

# NIH GUIDE

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**For Grants  
and  
Contracts**

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**U.S. DEPARTMENT OF HEALTH  
AND HUMAN SERVICES**

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 20, No. 38  
October 11, 1991

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NOTICES

HHS GRANTS AND CONTRACTS TRAINING COURSE

P.T. 34; K.W. 1014002, 1014006

Public Health Service

SUMMARY: The Office of the Assistant Secretary for Health, Department of Health and Human Services (HHS), announces a training course, "Orientation to U.S. Department of Health and Human Services Grants and Contracts Activities for Applicants and Recipients of Awards," that will be presented eight times at locations around the country during FY 1992. Complete information about locations and dates is provided below under SUPPLEMENTARY INFORMATION.

To receive consideration for a particular course session, applications must be received by the close of business on the deadline date specified under SUPPLEMENTARY INFORMATION below.

SUPPLEMENTARY INFORMATION

COURSE DESCRIPTION: This is a two-day course that is designed to provide applicants for and recipients of HHS grants and contracts a better understanding of the procedures and expectations in applying for funding and administering an award from HHS. Day One of the course concentrates on the grants process; Day Two is devoted to contracting. Students will be provided with a broad overview of conducting business with HHS including: the organization of the Department, when the grant or contract mechanism is used, the structure of HHS contracts and grants processes, how to identify grant and contract funding opportunities, how to submit effective proposals/applications, and how to properly administer a contract or grant after it has been awarded.

TARGET POPULATION: Grants and contracts staff of organizations that are presently doing business with HHS or that plan to submit applications for grants and/or proposals for contracts. The course is intended for staff who are inexperienced with the grant and contract mechanisms.

DATES - 1991	LOCATIONS	APPLICATION DEADLINES
Nov. 18-19	Atlanta, GA	November 1
Dec. 4 - 5	Rockville, MD	November 1
DATES - 1992		
Jan. 27-28	San Diego, CA	November 1
Mar. 18-19	Dallas, TX	November 1
May 18-19	San Francisco, CA	March 1
Jun. 15-16	Rockville, MD	March 1
Jul. 13-14	Boston, MA	March 1
Aug. 10-11	Chicago, IL	March 1

All courses will be held from 8:30 a.m. to 5:00 p.m. both days.

Selection will be made on a first-come, first-served basis. Early application is encouraged because these offerings are filled rapidly.

#### COURSE OUTLINE

##### DAY 1

Introduction to HHS Assistance (grants/cooperative agreements) and Acquisition (contracts): HHS Mission and Organizational Structure; Assistance vs. Acquisition (The Federal Grant and Cooperative Agreement Act); HHS Grant and Contract Expenditures and Recipients; Introduction to Types and Purposes of HHS Grants; Roles of HHS Grants and Program Management Staff.

Seeking and Applying for HHS Grants/Cooperative Agreements: Sources of Information; Understanding Program Announcements; The Application Package; The Complete, Effective Application; Competition and Objective Review.

Negotiation and Award Process for Grants/Cooperative Agreements: Cost Analysis and Preaward Review; Negotiating - Clarifying and Revising Proposed Activities; Funding Outcomes; Contents of a Grant Award Document; General and Special Conditions.

Grant/Cooperative Agreement Post-Award Issues and Concerns: Monitoring; Audit; Appeals; Progress Reports; Drawdowns; Financial Status Reports; Grant Budget Control; Cost Principles and Unallowable Costs; Purchasing; Property Management.

##### DAY 2

Seeking HHS Contracts: Identifying HHS Contracting Opportunities; The Legal Framework of HHS Contracting; Small Business Contracting Programs; Roles of HHS Contracting and Project Staff.

Responding to Contract Solicitations: Small Purchases - \$25,000 or Less; Purchases Greater Than \$25,000; Preparing the Technical Proposal; Preparing the Business Proposal.

Proposal Submission, Contract Negotiation, and Award: Proposal Submission and Evaluation; Negotiation and Award.

Contract Administration: Initial Contract Administration Steps; Significant Contract Administration Concerns.

CLASS SIZE: Limited to 30 participants per session to maximize interaction and only one individual per institution, per session.

ATTENDANCE: Those accepted will be expected to attend both days of the course. A Certificate of Attendance will be issued to all participants who attend for both days.

COST: There will be no charge for this course. Travel and accommodations will be the responsibility of participants.

#### NOTIFICATION OF APPLICANTS

Applicants selected will be notified of their acceptance and provided with information on the exact location of courses and suggested accommodations. Persons not selected will not be notified.

TO APPLY: Submit a letter on the employing organization's letterhead that provides the following information:

Name of applicant  
Employing organization: name, address, and telephone number  
Position title of applicant  
Years of experience with HHS grants, contracts, or both

Principal area of interest (grants, contracts, or both)  
Reason for wanting to take this course (100 words or less)  
Course session desired

SEND LETTER OF APPLICATION TO:

Training Coordinator  
Grants Policy Branch  
Division of Grants and Contracts  
Office of the Assistant Secretary for Health, HHS  
Parklawn Building, Room 17A-45  
5600 Fishers Lane  
Rockville, MD 20857

NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

National Institutes of Health  
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

NORTH MIDWESTERN WORKSHOP

DATES: October 17 and 18, 1991

WORKSHOP SITE:  
Westin Hotel  
Renaissance Center  
Detroit, MI  
Telephone: (313) 568-8000

SPONSORS:  
Children's Hospital of Michigan  
3901 Beaubien Blvd.  
Detroit, MI 48201

Wayne State University  
4237 Scott Hall  
Detroit, MI 48201

REGISTRATION CONTACT:  
Mr. Jerome Wilczynski  
Vice President for Operations  
Children's Hospital of Michigan  
3901 Beaubien Blvd.  
Detroit, MI 48201  
Telephone: (313) 745-5450

TOPIC: Protection of Human Subjects in Research: The Vulnerable Patient

WEST COAST WORKSHOP

DATES: January 23 and 24, 1992 (REVISED DATES)

WORKSHOP SITE: Los Angeles, CA

SPONSORS:  
University of Southern California  
Los Angeles, CA 90089-4014

California State University - Los Angeles  
5151 State University Drive  
Los Angeles, CA 90032-8202

REGISTRATION CONTACT:  
Ms. Lily Patterson  
Assistant to the Director  
Research and Sponsored Programs  
California State University - Los Angeles  
5151 State University Drive  
Los Angeles, CA 90032-8202  
Telephone: (213) 343-3820

TOPIC: Protection of Human Subjects

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:  
University of Texas Health Science Center at San Antonio  
7703 Floyd Curl Drive  
San Antonio, TX 78284-7972

St. Mary's University  
One Camino Santa Maria  
San Antonio, TX 78228-8572

REGISTRATION CONTACT:  
Ms. Angie Khan  
Institutional Coordinator of Research Review  
University of Texas Health Science Center at San Antonio  
7703 Floyd Curl Drive (Room 402L)  
San Antonio, TX 78284-7972  
Telephone: (512) 567-2351

TOPIC: Identifying and Assessing Risks in Human Subject Research

NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

SPONSORS:  
University of Pennsylvania  
133 South 36th Street  
Suite 300  
Philadelphia, PA 19104-3246

Lincoln University  
Lincoln University, PA 19352

REGISTRATION CONTACT:  
Ms. Lynn Bevan  
Assistant Director  
Office of Research Administration  
University of Pennsylvania  
133 South 36th Street, Suite 300  
Philadelphia, PA 19104-3246  
Telephone: (215) 898-2614

TOPIC: The Shifting Ground: Current Issues for the Protection of Human Subjects on Biomedical and Behavioral Research

For further information regarding these workshops and future NIH/FDA National Protection of Human Subjects Workshops, please contact:

Ms. Darlene Marie Ross  
Executive Assistant for Education  
Division of Human Subject Protections  
Office for Protection from Research Risks  
National Institutes of Health  
9000 Rockville Pike

Building 31, Room 5B59  
Bethesda, MD 20892  
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

COLLABORATIVE STUDIES ON THE GENETICS OF ASTHMA

RFA AVAILABLE: HL-92-04-L

P.T. 34; K.W. 0715013, 1002019, 1002058, 0760015

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: February 3, 1992

Application Receipt Date: April 6, 1992

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. The purpose of this initiative is to encourage collaborative molecular genetic studies of asthma in human pedigrees, combining molecular genetic and cellular approaches with rigorous statistical genetic techniques, to provide a better understanding of the major genes involved in asthma.

The program will have the participation of the National Institute of Allergy and Infectious Diseases (NIAID) scientific staff; NIAID has particular interest in study components related to immune markers for asthma.

HEALTHY PEOPLE 2000

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

MECHANISM OF SUPPORT

The support mechanism for this program will be the cooperative agreement (U01), an assistance mechanism that is similar to the traditional NIH research grant. It differs from a research grant in the extent and nature of NHLBI staff involvement. Although the financial plans for fiscal year 1992 include \$2,250,000 for the total costs of this program, awards pursuant to this RFA are contingent upon receipt of funds for this purpose. It is anticipated that up to three awards will be made under this program. The specific number to be funded, however, will depend on the merit and scope of the applications received and the availability of funds.

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

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

ELIGIBILITY

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

INQUIRIES

Inquiries regarding this program and requests for the RFA document may be addressed to:

Susan P. Banks-Schlegel, Ph.D.  
Project Scientist, Asthma and Cystic Fibrosis  
Division of Lung Diseases  
National Heart, Lung, and Blood Institute  
Westwood Building, Room 6A15  
Bethesda, MD 20892  
Telephone: (301) 496-7332  
FAX: (301) 496-9886

For fiscal and administrative matters, contact:

Tanya McCoy  
Grants Management Specialist  
Grants Operations Branch  
Division of Extramural Affairs  
National Heart, Lung, and Blood Institute  
Westwood Building, Room 4A17  
Bethesda, MD 20892  
Telephone: (301) 496-4970

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.838. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended: 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to review by a Health Systems Agency.

#### GRANTS FOR HEALTH SERVICES DISSERTATION RESEARCH

RFA AVAILABLE: HS-92-01

P.T. 34; K.W. 0730050, 0745035

Agency for Health Care Policy and Research

Application Receipt Date: January 23, 1992

#### PURPOSE

The Agency for Health Care Policy and Research (AHCPR) announces the availability of a Request for Applications (RFA) for grants for health services dissertation research. The AHCPR conducts research that will enhance the quality, appropriateness, and effectiveness of health care services. The provision of dissertation grant support is part of the effort of the AHCPR to stimulate the development of innovative and timely research on issues related to the delivery of health care services. Grant support is designed to aid the career development of new health services researchers and to encourage individuals from a variety of academic disciplines and programs to study complex health services delivery problems.

#### HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. AHCPR urges applicants to submit grant applications with relevance to specific objectives of this initiative. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report; Stock No. 017-001-00474-0) (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, (telephone 202-783-3238).

#### ELIGIBILITY REQUIREMENTS

A student applying for a dissertation research grant must be enrolled in an accredited doctoral degree program in the social, management, medical, or health sciences. The student must also be conducting or intending to conduct dissertation research on issues related to the delivery of health care services as described below. The proposed Principal Investigator must be a registered doctoral candidate in resident or nonresident status. All requirements for the doctoral degree other than the dissertation must be completed by the time of the award. This information must be verified in a letter of certification from the thesis chairperson and submitted with the grant application (see Application Requirements).

The applicant may be either the institution that will administer the grant on behalf of the proposed Principal Investigator or the proposed Principal Investigator applying as an individual. Whenever feasible, the proposed Principal Investigator is encouraged to have the application administered through an institution.

A proposed Principal Investigator for dissertation research grant support need not be a citizen of the United States. However, an investigator who is not a citizen and does not have a permanent resident visa must apply through an institution.

#### MECHANISM OF SUPPORT

This RFA will use the AHCPR grant-in-aid (R03). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement.

## FUNDS AVAILABLE

AHCPR expects to fund about 10 to 20 dissertation research projects in 1992. Awards will depend on the availability of funds.

## RESEARCH OBJECTIVES

Only applications that propose studies in the areas identified in section 902 of the Public Health Service Act are eligible for support. Section 902 authorizes research in the following areas:

- o Effectiveness, efficiency, and quality of health care services
- o Outcomes of health care services and procedures
- o Clinical practice, including primary care and practice-oriented research
- o Health care technologies, facilities, and equipment
- o Health care costs, productivity, and market forces
- o Health promotion and disease prevention
- o Health statistics and epidemiology
- o Medical liability

Applicants are encouraged to discuss the suitability of their research topics by letter or by phone with AHCPR staff members.

## SPECIAL REQUIREMENTS

The budget of an application for a dissertation research grant must not exceed \$20,000 in total direct costs for the entire project period. An application that exceeds this amount will be returned to the applicant.

Investigators must only request support for the amount of time necessary to complete the dissertation. A dissertation research grant usually is awarded for a period of 12 months or less but may be awarded for up to 17 months.

An investigator who receives support for dissertation research under a grant from AHCPR may not at the same time receive support under a predoctoral or fellowship grant awarded by any other agency of the U.S. Department of Health and Human Services.

## SPECIAL INSTRUCTIONS TO APPLICANTS CONCERNING INCLUSION OF WOMEN AND MINORITIES IN RESEARCH STUDY POPULATIONS

AHCPR observes NIH policy requiring applicants for research grants to include minorities and women in study populations. If women or minorities are excluded or inadequately represented in research, a clear compelling rationale should be provided. All applications for research submitted to AHCPR are required to address this policy with respect to the inclusion of women and minorities. Applications without such documentation will not be accepted for review.

## REVIEW CONSIDERATIONS

Dissertation research grant applications will be reviewed under AHCPR review procedures by non-Federal experts, senior AHCPR staff members, and other experts in the Federal Government. Reviewers will be selected on the basis of their health services research accomplishments and knowledge and their experience in research career development. Because reviews are rigorous, considerable methodological detail is important in the narrative of the application. All elements of the application will be considered in the review process. Primary emphasis will be given to the scientific merit, feasibility, and relevance of the project to the AHCPR research priorities noted above.

Applications may be subject to triage to determine their scientific merit relative to other applications received in response to this RFA. The AHCPR will withdraw from further competition those applications judged by triage to be noncompetitive for award and notify the Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review. Review results and funding decisions will be announced approximately five months after the submission date. Review criteria, funding decisions, and continuation of support are described below.

### Review Criteria

Applications are reviewed to determine their suitability to review criteria in four major areas: problem significance, research design, personal qualifications and support structure, and budgetary appropriateness. Detailed criteria for these areas, as they relate to dissertation research, are provided in the RFA.



## APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 10/88) must be used in applying for these grants, in accordance with the special instructions described here and in the application kit. Research grant application materials, special instructions for dissertation grant applications, and the RFA are available from:

Moshman Associates Inc.  
7315 Wisconsin Avenue  
Suite 410, North Tower  
Bethesda, MD 20814  
Telephone: (301) 229-3000

Applications must be submitted by Thursday, January 23, 1992, to Division of Research Grants, Westwood Building, Room 240, National Institutes of Health, Bethesda, MD 20892\*\*. A letter from the faculty committee or university official directly responsible for supervising the development and progress of the dissertation research must be submitted with the application. The letter must (1) fully identify the members of the committee and certify their approval of the dissertation proposal, (2) certify that all requirements for the doctoral degree except the dissertation are completed (or will be completed by the time for the grant award), and (3) note that the university official or faculty committee expects the doctoral candidate to proceed with the approved project proposal with or without AHCPR support.

## FUNDING DECISIONS

Reviewers will provide recommendations with regard to the scientific and technical merit of the application and whether it should receive further consideration. Funding decisions are based on the recommendations of the reviewers, the relevance of the project to program priorities, and the availability of appropriated funds.

## INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged. Direct inquiries regarding instructions for completing the application and requests for the RFA to:

Office of Scientific Review  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A-20  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-3091

Direct inquiries regarding fiscal and administrative matters to:

Ralph Sloat  
Chief, Grants Management Branch  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A-27  
Rockville, MD 20857  
Telephone: (301) 443-4033

## AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.226. Awards are made under authority of title IX of the Public Health Service Act, as amended (42 USC 299), and administered under PHS grants policies and in accordance with regulations of Title 42 of the Code of Federal Regulations, Part 67, Subpart A. The requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," are not applicable to AHCPR research grant programs.

## NEW THERAPIES FOR THE TREATMENT AND CURE OF CYSTIC FIBROSIS

RFA AVAILABLE: DK-92-02

P.T. 34; K.W. 0715165, 0755035, 0755040

National Institute of Diabetes and Digestive and Kidney Diseases  
National Heart, Lung, and Blood Institute  
Cystic Fibrosis Foundation

Letter of Intent Receipt Date: January 17, 1992  
Application Receipt Date: February 21, 1992

## PURPOSE

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Heart, Lung, and Blood Institute (NHLBI), and the Cystic Fibrosis Foundation (CFF) announce the availability of a Request for Applications (RFA) for investigator-initiated research grant applications to develop and characterize new therapeutic approaches for the treatment and ultimate cure of cystic fibrosis (CF).

This solicitation is intended to capitalize on the identification of the CF gene, encoding the cystic fibrosis transmembrane conductance regulator (CFTR) protein, and many of the mutations responsible for the defective function of this protein in CF. This program will augment the ongoing NIDDK, NHLBI, and CFF research programs in CF by providing an opportunity for investigators to translate progress in understanding the etiology and pathophysiology of CF into advances in treatment of CF.

The identification and cloning of the CF gene and prediction of the structure of its protein product now present the opportunity to direct therapy of CF at the basic defect. Promising approaches include gene therapy, protein therapy, and pharmacologic therapy. These developments together with recent advances in gene transfer technology, structure/function analysis, membrane physiology, development of immortalized cells, and other systems for study of CF should permit development of these therapeutic approaches.

## MECHANISM OF SUPPORT

The NIDDK and the NHLBI plan to support approximately 10 to 12 applications submitted in response to this solicitation and \$2 million for this program has been included in the financial plans for fiscal year 1992. However, the specific number of applications to be funded will depend upon the overall merit, the scope of the applications received, and availability of funds. The CFF anticipates supporting a similar number of applications. Although this solicitation is included in the NIDDK and NHLBI funding plans for Fiscal Year 1992, support for this solicitation is contingent upon receipt of appropriated funds for this purpose. Since a variety of approaches would represent valid responses to this solicitation, it is anticipated that there will be a range of costs among individual grants awarded, however, prudent principles of cost-containment should be applied. With respect to post-award administration, the current policies and requirements that govern the research grant programs of the NIH as described in the PHS Grants Policy Statement will prevail.

Projects within the upper 40th percentile of the NIH- approved but unfunded applications are eligible for support by the Cystic Fibrosis Foundation (CFF). Principal investigators will be responsible for forwarding copies of their critiques and applications to the CFF for consideration for this award mechanism. CFF support will be determined by project scope, and duration of funding will be limited to two years; no funds for indirect costs will be provided.

## REVIEW PROCEDURES AND CRITERIA

Upon receipt, applications initially will be reviewed by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Applications also will be reviewed by NIH staff for responsiveness to the objectives of this RFA. Applications will first be reviewed for scientific and technical merit by an Initial Review Group, that will be convened by the Review Branch, Division of Extramural Activities, NIDDK. This group will be composed primarily of non-federal scientific consultants. The applications will then be reviewed by the National Diabetes and Digestive and Kidney Diseases Advisory Council and the National Heart, Lung and Blood Advisory Council. Review criteria include the extent of relevance and/or contribution of the proposed research to the overall goals and objectives of the RFA; the novelty, originality, and feasibility of the approach; the training, experience, and research competence of the investigator(s); the adequacy of the experimental design; the suitability of the facilities; and the appropriateness of the requested budget to the work proposed.

## METHODS OF APPLYING

Applications must be submitted on form PHS 398 (rev. 10/88), which is available from an applicant institution's Office of Sponsored Research and from the NIH Division of Research Grants, Office of Grants Inquiries, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892 (telephone: 301/496-7441). Applicants must use the conventional format for research project grant applications and ensure that the points identified in this announcement are fulfilled. To identify the application as a response to this RFA, check "yes" on item two of page one of the application and enter the title "New Therapies for the Treatment and Cure of Cystic Fibrosis" and the RFA number DK-92-02. The complete timetable for review is available in the RFA.

NIH policy requires that applicants for clinical research grants and cooperative agreements include minorities and women in study populations so that research findings can benefit all persons with the disease, disorder or condition under study. Specific information concerning the NIH policy on inclusion of women and minorities can be found in the NIH Guide for Grants and Contracts Vol. 19, No. 31, August 24, 1990, pages 18-19, and Vol. 19, No. 35, September 28, 1990, respectively.

As in the case with research project grant applications, applicants are requested to furnish their own estimates of the time required to achieve the objectives of the proposed research project. At the end of the initial award period, renewal applications may be submitted for further competitive review through the traditional research grant program of the NIH.

Applications must be received by February 21, 1992. Any application not received by this date will be returned to the applicant.

#### INQUIRIES

It is essential that investigators obtain the RFA. For copies of the full RFA or for further information, investigators should contact the following individuals:

Judith Fradkin, M.D.  
Chief, Endocrinology and Metabolic Diseases Programs Branch  
Division of Diabetes, Endocrinology, and Metabolic Diseases  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 603  
Bethesda, MD 20892  
Telephone: (301) 496-7791

Susan Banks-Schlegel, Ph.D.  
Director, Asthma and Cystic Fibrosis Program  
Division of Lung Disease  
National Heart, Lung, and Blood Institute  
Westwood Building, Room 6A15  
Bethesda, MD 20892  
Telephone: (301) 496-7332

For fiscal and administration matters contact:

Sharon Tempchin  
Grants Management Specialist  
Grants Management Branch  
Division of Extramural Activities  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 639  
Bethesda, MD 20892  
Telephone: (301) 496-7467

Tanya T. McCoy  
Grants Management Specialist  
Grants Operations Branch  
Division of Extramural Affairs  
National Heart, Lung, and Blood Institute  
Westwood Building, Room 4A17  
Bethesda, MD 20892  
Telephone: (301) 496-4970

For more information about the CFF funding mechanism, contact:

Cystic Fibrosis Foundation  
6931 Arlington Road  
Bethesda, MD 20814  
Telephone: (301) 951-4422

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.838, Lung Diseases Research, and No. 93.847, Diabetes, Endocrinology, and Metabolism. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

#### ONGOING PROGRAM ANNOUNCEMENTS

##### RESEARCH GRANTS ON NEURAL SYSTEMS AND MENTAL, NEUROLOGICAL AND AGING DISORDERS

PA: PA-92-07

P.T. 34; K.W. 0705055, 0710010, 0715138

National Institute of Mental Health  
National Institute of Neurological Disorders and Stroke  
National Institute on Aging

## INTRODUCTION AND BACKGROUND

The National Institute of Mental Health (NIMH), the National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute on Aging (NIA) invite applications for any of the available research grant mechanisms to fund research that incorporates neural systems research into the study of brain function and behavior. The understanding of functional neural systems is of fundamental interest to NIMH, NINDS and NIA, because abnormalities of specific neural systems may underlie behavioral and functional disorders.

Neural systems research refers to studies of the interactions between individual neurons, groups of neurons, or nuclei within the brain. The key factor is the multi-synaptic nature of such interactions. The aim of the neural systems research supported under this announcement is to define particular circuits and to understand the contribution(s) of circuit elements in normal and abnormal brain function. Independent measures include, but are not limited to, the following disciplines: anatomy, physiology, biochemistry, pharmacology, psychology, and other behavioral sciences. Also of interest would be studies of the potential plasticity of the cellular elements subsequent to neuronal cell loss and/or injury. Studies are also encouraged that aim to clarify functional changes across the life span and the impact of the endocrine and immune systems, and the environment on the functional activity of the neural circuit.

In these early years of the "Decade of the Brain," many of the technical and analytical tools needed for studying and understanding the brain and its myriad systems are in place. To capitalize on these significant opportunities for rapid progress at this auspicious time, NIMH, NINDS, and NIA emphasize their commitment to provide funding for neural systems research.

### SCOPE

Applications are requested for the following mechanisms: traditional research grants (R01), First Independent Research Support and Transition (FIRST) awards (R29), small grants (R03), program projects (P01), institutional training grants (T32), career development awards (K-series), and individual fellowships (F-series), for research and research training for the study of the normal and abnormal functioning of neural systems, including development, maintenance, and pathology over the life span of the organism. The following are examples of broad research topics that would be of interest. This list is not intended to be comprehensive, nor are the examples meant to be exclusive.

- o Neuroanatomical identification of neural circuits and their intrinsic connectivity and interactions with other circuits that form the basis of normal and abnormal behaviors
- o Immunocytochemical localization of neuropeptides and in situ hybridization quantitation of neuropeptide gene expression in neural circuits subserving specific functions
- o Electrophysiological studies of the activity of neurochemically discrete populations of neurons and neural circuits
- o Biochemical characterization of neurotransmitters in neuronal pathways mediating specific behaviors and elucidation of the functional dynamics of these circuits
- o Neuroanatomical, functional, and biochemical interactions among the nervous, endocrine, and immune systems
- o Organization of circadian systems and the interaction between these systems and neuroendocrine, neuropeptide, and neurotransmitter systems
- o The influence of behavioral and environmental factors, such as stress or experience, in altering the structure and function of specific neural circuits
- o Characterization of the host-graft neural circuit interactions involved in brain tissue transplantation
- o Developmental studies of neural circuit maturation; the role of trophic factors in neural pathway maintenance, neural circuit plasticity, and response to injury
- o Mechanisms underlying atypical synaptic connectivity or organization in specific neural circuits that may lead to mental disorders
- o Structural and functional studies of the cortical and subcortical systems that have been implicated in the pathophysiology of mental disorders, exclusive of the neurodegenerative diseases of the aged
- o Functional brain imaging studies of neural circuits involved in behavioral processes that have been shown to be aberrant in mental disorders

Applications may include any of a wide array of methods and approaches, for example, histochemical, electrophysiological, neurochemical, neuropharmacological, and neuroimaging. The studies may be conducted on humans and/or animals.

## ELIGIBILITY

Applications may be submitted by public or private, nonprofit or for-profit organizations such as universities, colleges, hospitals, laboratories, research institutions, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

## APPLICATION RECEIPT AND REVIEW SCHEDULE

Dates for the submission of new research applications (R01, R29, R03, P01, and K-series) and review cycles are as follows:

Receipt Dates	IRG Review	Council Review	Earliest Award
Feb 1/Mar 1*	May/Jun	Sep/Oct	Dec 1
Jun 1/Jul 1*	Oct/Nov	Jan/Feb	Apr 1
Oct 1/Nov 1*	Feb/Mar	May/Jun	Jul 1

\*Amended research applications and competing renewals are to be submitted on the latter dates.

Applications received after the above receipt dates are subject to assignment to the next review cycle or may be returned to the applicant.

BECAUSE INSTITUTIONAL TRAINING GRANTS (T32) AND INDIVIDUAL FELLOWSHIP APPLICATIONS (F-series) HAVE DIFFERENT DEADLINES AND APPLICATION PROCEDURES, APPLICANTS ARE ADVISED TO CONTACT PROGRAM STAFF LISTED BELOW AND OBTAIN NECESSARY DOCUMENTATION PERTAINING TO THOSE MECHANISMS.

## APPLICATION PROCESS

Applicants must use the current version of grant application form PHS 398 (rev. 10/88) for research and training (T32) grants or application form PHS 416 (rev. 4/89) for fellowships. The number and title of the program announcement, "PA-92-07, NEURAL SYSTEMS AND MENTAL, NEUROLOGICAL AND AGING DISORDERS," must be typed in item number 2 on the face page of the PHS 398 application form or item 3 on the face page of the PHS 416.

Application kits containing the necessary forms and instructions for research grants may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the program officials listed below may be contacted for the necessary application material.

The signed original and the appropriate number of legible copies of the completed application must be sent to:

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

## REVIEW PROCESS

The Division of Research Grants, NIH, serves as a central point of receipt of applications for most PHS discretionary grant programs. Interest areas indicated in this announcement overlap with those of other Institutes. The customary peer review procedures will apply. The initial review groups, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by the appropriate national advisory council whose review may be based on policy considerations as well as scientific merit.

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

Applications for ADAMHA and NIH grants and cooperative agreements are required to include both women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including either women or minorities is provided. This requirement is intended to ensure that research findings will be of benefit to all persons at risk of the disease, disorder, or condition under study. For the purpose of these policies, clinical research involves human studies of etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders or conditions, including but not limited to clinical trials; and minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics).

ADAMHA and NIH recognize that it may not be feasible or appropriate in all clinical research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

Applications should include a description of the composition of the proposed study population by gender and racial/ethnic group, and the rationale for the numbers and kinds of people selected to participate. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applications should incorporate in their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities in sufficient numbers to permit assessment of differential effects is not feasible or is not appropriate, the reasons for this must be explained and justified. The rationale may relate to the purpose of the research, the health of the subjects, or other compelling circumstances (e.g., if in the only study population available there is a disproportionate representation in terms of age distribution, risk factors, incidence/prevalence, etc., of one gender or minority/majority group).

If the required information is not contained within the application, the review will be deferred until it is complete. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If gender and/or minority representation/justification are judged to be inadequate, reviewers will consider this as a deficiency in assigning the priority score to the application.

All applications for clinical research are required to address these policies. Funding components will not award grants that do not comply with these policies.

#### REVIEW CRITERIA

Applications will be reviewed in accordance with the standard criteria appropriate for the grant mechanism.

#### AWARD CRITERIA

Awards will be made on the basis of overall scientific and technical merit of the research as determined by peer review, the program needs and balance of the awarding Institute, and availability of funds.

#### TERMS AND CONDITIONS OF SUPPORT

Grant funds may be used for expenses clearly related and necessary to conduct research projects, including direct costs that can be specifically identified with the project and allowable indirect costs of the institution. Funds may not be used to establish, add a component to, or operate a treatment, rehabilitation, or prevention intervention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for costs required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield generalizable knowledge and/or make a significant contribution to theoretical concepts.

Grants must be administered in accordance with the PHS Grants Policy Statement (rev. 10/90). Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards.

#### PERIOD OF SUPPORT

Support may be requested for a period of up to five years or up to three years for fellowships. Annual awards will be made subject to continued availability of funds and progress achieved. A competing supplemental application may be submitted during an approved period of support to expand the scope or protocol of a project during the approved period. A competing continuation (i.e., renewal) application may be submitted before the end of an approved period of support to continue a project.

#### INQUIRIES

Additional information concerning this announcement may be obtained by contacting:

Michael F. Huerta, Ph.D., Chief  
Neural Systems Program  
Division of Basic Brain and Behavioral Sciences  
National Institute of Mental Health  
5600 Fishers Lane, Room 11-105  
Rockville, MD 20857  
Telephone: (301) 443-3948  
Fax: (301) 443-4822

Herbert C. Lansdell, Ph.D.  
Division of Fundamental Neurosciences  
National Institute of Neurological Disorders and Stroke  
Federal Building, Room 916  
Bethesda, MD 20892  
Telephone: (301) 496-5745  
Fax: (301) 402-1501

Andrew A. Monjan, Ph.D., M.P.H.  
Deputy Associate Director  
Neuroscience and Neuropsychology of Aging Program  
National Institute on Aging  
9000 Rockville Pike  
Bethesda, MD 20892  
Telephone: (301) 496-9350  
Fax: (301) 496-1494

Information on grants management issues may be obtained from:

Steven J. Hudak  
Grants Management Section  
National Institute of Mental Health  
5600 Fishers Lane, Room 7C-26  
Rockville, MD 20857  
Telephone: (301) 443-4596

Patricia Driscoll  
Grants Management Branch  
National Institute of Neurological Disorders and Stroke  
Federal Building, Room 1004  
7500 Wisconsin Avenue  
Bethesda, MD 20892  
Telephone: (301) 496-9231

Margaret Kuhn  
Grants Management Office  
National Institute on Aging  
Building 31, Room 5C07  
Bethesda, MD 20892  
Telephone: (301) 496-1472

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.242, 93.853, 93.854. Awards are made under the authority of Section 301 of the Public Health Service Act as amended, PL 78-410, 42 U.S.C. 241, the National Institute of Mental Health, the National Institute of Neurological Disorders and Stroke, and the National Institute on Aging will accept applications in response to this announcement under the receipt dates listed herein.

#### NATIONAL RESEARCH SERVICE AWARD INDIVIDUAL FELLOWSHIPS

PA: PA-92-08

P.T. 22; K.W. 0720005, 0730050

Application Receipt Dates: January 10, May 10, and September 10

Agency for Health Care Policy and Research

#### PURPOSE AND SCOPE

The Agency for Health Care Policy and Research (AHCPR) announces the availability of postdoctoral National Research Service Award (NRSA) individual fellowships (F32) in health services research. These postdoctoral research fellowships provide opportunities for academic training as well as experience in applying research methods to the systematic analysis and evaluation of the organization, financing, utilization, and delivery of health care services. Trained health services researchers have an opportunity to address current policy issues and contribute to an understanding and resolution of problems in the Nation's health care system.

Applied health services research draws on a variety of conceptual and statistical models to address policy issues. This often requires collaborative efforts among various disciplines, employment of empirical approaches, and analysis of complex data sets.

NRSA research training must provide the conceptual and methodological foundation to empirically address a variety of topics, including the following:

- o Medical effectiveness and patient outcomes research
- o Health care services for underserved/disadvantaged populations (for example, minority health issues, rural health care, methods to improve access/availability)

- o Costs, access, and quality of care for the uninsured and underinsured
- o Health care services for individuals with HIV infections
- o Medical liability issues and malpractice
- o Clinical practice-oriented primary care, including the natural history and management of conditions commonly encountered in primary care practice
- o Relationships between allocations of health care resources and their effects on health status and outcomes
- o Factors affecting the dissemination and transfer of health care technologies and the design of new methods to assess these technologies
- o Cost-effectiveness and cost-benefit analysis of diagnostic procedures and therapeutic interventions
- o Health problems of the frail and elderly, studying such factors as the sources of funding, alternative modes of care, and the availability and nature of care provided by physicians and other providers, including informal support
- o Epidemiology of chronic illness and geriatric medicine
- o Health economics and the role of market forces in health care delivery

AHCPR plans to award a limited number of fellowships each fiscal year as funds are available. There are three application and review cycles per year. See the schedule below for application deadlines, dates for review and notification of award, and possible start dates. This announcement is in effect until a replacement or termination notice is published.

#### ELIGIBILITY

Applicants for postdoctoral fellowships must, at the time they apply, be citizens of the United States, noncitizen nationals, or noncitizens who have been lawfully admitted to the United States for permanent residence and have in their possession an Alien Registration Receipt Card (I-151 or I-551). Noncitizen nationals are persons who, although not U.S. citizens, owe permanent allegiance to the United States. They are generally persons born in lands that are not States but are under the sovereignty, jurisdiction, or administration of the United States, such as American Samoa. Individuals on temporary or student visas are not eligible.

Applicants must have received, by the beginning date of the NRSA appointment, a Ph.D., M.D., D.M.D., or equivalent doctoral degree from an accredited domestic or foreign institution. Certification from an authorized official of the degree-granting institution that all degree requirements have been met is acceptable.

An NRSA fellowship may not be used to support studies leading to the M.D., D.D.S., D.O., or equivalent professional degree nor do they support residency training.

#### APPLICATIONS

Prior to making formal application, an individual applicant must be accepted by an appropriate institution and by a sponsor who will supervise the training and research experience. The organizational setting must be nonprofit, either public or private. The applicant's research training plan must include a description of the proposed activities under award and the aims, significance, and experimental design and methods of the research proposal. The sponsor must describe in detail the research training plan and the availability of suitable staff and facilities. Formal training is not necessarily limited to a single academic institution or discipline. The sponsor must be an established investigator who is active in health services research and who personally will supervise the applicant's training and research program.

Fellowship applicants requesting continued training at the doctorate institution or under the same sponsor at an institution where they have been training for more than a year must describe those opportunities for new or additional training experiences that will broaden the scientific background and perspective.

Period of support: Applications may be for one, two, or three years of fellowship support. No one is eligible for more than three years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional training grants and individual research fellowships.

Submission and review: Applicants must submit the original and two copies of form PHS 416-1 (rev. 7/88 or 4/89), Individual National Research Service Award Application. If the applicant is a noncitizen national, a notarized statement of permanent residence is required. NRSA fellowship application material is available from:



Director, Office of Scientific Review  
 Agency for Health Care Policy and Research  
 Parklawn Building, Room 18A-20  
 Rockville, MD 20857  
 Telephone: (301) 443-3091

Applications are NOT to be sent to AHCPR. As shown on the mailing label in the application package, completed applications must be addressed as follows:

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

The following is the schedule for individual NRSA application receipt and review for fellowship applications assigned to AHCPR:

Application Receipt Deadline	Study Section Review	Notification to Applicant	Earliest Possible Start Date
September 10	February	April	May
January 10	June	July	August
May 10	October	November	December

#### REVIEW CRITERIA

Applications for NRSA fellowships will be reviewed by an appropriate review committee that includes non-Federal consultants from appropriate scientific fields. The committee will use the following criteria in evaluating applications:

- o Applicant's past academic and research accomplishments
- o Applicant's research goals
- o Research training program proposed
- o Qualifications of sponsor and appropriateness of the training environment
- o Reference reports and other relevant information

The recommendations of the review committee, program interests, and availability of funds will be considered in making the final selection of awardees.

#### STIPENDS AND OTHER TRAINING COSTS

Research fellowship awards include a stipend for the fellow and an allowance to the sponsoring institution. The stipend level is determined by the number of years of relevant postdoctoral experience at the time the award is issued. Relevant experience may include research experience, teaching, internship, residency, and other time spent in full-time studies in a health-related field beyond that of the qualifying doctoral degree. Postdoctoral stipends as of August 1991 are listed below:

Years of relevant experience	Annual stipend	Years of relevant experience	Annual stipend
None	\$18,600	4	\$28,200
1	19,700	5	29,500
2	25,600	6	30,800
3	26,900	7 or more	32,300

AHCPR will provide up to \$3,000 per 12-month period to non-Federal sponsoring institutions to cover such awardee expenses as tuition and fees, health insurance, research supplies, equipment, travel to scientific meetings, and related items. No allowance is provided for dependents or for an individual's travel to the training site.

The Tax Reform Act of 1986 (P.L. 99-514) affected the tax liability of all individuals supported under National Research Service Awards 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 (IRS) and the courts. Potential applicants should consult IRS to clarify the applicability of the tax laws to their situations and to determine what steps must be taken to fulfill tax obligations.

## CONDITIONS OF THE AWARD

Fellowships are awarded for full-time research training. However, it is recognized that there is a close interrelationship between teaching and research in the academic environment. Fellows are permitted, with the approval of the sponsor, to undertake teaching that can contribute meaningfully to their academic training. Any teaching undertaken by a fellow may not occupy more than ten percent of work time during the year or exceed four hours per week.

NRSA stipends may be supplemented by the sponsoring institution from non-Federal funds. No Federal funds may be used for stipend supplementation without permission from AHCPR. Under no circumstances may the conditions of stipend supplementation detract from or prolong the training.

An NRSA research fellowship may not be held concurrently with another Federally sponsored fellowship or similar Federal award that provides a stipend or otherwise duplicates provisions of the NRSA. However, an individual may accept concurrent educational remuneration from the Department of Veterans Affairs, such as support under the G.I. Bill and Federal loan funds.

Activation: The awardee must start work on the fellowship within six months of the date of issue of the award notice.

Payback provision: Before an award is made, the fellow must sign an agreement to fulfill the legislatively mandated payback requirements. Recipients are required to agree to conduct full-time health services research or related teaching or both for a period of time equal to the period of NRSA support in excess of 12 months. The NRSA Project Officer may be contacted for further specifics of the payback provision. After an individual has had 12 months of NRSA support, all subsequent support is subject to payback.

Recipients must begin the obligated service on a continuous basis within two 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 three years.

Under certain conditions, the Secretary of Health and Human Services may extend the period for undertaking service or for repayment, permit breaks in service, or otherwise waive or suspend the payback obligation of an individual.

## INQUIRIES

Further program information is available from:

NRSA Project Officer  
Center for Research Dissemination and Liaison  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A-10  
Rockville, MD 20857  
Telephone: (301) 443-2904

Further fiscal and administrative information is available from:

Chief, Grants Management Branch  
Agency for Health Care Policy and Research  
Parklawn Building, Room 18A-27  
Rockville, MD 20857

## AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.225. The authority for NRSA is Section 487 of the Public Health Service Act, as amended (42 U.S.C. 288). Title 42 of the Code of Federal Regulations, Part 66 and the PHS Grants Policy Statement are applicable. The requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs," are not applicable to AHCPR training grant programs.

\*\*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