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. 20, No. 47
December 20, 1991

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

ERRATUM

NOTE: The NIH Guide for Grants and Contracts will not be published on December 27, 1991 and January 3, 1992. The next issue will be on January 10, 1992.

NOTICES

NIH REGIONAL SEMINAR IN GRANTS ADMINISTRATION

P.T. 42; K.W. 1014006

National Institutes of Health

The Grants Policy Office of the National Institutes of Health is sponsoring a two-day seminar on program funding and grants administration. The seminar covers topics of interest to both academic researchers and grants administrators and will be held on January 23-24, 1992, at the University of Houston, Houston, Texas.

The conference is designed for an audience of researchers and research administrators at institutions in the southwest region of the country. Those interested from other regions are also welcome. Investigators and staff from small and minority colleges, for-profit research organizations, hospitals, universities, and research institutes are encouraged to attend.

Discussions of current issues that affect NIH funding and grants administration are included to give conference participants a comprehensive, up-to-date view of NIH-sponsored research. The first day of the conference focuses on current areas of interest to the research programs of the various awarding components that comprise the NIH. Preparation of an NIH application and the NIH review process are included as agenda topics. In addition, a panel of Principal Investigators will give their perspective and advice on writing a successful application. The program for the second day covers topics associated with pre-award and post-award administration of NIH grants and contracts. Policy and procedural issues affecting NIH grants administration form the basis of the program. General discussions on current issues and the changes they precipitate are integrated with more specific discussions regarding special career development programs, cost management and award practices, and electronic grant application development.

Mr. Geoffrey Grant, Grants Policy Officer in the Office of Extramural Research at NIH and program and grants management staff from several NIH institutes and centers and representatives from the Division of Research Grants are featured speakers. Time will be available each day for conference participants to meet informally

with the NIH representatives to discuss topics of special interest.

Conference schedule and fee information will be mailed in December. For more information, contact Ms. Linda Keng, (713) 749-3412.

SALARY LIMITATION ON GRANTS AND CONTRACTS

P.T. 34; K.W. 1014006

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

The purpose of this notice is to inform grant and cooperative agreement applicants and contract offerors of the Congressionally-mandated provision for the limitation of salary for the second consecutive year of funding.

Section 212 of the Appropriations Act of the Department of Health and Human Services for fiscal year (FY) 1992 (October 1, 1991-September 30, 1992) (Public Law 102-170) limits the amount of the direct salary of an individual under a grant or contract award issued by the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to no more than $125,000 per year (for 100 percent effort). This requirement is an increase from the limitation of $120,000 in FY 1991.

NIH and ADAMHA will apply the restriction to all grant, cooperative agreement, and contract awards and to all funding amendments to existing grants and contracts made during FY 1992 and with FY 1992 funds. The salary limitation applies to amounts PERMITTED in grant and contract awards as well as CHARGED to those awards.

However, an individual's institutional salary, per se, is NOT constrained by this legislative provision. An institution may supplement an individual's salary with non-HHS funds.

NIH and ADAMHA grant and contract awards that indicate direct salaries of individuals in excess of a RATE of $125,000 per year will include an appropriate notification, such as:

> According to the HHS Appropriations Act, "None of the funds appropriated in this title for the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of $125,000 per year." The application/proposal for this project proposed a salary at a rate greater than $125,000 per year. This award has been reduced accordingly.

Grant applications and contract proposals submitted to the NIH and ADAMHA should continue to request funding at the regular rates of pay of all individuals for whom reimbursement is requested. NIH and ADAMHA will make downward adjustments of direct salary amounts in excess of the ceiling rate and fringe benefits based upon the budget approved as part of the original award. Corresponding indirect costs will also be adjusted.

Following is an EXAMPLE of this process:

Individual's institutional base salary per year	$150,000
Research effort requested on grant application or contract proposal	50%
Direct salary requested	$ 75,000
Fringe benefits requested (25% of salary)	$ 18,750
Applicant organization's indirect costs rate	47%
Amount requested - salary plus fringe benefits plus associated indirect costs	$137,813

If a grant/contract is to be awarded, the amount included in the award for the above individual will be calculated as follows:

Direct salary - restricted to RATE of $125,000 times effort (50%) to be devoted to project	$ 62,500
Fringe benefits (25% of allowable salary)	$ 15,625
Subtotal	$ 78,125
Associated indirect costs at 47% of subtotal	$ 36,719
Total amount included due to salary limitation	$114,844
Amount of reduction due to salary limitation ($137,813 requested minus $114,844 awarded)	$ 22,969

Grantee and contractor organizations are reminded of these important points:

o The salary limitation provision does NOT apply to payments made to consultants under an NIH or ADAMHA grant or contract (however, as with all costs, such payments must continue to meet the test of reasonableness).

o The salary limitation provision DOES apply to those subawards/subcontracts for substantive work under an NIH or ADAMHA grant or contract.

o Unobligated funds from a prior grant/contract period "carried over" INTO a FY 1992 award period ARE subject to the salary limitation provision.

o In a noncompeting continuation application (type 5) setting, a grantee organization is NOT permitted to either (1) redistribute an amount of "excess" salary among other budget categories nor (2) increase the principal investigator's effort on the project, in an attempt to apply for the full level of funding as previously recommended by the peer review process.

For further information, contact any of the grants management offices of the funding components of the NIH and ADAMHA.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

MULTICENTER STUDIES OF DIET AND LIPOPROTEINS IN HUMANS

RFA AVAILABLE: HL-92-03-H

P.T. 34; K.W. 0710095, 0755015, 0715040, 0755018, 0765020, 0710030

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: February 15, 1992
Application Receipt Date: April 23, 1992

PURPOSE

The Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute (NHLBI), announces the availability of a Request for Applications (RFA) on the above subject. The purpose of this program is to fund collaborative studies for investigations into the effects of diet on lipid and lipoprotein metabolism, hemostatic parameters, and other pathophysiological processes related to atherogenesis. The administrative structure will be similar to that of a multicenter clinical trial. A group of Field Centers will develop common protocols and feed standardized experimental diets, use standardized laboratory methods, and pool the data. A Coordinating Center will standardize data collection procedures, ensure sound statistical approaches to study design and data analysis, and arrange for quality control of outcome measures and experimental diets.

This RFA solicits applications to take part in a single competition. It is anticipated that awards will be made to one Coordinating Center and four Field Centers.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Multicenter Studies of Diet and Lipoproteins in Humans, is related to the priority areas of heart disease and stroke and nutrition. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

MECHANISM OF SUPPORT

The support mechanism for this program will be the cooperative agreement (U01), an assistance mechanism that is similar to the traditional NIH research grant. It differs from a research grant in the extent and nature of NHLBI staff involvement. Although the financial plans for fiscal year 1992 include $1,950,000 for the total cost of this program, awards pursuant to this RFA are contingent upon receipt of funds for this purpose. It is anticipated that up to five awards will be made under this program. The specific number to be funded, however, will depend on the merit and scope of the applications received and the availability of funds.

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

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.

ELIGIBILITY

Domestic, public and private for-profit and non-profit institutions and organizations are eligible to apply in response to this RFA. Awards in connection with this announcement will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with PHS policy governing awards to foreign institutions.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator must be included with the application.

REVIEW PROCEDURES

Upon receipt, applications will be reviewed by NHLBI staff for responsiveness to the objectives of this RFA. If an application is judged unresponsive, the applicant will be contacted and given the opportunity to withdraw the application or to have it considered for the traditional NIH grant program.

Applications judged to be responsive will be reviewed for scientific and technical merit by an initial review group that will be convened by the division of extramural Affairs, NHLBI, solely to review these applications.

This initial review may include a preliminary evaluation to determine scientific merit relative to the other applications received in response to the RFA (triage); the NIH will withdraw from further consideration applications judged to be non-competitive and promptly notify the Principal Investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated for scientific/technical merit by the customary peer review procedures, including, if deemed appropriate, a reverse site visit at the applicant's expense.

APPLICATION PROCEDURES

Letter of Intent

Prospective applicants are asked to submit a letter of intent that includes the names of the Principal and Co-Investigators, identify the cooperating institutions, and indicate whether the application will be for a Field Center, Coordinating Center, or both. The NHLBI requests such letters only for the purpose of providing an indication of the number and scope of applications to be received and, usually does not acknowledge their receipt. A letter of intent is not binding, it will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for applications. This letter of intent is to be received no later than February 15, 1992, and is to be sent to:

Dr. C. James Scheirer
Review Branch, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 548B
Bethesda, MD 20892
Telephone: (301) 496-7363
FAX: (301) 402-1660

Format for Applications

Use form PHS 398 (rev. 10/88, reprinted 9/89), the application for the traditional NIH research project grant. Copies of this form are available in the applicant institution's office of sponsored research and may be obtained from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone: 301/496-7441.

INQUIRIES

Direct inquiries regarding this program and requests for the RFA to:

Abby G. Ershow, Sc.D.
Project Scientist, Lipid Metabolism-Atherogenesis Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 401
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1681
FAX: (301) 496-9882

Direct inquiries regarding fiscal and administrative matters to:

Marie A. Willett
Chief, Heart and Vascular Grants Management Section
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11C
Bethesda, MD 20892
Telephone: (301) 496-7255
FAX: (301) 402-1200

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.838. Grants will be awarded under the authority of the Public Health Service Act, Title III, 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 to review by a Health Systems Agency.

NEW DNA SEQUENCING TECHNOLOGY IN SUPPORT OF THE HUMAN GENOME PROGRAM

RFA AVAILABLE: HG-92-01

P.T. 34; K.W. 1215018, 1002058, 0755045, 1004017

National Center For Human Genome Research

Letter of Intent Receipt Date: January 31, 1992
Application Receipt Date: March 17, 1992

The National Center for Human Genome Research (NCHGR) announces the availability of a Request for Applications (RFA) for research projects to develop new approaches to DNA sequencing that will be rapid and cost- effective when applied to large-scale sequence analysis.

INTRODUCTION

The NCHGR sponsors basic and applied research concerned with the development and application of new technologies for the characterization and analysis of the human genome and the genomes of selected model organisms. The activities encompassed by the NCHGR program include genetic and physical mapping, DNA sequencing, informatics related to mapping and sequencing, and technology development that will facilitate all of these efforts.

BACKGROUND

A major long-term goal of the Human Genome Program is to identify all the genes and regulatory functions encoded in the three billion base pairs of human DNA. In order to attain this second objective, DNA sequencing technology must be further developed so that the cost will be significantly decreased and the rate significantly increased.

To stimulate the necessary technology development, NCHGR will provide support for innovative and high-risk projects that attempt completely new approaches and projects that propose significant improvements in available technology. The purpose of this RFA is to stimulate investigation of totally new approaches and approaches that have the potential to make revolutionary advances in current gel-based techniques. Thus, high risk projects that are based on sound scientific principles are encouraged.

RESEARCH SCOPE

Applications are encouraged that address:

o the development of new sequencing methods that will allow large-scale sequencing of DNA at a cost significantly below 50 cents per base pair, or

o the improvement of, by at least 10-fold, current methods that are applicable enough for large-scale DNA sequencing.

Applications to pursue DNA sequencing projects using state- of-the-art techniques will not be considered responsive to this RFA. Applications that are solely directed toward informatics, e.g., development of software and data bases to support large-scale sequencing projects, or development of algorithms and analytical tools to interpret genomic information, must be submitted under the program announcement, "Mapping, DNA Sequencing, and Technology Development in Support of the Human Genome Program," PA-90-20, published in the NIH Guide for Grants and Contracts on July 27, 1990, Vol. 19, No. 28.

Applications are particularly encouraged from scientists, such as engineers and physicists, and institutions, such as for-profit institutions and biotechnology companies, that have not traditionally requested research support from the NCHGR. Applicants whose expertise is primarily non-biological are especially encouraged to interact closely with biologists during the development of the research plan. Applications from minority investigators and women are encouraged.

MECHANISM OF SUPPORT

Support for this program will be through the Pilot Projects/Feasibility Studies (R21) and Traditional Research Grant (R01) mechanisms. Other mechanisms, including the Research Program Project (P01) and Developmental Grants (P20), will also be considered when appropriate. The total amount of support available for grants under this RFA will be $2.0 million (direct and indirect costs) for the first year of the project and is contingent upon appropriation of funds for this purpose. It is anticipated that approximately five to ten awards will be made, representing a mix of research topics and mechanisms.

ELIGIBILITY

Domestic universities, medical colleges, hospitals, corporations and other public, private, and for-profit research institutions, including State and local government units, are eligible. Collaborations between scientists in academia and industry are especially encouraged.

LETTER OF INTENT

Potential applicants are asked to submit a letter of intent by January 31, 1992. This letter is to include a descriptive title of the proposed research, names of the principal investigator and other key investigators and their institutions. Letters of intent are to be sent to:

Robert L. Strausberg, Ph.D.
Program Director, Technology Development Program
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
E-mail: CXR@CU.NIH.GOV

REVIEW PROCEDURES

Applications in response to this announcement will be reviewed in accordance with the customary NIH peer review procedures.

Applications will be screened for responsiveness to this RFA by NCHGR staff. Any application deemed non-responsive will be returned to the applicant or referred to the Division of Research Grants (DRG) for reassignment as an unsolicited application according to DRG referral guidelines at the discretion of the applicant. If a large number of responsive applications is received, a preliminary peer review will be organized by the Office of Scientific Review, NCHGR, to identify the most meritorious applications. Applications that are deemed non-competitive by this process will receive only a brief critique, will not be reviewed further, and the applicant will be notified.

The remaining applications will be reviewed for scientific and technical merit by the Genome Research Review Committee or another appropriately constructed review committee with the NCHGR. Review criteria will include the following: (1) originality and innovativeness of the approach including supporting background documentation explaining the evolution of the proposed approach; (2) feasibility of the research as demonstrated by a well-developed, detailed experimental design; (3) overall scientific and technical merit of the research; (4) the potential of the proposed work to attain the research objectives outlined in this RFA; (5) training, experience, and research competence, of the investigator(s); (6) adequacy of available facilities; (7) provision for the protection of human subjects and the humane care of animals; and (8) appropriateness of the requested budget for the work proposed.

AWARD CRITERIA

Applications will compete for funds set aside for this purpose. The following will be considered in making funding decisions: (1) quality of the proposed project as determined by peer review; (2) value of the research for achieving the goals of the Human Genome Program; (3) balance among research goals with respect to the NCHGR grant portfolio, and (4) availability of funds.

METHOD OF APPLYING

Applications must be submitted using the form PHS 398 (rev. 10/88). The RFA label available in the revised application kit 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 for review. Application kits are available in the business or grants office at most academic or research institutions, and from the Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441. Because of the specialized interest of this NCHGR program, and the potential for overlap with other NIH programs, it is strongly recommended that potential applicants contact NCHGR staff to discuss research objectives and appropriate mechanisms.

INQUIRIES

Prospective applicants are encouraged to contact the staff members very early in the planning phase of the application.

For more information regarding specific research areas or mechanisms and for a copy of the RFA, contact:

Robert L. Strausberg, Ph.D.
Program Director, Technology Development Program
National Center for Human Genome Research
Building 38A, Room 610
Bethesda, MD 20892
Telephone: (301) 496-7531
E-mail: CXR@CU.NIH.GOV

For information about PHS Grant Policy, applicants may contact:

Ms. Alice Thomas
Chief, Grants and Contracts Management Branch
National Center for Human Genome Research
Building 38A, Room 613
Bethesda, MD 20892
Telephone: (301) 402-0733

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.172. Awards will be made under the authority of the Public Health Service Act, Sections 301 (Public Law 78-410, as amended 42 U.S.C. 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirement of Executive Order 12372 or to Health Systems Agency review.

PREDOCTORAL FELLOWSHIP AWARDS FOR MINORITY STUDENTS

RFA AVAILABLE: GM-92-01

P.T. 22, FF; K.W. 0720005

National Institute of General Medical Sciences

Application Receipt Date: April 22, 1992

PURPOSE AND BACKGROUND INFORMATION

The National Institute of General Medical Sciences (NIGMS) announces the availability of a Request for Applications (RFA) for individual National Research Service Award (NRSA) Predoctoral Fellowships for Minority Students. This program provides up to five years of support for research training leading to either the Ph.D. degree or the combined M.D./Ph.D. degrees in the biomedical sciences for highly qualified students from underrepresented minority groups. Support is NOT available for individuals enrolled in medical schools UNLESS they are enrolled in a combined M.D./Ph.D. and other combined professional/research Ph.D. degree program in biomedical research.

The intent of this Minority Predoctoral Fellowship Program is to make graduate fellowships available to underrepresented minority graduates from all institutions, including the many minority undergraduate students who have participated in the various NIH-sponsored programs to prepare them for research careers.

ELIGIBILITY REQUIREMENTS

Eligibility for these awards is limited to students who are U.S. citizens, non-citizen nationals, or permanent residents from ethnic/racial groups that are underrepresented in research in the biomedical sciences in the U.S. For the purpose of this announcement, underrepresented minority students are defined as individuals belonging to a particular ethnic or racial group that has been determined by the applicant's graduate institution to be underrepresented in biomedical or behavioral research. In making these awards, the NIH will give priority consideration to applications from Blacks, Hispanics, Native Americans, Pacific Islanders, and other ethnic or racial group members who have been found to be underrepresented in biomedical or behavioral research nationally. In addition, an applicant MUST currently be enrolled in a Ph.D. or combined M.D./Ph.D. graduate program in the biomedical sciences or have been accepted by and agreed to enroll in such a graduate program the following academic year.

Graduates of the NIGMS Minority Access to Research Careers Program are encouraged to apply for the MARC Predoctoral Fellowship Program.

MECHANISM OF SUPPORT

The mechanism of support is the individual fellowship (F31) awarded under the auspices of the National Research Service Award Act. Except as otherwise stated in the RFA, awards will be administered under the PHS Grants Policy Statement and the Guidelines for National Research Service Awards. Fellowships are subject to the payback obligation of the National Research Service Award Act.

The fellowship provides a stipend for the student's living expenses, applicable tuition and fees, and an annual institutional allowance that may be used for travel to scientific meetings and laboratory and other training expenses.

For FY 1992, the NIGMS anticipates making at least 45 new fellowship awards if sufficient numbers of high quality applications are received. The period of fellowship support requested in response to this present RFA may not exceed five years.

Funding will be provided by the NIGMS and the following other awarding components of the NIH and the Alcohol,

Drug Abuse and Mental Health Administration: the National Cancer Institute, the National Institute of Child Health and Human Development, the National Institute of Deafness and Other Communication Disorders, the National Institute of Drug Abuse, the National Institute of Environmental Health Sciences, the National Eye Institute, National Center for Human Genome Research, and the National Center for Research Resources.

METHOD OF APPLYING

The single receipt date for applications is April 22, 1992. The fellowship application form PHS-416-1 (revised 4/89) must be used in applying for these grants. These forms are available at most university business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Bethesda, Maryland 20892; and from the NIH program administrators named below.

REVIEW CRITERIA

The review criteria include the academic record and research experience of the applicant; the quality of the graduate program in which the applicant is already enrolled or plans to enroll; the qualifications and research/research training experience of the sponsor or research advisor; and, for advanced graduate students, scientific significance, originality and feasibility of the proposed research.

INQUIRIES

Written and telephone inquiries and requests for the RFA are encouraged and may be directed to:

Dr. Michelle Broido
National Institute of General Medical Sciences
Westwood Building, Room 907
Bethesda, MD 20892
Telephone: (301) 496-7309

For fiscal and administrative matters, contact:

Ms. Ruth Monaghan
Deputy Grants Management Officer
National Institute of General Medical Sciences
Westwood Building, Room 953
Bethesda, MD 20892
Telephone: (301) 496-7746

AUTHORITY AND REGULATIONS

Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended, 42 USC 288) and administered under PHS grant policies and Federal Regulations 42 CFR Part 66. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

RESEARCH GRANTS RELATED TO NEURONAL CEROID LIPOFUSCINOSES INCLUDING BATTEN DISEASE

PA: PA-92-25

P.T. 34; K.W. 1002030, 1002019, 0755020, 0765035

National Institute of Neurological Disorders and Stroke

PURPOSE

This program announcement is intended to emphasize the current interest of the National Institute of Neurological Disorders and Stroke (NINDS) in the neuronal ceroid lipofuscinoses (NCL), and to increase the NINDS support of both basic and clinical investigations in these disorders. Therefore, the Developmental Neurology Branch, Division of Convulsive, Developmental and Neuromuscular Disorders, NINDS, encourages the submission of research project grant applications (R01), and program project (P01) and center (P50) applications for basic and clinical research studies of the NCL.

BACKGROUND

The NCL are a group of hereditary neurodegenerative diseases in children and adults in which an autofluorescent lipopigment, ceroid, accumulates in the central nervous system and other tissues. Clinically, these diseases are characterized by a progressive encephalopathy, loss of vision, and seizures. There are three childhood types of ceroid lipofuscinosis and possibly several adult types. Although in general these types are clinically distinct, combinational and transitional forms occur. The ceroid lipofuscinoses are inherited by autosomal recessive transmission with the exception of one rare adult type that shows autosomal dominant transmission. The etiology is unknown. The incidence is about three per 100,000 births. There is no known effective therapy.

The juvenile type, or Batten disease, exemplifies the devastating effects that these disorders have on affected individuals and their families. Onset occurs at between five and ten years of age, usually with visual failure and seizures, and the course is that of a slowly progressive encephalopathy, usually leading to death in eight to ten years. Pathologically the brain shows moderate atrophy. There is massive accumulation of ceroid in neurons and macrophages, the ganglionic layer of the retina, and other tissues.

RESEARCH GOALS AND SCOPE

The goal of this program announcement is to stimulate investigations to: delineate clinical and genetic types of NCL; identify and localize the gene(s) responsible for them; determine the biochemical defects that result from the action of these genes; and develop measures for the prevention, early diagnosis, and treatment of these disorders.

The research scope of this program encompasses all aspects of the neurobiology of the neuronal ceroid lipofuscinoses by a wide variety of experimental approaches and methods. Some examples are given below, but applications are not limited to these. Applications with new and innovative strategies are strongly encouraged.

o Biochemistry

Biochemical studies should utilize state-of-the-art techniques to identify and quantify the structural and mechanistic biochemical defects underlying NCL. Studies employing either human or animal tissues may be pursued, but careful attention in protocol designs must be given to identifying and explaining discrepancies among new and existing data that may arise from differences in the source, handling and preparation of tissue samples or variability in clinical diagnostic criteria.

o Genetics

Genetic studies should focus on elucidating the hereditary basis of NCL and explaining the heterogeneity of NCL with respect to age of onset and clinical manifestations. Studies applying techniques of molecular biology should focus on identifying genetic defects associated with particular loci and the consequences of any defects with respect to the production, processing, and function of relevant proteins within cells. Research utilizing large informative families are particularly useful in identifying and mapping the gene or genes responsible for NCL.

o Pathology

Comparative studies in humans and experimental animals may be useful in characterizing precisely the pathological changes and the nature of the accumulating lipopigment. Examination by neuroimaging techniques may be useful in identifying early structural and functional changes.

o Animal Models

Animal models comparable to the human disease should provide direct critical information about the pathogenesis and genetics of these disorders, and make possible the determination of the basic metabolic defect, detection of early biochemical changes, characterization of the chemical pathology and recognition of the heterozygous carriers.

ELIGIBILITY

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal government. Applications from minority individuals and women are encouraged. Minority institutions are encouraged to apply, and other institutions are encouraged to establish collaborative arrangements with minority institutions.

MECHANISM OF SUPPORT

Support for this program will be through the traditional research grant (R01) program. Successful applicants will direct and carry out the research projects. Consortium agreements are encouraged to facilitate investigator interaction and to promote research efficiency. Program projects (P01) and centers (P50) are also encouraged, particularly to assemble research talent and inter-related projects that are scientifically strengthened by the interaction promoted in program projects and centers.

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 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.

APPLICATION PROCEDURES

Applications must be prepared on form PHS 398 (rev. 10/88, reprinted 09/89) 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
Bethesda, MD 20892
Telephone: (301) 496-7441

Applicants considering submitting a program project application are urged to obtain a copy of the NINDS "Guidelines" for program project and center applications from the NINDS staff contact listed below.

Check "Yes" in item 2 on the face sheet of the application and type "Neuronal Ceroid Lipofuscinoses PA-92-25," in the space provided.

The original and six copies of the application must be mailed to the following address:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892
Telephone: (301) 496-7273

REVIEW PROCEDURES

Applications in response to this announcement will be reviewed by an initial review group for scientific merit and by the National Advisory Council of the appropriate Institute, Center, or Division according to the following schedule:

RECEIPT DEADLINE	INITIAL REVIEW	COUNCIL REVIEW	EARLIEST START DATE
Feb 1	Jun/Jul	Sep/Oct	Dec 1
Jun 1	Oct/Nov	Jan/Feb	Apr 1
Oct 1	Feb/Mar	May/Jun	Jul 1

INQUIRIES

For further information concerning this program announcement, applicants may contact:

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

For budgetary and administrative matters, contact:

Gary P. Fleming, J.D., M.A.
Grants Management Specialist
Grants Management Branch, DEA
National Institute of Neurological Disorders and Stroke, NIH
Federal Building, Room 1004
Bethesda, MD 20892
Telephone: (301) 496-9231

AUTHORITY AND REGULATIONS

The program to which the intended grants relate is described in the Catalog of Federal Domestic Assistance, Nos. 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 grants 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.

ERRATUM

CENTERS FOR RESEARCH ON MENTAL HEALTH SERVICES FOR CHILDREN AND ADOLESCENTS

PA: PA-92-20

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

National Institute of Mental Health

This Program Announcement was published in the NIH Guide for Grants and Contracts on November 29, 1991, Vol. 20, No. 45. In the Section entitled "Inquiries" an incorrect telephone number was published. The correct telephone number for the Services Research Branch, Division of Applied and Services Research, National Institute of Mental Health, is (301) 443-3364.

All other aspects of the Announcement remain unchanged.

**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

Happy Holidays