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The NIH Guide announces scientific
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NOTICES

NIH REGIONAL WORKSHOPS ON IMPLEMENTATION OF THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

P.T. 42; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health, Office for Protection from Research Risks, is continuing to sponsor a series of workshops in implementing the Public Health Service Policy on the Humane Care and Use of Laboratory Animals. The workshops are open to institutional administrators, members of animal care and use committees, laboratory animal veterinarians, investigators and other institutional staff who have responsibility for high-quality management of sound institutional animal care and use programs.

Date: March 22-23, 1988

Location: Durham, North Carolina

Contact:

Ms. Sandy Huskins or
Ms. Pat McAdams
Duke University
Creative Conference Planners
2900 Harriman Avenue
Durham, North Carolina
Telephone: (800) 845-1054 or (919) 782-1905

Date: May 17-18, 1988

Location: Albany, New York

Contact:

Ms. Madelyn Cicero
Office for Research
State University of New York at Albany
Albany, New York 12222
Telephone: (518) 442-3510

Date: June 2-3, 1988

Location: Kansas City, Kansas

Contact:

Mr. David Baldwin
Associate Director of Continuing Education
University of Kansas Medical Center
39th and Rainbow Boulevard
Kansas City, Kansas 66103
Telephone: (913) 588-4488

Date: September 27-28, 1988

Location: Atlanta, Georgia

Contact:

Office of Continuing Medical Education
Emory University School of Medicine
1440 Clifton Road, N.E.
Atlanta, Georgia 30322
Telephone: (404) 727-5695

Other workshops are being planned and will be announced in future issues of the NIH Guide for Grants and Contracts.

For additional information contact:

Ms. Roberta Garfinkle
Executive Assistant for Animal Welfare Education
Office for Protection from Research Risks, NIH
Building 31, Room 4B09
Bethesda, Maryland 20892

NIH/FDA REGIONAL WORKSHOPS - PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

National Institutes of Health

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institution officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. The current schedule includes:

o Date: March 14-15, 1988

Location: San Diego, California

Title of Workshop: "Research with Populations at Risk"

Contact:

Ms. Sandra Martinez
San Diego State University Foundation
5178 College Avenue
San Diego, California 92182-1900
Telephone: (619) 265-5731

o Date: May 9-10, 1988

Location: Cleveland, Ohio

Title of Workshop: "IRB's in the 1990's: Challenges in the Protection of Human Subjects"

Contact:

Office of Continuing Medical Education
Case Western Reserve University
School of Medicine
2119 Abington Road, Room WG-42
Cleveland, Ohio 44106
Telephone: (216) 368-2408

o Date: May 12-13, 1988

Location: Baltimore, Maryland

Title of Workshop: "Protecting Human Subjects in Research"

Contact:

Dr. Thomas E. Malone or
Dr. Maria C. Freire
University of Maryland
Graduate School, Baltimore
660 West Redwood Street
Baltimore, Maryland 21201
Telephone: (301) 328-7131

Additional workshops will be announced later. For further information regarding education programs contact:

Darlene Marie Ross
Education Program Coordinator
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 4B09
9000 Rockville Pike
Bethesda, Maryland 20892
Telephone: (301) 496-8101

REQUIREMENTS FOR TIMELY SUBMISSION OF HUMAN SUBJECTS CERTIFICATIONS, ANIMAL WELFARE VERIFICATIONS, AND FINANCIAL STATUS REPORTS

P.T. 34; K.W. 1014002, 0201011, 1014003, 0783005

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

This notice strongly emphasizes to Public Health Service (PHS) grant recipients the necessity of submitting human subject certifications, animal welfare verifications, and Financial Status Reports (reports of expenditures) that are both timely and complete.

The recently expressed interest of the Congress for an expedited referral, review, and award process for grant applications in Acquired Immune Deficiency Syndrome (AIDS) research, make it especially critical that grantee organizations take extra care to ensure the accurate preparation and timely submission of routine forms and assurances.

PHS awarding components cannot issue a Notice of Grant Award (regardless of its "type," that is, "new," "competing continuation," "noncompeting continuation") until all the required information regarding human subjects, animal welfare, and the Financial Status Report have been received and reviewed. Equally important, of course, is the information concerning the budgetary detail and the progress report. Incomplete and/or untimely information may result in late awards, which place a considerable burden on both PHS and grantee organization staff. Greater attention to requirements for submission of complete information will facilitate the timely issuance of Notices of Grant Award.

The "Application for Public Health Service Grant," Form PHS 398 (revised 9/86), contains instructions for applicant organizations proposing a new or competing continuation project involving the use of human subjects and/or vertebrate animals. These instructions have been further clarified via a notice in the August 14, 1987, edition of the NIH Guide for Grants and Contracts (Vol. 16, No. 28). Human subjects/animal welfare instructions are also included in the "Application for Continuation of a Public Health Service Grant," Form PHS 2590 (revised 9/86). Grantees are requested to submit complete noncompeting continuation applications (Form PHS 2590) directly to the awarding component eight weeks before the begin date of the scheduled budget period so that the awarding component may issue the Notice of Grant Award two weeks before the start of the budget period.

As stated on page 56 of the PHS Grants Policy Statement (revised 1/87), a Financial Status Report "is required as documentation of the financial status of grants according to the official accounting records of the grantee organization" and "must be submitted for each budget period no later than 90 days after the close of the budget period." We ask that each grantee organization review its procedures and practice in submitting Financial Status Reports with a view toward meeting completely the 90-day filing requirement. Those grantees that fail to submit accurate and timely Financial Status Reports place continuation of grant support at considerable risk.

AVAILABILITY OF DATABASE AND SERUM COLLECTION OF THE CHILD HEALTH AND DEVELOPMENT STUDIES

P.T. 36; K.W. 0780005, 1004008

National Institute of Child Health and Human Development

The National Institute of Child Health and Human Development (NICHD) announces the availability of the database and serum collection of the Child Health and Development Studies (CHDS). These important biomedical and psychosocial resources have now been placed in the public domain.

Copies of the database can be obtained on magnetic tape with a User's Guide at cost from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia, 22161, of the U.S. Department of Commerce. The telephone number for sales is (703) 487-4650, and the current cost is \$400. The NTIS accession number is PB88-129440. Additional information may be obtained by calling the NTIS Computer Products Office at (703) 487-4763.

Access to the serum collection, stored at -20 C at the Frederick Cancer Research Facility (FCRF), can be gained through the custodian of the serum collection, Gilman D. Grave, M.D., Chief, Endocrinology, Nutrition and Growth Branch, NICHD, Bethesda, Maryland, 20892. In order to preserve the serum

collection in a useful state as long as possible, access will be limited to those investigators who have developed written protocols that have been favorably reviewed by the appropriate Institutional Review Committee and overseers of the CHDS serum collection.

History of the Child Health and Development Studies (CHDS)

The Child Health and Development Studies (CHDS) were designed and initiated by Dr. Jacob Yerushalmy, Professor of Biostatistics at the University of California at Berkeley in 1959. He served as principal investigator of the studies until his death in 1973, when Dr. Barbara J. van den Berg assumed that role. The CHDS were begun as a cooperative endeavor of the Division of Biostatistics of the School of Public Health at Berkeley, the Kaiser Foundation Research Institute, and the Permanente Medical Group. On June 1, 1972, administrative responsibilities were transferred from the Kaiser-Permanente organization to the University of California at Berkeley. The CHDS were supported by the National Institute of Neurological Diseases and Blindness from 1960 through 1963 and by the National Institute of Child Health and Human Development from 1964 until 1979.

The User's Guide

In FY 1983 the NICHD awarded a contract to the Regents of the University of California at Berkeley (Barbara J. van den Berg, M.D., Ph.D., Principal Investigator) to create a User's Guide to the Data Files of the Child Health and Development Studies. The User's Guide includes:

- (1) A printed brochure which describes the CHDS in general terms;
- (2) A computer text file listing all of the 25 CHDS data files with a description of each file; and
- (3) A detailed description of all the variables and questionnaires used to generate each record type. This describes the assembled data on: 1) Parental background; 2) Pregnancy and delivery; 3) Child health; and 4) Stages of development at 5 years, 9-11 years, and 15-17 years. The data are organized in 25 separate files, formatted in the SSPS-X system with in-depth documentation regarding background, study population, variables, and values within variables.

Objectives and Design of the CHDS

The main objectives of the CHDS were to relate biologic, genetic, medical, and environmental factors in the parents to the normal and abnormal development of their offspring. Special emphasis was placed on the relationships of events during pregnancy, labor, and delivery to fetal death, perinatal mortality, congenital defects, infant morbidity/mortality, and growth and development during infancy and childhood. A longitudinal study design was used to generate data on mothers, fathers, and their offspring. Data were gathered from four sources: (1) Pregnancy interviews; (2) Medical records of pregnancy, labor, and delivery; (3) Medical records of the offspring; and (4) Developmental examinations of subcohorts of the children at ages 5, 9-11, and 15-17.

Serum Collection

Between August 1959, and September 1966, the CHDS enrolled 20,754 pregnant women. At the enrollment a sample of blood was drawn for: (1) Routine laboratory work; (2) Blood typing by the Boston Blood Grouping Laboratory; and (3) Serum samples for future research. Serum samples were drawn during each trimester of pregnancy and postpartum. An average of three samples per pregnancy was obtained from 18,400 pregnancies. Serum samples were also collected from approximately 12,000 husbands. Cord blood was also collected for blood group typing. Serum samples from newborns were saved only at the end of the enrollment period, and approximately 3,000 samples are stored in the serum collection.

Usefulness of the CHDS Database and Serum Collection

The large, longitudinally assembled data file and serum collection are unique and will continue to be of value in the investigation of problems of maternal, infant, and child health and development. The cohort of 20,500 pregnant women and their 18,751 children who survived the neonatal period (including 66 pairs of monozygotic and 115 pairs of dizygotic twins) is broadly representative from ethnic and socioeconomic viewpoints. The sample size is large enough to generate and test many hypotheses relating to pregnancy and child development. Examples of subjects for which the CHDS data files are useful include: smoking and low birthweight; teratogenicity of drug exposure in early

pregnancy; development of neoplasms in CHDS subjects and their offspring; determinants and consequences of low birthweight and premature delivery; morbidity in pregnancy; blood pressure and consequences of hypertension in pregnancy; growth; morbidity; utilization of medical care; convulsive disorders; congenital defects; consequences of child spacing patterns; obesity; effects of illness on weight and height; normal behavioral development; and the effects of events during pregnancy and delivery on aberrant physical and behavioral development.

As the cohort of approximately 18,000 children grows older (they are now in their third decade), more knowledge will be developed about the effects of gestational and perinatal events on subsequent physical and psychological development. Many of this cohort now have offspring of their own. This permits the possibility of studying intergenerational effects. As the original subjects and their offspring have increased in age, various kinds of malignancies have developed. The CHDS data files are currently being linked with those of the California Mortality Linkage System (CAMLIS) and to the California Tumor Registry. The CHDS serum collection will be useful in studying possible antecedents of these malignancies, as well as in correlating congenital defects in offspring with the development of malignancy in the parents.

The CHDS Resources: A brief description of the generation of the data files and serum collection follows:

A. Pregnancy Interview: Early in pregnancy gravidas participated in an extensive interview. This interview covered the women's marital and reproductive history, including outcomes and dates of previous pregnancies, and birth weight and duration of gestation of her liveborn children. Information was also obtained on the health history of the gravida, her husband and her children, on gravida's and husband's level of education, occupation and income. Questions were asked about smoking habits, beverages consumed, including alcohol and coffee intake. Gravidas also responded to questions relating to their present pregnancy, on usage and type of contraceptives, planning of pregnancy, menstrual history, etc. During the gravida's first visit, a sample of blood was typed in the following systems: ABO, D, Dd, Ee, MN, Ss, Kell, Duffy, Lutheran, and P. Blood samples of the husbands and of the infants' cord blood were likewise typed.

B. Medical Records on Pregnancy, Labor and Delivery: All medical information on visits to any of the clinics of Kaiser Foundation Hospitals has been assembled in one data file for each patient. From these records, observations during pregnancy (including all routine body weight and blood pressure measurements), and laboratory results, comprehensive data on labor and delivery have been abstracted and coded. Also, all medically attended intercurrent diseases and drug prescriptions were abstracted and coded.

C. Medical Records of the Offspring: The medical records of the offspring's visits to the pediatric clinics and hospitals are assembled in one data file for each child. The data files include medical data for each visit, with diagnosis and treatment, physical growth measurement, and measurements of blood pressure. These abstracted records represent the CHDS basic health file on the children. Information on congenital anomalies, severe, and non-severe, has been completely coded. Birth weight and length, as well as all subsequent measurements of height and weight are available in coded form.

D. Developmental Examinations on Subcohorts of the Children: Substantial additional information has been assembled from developmental examinations for subcohorts of the children. Eligibility was defined by birthdate within specified limits and residence in the San Francisco East Bay area.

(1) Five-Year-Olds: At their fifth birthday, 4,000 of the children were invited for special developmental examinations and follow-up interviews. Examinations included a general physical examination and tests of acuity of vision, hearing, speech and cognitive ability, and the mothers responded to a 42-item inventory of the child's behavior and mother-child relationship. (2) Nine-to-Eleven-Year-Olds: Thirty-six hundred children were examined at their ninth, tenth, or eleventh birthday. This examination included anthropometrics and cognitive ability tests. In addition to an interview on the health and well-being of the family, the mothers of 9-11-year-old children responded to a 100-item inventory relating to the child's behavior and mother-child relationship. A cognitive ability test for the mother was also included. Blood pressure measurements and screening of vision, hearing, and speech were done for a separate sample of 698 children at nine years of age. (3) The Adolescent Study (Fifteen-to-Seventeen-Year-Olds): In 1977 examinations of 2,000 adolescent CHDS offspring, 15-17 years old, were undertaken to investigate precursors of hypertension. The data collected include several measurements of blood pressure, lung function tests, anthropometric

measurements, interviews and questionnaires regarding health history and life-style. A cognitive ability test was also administered. The mothers participated in these examinations, with a protocol similar to that of their adolescent offspring.

E. The Serum Collection of the Child Health and Development Studies: The serum collection is useful as a resource for epidemiological research. The value of this large collection of serum lies in its power when used for retrospective case control studies [see Kolata, G. A new kind of epidemiology. Science 1984; 224:481.] Epidemiologists can exploit the power inherent in previously collected serum collections to establish baseline values in relation to diseases and conditions that become manifest later on, e.g., studies of antibodies, hormones, and vitamins in relation to later incidence of cancer, immune deficiency states, heart disease, and slow virus infections. The CHDS population is ethnically and sociologically diverse and is ideal for epidemiological studies.

Use of the Results

By using the data files and serum collection of the CHDS in conjunction with a current address file investigators will be able to design retrospective case control studies and/or prospective studies that will help answer questions relating to past influences on future events in both biomedical and psychosocial spheres. Potential uses for the data and serum collections include establishing the effects on later growth and development of the offspring of abnormalities and perturbations during pregnancy as well as performing retrospective case-control studies to ascertain biochemical and serological antecedents of later neoplastic, neurologic, and cardiovascular disease. The large number of monozygotic pairs of twins in the CHDS is valuable for performing genetic studies. The multigenerational nature of the CHDS also makes certain kinds of genetic studies possible. The ability of investigators to recall subjects for future studies will allow tests of associations either not considered or not possible in earlier years of data analysis of the CHDS, especially in conjunction with the serum collection.

The identification of men, women, and children in the CHDS population who have acquired a form of cancer is possible by matching procedures linking the CHDS records with the data of cancer registries and with death certificates. Both of these registrations in California are well-developed and organized.

The study population is large enough to select suitable controls for identified cases. This makes the data set useful for case-control studies. It may be possible to pool data from the CHDS population with data of other prospective studies to increase the numbers of specific types of cancer or of specific locations. The serum samples would also be useful to generate new hypotheses regarding cancer etiology by examining various biochemical entities in serum samples of cases and of controls, or to test hypotheses generated by other studies.

DATED ANNOUNCEMENTS (RFPs AND RFAs AVAILABLE)

PREPARATION OF RADIOLABELED MATERIALS

RFP AVAILABLE: NCI-CM-97561-44

P.T. 34; K.W. 1003006, 1003008, 0780010

National Cancer Institute

The Drug Synthesis and Chemistry Branch (DS&CB), Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI), is seeking organizations having capabilities, resources, and facilities to synthesize, store, and distribute radiolabeled compounds of high purity via synthesis in 1 to 100 millicurie quantities. The major emphasis will be on the preparation of the desired radiolabeled compounds via synthetic procedures using carbon -14 and tritium. This will involve a wide variety of compounds, such as heterocyclic compounds, alkaloids, peptides, nucleosides, anionic dyes, etc. Compounds required may include one or more of the following elements: carbon, tritium, sulphur phosphorus, iodine, and the isotope deuterium.

Materials will be stored and shipped by the contractor. The contractor must provide low temperature storage for 150 radiolabeled compounds. A broad nuclear regulatory commission (NRC) or equivalent license is required. Methods will be available for "cold run" in many but not all instances. All materials must be completely characterized and assayed as to identity,

chemical purity and radiopurity. A well-equipped analysis laboratory, including HPLC dedicated to radiosynthesis work, and adequate library facilities should be available. It is anticipated that an incrementally funded contract will be awarded for a period of three years beginning on or about January 17, 1989. The principal investigator should be trained in organic chemistry and should have recent experience in radiochemical synthesis. In lieu of a Ph.D., equivalent recent experience will be considered.

RFP No. NCI-CM-97561 will be issued on or about February 29, 1988, and proposals will be due approximately six weeks thereafter.

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

Johnny Jordan
Contract Specialist
Treatment Contracts Section
Research Contracts Branch
National Cancer Institute
National Institutes of Health
Blair Building, Room 216
Bethesda, Maryland 20892
Telephone: (301) 427-8737

SPEECH PROCESSORS FOR AUDITORY PROSTHESES

RFP AVAILABLE: NIH-NINCDS-88-04

P.T. 34; K.W. 0740030, 0706000

National Institute of Neurological and Communicative Disorders and Stroke

The National Institute of Neurological and Communicative Disorders and Stroke has a requirement to design, develop and evaluate speech processors for use with implanted auditory prostheses in deaf adults and/or children.

Offeror should have research experience in psychoacoustics and acoustic phonetics and have access to a computer system suitable for performing this research and also have access to humans with multichannel auditory prosthesis or a collaborative arrangement with a research group studying such human implants.

This requirement represents the recompetition of current contracts with Research Triangle Institute, Stanford University and The University of Melbourne; the incumbents are expected to reapply.

This RFP-NIH-NINCDS-88-04 will be issued on or about February 19, 1988, with the closing date for receipt of proposals set for April 18, 1988.

To receive a copy of the RFP, please supply this office with two self-addressed mailing labels. All responsible sources may submit a proposal which will be considered by the agency. The RFP will be available upon written request to:

Contracting Officer
Contracts Management Branch
National Institute of Neurological and Communicative
Disorders and Stroke
National Institutes of Health
Federal Building, Room 901
Bethesda, Maryland 20892

ACQUISITION, CHARACTERIZATION, MAINTENANCE AND DISTRIBUTION OF HYBRIDOMA CELL LINES AND THE MAINTENANCE OF A HYBRIDOMA DATA BANK

RFP AVAILABLE: NIH-NIAID-IAIDP-89-1

P.T. 34; K.W. 0780015, 0760030, 0780000, 1004017

National Institute of Allergy and Infectious Diseases

The Immunobiology and Immunochemistry Branch, Immunology, Allergy and Immunologic Diseases Program of the National Institute of Allergy and Infectious Diseases is soliciting proposals for the maintenance of a Hybridoma Bank for the storage (frozen state) and distribution of hybridoma cell lines to scientific investigators, and the maintenance of a hybridoma data bank.

The offeror must have the experience to successfully expand acquired hybridoma lines in continuous culture, characterize lines biologically and chemically, and cryopreserve the lines. The offeror must also have experience in shipping frozen biological material worldwide. Ability to perform extensive computer literature searches is also required.

RFP NIAID-IAIDP-89-1 will be available February 19, 1988. Responses are due by April 5, 1988.

One cost-reimbursement type contract may be awarded as a result of this solicitation. It is expected that the contract will have a five-year period of performance. Any responsible offeror 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 in writing and addressed to the office below:

Mr. Bill Roberts
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5333 Westbard Avenue
Westwood Building, Room 707
Bethesda, Maryland 20892

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

GENETICS OF CELL LINEAGES DURING MAMMALIAN EMBRYOGENESIS

RFA AVAILABLE: 88-HD-07

P.T. 34; K.W. 1002019, 0780015, 0775000, 1002008

National Institute of Child Health and Human Development

Application receipt date: May 6, 1988

The Genetics and Teratology Branch (GTB) of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) is inviting research grant applications focusing on the genetics of cell lineages during mammalian development. This initiative has important ramifications for both basic science and clinical studies. The information expected from the investigation of the genetics of cell lineage determination is central to a further understanding of the underlying principles that direct normal patterns of growth, differentiation and morphogenesis and against which aberrations of these processes can be understood. The primary goal of this RFA is to support a group of projects that are devoted to the investigation of the genetic basis of cell lineage determination during mammalian embryogenesis. It is expected that the latest molecular genetic technologies will be employed. The production of chimeric and transgenic animals for these studies is encouraged, but not required.

Applications should be submitted on Form PHS 398. The RFA label available in the 9/86 version of form PHS 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.

This program will be funded through the traditional individual research project award program of NICHD. Grant applications will be reviewed at a single competition by an initial review group convened by the NICHD. It is anticipated that five (5) grants will be awarded under this program, contingent upon the receipt of a sufficient number of meritorious applications and the availability of funds. Requests for copies of the full RFA should be addressed to:

Joel M. Schindler, Ph.D.
Genetics and Teratology Branch
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
Executive Plaza North Room 643C
Bethesda, Maryland 20892
Telephone: (301) 496-5541

ONGOING PROGRAM ANNOUNCEMENTS

RESTITUTION OF FUNCTION AND REHABILITATION AFTER INJURY TO THE NERVOUS SYSTEM

P.T. 34; K.W. 0785110, 0415000, 0705055, 0715005, 0715210

National Institute of Neurological and Communicative Disorders and Stroke

BACKGROUND

The Division of Stroke and Trauma of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) invites grant applications for the support of research on the restitution of function and the functional rehabilitation of victims of injury to the nervous system. The number of severely impaired victims of head injury, for example, is increasing at a rate that may be becoming beyond the capacity of the health-care system to provide essential services. According to some estimates, each year about 400,000 Americans sustain head injuries severe enough to require admission to a hospital. Perhaps a tenth of those, or about 40,000, are unable to return to the kind of life they led before their accidents. Especially tragic is that these victims are usually in the age group of 15-24 years. The damage that prevents the severely injured victims of head and of spinal cord trauma from returning to their previous ability to participate in society or even to function adequately is as varied as are the functions of the nervous system. Depending upon the area or areas of the nervous system that are damaged and on the severity of that damage, the injury can result in loss of motor function, sensation, intellect, or memory--or any combination of these. Some victims of nervous system injury do not survive; some, particularly victims of severe head injury, remain in a coma for some time. Most suffer some degree of physical, emotional, intellectual, or psychological handicap that limits their ability to function normally or even adequately.

RESEARCH GOALS AND SCOPE

The overall goal of the research invited in this announcement is to encourage and support research that can help restore the victims of severe injury to the nervous system to a functional capacity that will permit them to regain some control over their environment, and thus their lives, and to reduce or eliminate their dependence on care givers.

The NINCDS supports basic, clinical, and applied research on trauma to the nervous system and regeneration of the damaged nervous system. Among the topics that would be appropriate subjects for grant applications include the causes of nervous system trauma; the results of trauma to the nervous system, such as edema, coma, speech and communication deficits; defects in cognition and learning; sensory impairments; motor impairments, such as hemiplegia and paraplegia; degeneration of neuronal elements after injury; neural growth inhibitors; neural implantation for functional restoration; regeneration of neuronal and non-neuronal elements of the central, peripheral, and autonomic nervous systems in relation to the restoration of function; and neural plasticity and trophic factors. For applied and clinical approaches, appropriate and desirable goals for research would include the adaptation and improvement of imaging modalities for more effective diagnosis, quantification of severity, and prognostic assessment of injury; determination of the importance of the timing of treatment after an injury; and development of therapeutic modalities that retard, prevent, or reverse damage after nervous system injury.

MECHANISM OF SUPPORT

The support mechanism for grants in this area will be the individual research grant (R01), the FIRST award (R29), and the program project grant (P01). Under these mechanisms, the principal investigator and any participating investigators will plan, direct, and perform the research. Potential applicants for program project grants should contact the NINCDS representative listed below as early as possible in the planning stages for advice and guidance.

APPLICATION AND REVIEW PROCEDURES

Applications must be prepared on form PHS 398 (revised 9/86) according to the applicable instructions included in the application kit. These kits are available from the business offices of most institutions eligible to receive Federal grants or from the Division of Research Grants, NIH. Receipt dates for new grant applications are February 1, June 1, and October 1. On page 1 of form PHS 398, check "yes" in item 2 and type: "NINCDS Announcement: RESTITUTION OF FUNCTION AND REHABILITATION AFTER NERVOUS SYSTEM INJURY." Use

the mailing label provided in the application kit to mail the signed original and six exact copies of it to the Division of Research Grants. If the application is for a program project, send the original and four copies to DRG and two copies to the NINCDS at the address cited below.

Research project grant (R01) and FIRST award (R29) applications will be reviewed for scientific and technical merit by an appropriate study section in the Division of Research Grants. Program project grant (P01) applications will be reviewed by an appropriate review group in the NINCDS. A second review will be by the National Advisory Neurological and Communicative Disorders and Stroke Council.

Applications judged to be within the purview of other Institutes of the NIH will be assigned accordingly. The National Institute on Disability and Rehabilitation Research (NIDRR), Department of Education, supports research on rehabilitation. As appropriate, applicants are urged to contact the NIDRR for guidelines and standard application forms.

For further information contact:

Dr. Mary Ellen Michel
Division of Stroke and Trauma, NINCDS
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The NIH Program is described in the Catalogue of Federal Domestic Assistance, Number 13.853 and 13.854, Stroke, Nervous System Trauma. Grants will be awarded under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended: 42USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This NIH program is not subject to the intergovernmental review requirements of Executive Order 12372 or to review by a Health Systems Agency.

**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