

# NIH GUIDE

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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.

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## NOTICES

### NATIONAL INSTITUTES OF HEALTH ACQUIRED IMMUNODEFICIENCY SYNDROME RESEARCH LOAN REPAYMENT PROGRAM

P.T. 44; K.W. 1014006

National Institutes of Health

**SUMMARY:** Pending approval by the Office of Management and Budget (OMB) under the requirements of the Paperwork Reduction Act of 1980, the National Institutes of Health (NIH) announces the availability of educational loan repayment under the NIH Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program ("Program"). The Program, which is authorized by section 487A of the Public Health Service (PHS) Act (42 U.S.C. 288-1), as added by section 634 of the Health Omnibus Programs Extension of 1988 (Pub. L. 100-607), provides for the repayment of a sizeable portion of the accumulated educational loan debt of health professionals who agree to conduct, as employees of the NIH, research with respect to AIDS. The Program provides for repayment up to \$20,000 of the principal and interest of the educational loans of such health professionals for each year of such obligated service. The Program is limited to health professionals who have a substantial amount of educational loan debt relative to income, and who were NOT employed by the NIH during the period of November 4, 1987 through November 3, 1988. The purpose of the Program is to increase the number of persons conducting AIDS research at the NIH. The NIH, through this notice, invites health professionals interested in engaging in AIDS research to apply for participation in the NIH AIDS Research Loan Repayment Program.

**DATE:** Interested persons may request information about the Program and request applications beginning on December 1. Applications are presently under development, and a list of interested persons will be maintained to forward application materials once available.

**ADDRESS:** Information regarding the Program may be obtained by calling or writing:

Mr. Marc Horowitz, J.D.  
Director, NIH AIDS Research Loan Repayment Program  
Office of AIDS Research  
National Institutes of Health  
Shannon Building, Room 201  
9000 Rockville Pike  
Bethesda, Maryland 20892  
Telephone: (301) 496-0357

**SUPPLEMENTARY INFORMATION:** On November 4, 1988, the United States Congress enacted Public Law 100-607, the "Health Omnibus Programs Extension of 1988", which in part, directs the NIH to establish a program of educational loan repayment to attract additional investigators into AIDS research. The Program provides for the repayment of a sizeable portion of the accumulated educational loan debt of health professionals who are employed by the NIH after November 4, 1988, to engage in AIDS research.

Under the Program, the NIH will repay qualified educational loan debt incurred by health professionals to pay for their undergraduate, graduate, and/or medical educational expenses that exceeds 20 percent of the annual NIH salary or stipend at the rate of one-third of the debt each year, up to the statutory limit of \$20,000 per year for each year of obligated service, IF an individual selected to participate in the Program agrees to serve at least 2 years as an employee of the NIH engaged in AIDS research. Under the Program, participants may annually receive a pro rata share of the total available program funds, up to 1/3 of their accumulated debt or the statutory limit of \$20,000, whichever is less.

NIH will repay lenders for the principal, interest, and related expenses (such as the required insurance premiums on the unpaid balances of some loans) of qualified Government (Federal, State, local) and commercial educational loans obtained by participants for: (1) undergraduate, graduate, and health professional school tuition expenses; (2) other reasonable educational expenses required by the school(s) attended, including fees, books, supplies, educational equipment and materials, and laboratory expenses; and (3) reasonable living expenses, including the cost of room and board, transportation and commuting costs.

The following loans are NOT repayable under the Program: (1) loans not obtained from a Government entity or commercial lending institution, such as loans from friends and relatives; (2) loans for which contemporaneous documentation is not available; and (3) loans, or those portions of loans, obtained for educational or living expenses which exceed the "reasonable" level as determined by the standard school budget for the year in which the loan was made and are not judged by the NIH to be reasonable based on appropriate contemporaneous documentation.

In addition, for educational loans that contain provisions for loan forgiveness in exchange for a future service obligation, the NIH will NOT repay loans and/or penalties that may result from failure to serve as required under the conditions of such loans. This includes, but is not limited to: (1) Physicians Shortage Area Scholarship Program; (2) Public Health and National Health Service Corps Scholarship Program; (3) Armed Forces (Army, Navy, or Air Force) Health Professions Scholarship Programs; and (4) Indian Health Service Scholarship Program.

Finally, payments will NOT be made under the Program for loans that participants have already repaid.

In return for the repayment of their educational loans, participants must agree to: (1) engage PRIMARILY in AIDS research as employees of the NIH for a minimum period of 2 years; (2) make payments to lenders on their own behalf for periods of Leave Without Pay (LWOP); and (3) pay monetary damages as required for breach of the 2 year service obligation. Applicants must submit a signed contract, prepared by the NIH, containing this service agreement at the time they apply for consideration under the Program. Substantial monetary penalties will be imposed for breach of contract.

AIDS research could include such activities as studies of the human immunodeficiency virus, opportunistic agents, epidemiology, the pathophysiology of AIDS infection, the development of models of AIDS infection, cofactors predisposing to AIDS, and the development of prophylactic and therapeutic regimens. AIDS researchers include scientists who are intellectually engaged in the process of providing scientific direction and guidance in programs of original AIDS research, specifically epidemiologists, statisticians and others, who are involved in the design and conduct of research studies. The duties of such scientists may include the generation and design of studies; the collation and analysis of data; and/or the preparation and publication, as author or co-author, of studies in peer-reviewed journals.

Since the Program is designed for health professionals who have not yet repaid their educational loan debt, it is anticipated that most participants will still be in the developmental stages of their careers. Consequently, it is expected that most participants will be appointed as Clinical Associates (under the Commissioned Corps or service fellowship programs), or as Staff or Senior Staff Fellows. Participants who are more senior may be employed as NIH Special Experts or may be appointed in the competitive Civil Service or as Commissioned Officers in the Commissioned Corps.

Initial contracts will cover a 2-year service period. At the conclusion of this initial contract, participants may apply and be recommended for a 1-year continuation contract, under normal application and approval procedures. Continuation contracts may be approved on a year-to-year basis, up to a maximum of 5 years, contingent upon appropriation of funds.

Loan repayment contracts will be approved by the NIH contingent upon a firm employment commitment having been made and verified by the appropriate NIH Personnel Office and after passage of the appropriation act for the fiscal year during which the applicant will enter on duty. In some instances, this may result in some delay between the firm employment commitment and final contract approval. Loan repayments may NOT be made prior to the participant's entrance on duty as an employee of the NIH.

Under the Program, payments will be made directly to lenders on a quarterly basis at the completion of each quarter of the participants' satisfactory service.

#### ELIBILITY CRITERIA

Specific eligibility criteria with regard to participation in the NIH AIDS Research Loan Repayment Program include the following.

(1) Participants must have a Ph.D., M.D., D.O., D.D.S., D.M.D., D.V.M., or equivalent degree.

(2) Participants must be U.S. citizens or permanent residents.

(3) Participants must have educational debt in excess of 20 percent of their annual NIH salary or stipend at entrance on duty, resulting from governmental or commercial loans obtained to support their undergraduate and/or graduate education.

(4) Individuals employed by the NIH during the period of November 4, 1987 through November 3, 1988, are INELIGIBLE.

(5) Participants may be appointed under a temporary or permanent employment mechanism, so long as their employment has the potential to last a minimum of 2 years.

(6) Individuals with existing service obligations to Federal, State, or other entities will NOT be considered for the Program UNLESS AND UNTIL the existing service obligation is discharged.

(7) Applicants will NOT be excluded from consideration under the Program on the basis of race, color, creed, religion, sex, handicap, age, national origin, or political affiliation.

#### Additional Program Information

This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs.

This program is subject to OMB clearance under the requirements of the Paperwork Reduction Act of 1980. A Request for OMB Review and Approval of information collection associated with the program is being prepared by the NIH, and will be sent to OMB for review and approval prior to implementation of the Program.

Assignment of the Catalog of Federal Domestic Assistance number for the Program is pending.

#### REVISION IN RECEIPT DATE FOR NIEHS TRAINING PROGRAM AWARDS (T 32)

P.T. 44; K.W. 1014006, 0720005

National Institute of Environmental Health Sciences

Beginning with applications submitted for funding July 1, 1991, the National Institute of Environmental Health Sciences (NIEHS) will review institutional training grant applications received for the May 10 receipt date/January Council cycle only. No new or competitive renewal applications will be assigned to the NIEHS after May 10, 1990 until May 10, 1991.

#### GUIDELINES FOR INVESTIGATOR-INITIATED CLINICAL TRIALS, DEMONSTRATION AND EDUCATION RESEARCH PROJECTS, AND LARGE COMMUNITY-BASED STUDIES

P.T. 34; K.W. 1014006, 0755015, 0403004

National Heart, Lung, and Blood Institute

New guidelines are available for Investigator-Initiated Clinical Trials, Demonstration and Education Research Projects, and large community-based studies that are expected to be submitted for review under the auspices of the National Heart, Lung, and Blood Institute (NHLBI) of NIH. The intent of the new guidelines is to ensure that proposed studies are consonant with the program and fiscal priorities of the Institute. In addition, NHLBI will routinely consider the need for involvement by Institute scientific staff in the cited type of projects and, therefore, the use of the cooperative agreement as the mechanism of support.

Details of these policies can be obtained from:

Ronald G. Geller, Ph.D.  
Director, Division of Extramural Affairs  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Westwood Building, Room 7A/17  
Bethesda, Maryland 20892  
Telephone: (301) 496-7416

ESTABLISHMENT OF DOLLAR LIMITS FOR PROGRAM PROJECT AND SPECIALIZED CENTERS OF RESEARCH (SCOR)

P.T. 04; K.W. 1014006, 0710030, 0735000

National Heart, Lung, and Blood Institute

Effective with the receipt of applications due after January 1, 1990, the following limitations will apply:

1) NEW PROGRAM PROJECT AND SCOR APPLICATIONS:

New applications that are assigned to the National Heart, Lung, and Blood Institute (NHLBI) may request up to \$1.0 million direct costs in the first year with a maximum increase of no more than 4 percent in each additional year requested in that application.

Requests for special equipment which cause the applications to exceed these limits, however, will be permitted and considered on an individual basis. Applicants should make every attempt to include all equipment in the ceiling amount and to discuss the equipment request with NHLBI staff early in the planning phase of their application. All requests for equipment that cause the application to exceed the limits will require in-depth justification and will be carefully considered throughout the review process. Final decisions will depend on the nature of the justification and the Institute's fiscal situation.

2) COMPETING RENEWAL PROGRAM PROJECT AND SCOR APPLICATIONS:

Competing renewal applications may request up to \$1.0 million direct costs, or a 10 percent increase over the recommended amount shown on the award statement for the last non-competing year, whichever is greater, with a maximum increase of no more than 4 percent in each succeeding year. The same policy regarding equipment which is stated above under "New Applications" applies to competing renewals. APPLICATIONS THAT EXCEED THESE LIMITS WILL BE RETURNED TO THE APPLICANT. These guidelines also apply to all other NHLBI Center mechanisms.

Questions about these new policies may be directed to:

Ronald G. Geller, Ph.D.  
Director, Division of Extramural Affairs  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Westwood Building, Room 7A/17  
Bethesda, Maryland 20892  
Telephone: (301) 496-7416

DATED ANNOUNCEMENTS (RFPs AND RFAs)

SOURCES OF ACELLULAR PERTUSSIS VACCINES FOR CLINICAL TRIALS

P.T. 34; K.W. 0740075, 0755015, 0710070, 0715006

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) is soliciting the interest of manufacturers of acellular pertussis vaccine in having their products considered for Phase II clinical trials and eventually for large-scale field trials. Although sources of pertussis vaccines are sought, no contract will result from this announcement.

In order to be considered, vaccines must contain an acellular pertussis component formulated with diphtheria and tetanus toxoids (DTP) to meet U.S. licensing requirements, and data of successful phase I clinical studies. Quantities of vaccine sufficient to conduct the trials must also be made available without cost to the government. Manufacturers are asked to outline the basic manufacturing methods and content of the acellular pertussis component of their vaccine.

Selected products will be evaluated for safety and immunogenicity in several Vaccine Evaluation and Treatment Units, university-based research contract programs supported by the Division of Microbiology and Infectious Diseases, NIAID. Reactogenicity and immunogenicity will be evaluated by the evaluation units using standardized clinical protocols, and serological responses of a sample of subjects will be confirmed by an independent U.S. Government laboratory. The products of several manufacturers may be compared to each

other and to DTP formulated with a whole cell pertussis component to facilitate selection of vaccine(s) for field trials. NIAID plans to cross-reference the manufacturer's Investigational New Drug (IND) or Master File for information in support of the studies submitted under the NIAID's IND.

Interested parties are encouraged to respond by December 31, 1989, by contacting:

David L. Klein, Ph.D.  
Bacterial Vaccines Program Officer  
Respiratory Diseases Branch  
Division of Microbiology and Infectious Diseases  
National Institute of Allergy and Infectious Diseases  
Westwood Building, Room 750  
5333 Westbard Avenue  
Bethesda, Maryland 20892  
Telephone: (301) 496-5305

Respondents are invited to discuss additional terms or conditions with NIAID.

#### LIVER TRANSPLANTATION CENTERS

RFP AVAILABLE: RFP-NIH-NIDDK-90-1

P.T. 34; K.W. 0745065, 0755018

National Institute of Diabetes, and Digestive and Kidney Diseases

The National Institute of Diabetes and Digestive and Digestive and Kidney Diseases (NIDDK) has a requirement to support a fully operational liver transplantation database for the collection of data from patients in the United States who have been evaluated and have had liver transplantation for a variety of end-stage liver diseases. The overall goal of this Liver Transplantation Database is to answer important research questions about liver transplantation. This project will consist of contracts for one to three Liver Transplantation Centers to join other transplantation centers that are already participating with a coordinating center in the database. This study is organized into four phases: Phase one is a transition and start up period during which time the transplantation centers will hire the appropriate personnel, acquire the necessary equipment and supplies and familiarize themselves with the data forms, manual of operations, protocols and plans for the liver transplantation database. This transition phase will last for 1 to 4 months. Phase two is a recruitment period that is planned to last for 3 years or until at least 750 patients and no more than 1500 patients who have been transplanted have been entered into the database. The third phase will be a followup period that will last for 2 years after entry of all patients into the database. No additional patients will be entered into the database during this followup phase, but all patients will continue to be followed. The fourth phase is the analysis period, for which an additional two years will be allowed for completion of the data analysis and storage of data. During this period patients do not need to be followed as a part of this database.

During this operational phase, the Transplantation Centers will be involved in applying the methodology developed during the preceding development and pilot phase.

The Transplantation Centers will be responsible for patient recruitment and for collecting the required data and submitting it to the Coordinating Center. The Centers will be expected to recruit a sufficient number of patients evaluated for liver transplantation to provide the Liver Transplantation Database with at least 40 liver transplantation patients a year. The Transplantation Centers will also be responsible for collecting data on the harvesting procedure.

This Request for Proposals, RFP No. NIH-NIDDK-90-1, will be issued on or about November 28, 1989, with a closing date set for February 28, 1990. To receive a copy of this RFP, please supply this office with two self-addressed mailing labels and cite the RFP number referenced above. Requests must be in writing and addressed to:

Shirley A. Shores  
Contracting Officer  
National Institute of Diabetes, and Digestive and Kidney Diseases  
Westwood Building, Room 602  
Bethesda, Maryland 20892



Telephone requests will not be honored. This advertisement does not commit the Government to make an award.

ONGOING PROGRAM ANNOUNCEMENTS

CENTERS FOR THE NEUROSCIENCE OF MENTAL DISORDERS:  
SCHIZOPHRENIA AND OTHER SEVERE MENTAL ILLNESSES

P.T. 04; K.W. 1002030, 0715129, 0715177, 0414015

National Institute of Mental Health

The National Institute of Mental Health (NIMH) announces a new initiative to encourage the establishment of Centers which will integrate basic and clinical neuroscience approaches to research on schizophrenia and other severe mental illnesses. The goal of these collaborations should be the pursuit of newly formed hypotheses of brain-behavior relationships in defined areas of mental illness through innovative research designs and state-of-the-art technologies.

Applicants may request support for a period of up to 5 years, followed by a competitive renewal application for a second 5-year period. It is anticipated that individual projects which are developed as outgrowths of a Center grant will seek independent funding. Approximately \$4 million will be available to support one to three new grants under this announcement. However, the exact amount of funding will depend on appropriated funds, the quality of proposals, and program priorities at the time of award.

This announcement supersedes the prior announcement (MH-87-07): Centers for Neuroscience and Schizophrenia) and will govern future applications for competing renewals by new and currently funded Centers.

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) urges applicants to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in any given study, a clear rationale for their exclusion should be provided.

ADAMHA urges applicants to consider the inclusion of women in the study populations for all clinical research efforts. Exceptions would be studies of diseases which affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If women are not to be included, a clear rationale should be provided for their exclusion.

NIMH will accept applications in response to this announcement under the receipt date of June 1, 1990, for funding in fiscal year 1991. In subsequent years, the June 1 receipt date will be in effect.

Applicants are strongly urged to contact the individual listed below by telephone to indicate that they intend to submit an application for a Centers Grant. The purposes of such contact are to provide guidance to the applicant on the eligibility and acceptability of the proposed center grant structure and to assist staff in planning the review workload. In addition, individuals who intend to apply for a Centers Grant should request a copy of the complete announcement before initiating the application process from:

Henry Khachaturian, Ph.D.  
Chief, CNMD Program  
Neurosciences Research Branch  
Division of Basic Sciences  
National Institute of Mental Health  
Room 11-105, Parklawn Building  
5600 Fishers Lane  
Rockville, Maryland 20857  
Telephone: (301) 443-3948



## CENTERS FOR NEUROSCIENCE RESEARCH

P.T. 04; K.W. 1002030, 0715129, 0710030

National Institute of Mental Health

The National Institute of Mental Health (NIMH) announces a new program to provide a unifying research framework in the form of a Center to pursue novel and focused hypotheses in basic neuroscience research on mental health and mental illness. It is expected that this mechanism will encourage investigators representing a variety of disciplines to bring to the field of mental health research the full range of expertise and advanced technologies available in the basic sciences.

Applicants may request support for up to 5 years, followed by a competitive renewal application for a second 5-year period. Approximately \$4 million will be available to support one to three new grants under this announcement. The exact amount of funding will depend on appropriated funds, the quality of proposals, and program priorities at the time of award.

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) urges applicants to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in any given study, a clear rationale for their exclusion should be provided.

ADAMHA urges applicants to consider the inclusion of women in the study populations for all clinical research efforts. Exceptions would be studies of disease which affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If women are not to be included, a clear rationale should be provided for their exclusion.

The receipt date for applications is June 1 of each year, beginning June 1, 1990.

Applicants are strongly urged to contact the individual listed below by telephone to indicate that they intend to submit an application for a Centers Grant. The purposes of such contact are to provide guidance to the applicant on the eligibility and acceptability of the proposed center grant structure and to assist staff in planning the review workload. In addition, individuals who intend to apply for a Centers Grant should request a copy of the complete announcement before initiating the application process from:

Henry Khachaturian, Ph.D.  
Neurosciences Research Branch  
Division of Basic research  
National Institute of Mental Health  
Room 11-105, Parklawn Building  
5600 Fishers Lane  
Rockville, Maryland 20857  
Telephone: (301) 443-3948

## NCI/MARC SUMMER TRAINING SUPPLEMENT

P.T. 42, FF; K.W. 0720005, 0715035, 1014006

National Cancer Institute

Application Receipt Date: February 1, 1990

The Comprehensive Minority Biomedical Program (CMBP) of the Division of Extramural Activities (DEA), National Cancer Institute (NCI), invites interested grantee institutions that have Minority Access to Research in obtaining laboratory research experience at the NCI. This program announcement shall be re-issued on an annual basis.

Background Information: The NCI, through a co-funding arrangement with the Minority Access to Research Careers (MARC) program of the National Institute of General Medical Sciences (NIGMS) provides support for research training to minority individuals and institutions, as well as conference grant support, to further address and enhance the mission of the National Cancer Program. The NCI/MARC Summer Training Program is an extension of the co-funding process.

**Objectives:** To increase research training opportunities in the NCI for underrepresented minority scholars, and increase the number of minority scholars entering into cancer-related research careers through the influence of short-term laboratory training at the NCI.

**Funding Provisions:** The supplement will provide the following: (1) A subsistence of \$250.00 per week (\$2,500 for a maximum ten-week period), and (2) round-trip transportation (from MARC student's academic institution to the National Institutes of Health, Bethesda, Maryland, and return to student's academic institution). Indirect costs may be awarded to the institution for up to a maximum of 8 percent of the direct costs.

**Mechanism of Support:** A MARC honors training grant to the academic institution requesting support for a student will be administratively supplemented. Unless otherwise noted, all PHS and NIH grants policies apply to applications received in response to this announcement.

**Evaluation Criteria:** Applications in response to this announcement will be considered by NCI staff, after which final selection of a student for laboratory experience shall be made.

Applications found to be responsive to the announcement shall be considered eligible; those found to be unresponsive shall be considered ineligible. A letter from the CMBP Director will be sent to the grantee institution stating the reason for the outcome of the evaluation.

**Eligibility Criteria:**

All domestic institutions with active MARC research training grants are eligible to apply.

**Method of Applying**

In lieu of submitting a Standard Form PHS 398 the principal investigator must submit a letter, countersigned by an authorizing official of the grantee institution, requesting support of a student for short-term laboratory training at the NCI.

This letter shall constitute an application and must include or be accompanied by the following:

- o A statement from the student that describes his/her research interests and career objectives along with a brief resume;
- o Two (2) letters of recommendation;
- o A current official college/university transcript;
- o The student's selection of three (3) NCI laboratory choices prioritized by level of interest;
- o The title of the announcement;
- o A copy of the face page of the active MARC grant, including the grant number and period of award;
- o A description of the personnel to which the student shall report his/her NCI laboratory experience.

A list of NCI laboratory choices will be available to all applicants through the CMBP office.

All application packages must be received by the CMBP no later than February 1, 1990.

The 10-week training period may be between May 15, 1990 and August 15, 1990, inclusive. Under this announcement, funding is available for this period only.

More than one supplemental application may be submitted by the grantee institution but only one student per institution will be selected for summer laboratory experience.

Supplemental applications to active MARC undergraduate training grants may be submitted directly to the CMBP with a copy to the MARC program.

Program Director  
Comprehensive Minority Biomedical Program  
Division of Extramural Activities  
National Cancer Institute  
9000 Rockville Pike  
Building 31, Room 10A04  
Bethesda, Maryland 20892  
Telephone: (301) 496-7344

Program Director  
Minority Access to Research Careers  
National Institute of General Medical Sciences  
9000 Rockville Pike  
Westwood Building, Room 9A18  
Bethesda, Maryland 20892  
Telephone: (301) 496-7941

This program is described in the Catalogue of Federal Domestic Assistance, No. 13.398 Cancer Research Manpower. Federal Agency: National Institutes of Health, Public Health Service, Department of Health and Human Services. Authorization: Public Health Service Act, Service 413, as amended by Public Law 99-158, 42 U.S.C. 285a; Public Health Service Act, Section 487 as amended by Public Law 99-158, 42 U.S.C. 288. 3.399 Cancer Control. Federal Agency: National Institutes of Health, Public Health Service, Department of Health and Human Services Authorization: Public Health Service Act, Section 301, Public Law 78-410, 42 U.S.C. 241, and Section 412, as amended by Public Law 99.158, 42 U.S.C. 285A-1.