applications are also reviewed by the Council, Board or other advisory group to the NIH or ADAMHA Institutes that will support the research training. These advisory groups will consider, among other elements, the initial review group's comments on the plan to recruit individuals from underrepresented minority groups into the training program. Final selection will be made based on the initial review group and advisory groups' recommendations contingent upon the availability of funds. The applicant will receive a summary statement of the initial review group's recommendation promptly upon its completion and will be notified of the final action shortly after the Advisory Group meeting.

REVIEW SCHEDULE

AN EXPEDITED REVIEW PROCESS HAS BEEN ESTABLISHED FOR AWARDS TO BEGIN JULY 1, 1988.

Application Receipt Date	Initial Review Meeting	Council/Board Meeting	Earliest Start Date
Nov. 12	December	January	July 1

Applications received after Nov. 12, 1987 will not be considered for this review.

APPLICATION PROCEDURES

Applications should be made on grant application form PHS 398 (Rev. 9/86). This revision contains special instructions for institutional NRSAs. Forms are usually available at local educational institutions. If not available locally, send a request accompanied by a self-addressed mailing label to:

Office of Grants Inquiries
Division of Research Grants
Westwood Building, Room 449
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7441

The RFA label available in the 9/86 revision of the Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time.

The completed original application and four (4) copies should be sent or delivered to:

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

Two (2) additional copies of all applications responding to the RFA should be sent to:

Dr. Anthony Demsey, Review Branch
National Institute of Diabetes and Digestive
and Kidney Diseases
Westwood Building, Room 406
Bethesda, Maryland 20892

ADDITIONAL INFORMATION

For more detailed information on the research policies and procedures governing NRSA institutional research training grants, the applicant is referred to the NIH Guide Volume 16, Number 20, June 12, 1987 and to the special edition of the NIH Guide for Grants and Contracts Vol. 13, Number 1, January 6, 1984.

For further information regarding this RFA, applicants interested in primary care medicine related to general pediatrics, obstetrics and gynecology should contact:

Ms. Hildegard Topper
National Institute of Child Health and
Human Development
National Institutes of Health
Building 31, Room 2A04
Bethesda, Maryland 20892
Telephone: (301) 496-1848

Those interested in primary care medicine as it relates to general internal medicine, should contact:

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

Those interested in primary care medicine as it relates to general dentistry, should contact:

Dr. Thomas Valega
National Institute of Dental Research
National Institutes of Health
Westwood Building, Room 510
Bethesda, Maryland 20892
Telephone: (301) 496-6324

Those interested in primary care medicine mainly as it relates to mental disorders and/or alcohol and drug abuse should contact:

Dr. Douglas Kamerow
National Institute of Mental Health
Primary Care Research Program
Parklawn Building, Room 18C-14
Rockville, Maryland 20857
Telephone: (301) 443-3364

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH GRANTS RELATED TO MOTOR NEURON DISEASES: AMYOTROPHIC LATERAL SCLEROSIS, ATAXIA, AND OTHER SYSTEM DEGENERATIONS

P.T. 34; K.W. 0705055, 0715140, 0715125, 0755020, 0785055, 1002019, 0710075

National Institute of Neurological and Communicative Disorders and Stroke

The Division of Demyelinating, Atrophic, and Dementing Disorders (DDADD) of the National Institute of Neurological and Communicative Disorders and Stroke, a component of the National Institutes of Health, invites grant applications for support of basic and clinical research on amyotrophic lateral sclerosis, spinocerebellar atrophy, and other system degenerations. This is a reissuance of the Program Announcement previously published on May 16, 1980.

Amyotrophic lateral sclerosis, the most commmon of the motor neuron diseases, is characterized by degeneration of the corticospinal tracts and by atrophy and loss of motor neurons of the anterior horns of the spinal cord, brain stem, and precentral gyri. These changes are associated with weakness and atrophy of the affected skeletal muscles. Onset of the disease usually occurs between 40 and 65 years of age. Familial forms are known and some of these may be hereditary.

Ataxias are a heterogenous group of disorders characterized by awkwardness of movement and failure of muscular coordination of the body, extremities, eyes, and speech. Some of these are hereditary. Friedreich's ataxia, the most common form of spinocerebellar degeneration is inherited mainly as an autosomal recessive disorder. The disease usually appears before 20 years of age. The spinocerebellar and corticospinal tracts, posterior columns, and peripheral nerves are involved. Damage to the heart may occur and some patients suffer from diabetes mellitus. Although enzymatic changes have been reported, biochemical abnormalities have not been identified in most patients with ataxia.

"Linking forms" among various system degenerations have suggested a spectrum of possibly related disorders. Although genetic and sporadic forms are known, the etiology and pathogenesis of these diseases and effective treatments remain to be found.

RESEARCH GOALS AND SCOPE

There is a paucity of understanding about these disorders at all but clinical and pathological levels. Basic and clinical research proposals are solicited. Studies might address the normal and abnormal biology of motor and other neurons, central nervous system response to endogenous and environmental toxins, new and sensitive probes for detection of conventional and unconventional infectious agents, development of new animal models, identification of metabolic, endocrine, immunological abnormalities, changes in extraneural tissues, genetic linkage, tests for "populations at risk," early diagnosis, epidemiology, and new therapeutic modalities.

MECHANISMS OF SUPPORT

Applications may be submitted for program project grants (P01), individual research project grants (R01), and the First Independent Research Support and Transition (FIRST) Award (R29).

Program projects may include human research as well as experimental animal approaches, depending upon the local facilities and those of cooperating institutions. These should include technical and professional expertise, interest, physical resources, patients, and the ability to carry out the desired objectives. Applicants should develop a comprehensive research program, each phase of which is directed to a specific aspect of amyotrophic lateral sclerosis or other system degenerations. Potential applicants are encouraged to consult with the staff of DDADD early in the planning stage.

Individual applicants may propose any investigational aspect, basic or clinical, of amyotrophic lateral sclerosis or system degenerations.

Deadlines for receipt of P01, R01, and R29 applications are October 1, February 1, and June 1.

REVIEW PROCEDURES AND CRITERIA

Applications should be prepared on form PHS 398 (Rev. 9/86) following instructions contained in the application kit. Application kits are available at most institutional business offices or could be obtained from the Division of Research Grants, NIH. Program project applications should conform to the style and format recommended by this Institute; this information is available from the staff person listed below. Program project proposals will be reviewed initially and judged for scientific merit by one of the NINCDS program project review committees. Individual research projects receive a similar review by the appropriate study section of the Division of Research Grants. Both reviews will be conducted in accordance with NIH policy and procedures involving peer review. Applicants may request dollar amounts commensurate with the objectives to be accomplished for a period not to exceed five years. The support mechanism for this program will be the grant-in-aid. Awards will be made to the applicants based on scientific merit of proposal, availability of funds, responsiveness to this announcement, and relevance to the Program. The phrase "Research Grants Related to Motor Neuron Diseases: Amyotrophic Lateral Sclerosis, Ataxia, and Other System Degenerations" should be typed in block No. 2 on the first (face) page of the application.

Completed applications should be submitted according to the deadlines for the review schedule mentioned above (also supplied in the application kit) and mailed to the following address:

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

INQUIRIES AND CORRESPONDENCE

One copy of the application should be sent to the address below. Applicants needing further information including format for program project applications may contact:

Dr. A. P. Kerza-Kwiatecki
Health Scientist Administrator
Division of Demyelinating, Atrophic,
and Dementing Disorders
Room 702, Federal Building
Bethesda, Maryland 20892
Telephone: (301) 496-1431

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS 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

*U.S. G.P.O. 1987-181-189:60009