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. 41
December 9, 1988

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No. 41

DATED ANNOUNCEMENTS (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

DATED ANNOUNCEMENTS (RFPs AND RFAs)

FUNCTIONAL NEUROMUSCULAR STIMULATION FOR RESTORATION OF HAND GRASP

RFP AVAILABLE: RFP-NIH-NINDS-89-09

P.T. 34; K.W. 0740050, 0715140, 0745047

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke has a requirement to develop and evaluate ways to enhance the utility of functional neuromuscular stimulation (FNS) systems for hand grasp.

Offerors should have experience in microtelemetry and design of electrical stimulator systems. Expertise with clinical implementation of hardware systems for FNS, biomechanical modeling and control theory are required. A clinical center, staff, and quadriplegic patient base are also required.

This is an announcement of an anticipated Request for Proposals. RFP-NIH-NINDS-89-09 will be issued on or about December 30, 1988, with a closing date for receipt of proposals for March 6, 1989.

This requirement represents the recompetition of a current contract with Case Western Reserve University and the incumbent is expected to reapply. It is anticipated that one contract award will be made.

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 shall be considered by the agency.

The RFP will be available upon written request to:

Contracting Officer, Contracts Management Branch
National Institute of Neurological Disorders and Stroke
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, Maryland 20892

COMMUNITY PROGRAMS FOR CLINICAL RESEARCH ON AIDS

RFP AVAILABLE: RFP-NIH-NIAID-AIDSP-89-11

P.T. 34; K.W. 0715008, 0403004, 0755015

National Institute of Allergy and Infectious Diseases

The AIDS Program, National Institute of Allergy and Infectious Diseases, NIH, is establishing a new initiative, Community Programs for Clinical Research on AIDS. The goals of this program will be the establishment of a community-based research capability and the performance of clinical evaluations of drugs and therapies for the treatment of HIV infection and its sequelae by community practitioners.

This new initiative, Community Programs for Clinical Research in AIDS (CPCRA), is an effort to expand the scientific base of understanding of the clinical management of persons with HIV infection and particularly to offer the opportunity to health care providers and HIV-infected persons not involved with an existing NIAID-supported AIDS Clinical Trials Unit (ACTU) the possibility of participating in government-supported AIDS research if they so desire. The CPCRA will use a contract mechanism designed to: 1) act as a catalyst for research by providing support for the establishment of a research capability in those locations with little or no previous experience in the conduct of clinical trials; and 2) provide support for specific community based clinical trials to be conducted by groups or organizations which have already demonstrated ability to conduct community based clinical trials.

The research supported by this program will be designed for the testing of experimental agents or therapies which may have use against HIV and its sequelae or for agents in wide use which are neither proven effective nor safe. The unifying concept of this program is the establishment of a strong scientific base from which to conduct these trials in order to derive maximum pharmacologic, epidemiologic and therapeutic results from the projects performed. This program is intended to foster community-based research relevant to the long-term clinical management of persons infected with HIV as well as initiation of high quality clinical research designed specifically to

include communities here-to-fore under-represented in HIV related research such as members of minority groups, sexual partners of persons with HIV infection and users of IV drugs, and those persons who are geographically isolated from ACTU sites.

The projects supported as Community Programs for Clinical Research on AIDS will be administered as a separate new entity in NIAID's AIDS Program and will work closely in conjunction with existing AIDS Program activities. These projects will be established for two different activities designed toward the goal of the conduct of community-based clinical trials on AIDS. These activities can be thought of as Stage I - Research Capability Establishment and Stage II - Conduct of Clinical Trials.

Stage I - Research Capability Establishment:

Contracts will be awarded for support required to build a research capability in existing or newly created community clinics where practitioners who care for a large HIV-infected population desire to embark upon clinical research. Stage I support may include funds to hire research and administrative personnel and/or other necessary staff, purchase computer equipment or lease space or facilities required for the establishment of a research capability. The culmination of Stage I will be the actual conduct of a community-based clinical trial.

Stage II - Conduct of Clinical Trials:

Contracts will be awarded for the conduct of specific community-based clinical trials of drugs or therapies relevant to the long-term management of persons infected with HIV and its clinical sequelae. Organizations submitting a proposal for support under Stage II of this program will be required to document existing capability to perform this type of research. Stage II support may include funds for continued support of existing research capability (as listed above) and support for activities directly related to the conduct of specific community-based clinical trials.

To perform the work required by these contracts the offeror must have access to a substantial patient population infected with HIV, significant experience in the care of persons infected with HIV, and community support for embarking on this type of research activity.

This NIAID-sponsored project will take up to two years to complete for Stage I activities, and up to five years to complete for Stage II clinical trials. A cost-reimbursement contract is anticipated. It is also anticipated that several awards will be made in FY 1989 with the possibility of future issuing of this or a similar request for proposals.

This is an announcement for an anticipated Request for Proposal (RFP). RFP-NIH-NIAID-AIDSP-89-11 shall be issued on or about January 17, 1989, with a closing date tentatively set for April 16, 1989. In order to assist offerors unfamiliar with the request for proposal and proposal submission processes, there will be a series of pre-proposal conferences, to be announced.

Direct requests for the RFP in writing to:

Ms. Brenda J. Velez
Contract Management Branch
Westwood Building, 5333 Westbard Avenue, Room 707
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7117

To receive a copy of the RFP, please supply this office with 3 self addressed mailing labels. All responsible sources may submit a proposal which will be considered.

This advertisement does not commit the Government to award a contract.

ONGOING PROGRAM ANNOUNCEMENTS

NATIONAL RESEARCH SERVICE AWARDS FOR INSTITUTIONAL RESEARCH TRAINING GRANTS IN ACQUIRED HUMAN IMMUNODEFICIENCY VIRUS (HIV) SYNDROME

P.T. 44; K.W. 0720005, 0715008

National Institute of Mental Health
National Institute on Alcohol Abuse and Alcoholism

The National Institute of Mental Health (NIMH) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA), seek applications for research training in several areas related to the HIV syndrome to answer the critical need for well-trained researchers to make progress in understanding and dealing with the extraordinarily complex characteristics of the disease. The applicant institution must have the staff and facilities to conduct the proposed research training and in a suitable environment for performing high quality work. Awards for institutional grants may be made for project periods of up to five years. In FY 1989, a total of $2,174,000 will be available from NIMH for institutional and individual National Research Service Awards related to HIV. In FY 1989, a total of $181,000 will be available from NIAAA for institutional and individual National Research Service Awards related to HIV. Availability and amount of funds for future years are contingent upon annual appropriations. There is an initial (one time only) receipt date for this program announcement of January 18, 1989. Thereafter, NIMH and NIAAA will accept applications in response to this announcement under the Public Health Service receipt dates for AIDS applications: May 1, September 1, January 2. Potential applicants may also wish to see the NIMH/NIAAA announcement for individual fellowships. Potential applicants interested in obtaining further information should contact:

Ellen S. Stover, Ph.D.
AIDS Coordinator
Room 17C-04
National Institute of Mental Health
Telephone: (301) 443-7281

Daniela Seminara, Ph.D.
Biomedical Research Branch
Division of Basic Research, Room 14c-20
National Institute on Alcohol Abuse and Alcoholism
Telephone: (301) 443-4223

The mailing address for both of the above is:

5600 Fishers Lane
Rockville, Maryland 20857

NATIONAL RESEARCH SERVICE AWARDS FOR RESEARCH TRAINING FOR INDIVIDUAL FELLOWS IN ACQUIRED HUMAN IMMUNODEFICIENCY (HIV) SYNDROME

P.T. 22; K.W. 0720005, 0715008

National Institute of Mental Health
National Institute on Alcohol Abuse and Alcoholism

The National Institute of Mental Health (NIMH) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA), seek applications for individual fellows for research training in several areas related to HIV syndrome to answer the critical need for well-trained researchers in order to make progress in understanding and dealing with the extraordinarily complex characteristics of the disease. Applicants must propose research training in specified areas and demonstrate that the proposed program offers them an opportunity to use and enhance their skills and knowledge. In fiscal year 1989, a total of $2,174,000 will be available from NIMH for individual and institutional National Research Service Awards. In fiscal year 1989, a total of $181,000 will be available from NIAAA for individual and institutional National Research Service Awards related to HIV. Availability and amount of funds for future years are contingent upon annual appropriations. There is an initial (one time only) receipt date for this program announcement of January 18, 1989. Thereafter, NIMH and NIAAA will accept applications in response to this announcement under the Public Health Service receipts dates for AIDS applications: May 1, September 1, January 2. Potential applicants may also wish to see the NIMH/NIAAA announcements for institutional fellowships. Potential applicants interested in obtaining further information should contact:

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Daniela Seminara, Ph.D.
Biomedical Research Branch
Division of Basic Research, Room 14C-20
National Institute on Alcohol Abuse and Alcoholism
Telephone: (301) 443-4223

The mailing address for both of the above is:

5600 Fishers Lane
Rockville, Maryland 20857

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANTS

P.T. 36; K.W. 0735000

Division of Research Resources

Application Receipt Date: March 31, 1989

BACKGROUND

The Division of Research Resources (DRR) is continuing its competitive Biomedical Research Support (BRS) Shared Instrumentation Grant (SIG) Program initiated in Fiscal Year 1982. The program was established in recognition of the long-standing need in the biomedical research community to cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment. The objective of the program is to make available, to institutions with a high concentration of PHS-supported biomedical investigators, research instruments which can only be justified on a shared-use basis and for which meritorious research projects are described.

An eligible institution may submit more than one application for different instrumentation for the March 31, 1989, deadline. However, if multiple applications are submitted for similar instrumentation from one or more eligible components of an institution, then documentation from a high administrative official must be provided, stating that the multiple applications are a coordinated institutional resource plan, not an unintended duplication.

RESEARCH GOALS AND SCOPE

This program is designed to meet the special problem of acquisition and updating of expensive shared-use instruments which are not generally available through other PHS mechanisms, such as the regular research project, program project and center grant programs, the Biomedical Research Technology Grant Program, or the Biomedical Research Support (BRS) Grant Program. Proposals for the development of new instrumentation will not be considered.

ELIGIBILITY

The BRS Shared Instrumentation Grant Program is a subprogram of the BRS Grant Program of DRR. Awards are made under the authority of the BRS program and are made to institutions only, not to individuals. Therefore, eligibility is limited to institutions which receive a BRS grant award. Awards are contingent on the availability of funds.

MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants provide support for expensive state-of-the-art instruments utilized in both basic and clinical research. Applications are limited to instruments that cost at least $100,000 per instrument or system. The maximum award is $400,000. Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers and cell sorters. Support will not be provided for general purpose equipment or purely instructional equipment. Proposals for "stand alone" computer systems will only be considered if the instrument is solely dedicated to the research needs of a broad community of PHS-supported investigators.

Awards will be made for the direct costs of the acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the normal purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is $400,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. Cost sharing is not required. If the amount of funds requested does not cover the total cost of the instrument, the application should describe the proposed source(s) of funding for the balance of the cost of the instrument. Documentation of the availability of the remainder of the funding, signed by an appropriate institutional official, must be presented to DRR prior to the issuance of an award.

A major user group of three or more investigators should be identified. A minimum of three major users must have PHS peer-reviewed research support at the time of the award. The application must show a clear need for the instrumentation by projects supported by multiple PHS research awards and demonstrate that these projects will require at least 75 percent of the total usage of the instrument. Major users can be individual researchers, or a group of investigators within the same department or from several departments at the applicant institution. PHS extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument can be made available to other users upon the advice of the internal advisory committee. These users need not be PHS awardees, but priority should be given to PHS-supported scientists engaged in biomedical research.

ADMINISTRATIVE ARRANGEMENTS

Each applicant institution must propose a Principal Investigator who can assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility should also be utilized. The Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation of all reports required by the NIH, for relocation of the instrument within the grantee institution if the major user group is significantly altered and for continued support for the maximum utilization and maintenance of the instrument in the post-award period.

A plan should be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument should be described.

If a grant award is made, a final progress report will be required which describes the use of the instrument, listing all users, and indicating the value of the instrumentation to the research of the major users and to the institution as a whole. This report is due within 90 days following the end of the project period.

REVIEW PROCEDURES AND CRITERIA

Applications are reviewed by specially convened initial review groups of the Division of Research Grants (DRG) for scientific and technical merit and for program considerations by the National Advisory Research Resources Council (NARRC) of the DRR. Approximately half of the applications will be reviewed at the September 1989 NARRC meeting and the remainder at the NARRC meeting in February 1990. Funding decisions on all applications received for the March 31, 1989 deadline will not be made until the program receives an appropriation for FY 1990. The Council date will not effect funding decisions.

Criteria for review of applications include the following:

- The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.

- The availability and commitment of the appropriate technical expertise within the major user group or the institution for use of the instrumentation.

- o The adequacy of the organizational plan and the internal advisory committee for administration of the grant including sharing arrangements for use of the instrument.

- o The institution's commitment for continued support of the utilization and maintenance of the instrument.

- o The benefit of the proposed instrument to the overall research community it will serve.

METHOD OF APPLYING

Copies of a more detailed announcement are being mailed to Program Directors of BRS grants and to sponsored program offices at all institutions currently receiving BRS grants. Interested investigators should obtain the complete announcement prior to preparing an application.

Applications must be received by March 31, 1989. Applications received after this date will not be accepted for review in this competition. The original and four copies should be sent to:

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

If appendix material is submitted, four collated sets must be included with the application package. Identify each of the four sets with the name of the principal investigator and the project title. This material will not be routinely duplicated and will be used in a limited way by members of the initial review group.

Two copies of the application and one copy of any appendix material should be addressed to:

Biomedical Research Support Program
Division of Research Resources
National Institutes of Health
Westwood Building, Room 10A06
5333 Westbard Avenue
Bethesda, Maryland 20892

Inquiries should be directed to the Biomedical Research Support Program Office at (301) 496-6743.

This program is described in the Catalog of Federal Domestic Assistance number 13.337, Biomedical Research Support. Awards will be made under the authority of the Public Health Service Act, 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 A-95 Clearinghouse or Health Systems Agency Review.

RESEARCH CAREER AWARDS IN THROMBOSIS

P.T. 34; K.W. 0715040, 0785035, 0745020, 0411005

National Heart, Lung, and Blood Institute

The objective of the Research Career Awards in Thrombosis is to support the professional development of individuals who can serve expanding and evolving research, teaching, and clinical requirements in the area of thrombosis and thromboembolic disorders. This announcement emphasizes the need for increased research training in this area and encourages individuals to submit applications for support using the three existing research career development awards sponsored by the NHLBI: Physician Scientist Award (PSA) (K11); Clinical Investigator Award (CIA) (K08); and Research Career Development Award (RCDA) (K04).

Applications submitted in response to this announcement will be brought to the special attention of the National Heart, Lung, and Blood Advisory Council and will receive special consideration for support by the NHLBI.

BACKGROUND

Thromboembolic events give rise to serious clinical disease and contribute significantly to the nation's health care burden. Both thrombosis and

atherosclerosis are important factors in cardiovascular disease. In 1985, they accounted for almost 1 million deaths. In addition, 153,000 persons in the United States died of cerebrovascular disease, the third leading cause of death in 1985. The economic burden of cardiovascular diseases in 1984, was an estimated $110 billion. It is further estimated that six million episodes of venous thrombosis occur annually accounting directly for 50,000 hospital deaths due to pulmonary embolism and contributing to the deaths of another 100,000 patients. In all, the impact of thromboembolism and thromboembolic disorders on mortality and morbidity is impressive.

Substantial progress has been made towards understanding the basic mechanisms operating in thrombosis, the impact of thromboembolic phenomena on organ systems, and the techniques needed to prevent and treat thrombosis. Specific areas of progress include molecular and cellular pathology of thrombosis, biochemistry of coagulation and fibrinolysis, biology of vessel growth, endothelial cell function and vascular reactivity, the blood-vessel interface, and how cellular components interact with the vascular endothelium, thus contributing to the development of thrombosis. Therapeutic options are now readily available for the management of thrombosis and other treatment modalities are under development. Prevention of thrombosis and thromboembolic disorders, development of more effective therapies, and the appropriate choice of treatment demands a thorough understanding of all these facets of the subject.

The major strides which have taken place in basic and clinical understanding of thrombosis suggest that an unprecedented opportunity exists for major improvements in the way patients with these disorders are managed. In addition, the enormous health and economic impact of arterial and venous thrombosis argues strongly for giving this area increased attention. This announcement is prompted by the need to provide increasing numbers of basic and clinical investigators in the area of thrombosis and thromboembolic disorders, so that rapid and effective progress in the area can be made.

Candidates submitting research career development proposals in response to this program announcement should focus on topics such as those listed below:

- o basic research projects that lead to better understanding of mechanisms in thrombosis and thromboembolic disorders;
- o clinical research projects that will improve the detection of high risk patients and prevent thrombosis;
- o applied research projects that lead to improved diagnosis and therapeutic approaches to thrombosis;
- o effective, safe monitoring techniques for patients undergoing anti-thrombotic therapy; or
- o studies that deal with the logistical, economic, social, and behavioral aspects of thrombosis and thromboembolic disease.

Individual training programs that offer research and career development opportunities in all areas related to thrombosis and thromboembolic disorders are welcomed. While the proposed training should be focused, if candidates do not possess skills in research design and biostatistics, the applicant should consider including these training areas in the plan. The background training of candidates for these research training programs may have been in hematology, cardiology, surgery, orthopedics, radiology, clinical pharmacology, pathology, or epidemiology.

MECHANISMS OF SUPPORT

The three support mechanisms for these Research Career Awards in Thrombosis are summarized in this announcement and provide for several levels of career development. Detailed guidelines for each of the three support mechanisms can be obtained from your business office, from the Division of Research Grants, NIH, (301) 496-7441, or from Dr. Fann Harding, Division of Blood Diseases and Resources, (301) 496-1817. Only citizens and non-citizen nationals are eligible for support under these programs.

A. PHYSICIAN-SCIENTIST AWARD - PSA (K11)

Provides support through a two-phase award to physicians to undertake 5 years of special study in basic science with a supervised research experience. Newly trained clinicians are encouraged, during Phase I of the award, to develop independent research skills and experience in a fundamental science which can be applied, during Phase II, towards problems in thrombosis and thromboembolic disorders.

- Award is made to an institution on behalf of a candidate whose primary sponsor is an accomplished basic science investigator who will provide guidance for the entire award period.
- Selection is by national competition.
- Training support is for 5 years for full-time effort. Phase I entails two or three years of creative and detailed basic science learning experience; Phase II entails two or three years of intensive research activity under general guidance of a qualified sponsor.
- Salary is up to $40,000 per year plus fringe benefits for 100 percent effort.
- During Phase I, up to 10 percent of the primary sponsor's salary and commensurate fringe benefits may be requested.
- Research and development support is provided up to $10,000 per year increasing to $20,000 per year in Phase II.
- Salary supplementation is encouraged from non-government sources.
- Indirect costs of 8 percent of total direct costs, exclusive of tuition, fees, and equipment expenditures, or actual rate, whichever is less, may be requested.
- Awardees must inform the NIH for each of five years following the completion of the award about academic status, publications, and research grants and contracts received.
- PSA application may not be submitted concurrently with other development awards, such as CIA, RCDA, FIRST Award, or Academic Award.
- Use application form PHS 398 Rev. 9/86, with special PSA instructions.

B. CLINICAL INVESTIGATOR AWARD - CIA (K08)

Provides five years of support to physicians, usually with not less than 3 years of postdoctoral clinical training nor more than 7 years of total postdoctoral clinical and research experience by the time an award is made. The objective is to encourage the development of clinical, basic, and behavioral research interests.

- Award is made to an institution on behalf of a candidate who has an appropriate sponsor willing to assume responsibility and provide guidance for candidate's research program.
- Selection is by national competition.
- Salary is up to $40,000 per year plus fringe benefits for first year.
- Research support is provided up to $10,000 per year.
- Training period is 5 years for full-time effort.
- Salary supplementation is allowed from non-federal funds.
- Indirect costs of 8 percent of total direct costs or actual rate, whichever is less, may be requested.
- Awardees must inform the NIH for each of five years following the completion of the award about academic status, publications, and research grants and contracts received.
- CIA application may not be submitted concurrently with other development awards, such as PSA, RCDA, FIRST Award, or Academic Award.
- Use application form PHS 398 Rev. 9/86, with special CIA instructions.

C. RESEARCH CAREER DEVELOPMENT AWARD - RCDA (K04)

Supports investigators who have demonstrated outstanding research potential. Provides salary only for investigators who normally have 5 years of postdoctoral experience at the time of application, including 2 years of experience as an independent investigator with independent peer-reviewed support. Support must be available to carry out the research project for which the RCDA salary is provided. This award may not substitute for other sources of research support since the objective is to provide relief from responsibilities that prevent full-time (not less than 80 percent basic, clinical, or behavioral research) pursuit of an academic research career. New investigators and well-established investigators are not eligible for this Award.

- Candidate is nominated by and an award is made to an institution on behalf of the candidate.
- Selection is by national competion.
- Salary is up to $40,000 per year plus fringe benefits.
- Award period is 5 years.
- Salary supplementation is allowed from non-federal funds.
- Indirect costs of 8 percent of total direct costs or actual rate, whichever is less, may be requested.
- RCDA application may be submitted concurrently with a regular research grant application but must not be submitted concurrently with other development awards, such as, PSA, CIA, FIRST Award, or Academic Award.
- Use application form PHS 398 Rev. 9/86, with RCDA instructions.

APPLICATION SUBMISSION AND REVIEW

The receipt dates are the traditional NIH dates: February 1, June 1, and October 1 for Council review October, February, and May, respectively. The PSA and CIA applications will be reviewed by the NHLBI Research Manpower Review Committee. Research Career Development Award applications will be reviewed for scientific merit through the regular NIH peer review system in the Division of Research Grants.

Applications submitted in response to this announcement should be identified by typing P.A./Research Career Awards in Thrombosis on the face page along with the title of your project.

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

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

A copy of the face page of this application should be mailed to:

Fann Harding, Ph.D.
National Heart, Lung, and Blood Institute
Division of Blood Diseases and Resources
Federal Building, Room 5A08
Bethesda, Maryland 20892
Telephone: (301) 496-1817

The programs of the Division of Blood Diseases and Resources of the National Heart, Lung, and Blood Institute are identified in the Catalog of Federal Domestic Assistance, number 13.839. Awards will be made 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 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 Health Systems Agency Review.

PATIENT OUTCOME ASSESSMENT RESEARCH PROGRAM ASSESSMENT TEAMS

P.T. 34; K.W. 1016002, 0730000

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

INTRODUCTION

The National Center for Health Services Research and Health Care Technology Assessment (NCHSR) invites researchers to submit grant proposals for organizing assessment teams that will identify, analyze, and minimize the sources of variation of medical care that result in adverse outcomes or inappropriate resource utilization. The ultimate goal of this research is to provide information to practitioners that will improve the outcome of the care provided and optimize utilization of scarce health care resources. These teams are a continuation of NCHSR's Patient Outcome Assessment Research Program (POARP) funded in fiscal year 1988, which in turn was built on over a decade of research and development on the quality and costs of medical care.

Health services research over the past 15 years has uncovered wide variations in the types and amounts of care furnished to individuals with apparently similar conditions. These variations may be considered appropriate when they reflect patient preferences or needs and the alternative treatments are roughly equivalent in effectiveness and efficiency. However, when these differences reflect the physician's practice style and are not associated with major improvements in either effectiveness or efficiency, questions arise regarding appropriateness. Others have observed that when information about procedures that have marginal benefit have been brought to the attention of physicians, the use of these procedures has decreased without a concomitant decrease in the quality of outcome. These findings have led policy makers, health care providers, insurers, and consumers to the belief that an improvement may be possible in many currently accepted patterns of medical care. What has ensued is an increasing interest in practice variations and outcomes-based research.

NCHSR has a long history of interest in the quality and funding of health care, which has led to our current involvement in this area of research. NCHSR's POARP program, started in fiscal year 1988, is currently funding studies of the treatment for prostatism, heart disease, hypertension, diabetes, and rheumatoid arthritis and the procedures in intensive care therapy and coronary artery bypass surgery. Funds from the Medicare Trust Fund have been increased in fiscal year 1989. They will be used in part to support four extramural assessment teams.

TEAM STAFFING

The four initial POARP assessment teams will be composed of 5-7 full-time equivalent professionals per team. The staffs will be multidisciplinary and should include both academic and community physicians. The goal of each assessment team will be to identify and analyze the outcomes and the costs of alternative practice patterns in order to develop and test feasible and acceptable methods for reducing inappropriate variations. Ultimately, this will lead to the development of patient outcome information that physicians and patients could use in making decisions. With this information, physicians will be able to improve quality of care. Each assessment team must have the following skills available to it: clinical competence in subject area (specialty/background), epidemiology, biostatistics, research design, economics, decision analysis, survey research, data management, and research synthesis and meta-analysis.

Practicing physicians will be a critical part of the assessment teams. The aim of the program is to improve quality of care by informing practicing physicians of scientific findings about the relationship between treatment and outcomes. Practitioners must be convinced of the value and validity of this research and, therefore, it is essential that their viewpoints be represented on the assessment team.

SELECTION OF STUDY SUBJECTS

Each team will select an important area of controversy for study and will be evaluated in part on the justification of its choice of topic. Criteria for selection of problems for study include differences between alternative treatments or settings with regard to benefits and risks to the patient, amount of unexplained medical practice variation, and volume of cases nationally. Priority will be given to studies that address the following issues:

- The benefits and risks to the patient, both short and long term, which include the patient's probability of survival and improved health both with and without the treatment.

- The amount of unexplained variation in medical practice among physicians for the particular illness. This variation indicates the potential for patient-outcome research findings to have an impact on physician behavior.

- The volume of cases and treatments in the population and the cost/charge per treatment. These factors reflect the sufficiency of data for analysis, the level of resources devoted to the treatment, and the importance of the problem to the population.

Other relevant criteria for choosing the treatments or illnesses to be examined are distribution across the Medicare population and providers. To avoid unnecessary duplication of applications, choice of conditions to be studied should take into account what is being done elsewhere--by other government agencies, by physicians and specialty groups, by private foundations, and by such nongovernment payers for health care as insurance companies and employers.

Priority will be given to the assessment of treatment controversies involving common operations and to the evaluation of the use of hospitals for medical conditions due to the implications for costs, equity, and patient safety.

Many conditions, illnesses, and their respective treatments have been identified as controversial. Examples include angina, arteriosclerosis, cataracts, gallstones, arthritis, prostatism, back pain, and respiratory disease.

ASSESSMENT TEAM FUNCTIONS

To postulate associations between practice variations and outcomes, assessment teams will conduct literature reviews and research syntheses of the condition to be assessed. The teams will then develop hypotheses for analyses of variations, using routine data bases and, where appropriate, international data bases (which also are routinely collected). Examples include Medicare (Parts A and B), Medicaid, State health department records, hospital discharge abstracts, population data sets of the National Center for Health Statistics (routinely collected on a periodic basis), census data, international data, national data sets, and data from the Copenhagen Collaborating Center for the Study of Regional Variations in Health Care (sponsored by the World Health Organization).

To evaluate and test the hypotheses developed, POARP teams may acquire person-specific or setting-specific data obtained from subsets of specially-derived data bases. These could include specific Medicare data, specific Medicaid data, longitudinal data sets (for example, chronic disease data banks and registries), medical records, insurance records, and peer review organization data files.

To resolve remaining discrepancies, POARP teams would collect data from special interviews and surveys. Ultimately, they would design carefully-focused epidemiologic or experimental clinical trials that NCHSR will consider conducting.

DEMONSTRATION AND DISSEMINATION OF FINDINGS

The teams will disseminate these research findings to physicians so that they may make better informed decisions about patient care. Dissemination will include demonstration both of what information influences physician behavior and of how that information is best provided to practicing physicians.

This effort is intended to demonstrate that physicians will voluntarily change their behavior when informed about scientific patient-outcome research findings and about treatment patterns in their own market areas.

The effectiveness of this demonstration will be evaluated in terms of reduced variations in medical practices, more appropriate use of medical resources, and improvements in patient outcomes. Improvements in patient outcomes could be measured through patient survival rates (such as 30-day, 1-year, and 5-year), functional status (e.g., activities of daily living, incontinence, and impotence), and quality of life (e.g., patient satisfaction).

In summary, NCHSR intends that this program will: (a) use good scientific methods and develop reliable information about patient outcomes, (b) disseminate this information to physicians, (c) provide information to

physicians about their own practice patterns, (d) evaluate the effects of this feedback, and (e) provide a basis for developing a consensus among physicians about appropriate treatments for many illnesses.

This research program for the assessment of patient outcomes has significance for saving lives, improving the quality of medical care, increasing and maintaining the functional abilities of patients, conserving resources, and reducing malpractice suits. Developing and disseminating better knowledge about patient outcomes will enable physicians and patients to make better informed decisions about treatment choices.

CRITERIA FOR SELECTION OF ASSESSMENT TEAMS

o Significance (scientific or technical) of the goals of the proposed project
o Adequacy of the proposed methodology
o Availability of data or adequacy of proposed plan to collect the data
o Appropriateness of the plan for organizing and managing the assessment
o Qualifications of the team in the disciplines appropriate to the assessment topic
o Reasonableness of the budget in relation to the assessment
o Adequacy of the facilities and resources available to the team
o Adequacy of plan to protect confidentiality

APPLICATION PROCEDURES

Investigators are encouraged to discuss research ideas with NCHSR staff members prior to submitting a proposal. They should be contacted no later than 3 weeks before the planned submission date.

Norman W. Weissman, Ph.D. (301/443-2345)
Jennifer Mayfield, M.D. (301/443-2080)
Marcel Salive, M.D. (301/443-5780)
NCHSR Division of Extramural Research
Room 18A-19
Parklawn Building
Rockville, Maryland 20857

Grants are awarded for investigator-initiated projects in health services research at colleges and universities and other nonprofit organizations for periods of up to 5 years. NCHSR requires the use of Form PHS 398, Grant Application (also used by the National Institutes of Health). A grant application kit may be obtained from:

NCHSR Review and Advisory Services Program
Room 18A-20
Parklawn Building
Rockville, Maryland 20857

Applications from State and local governments should be submitted on Form PHS 5161-1, Application for Federal Assistance (nonconstruction programs). These forms may be obtained either from NCHSR or the Division of Research Grants, NIH, at the address shown below.

All NCHSR research grant applications are reviewed by non-Federal experts for scientific and technical merit. Awards can be expected to contain conditions and requirements related to performance and reporting. It is possible that some applications will be deemed more suitable and approvable as pilot projects that require further planning and preliminary work. In those circumstances, NCHSR may elect to award up to $50,000, total direct costs, and encourage resubmission in another fiscal year. Such resubmissions, however, will compete without favor over other applications in the subsequent cycles. The submission and review schedule is:

NIH/DRG Submission	Study Section Review	Earliest Start Date
February 1	June	September
June 1	October	February
October 1	February	June

Completed applications are to be sent or delivered to:

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

State and local government applicants must submit an original and two copies of the application; others are required to submit an original and six copies. Type "NCHSR-POARP Teams" in item 2 on the face page of the application. It is helpful to the program if the applicant sends an information copy of the application to:

NCHSR Director of Extramural Research
Parklawn Building, Room 18A-19
Rockville, Maryland 20857

A copy of the November 1988 program note on POARP extramural assessment teams can be obtained from:

Publications and Information Branch, NCHSR
Parklawn Building, Room 18-12
Rockville, Maryland 20857
Telephone: (301) 443-4100

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