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. 17, No. 27
August 19, 1988

Vol. 17, No. 27, August 19, 1988

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DATED ANNOUNCEMENTS (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

NOTICES

AVAILABILITY OF NEW GUIDELINES FOR THE PROGRAM PROJECT (P01) GRANT OF THE NATIONAL CANCER INSTITUTE

P.T. 34; K.W. 0710030, 1014002

National Cancer Institute

The National Cancer Institute announces the availability of new guidelines for the PROGRAM PROJECT (P01) GRANT OF THE NATIONAL CANCER INSTITUTE. This comprehensive document includes relevant NIH and NCI policies; definitions of terms; delineation of roles of NCI program and review staff; detailed instructions for preparing an application using the new PHS 398 application forms; and a description of the single-tiered initial review process.

The guidelines become effective with the October 1, 1988, receipt date and will be in effect for two years on an experimental basis.

Please address requests for copies of this document to:

NCI Referral Officer
Westwood Building, Room 848
5333 Westbard Avenue
Bethesda, Maryland 20892

SOURCES SOUGHT

DEVELOPMENT OF A BIOADHESIVE SYSTEM FOR THE PREVENTION/ TREATMENT OF ORAL CANDIDIASIS

SOURCES SOUGHT

P.T. 34; K.W. 1002027, 0740020

National Institute of Dental Research

The National Institute of Dental Research seeks to identify sources with the capability to develop a sustained-release bioadhesive delivery system for an antifungal drug suitable for the treatment/prevention of oral candidiasis in patients of all ages.

This effort will consist of two phases. Specific technical requirements for Phase I will include:

(1) Formulation of potential bioadhesive sustained-release delivery systems suitable for the treatment of oral candidiasis for each of two antifungal drugs by combining the drugs with biocompatible bioadhesive materials. The drugs chosen shall have demonstrated antifungal activity and shall be approved by the United States Food and Drug Administration for the treatment and/or prevention of microbial infections in humans.

(2) Demonstration of the bioadhesive properties and determination of the kinetics of drug release for each of the delivery systems using appropriate in vitro test systems.

(3) Demonstration using appropriate in vitro methods that the drugs released from the delivery systems retain antifungal activity and are identical to the drugs in the starting formulation.

(4) Preparation of a detailed plan for additional research and development work, including in vivo studies to evaluate the efficacy of the delivery systems in an appropriate animal model.

Specific technical requirements for Phase II will include:

(1) Development of delivery system formulations suitable for testing in animals.

(2) Evaluation of the efficacy of the delivery systems for the prevention and treatment of oral candidiasis in an appropriate animal model.

(3) Development of plans for the production of drug delivery systems suitable for use in humans.

As a minimum, prospective offerors must exhibit capabilities in the following areas:

(1) Prior experience in the development and evaluation of biocompatible bioadhesive controlled- or sustained-release drug delivery systems including in vitro and in vivo evaluation and characterization of the systems.

(2) Prior experience with the microbiological methods required for in vitro and in vivo studies with Candida albicans and related species.

(3) Qualified personnel and suitable facilities for conducting appropriate animal studies on the efficacy of the drug delivery systems, with the data generated being suitable for the support of an Investigational New Drug Application.

(4) Prior experience in conducting research in support of an Investigational New Drug Application.

(5) Appropriate personnel and facilities to produce drug delivery systems suitable for use in humans or have access to such personnel and facilities.

This is not a Request for Proposal, and the Government is not committed to award a contract pursuant to this announcement. Responses should not include cost or pricing information. Sources believing they have the required capabilities necessary to undertake this project should submit six (6) copies of a resume addressing experience and capabilities by September 16, 1988, to the following:

Marilyn R. Zuckerman, Contract Specialist
Contract Management Section
National Institute of Dental Research
National Institutes of Health
Westwood Building, Room 521
Bethesda, Maryland 20892

DATED ANNOUNCEMENTS (RFPs AND RFAs)

PROGRAM ENHANCEMENT AND MAINTENANCE OF THE NATIONAL INSTITUTE OF DENTAL RESEARCH MICROBIOLOGICAL INFORMATION SYSTEM (MICRO-IS)

RFP AVAILABLE: NIH-NIDR-10-88-4R

P.T. 34; K.W. 1004008, 1004017, 1002027

National Institute of Dental Research

The National Institute of Dental Research (NIDR) has a requirement for program enhancement, maintenance, and user support for the current NIDR Microbiological Information System (MICRO-IS) which was designed and implemented on the NIH mainframe computers under a previous contract. System components shall be modified to improve user efficiency and cost effectiveness as improvements in computer technology become available.

The concepts and design of the MICRO-IS also shall be adapted for transportation to other computer systems using the language "C" in its standard form for most components. This version will be capable of full screen operation on personal computers or workstations as stand-alone facilities or terminals to other computer systems.

The basic method for microbial information transmission and computer entry to be used is that published by M. Rogosa, M. I. Krichevsky, and R. R. Colwell in the International Journal of Systemic Bacteriology in 1971 and subsequent enhancements which will be supplied by NIDR.

The contractor must have the capabilities to assign personnel with varying skills on short notice in the performance of new projects. The contractor's personnel must also be available for frequent unsheduled meetings.

This acquisition is a continuation of work currently being performed under an existing NIDR contract. All responsible sources may submit an offer which will be considered.

RFP NIH-NIDR-10-88-4R will be available on or about August 26, 1988, with proposals due on or about October 6, 1988.

Marilyn R. Zuckerman, Contract Specialist
Contract Management Section, NIDR
National Institutes of Health
Westwood Building, Room 521
5333 Westbard Avenue
Bethesda, Maryland 20892

CLINICAL CENTERS FOR A STUDY OF PEDIATRIC LUNG AND HEART COMPLICATIONS OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

RFP AVAILABLE: RFP-NHLBI-HR-88-09

P.T. 04; K.W. 0715120, 0715040, 0715165, 0770005, 0403020

National Heart, Lung, and Blood Institute

The purpose of this solicitation is to establish Clinical Centers for a collaborative clinical study of the lung and heart complications of human immunodeficiency virus (HIV) infection in infants and children. The objective of this program is to characterize the pulmonary and cardiovascular disorders that occur in association with HIV infection. The study will include the following groups: 1) infants and children with recently diagnosed, perinatally transmitted acquired immunodeficiency syndrome (AIDS) or other symptomatic HIV infection; 2) newborn infants of mothers infected with HIV; and 3) newborn infants of seronegative mothers at high risk of infection with HIV.

The program will require that a Clinical Coordinating Center (CCC) collect data from 5 or 6 participating Clinical Centers, each studying a minimum of 320 participants (140 pregnant women and 180 infants and children) over a 6-year period. The Clinical Centers will be responsible for 1) participating in the development and preparation of the study protocol, reporting forms, and manual of operations; 2) training staff to conduct the study as outlined in an approved study protocol and manual of operations; 3) during a two-year period recruit 40 infants and young children with newly diagnosed, perinatally transmitted AIDS or symptomatic HIV infection with or without pulmonary symptoms, 100 newborns of women in whom HIV antibody tests were positive during pregnancy (the women shall be enrolled during pregnancy and the pre and postnatal course of the infants shall be followed), 40 newborns of women from groups at high risk for HIV infection in whom HIV antibody tests were negative during pregnancy (the women shall be enrolled during pregnancy and the pre- and postnatal course of the infants shall be followed); 4) performing follow-up assessment of the participants in the manner specified in an approved manual of operations; 5) collecting and forwarding patient data to the CCC; 6) interacting with the CCC to provide data and information necessary for data analysis; and 7) working with other study investigators in the preparation and writing of reports and manuscripts for publication.

It is anticipated that RFP-NHLBI-HR-88-09 will be available on or about August 16, 1988, with proposals due on November 1, 1988. Copies of the RFP may be obtained by submitting a written request along with three (3) self-addressed mailing labels to:

National Heart, Lung, and Blood Institute, NIH
Contracts Operations Branch, DEA
Westwood Building, Room 654
Bethesda, Maryland 20892
Attn.: Pamela S. Randall

CLINICAL COORDINATING CENTER FOR A STUDY OF PEDIATRIC LUNG AND HEART COMPLICATIONS OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

RFP AVAILABLE: NHLBI-HR-88-10

P.T. 04; K.W. 0715120, 0715040, 0715165, 0770005, 0403020, 1004008

National Heart, Lung, and Blood Institute

The purpose of this solicitation is to establish a Clinical Coordinating Center for a collaborative clinical study of the lung and heart complications of human immunodeficiency virus (HIV) infection in infants and children. The objective of this program is to characterize the pulmonary and cardiovascular disorders that occur in association with HIV infection. The study will

include the following groups: 1) infants and children with recently diagnosed, perinatally transmitted acquired immunodeficiency syndrome (AIDS) or other symptomatic HIV infection; 2) newborn infants of mothers infected with HIV; and 3) newborn infants of seronegative mothers at high risk of infection with HIV.

The program will require that a Clinical Coordinating Center (CCC) collect data from 5 or 6 participating Clinical Centers, each studying a minimum of 320 participants (140 pregnant women and 180 infants and children) over a 6-year period. These participants will be recruited over a two-year period.

The CCC will be responsible for: 1) participating in and coordinating the development and preparation of the study protocol, reporting forms and manual of operations, and assuming responsibility for the typing, reproduction and distribution of these documents; 2) coordinating, managing and participating in periodic meetings of the CCC and clinical center staff with direction from NHLBI; 3) developing and testing a method of transmission of data between the clinical centers and the CCC; 4) preparing and distributing technical and statistical reports to the clinical centers and the NHLBI; 5) establishing and implementing a method, to be approved by the NHLBI, for on-going review of the clinical data; 6) developing computer software necessary to accomplish the above mentioned functions; 7) training clinical center staff in the use analysis techniques; and 8) developing new and/or modifying existing methods of analysis to meet the needs of the clinical centers.

This announcement is not a request for proposal (RFP). It is anticipated that RFP-NHLBI-HR-88-10 will be available on or about August 16, 1988, with proposals due on November 2, 1988. Copies of the RFP may be obtained by submitting a written request along with three (3) self-addressed mailing labels to:

National Heart, Lung, and Blood Institute, NIH
Contracts Operations Branch, DEA
Westwood Building, Room 654
5333 Westbard Avenue
Bethesda, Maryland 20892
Attn.: Pamela S. Randall

SPECIALIZED MATERIALS SCIENCE RESEARCH CENTERS

RFA AVAILABLE: 88-DE-6

P.T. 04; K.W. 0750000, 1009007, 1009008, 0706000, 1007009

National Institute of Dental Research

Application Receipt Date: March 10, 1989

The National Institute of Dental Research (NIDR) invites applications for the support of Materials Science Research Centers to conduct research leading to the development of new restorative materials. The overall intent of this RFA is to attract outstanding materials science and engineering investigators, including those with no prior experience in dental research, to the field of restorative dental materials science and to encourage collaboration between basic materials scientists, dental materials scientists, engineers, toxicologists, and clinical researchers.

BACKGROUND

Restorative materials research has been a cornerstone of dental research for many years. In 1986, the NIDR sponsored an international state-of-the art conference on restorative dental materials which developed a series of recommendations regarding research priorities and mechanisms for enhancing research. Based on these recommendations, the National Advisory Dental Research Council and the Institute's Program Advisory Committee have urged that the NIDR establish multidisciplinary materials science research centers that bring together basic materials scientists, biomedical engineers, and dental materials scientists.

RESEARCH GOALS

The objectives of this RFA are to: (1) involve basic materials science and biomedical engineering experts in multidisciplinary research leading to the development of new restorative dental and maxillo-facial materials; (2) establish and facilitate collaboration between these experts, dental materials researchers and industry; (3) study the physical, chemical, mechanical, and biological characteristics of the new materials; and (4) provide a focus for

training of scientists dedicated to pursue careers in dental materials research.

MECHANISM OF SUPPORT

Dental Materials Science Research Center applications funded under this RFA will be supported for a five-year period beginning on September 1, 1989. Subsequent support will be contingent upon program needs, availability of funds, and successful competitive reviews. Applicants may request up to $500,000 in direct costs for the first year. Modest increases may be requested for the subsequent four years to strengthen existing areas of research. It is anticipated that a minimum of two awards will be made in FY 89. However, award of grants for this program is contingent upon receipt of a sufficient number of high-quality applications. Policies governing research grant programs of the National Institutes of Health will prevail.

METHOD OF APPLICATION

Applications may be submitted by any domestic public or private non-profit or profit making organization. Applications should be prepared on Form PHS 398 (Rev. 9/86), Application for PHS Grant. On line 2 of the application from, insert the title of this RFA, "Specialized Materials Science Research Centers." 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.

Staff Contact:

A more detailed RFA may be obtained from:

Dr. Joyce A. Reese
Health Scientist Administrator
Caries and Restorative Materials Branch
National Institute of Dental Research
Westwood Building, Room 505
Bethesda, Maryland 20892-4500
Telephone: (301) 496-7884

NATIONAL RESEARCH SERVICE AWARDS FOR HEALTH SERVICES RESEARCH: INSTITUTIONAL AWARDS

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

National Center for Health Services Research and Health Care Technology Assessment (NCHSR)

Application receipt date: September 10, 1988

AUTHORITY AND PURPOSE

Under authority of Section 487 of the Public Health Service (PHS) Act as amended (42 USC 289 1-1), NCHSR will award National Research Service Award (NRSA) grants to eligible institutions to develop or enhance research training opportunities for individuals selected by them who are training for careers in health services research. The purpose of the NRSA program is to assist domestic institutions in supporting predoctoral and postdoctoral academic training. The awards allow trainees to gain experience in applying research methods to the systematic analysis and evaluation of health care services. Title 42 of the Code of Federal Regulations, Part 66, and the Public Health Service Grants Policy Statement are applicable.

BACKGROUND

Health services research deals with a broad range of issues, perspectives, and methods pertinent to understanding and modifying health care systems. Systematic analysis and evaluation of the organization, financing, utilization, and delivery of health care services often require collaborative efforts among various disciplines, use of empirical approaches, and analysis of complex data sets. Applied health services research draws on a variety of conceptual and statistical models to address policy issues.

Predoctoral and postdoctoral training in health services research can contribute to resolution of systemic and policy problems in several areas. NCHSR's research program addresses the organization, financing, and delivery of health services, particularly patient outcomes, technology assessment, and the role of market forces in health care delivery.

Research training should provide the conceptual and methodological foundation to investigate such concerns as primary care; survey design and methods and applied computer science; the effects on health status of the allocation of health care resources; dissemination and transfer of health care technologies and the design of new methods to assess these technologies; protocols for cost-effectiveness and cost-benefit analyses; health problems of the frail and elderly; and epidemiology of chronic illness, geriatric medicine, and health economics.

LEVELS OF TRAINING

The primary focus of the NRSA institutional grants is to encourage institutions to increase the number of postdoctoral trainees, since NCHSR supports predoctoral research through its Dissertation Research Grant Program. In recognizing that there may be program advantages in training a mixture of predoctoral and postdoctoral candidates, NCHSR will permit institutions to select either, subject to a ratio of not more than two predoctoral candidates for each postdoctoral student receiving support. Applications concentrating on postdoctoral training are encouraged.

APPLICANT ELIGIBILITY REQUIREMENTS

Qualified domestic, nonprofit, public or private institutions may apply for NRSA grants to support research training programs for development of competent investigators in the methods and techniques of conducting health services research. The applications should emphasize support of student multidisciplinary training rather than institutional development.

The training program director at the institution will be responsible for selection and appointment of trainees to receive the awards and for the overall direction of the program. The training program must provide opportunities for individuals to conduct supervised health services research with the primary objective of extending their skills and knowledge. Special attention should be given to appointment of minority students and women.

GENERAL PROVISIONS

Awards may not support study leading to the M.D.; neither may they support residency training. Individuals who wish to interrupt their medical studies for a year or more to engage in full-time research training before their medical degree also are eligible.

Trainees are required to pursue their research training on a full-time basis. Because of the close relationship between teaching and research in the academic environment, trainees are permitted, with the approval of NCHSR, to teach if it can contribute meaningfully to their academic training. Teaching by trainees may not take up more than 10 percent of work time during the year or exceed 4 hours each week.

TRAINEE ELIGIBILITY REQUIREMENTS

At the time of appointment, all trainees must be citizens of the United States, noncitizen nationals, or noncitizens who have been lawfully admitted to the United States for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551). Individuals on temporary or student visas are not eligible.

Predoctoral trainees must have received a baccalaureate degree as of the beginning date of their NRSA appointment and must be enrolled in a program leading to a Ph.D., Dr.P.H., or equivalent degree. Individuals to be trained at the postdoctoral level must have received, as of the beginning date of the NRSA appointment, a Ph.D., an M.D., or other relevant doctoral degree, or an equivalent degree from an accredited domestic or foreign institution. It is acceptable if an authorized official of the degree-granting institution certifies that all requirements for the doctoral degree have been met.

PAYBACK PROVISIONS

Before individuals can receive support under training grants, they must sign an agreement to fulfill the NRSA payback requirements. They require recipients to agree to conduct full-time health services research or related teaching or both for a period equal to the period of NRSA support in excess of 12 months. Once an individual has had 12 months of postbaccalaureate NRSA support, all subsequent support is subject to payback.

Recipients must begin the obligated service on a continuous basis within 2 years after termination of NRSA support. For individuals who fail to fulfill their obligation, the United States is entitled to recover the total amount

paid to the individual for the obligated period, plus interest. Financial repayment must be completed within 3 years. Under certain conditions, the Secretary of Health and Human Services may extend the period for undertaking service or repayment, permit breaks in service, or otherwise waive or suspend the payback obligation of an individual.

STIPENDS AND OTHER TRAINING COSTS

The stipend for predoctoral individuals at all levels of experience is $8,500 per year as of October 1, 1988. For postdoctoral trainees, the stipend for the first year of support is determined by the number of years of relevant postdoctoral experience at the time of appointment. Relevant experience may include research experience, teaching, internship, residency, or other full-time studies in a health-related field beyond that of the qualifying doctoral degree. As of October 1, postdoctoral stipends are:

Years of relevant experience	Stipend
0	$17,000
1	18,000
2	25,000
3	26,250
4	27,500
5	28,750
6	30,000
7 or more	31,500

NRSA stipends may be supplemented by institutions from non-Federal funds. No Federal funds may be used to supplement stipends unless specifically authorized under the terms of the program from which funds are derived. Under no circumstances may the conditions of stipend supplementation detract from or prolong the training.

The Tax Reform Act of 1986 (P.L. 99-514) affected the tax liability of all individuals supported under NRSA grants made under Section 487 of the Public Health Service Act. The interpretation and implementation of the tax laws are the domain of the Internal Revenue Service and the courts. Potential applicants should consult with the IRS to clarify how the tax laws apply to their trainees and to determine what steps must be taken by the trainees to fulfill tax obligations.

Tuitions, fees, and medical insurance are allowable trainee costs if they are required of all persons in a similar training status at the institution, without regard to the source of their support. Postdoctoral tuition is limited to that required for specific courses that support the approved training program. Costs of trainee travel may be requested, including attendance at scientific meetings that the institution determines to be necessary to the individual's training.

Institutional support of up to $1,500 for each predoctoral trainee and up to $2,500 for each postdoctoral trainee may be requested to defray the costs of expenses related to training such as staff salaries, consultant costs, equipment, research supplies, staff travel, and other expenses. The availability of funds may modify the maximum level of institutional costs awarded. An indirect cost allowance based on 8 percent of total allowable direct costs, or on the actual indirect costs rate, whichever is less, may be requested. State and local government agencies may request full reimbursement of indirect costs.

PERIOD OF SUPPORT

Institutional grants may be made for competitive segments of up to 5 years and are renewable. However, no individual trainee may receive more than 5 years of aggregate NRSA support at the predoctoral level and 3 years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional training grants and individual research fellowships. Any exception to this policy requires a waiver from NCHSR.

REVIEW PROCESS

Applications from institutions will be reviewed by a committee that will include non-Federal consultants from appropriate scientific fields. Each application should address: (1) the subject area or areas in which the proposed research or training will be conducted; (2) the resources and facilities available to students carrying out the research or training; and (3) the names, qualifications, and experience of the program director and principal staff members who will be responsible for the proposed program.

Criteria for review are the goals of the proposed training program and the probability of achieving them; the substantive content of the proposed program, including courses offered; the qualifications and responsibilities of the program director; the qualifications of the program's faculty, including current active engagement in health services research; and the history of the research program regarding its ability to recruit qualified trainees and their subsequent productivity in health services research. Additional criteria are the extent of institutional commitment to the program through provision of necessary space, curriculum time, financing support, and appropriate facilities; documented cooperation of related agencies in providing experience and research training sites for trainees; the number of students for whom support is requested; proposed methods for monitoring and evaluating the performance of trainees as well as the overall program; the degree to which the program focuses on postdoctoral training; the demonstrated ability of the program to recruit M.D.'s into health services research; and the reasonableness of the proposed budget in relation to the proposed research training.

NRSA proposals requesting significant amounts of grant funds for faculty or program support costs are unlikely to be funded. Although some additional faculty may be needed, funds awarded through this program are intended to support individual trainees, not develop or expand institutional programs in health services research.

APPLICATION PROCEDURES

Institutions must submit an original and six copies of Public Health Service form PHS 398, Institutional National Research Service Award Application (revised, September 1986), to:

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

Do not mail applications directly to NCHSR. NRSA application material is available from:

Chief, Review and Advisory Services Program
NCHSR
Parklawn Building, Room 18A-20
Rockville, Maryland 20857
Telephone: (301) 443-3091

REVIEW SCHEDULE

NIH/DRG submission deadline	Study section review	Notification to applicant	Earliest start date
September 10	March	April	July 1

ADDITIONAL INFORMATION

For more information, request "Institutional National Research Service Awards," a program note available from the NCHSR Publications and Information Branch, Parklawn Building, Room 18-12, Rockville, MD; 301/443-4100. Persons interested in NRSA grants for individuals may request "Individual National Research Service Awards."

ONGOING PROGRAM ANNOUNCEMENTS

MINORITY TRAVEL AWARD PROGRAM

P.T. 48, 42, FF; K.W. 0710030

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

DESCRIPTION

The Minority Travel Award Program (MTAP) provides support for minority students and faculty members of minority institutions to attend national scientific meetings.

Any NIDDK or NIAMS grantee wishing to obtain such travel funds for minority students and/or faculty may submit a supplemental grant application. Minority students may be from any domestic institution. Faculty must be from a minority institution. Approved applications will be funded as supplements to active grants. Such grants include individual project (R01, R29, R37), program project (P01), and center (P30, P50, P60) grants.

OBJECTIVES

The MTAP is part of an overall NIDDK and NIAMS effort to strengthen biomedical research and training in institutions with significant commitments to minorities and to increase the awareness and participation of minority scientists in biomedical research. The MTAP supports minority students and faculty from minority institutions to accompany principal investigators currently funded by NIDDK or NIAMS grants to scientific meetings. The MTAP is intended for minority students at various stages of academic development and for faculty members at minority institutions who have not been principal investigators on NIH regular research grants. The MTAP is intended to enhance awareness of biomedical research opportunities and to influence more minority students/faculty to become interested and involved in research and research training.

DEFINITIONS, ELIGIBILITY AND TERMS OF AWARD

1. Minority Student

A minority student is defined as anyone of the underrepresented minorities (including but not limited to Blacks, Hispanics, American Indians, and Pacific Islanders) at any stage of academic achievement (including but not limited to undergraduate, predoctoral, and postdoctoral students).

2. Minority Faculty

A minority faculty member is defined as a full-time faculty member of a minority institution who is interested or engaged in biomedical research. The minority investigator should not have been a principal investigator on any regular research grant from NIH. This does not exclude from candidacy minority faculty who have been supported by the NIH Minority Biomedical Research Support (MBRS) Program, the Minority Access to Research Careers (MARC) Program, training grants, fellowships, or other similar awards.

3. Minority Institution

A minority institution is defined as a medical or non-medical college, university, or equivalent school in which students of underrepresented minorities, as defined above, comprise the majority or significant proportion of the school enrollment.

4. Principal Investigator

Principal investigators of active NIDDK or NIAMS grants are eligible to submit supplemental applications on behalf of a minority student and/or faculty member. The principal investigator (or other designated senior investigator on the grant) is expected to serve as a guide or mentor for the student or faculty member while at the scientific meeting.

5. Travel Funds

Funds requested in the supplemental application are intended to support the minority student and/or faculty member while accompanying the principal investigator or designated senior investigator to a national scientific meeting. Travel funds can include air and ground transportation, a per diem allowance, and registration fees associated with the meeting.

6. Scientific Meeting

A scientific meeting in the context of this program is defined as any national scientific meeting related to the interests of NIDDK or NIAMS.

7. Other Considerations

In general, applications and awards are limited to travel to one meeting per student and/or minority faculty member per year. Supplemental applications should be submitted for a duration to coincide with the end of the appropriate budget period. An amount not to exceed $1,000 travel expenses per individual may be requested. The specific budget items must be justified in the application. If circumstances indicate that these limitations must be exceeded, a special justification should be included in the application.

8. Travel Report

In order to evaluate the effectiveness of this program, the minority student or faculty member is requested to prepare a brief report for submission through the principal investigator. This report is due 30 days after returning from the meeting and is to be sent to the appropriate Institute conctact person listed below. In addition, the report should be included in the annual and/or final grant progress report. The travel report should include but not be limited to the following elements:

a) Name, location, and general description of the meeting.

b) A listing of papers and symposia found to be of special interest.

c) Tangible and intangible benefits derived from attendance.

d) Suggestions for improvement of the MTAP to make the meeting experience more rewarding for the individual and his/her biomedical research goals.

PROJECT EVALUATION AND REVIEW CRITERIA

Applications submitted in response to this announcement will be reviewed for eligibility by the NIDDK/NIAMS Minority Affairs Advisory Committee, a committee of intramural and extramural staff, using the following criteria:

1. For Minority Students:

   - o Completion of the sophomore year in college, or enrollment in a predoctoral or postdoctoral program (exceptions will be considered if justification is furnished);
   - o Overall grade point average of at least 3.0 on a 4.0 scale;
   - o Recommendation from one science faculty member or researcher other than the principal investigator;
   - o A brief written statement of interest in attending the meeting, benefits to be derived, and long-range professional plans.

2. For Faculty at Minority Institutions:

   - o A brief written statement indicating research interests, benefits to be derived by attendance at the meeting, and long-range professional plans;
   - o Two letters of recommendation from the institution, including one from the Dean or Department Chairperson.

FUNDING

Successful applications will be funded as administrative supplements to the investigator's NIDDK or NIAMS grant. Funds awarded under this program are for the sole purpose of facilitating participation of minority students and faculty as described above.

HOW TO APPLY

Potential applicants are encouraged to contact the NIDDK or NIAMS program contact person listed below prior to preparing an application.

The principal investigator must submit a supplemental grant application through his/her institution on the standard form PHS 398 (Rev. 9/86), and should include only the following: (1) face page--item 2 should give the grant number of the active grant and specifically state "Minority Travel Award Program" (for example: Grant Number R01DK12345-06, "Minority Travel Award Program"); (2) budget page; (3) complete curricula vitae of the principal investigator and of the individual for whom support is being requested; and (4) information addressing the review criteria described above.

Applications may be submitted at any time. The requested start date for the supplemental application should be at least 90 days after the date of submission.

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

Dr. Anthony Demsey
Deputy Director, Division of Extramural Activities
National Institute of Diabetes and Digestive
and Kidney Diseases
Westwood Building, Room 406
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7083

Dr. Steven Hausman
Deputy Director, Extramural Activities Program
National Institute of Arthritis and Musculoskeletal
and Skin Diseases
Westwood Building, Room 403
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7495

MINORITY INVESTIGATOR RESEARCH ENHANCEMENT AWARD

P.T. 34, FF; K.W. 0710030

National Institute of Arthritis and Musculoskeletal and
Skin Diseases
National Institute of Diabetes and Digestive and
Kidney Diseases

DESCRIPTION

The Minority Investigator Research Enhancement Award (MIREA) provides support for faculty members of minority institutions to allow them to collaborate with principal investigators of active research grants funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) or the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Any domestic institution wishing to include faculty of minority institutions in one of its NIAMS- or NIDDK-funded research projects may submit a supplemental grant application for this purpose. Approved applications will be funded as supplements to active NIAMS or NIDDK grants. These may include, but are not limited to, individual project (R01, R37), program project (P01), and center (P30, P50, P60) grants.

OBJECTIVES

The MIREA is part of an overall NIAMS and NIDDK effort to strengthen biomedical research and training in institutions with significant commitments to minorities and thereby to increase the participation of minority scientists in biomedical research. The MIREA supports faculty members of minority institutions (hereafter referred to as "minority investigators") to collaborate with principal investigators currently funded by NIAMS or NIDDK research grants or center programs. The MIREA is intended for minority investigators who have completed their training but who have not served as principal investigators on NIH regular research grants. The MIREA is intended to enhance opportunities for long-term productive collaborations among investigators and eventually to increase the number of minority investigators holding research grants.

DEFINITIONS, ELIGIBILITY AND TERMS OF AWARD

1. Minority Institution

A minority institution is defined as a medical or non-medical college, university or equivalent school in which students of underrepresented minorities (including but not limited to Blacks, Hispanics, American Indians, and Pacific Islanders) comprise the majority or significant proportion of the school enrollment and which has a commitment to the special encouragement of minority faculty, students and investigators. The commitment of the institution to the faculty candidate's research and development must be clearly presented in the application, including a statement from the candidate's supervisor.

2. Minority Investigator

A minority investigator is defined as a faculty member of a minority institution who is engaged in biomedical research. Candidates for this award would be minority investigators who: (1) are citizens of the United States or permanent residents at the time of application, (2) have a doctoral degree or

equivalent in a biomedical or behavioral science, and (3) have the background to benefit from this program. The minority investigator should not already have spent an extended period of time in the applicant's laboratory and should not have been principal investigator on any NIH regular research grant. This does not exclude from candidacy minority investigators who have been supported by the NIH Minority Biomedical Research Support (MBRS) Program, the Minority Access to Research Careers (MARC) program, training grants, fellowships or other similar awards. The program will not pay stipends for student trainees nor support Candidates without previous research experience.

3. Principal Investigator

Principal investigators of active NIAMS or NIDDK grants are eligible to submit supplemental applications on behalf of a minority investigator. Although not excluded, MIREA applications from principal investigators in the final year of their project period will be evaluated on a case-by-case basis.

4. Research Project

The proposed research project for the supplement must be closely related to the currently funded research grant. It may represent an increased effort relative to an already approved objective of the research project or propose to enhance the effectiveness of the overall research. The proposed investigation must provide the minority investigator an opportunity to contribute intellectually to the program and to enhance his/her own potential as an independent investigator. The scope of the proposed work should be consistent with the minority investigator's proposed level of effort and length of tenure in the principal investigator's laboratory.

5. Length of Tenure

The length of tenure should not be less than three months nor more than 15 months. Short tenures (3-4 months) must represent the full-time effort of the minority investigator. For longer tenures, part-time commitments are acceptable but should not normally be less than 25 percent effort for any part of the award period.

6. Project Report

The principal investigator will prepare (at the time of the annual report and/or final progress report) a section summarizing the work conducted during the tenure of the minority investigator. This portion of the report should include, but not be limited to, the following elements: 1) a summary of the research project; 2) a summary of all pertinent results; 3) titles and/or copies of manuscripts or publications resulting from this research association; and 4) a statement of how the research experience will be integrated into the minority investigator's long-range or continuing research efforts.

PROJECT EVALUATION AND REVIEW CRITERIA

Applications submitted in response to this announcement will be reviewed for eligibility by the NIAMS/NIDDK Minority Affairs Advisory Committee, a committee comprised of intramural and extramural staff, using the following criteria:

1. The proposed research as described in the supplemental application should fit within the general scope of the approved and funded project.

2. The qualifications of the principal investigator and the minority investigator should indicate a high likelihood that the proposed work will be successful.

3. The proposed work should further the objectives of the MIREA program.

4. The length of time and budget requested should be appropriate for the proposed work.

Where questions of scientific content or expansion of project scope are involved, a review by non-Federal scientists will also be conducted, with subsequent second-level review by the cognizant Advisory Council as necessary.

FUNDING

Successful applications will be funded as administrative supplements to the investigator's grant. The maximum award (total direct costs) is $30,000 on an annualized basis, with projects of less or greater than a 12-month duration

prorated accordingly. Awards made under this program are for the sole purpose of facilitating participation by minority investigators as described above.

HOW TO APPLY

All potential applicants are encouraged to contact one of the program staff representatives listed below prior to preparing the application:

Dr. Steven Hausman
Deputy Director, Extramural Activities Program
National Institute of Arthritis and Musculoskeletal and
Skin Diseases
Westwood Building, Room 403
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7495

Dr. Anthony Demsey
Deputy Director, Division of Extramural Activities
National Institute of Diabetes and Digestive and
Kidney Diseases
Westwood Building, Room 406
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7083

The principal investigator must submit a supplemental grant application through his/her institution, on Standard Form PHS 398, limited to the following: (1) face page -- Item 2 should give the grant number of the active grant and specifically state "Minority Investigator Research Enhancement Award" (for example: Grant Number R01AR12345-06, "Minority Investigator Research Enhancement Award"); (2) budget page; (3) complete curriculum vitae of the minority investigator; (4) statement of commitment and support from the minority investigator's institution; (5) an outline of the research project as it relates to the parent grant; and (6) the expected benefit of the research experience to the minority investigator and how it will be integrated into the minority investigator's long-range or continuing research efforts.

Applications may be submitted at any time. The requested start date for the supplemental application should be at least 90 days after the date of submission.

The original and four copies of the application should be sent to:

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

Two copies of the application should be sent to the program staff person listed above who was contacted for information prior to preparation of the application.

This program is described in the Catalog of Federal Domestic Assistance, 13.846, 13.847, 13.848, and 13.849. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically at 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.

RESEARCH GRANTS ON INTENSIVE MONITORING OF SEIZURES

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

National Institute of Neurological and Communicative Disorders
and Stroke

I. INTRODUCTION

The Epilepsy Branch, Division of Convulsive, Developmental, and Neuromuscular Disorders, National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), encourages the submission of research project grant applications (R01) related to the research applications of intensive monitoring to the study of seizures.

II. BACKGROUND

Intensive monitoring is defined as prolonged electroencephalographic (EEG) monitoring synchronized with appropriate video and/or polygraphic recording. The value of intensive monitoring has now been established in the diagnostic evaluation and therapeutic management of many patients presenting with possible or intractable seizures.

In November 1984, an international conference on intensive neurodiagnostic monitoring critically reviewed current indications, techniques, and effectiveness of intensive monitoring. Directions for future technical development and expanded research applications were emphasized. The complete proceedings of this conference have been published (Advances in Neurology, Vol. 46, Raven Press, 1986)

Research opportunities exist in a number of areas. Different seizure types vary in their clinical features and response to therapy. Detailed analysis of clinical seizure manifestations (video and polygraphic recordings) correlated with surface, subdural, and/or depth electroencephalography may allow a determination of the specific neuropathways involved in the genesis and propagation of various seizure types. This knowledge would not only benefit the individual patient studied (leading to optimal drug and surgical therapy) but would also advance our understanding of brain circuitry.

This program is described in the Catalog of Federal Domestic Assistance No. 13.853, Clinical Basis Research, NINCDS. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency Review.

Three distinctive complex partial seizure subtypes have been suggested by analysis of recorded seizures. These are postulated to anatomically correlate with primary epileptogenic disturbances of the hippocampal gyrus, orbitofrontal cortex, and cingulate gyrus. The ability to anatomically localize a behavioral seizure has potential application in the selection of surgical candidates. The reliability of this localization must be confirmed by further correlation of seizure characteristics recorded by intensive monitoring with neuroanatomical information from other diagnostic modalities (depth recording, corticography, positron emission tomography, magnetic resonance imaging).

Detailed study of the clinical features of pseudoseizures (including psychogenic seizures) could lead to sufficient objective characterization to reliably distinguish them from epileptic seizures. In addition, subcategories of pseudoseizures may correlate with specific underlying medical or psychiatric problems which differ as to their appropriate management and prognoses.

Seizures in newborn infants are often not recognizable clinically. There is also considerable uncertainty as to whether certain observed behaviors represent true seizure activity and concerning the significance of certain EEG patterns. There is no uniformly agreed upon classification of neonatal seizures to guide diagnosis and therapy. Certain seizure types seen predominantly in early childhood also require more precise characterization to establish their specific etiologies, pathophysiologies, and natural histories.

Hard-wired EEGs synchronized with video monitoring can be used to monitor relatively immobile patients for hours at a time. Polygraphic monitoring of the electrocardiogram, respiratory effort and air exchange, eye movements, muscle tone, limb movement, etc., can be added if relevant to the particular study. More prolonged recordings lasting days to weeks on a relatively mobile patient in an inpatient setting can be accomplished with cable EEG telemetry or radio EEG telemetry. The combined techniques of telemetered EEG and video recording have proved useful in distinguishing seizures from nonepileptic attacks resembling seizures (psychogenic seizures, drug toxicity, episodic cerebral ischemia, psychiatric disorders, sleep disorders, movement disorders, and vascular headaches.) The ability to closely study a clinical seizure and its corresponding EEG changes is allowing detailed characterization and classification of seizures, resulting in ongoing revisions of the International Classifications of Epileptic Seizures and of Epileptic Syndromes.

Ambulatory cassette EEG modalities have been developed allowing a mobile outpatient to be studied in his home environment. This technique is particularly valuable if the seizures are rather infrequent or their elicitation requires interaction with the patient's habitual environment. Prolonged ambulatory EEG monitoring in the patient's own home environment (without video recording) is possible using a wearable cassette battery-powered EEG recording device.

Infrared video camera technology is now available but as yet there has been little research application of this technique for the study of nocturnal epileptic phenomena. The clinical distinction between nocturnal episodes of nonepileptic origin versus epileptic seizures remains problematic. Further research concerning variability in cerebral activation during sleep stage changes is needed to advance understanding of normal and abnormal sleep physiology and of the underlying mechanisms of nocturnal epilepsy.

III. RESEARCH GOALS

Investigators are encouraged to apply intensive monitoring to answer a variety of research questions. Both animal and human studies utilizing a variety of experimental approaches and methods would be responsive to this program announcement. Examples of research questions include but are not limited to the following: (1) What neuroanatomical pathways are involved in the genesis and spread of specific seizure types?; (2) Do differences among the clinical characteristics of pseudoseizures correlate with specific underlying conditions and prognoses?; (3) Do nocturnal epileptic phenomena have a unique pathophysiology amenable to innovative therapies?; (4) Are the neurocircuitries propagating seizures during the neonatal and early infancy periods different from those propagating seizures observed in older children or adults?

IV. MECHANISM OF SUPPORT

Support for this program will be through the traditional research grant-in-aid. Successful applicants will direct and carry out the individual research projects.

V. APPLICATION AND REVIEW PROCEDURES

Applications should be prepared on Form PHS 398 (revised 9/86) according to instructions contained in the application kit. Application kits are available from most institutional business offices or may be obtained from the Division of Research Grants at the address given below. Check "yes" in item two on the face sheet of the application and type "Grants Related to Intensive Monitoring of Seizures" in the space provided.

Applications must be responsive to the program announcement and the goals of NINCDS. They will be judged on scientific merit and program relevance in accordance with NIH policy and procedures involving peer review. An initial review will be made by an appropriate study section of the Division of Research Grants. A second level of review will be made by the National Advisory Neurological and Communicative Disorders and Stroke Council.

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

The original and five copies of the application should be mailed to the following address.

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

An informational copy of the application may be sent to the address below. Also, for further information, applicants may contact:

Philip H. Sheridan, M.D.
NIH, NINCDS, DCDND, EB
Federal Building, Room 114
7550 Wisconsin Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-1917

**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

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