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INFORMATION ITEMS

NEW PHS 398 FORMAT

For the ease of handling, we have bound the PHS 398 application form, instructions, three-part card, mailing label, and human subjects form (HHS 596) into one booklet. You will soon be receiving the application kit in this new format.

REVISED PHS 2590 KIT

We have recently revised the form and instructions to apply for continuation of a research grant (PHS 2590). Starting with the next round, please use this revision, dated 9/80.

GERIATRIC MEDICINE/DENTISTRY ACADEMIC AWARD

NEW RECEIPT DATE

NATIONAL INSTITUTE ON AGING

The new receipt date for the Geriatric Medicine Academic Award (see NIH Guide, Vol. 7, No. 12, September 1, 1978) and The Geriatric Dentistry Academic Award (see NIH Guide, Vol. 8, No. 13, October 26, 1979) will occur only once a year, on July 1, beginning July 1, 1981.
NOTICE
FORM PHS 398, RESEARCH GRANT APPLICATION - REMINDER TO APPLICANTS

1. A revision of the instructions for completing Form PHS 398 will be issued in the near future. Among the changes will be a clarification of the purpose of the appendix to the application. The appendix is to be used only for supplementary background material. It is not duplicated with the rest of the application and hence does not go to all members of an Initial Review Group; it is unlikely to receive the same in-depth review as the research plan.

Photographs, oversized documents, materials that do not reproduce well, publications and completed manuscripts should still be submitted in six sets as appendix material as presently required by the instructions. However, graphs, diagrams, tables and charts essential to a review group's understanding of the research project should be incorporated into the application itself, rather than be made part of the appendix.

Material of a substantially important nature belongs in the body of the application, not in the appendix. In no case should important preliminary data be submitted as an appendix to the application.

2. The Referral Office of the NIH Division of Research Grants will return incomplete applications. Applications will be considered incomplete if they fail to follow the instructions to Form PHS 398 or if the material presented is insufficient to permit an adequate review without the solicitation of a substantial amount of additional information.

The current instructions (page 7) indicate that additional material may be submitted after the receipt date for the application only if it has been specifically solicited or agreed to by prior discussion with an appropriate PHS staff member, i.e., usually the Executive Secretary of the Initial Review Group.

3. Applicant investigators are urged to follow closely the requirements detailed on page 13 of the Form PHS 398 instructions for revised applications. Revised applications will be returned without review if no substantial revisions have been made, unless documentation is provided indicating that a prior commitment for review has been agreed to by an appropriate PHS staff member.
REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIAID-81-3

PROGRAM PROJECTS IN LYMPHOCYTE BIOLOGY

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application receipt date: July 15, 1981

BACKGROUND INFORMATION

The Immunobiology and Immunochemistry Branch of the Immunology, Allergic and Immunologic Diseases Program of the NIAID supports fundamental studies on the structure and function of the immune system to gain an understanding of immune response mechanisms at their basic cellular and molecular levels as they function in health disease. Program Projects in Lymphocyte Biology represent an award mechanism which the Branch has employed to meet this objective. Each program project utilizes an integrated multidisciplinary approach for basic biologic studies of immunologically-functional lymphocyte populations. Five such program projects are now supported although support for two is scheduled to conclude in 1982. This request for applications (RFA) is intended to encourage the development of proposals from collaborating investigators and to coordinate the submission and review of new and renewal program project applications, providing an equitable opportunity for both to compete for funds currently available to the Program in this area of research.

RESEARCH GOALS AND SCOPE

The ultimate goal of these program projects is the attainment of a complete knowledge of the life history of immunocompetent cells and of the genetic and phenotypic factors that determine their fate and function in vivo and in vitro. The ultimate practical application would be the use of selected cloned lymphocytic cells and their products for the clinical care or reconstitution of immunodeficient individuals, to alleviate allergic states, to provide resistance to life-threatening infections and to correct aberrant or defective immunoregulatory mechanisms.

The scope of these program projects includes studies of every facet of the immune response, ranging from the initial step of antigen recognition to the final elaboration of immunologically distinctive products of specific lymphocytes.

This program is described in the Catalog of Federal Domestic Assistance number 13.855, Immunology, Allergic and Immunologic Diseases Research. 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 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 currently supported by this mechanism was designed to greatly expand knowledge of the morphologic and functional heterogeneity of lymphocyte populations and to develop the capability for identification and selection of lymphocyte subpopulations with specific immune reactivity or antigenic composition, for hybridization of such populations and for selective production of specific, biologically-active, lymphocyte products.

Proposals submitted in response to this RFA should consist of a number of integrated component projects utilizing multifaceted experimental approaches and the technical expertise of cell biologists, cellular immunologists, immunochemists, microbiologists, and geneticists. However, the proposal should clearly explain how the planned multidisciplinary approach can be expected to accomplish the stated goal more efficiently and effectively than a series of independent individual grant-supported studies.

Proposals should emphasize new ideas and new initiatives and should be concerned with the acquisition of new knowledge relevant to the immune system and its structure and function. Although proposals are expected to be based primarily on experimental laboratory investigations, the value and place of clinical studies are recognized. Inclusion of patient oriented studies or laboratory procedures utilizing human source materials is acceptable, provided such studies have an immunologic base or draw upon immunologically relevant technology.

Designation of an individual to serve as the program project director should be based upon accomplishment, experience as a senior scientist, and ability to assume both leadership of the investigative group and responsibility for scientific, professional, and administrative functions, and commitment of a significant amount of time to the project. Each component project in the proposal should have a designated principal investigator, also with a demonstrable record of accomplishment in one of the basic science disciplines or clinical specialties relevant to the particular subject of investigation.

MECHANISM OF SUPPORT

Program project grants are awarded to an institution in behalf of a program director for the support of a broadly based, multidisciplinary, long-term research program which has a specific major objective or basic theme. A program project generally involves the organized efforts of groups of investigators, members of which conduct research projects related to the overall program objective. The grant can provide support for the projects and for certain core resources shared by individuals in a program where the sharing facilitates the total research effort. Each component project supported under a program project grant is expected to contribute to and be directly related to a common theme; the projects should demonstrate an essential element of unity and interdependence. This program does not provide support for nonresearch components, such as a clinical referral service or a clinical laboratory service function.

Grant funds may be utilized to support the research activities of scientific and professional personnel, administration, consultation services, central support services, equipment, supplies, travel, and publication costs. Support for research-related costs of patient involvement and medical care may be authorized. Since
the Program cannot provide funds for new construction, adequate physical facilities must be available for the primary needs of the project. However, moderate alterations or renovations to enhance clinical or laboratory facilities may be allowed if they are necessary to meet objectives of the proposal.

Support of a program project in Lymphocyte Biology will be limited to a maximum of five years. If a competing renewal application is planned, it should be submitted only in response to an RFA. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years.

REVIEW PROCEDURES AND CRITERIA

The receipt date for applications will be July 15, 1981. They will undergo initial review in October by a review committee of the NIAID, and subsequent review by the National Advisory Allergy and Infectious Diseases Council in January 1982. It is planned that awards will be made during fiscal year 1982 to support at least two program project grants depending on the availability of funds. February 1, 1982 will be the earliest starting date for successful applicants.

For preliminary screening by NIAID staff, a "letter of intent" must be submitted by the prospective program director. Letters of intent should cover the following points:

1. A brief description of the intended project.
2. A description of available laboratory and clinical facilities.
3. Ongoing relevant research studies, identifying existing projects and sources of support.
4. Past research by members of the proposed investigative group relevant to the proposal.
5. The academic positions and major research interests of the program director and his professional staff who will be involved in the proposed studies.
6. Collaborative arrangements with other area laboratories and investigators and delineation of the roles and manner of anticipated participation and interaction of the principal investigators, consultants, and collaborators.

Letters of intent are due no later than May 1, 1981, and upon receipt will be screened by NIAID staff to determine the eligibility and suitability of the project proposals for this announcement.

Inquiries should be directed to:

Bernard W. Janicki, Ph.D.
Chief, Immunobiology and Immunochemistry Branch, IAIDP
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 757
National Institutes of Health
Bethesda, Maryland 20205
Telephone: (301) 496-7551
CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR OF LATE SUBMISSION

Based on the letter of intent, potential applicants will be promptly advised whether or not their proposal is found to be within the research goals and scope of the program as defined in this RFA. Applicants will then have an opportunity to correct deficiencies or weaknesses and to restructure their submissions accordingly. Formal applications that are not responsive to the RFA or are not received by July 15, 1981, will not be accepted for review and will be returned to the applicant.

METHOD OF APPLYING

Before preparing an application, the prospective applicant should request from NIAID staff a copy of the NIAID Information Brochure on Program Projects which contains details on the requirements for multidisciplinary grant applications.

Use the standard research grant application form PHS 398. In addition to following accompanying format instructions for the development of the application, include expanded material listed above for the letter of intent. For purposes of identification and processing, the words "Program Project in Lymphocyte Biology" should be typed on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement.

Application kits may be obtained from the institution's application control office. If not available there, they may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 448
Bethesda, Maryland 20205

Forward the original application and six (6) copies to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, Maryland 20205

In order to alert NIAID to the submission of the proposal, please forward a copy (not the original) of the cover letter and the application face page to: Chief, Program and Project Review Branch, NIAID, Westwood Building, Room 703, National Institutes of Health, Bethesda, Maryland 20205.
REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA
NIH-NHLBI-81G-D
DEMONSTRATION AND EDUCATION RESEARCH IN HEART, BLOOD VESSEL, LUNG, AND BLOOD DISEASES AND BLOOD RESOURCES

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
Application receipt date: August 1, 1981

BACKGROUND

This Request for Applications (RFA) provides the opportunity for potential applicants for National Research and Demonstration Centers to develop, and seek independent funds for, demonstration and education research. This RFA would help fulfill the congressional intent of Public Law 92-423 that the National Heart, Lung, and Blood Institute (NHLBI) establish centers "... for basic or clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases." The goal of this authorization was to stimulate rapid application of the results of basic laboratory and clinical research to patient care.

In 1975, after a national competition, grants for three National Research and Demonstration Centers were awarded; these grants are still active. The heart and blood vessel center is located at the Baylor College of Medicine in Houston, Texas; the blood center is located in Seattle, Washington; and the lung center is located at the University of Vermont in Burlington, Vermont. Funds for expansion beyond the original three centers were never available.

The National Heart, Lung, and Blood Advisory Council, hereinafter referred to as "the Council," has periodically reviewed the original concept for National Research and Demonstration Centers. The Council has expressed concern about the inadequate amount of demonstration and education research in the United States generally and about the need to enhance the magnitude of this research effort if the number of National Research and Demonstration Centers were to be increased. In September 1980, the Council recommended that the procedure for designating and supporting future National Research and Demonstration Centers be changed. This recommendation was subsequently accepted by the NHLBI. The Council suggested that a two-phase process be instituted in the creation or designation of new Centers and that an RFA for demonstration and education research be the first phase of the process.

Thus, the first phase is this RFA for demonstration and education research in health promotion and in the prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases. It is anticipated that the second phase, which will be announced in about one year, will invite applications for combining existing demonstration and education activities with ongoing clinical research and basic laboratory investigation so that an applicant's overall integrated effort could be
eligible for designation as a National Research and Demonstration Center.* Thus, contrary to the current concept of National Research and Demonstration Centers, grants for these Centers will not, in the future, support individual research projects but will support only the administrative mechanism necessary for bringing together existing projects.

The NHLBI has fostered the concept that National Research and Demonstration Centers must include three essential elements: basic laboratory research, clinical investigation, and demonstration and education activities. Mechanisms are already available for bringing together basic research, clinical research, and training.

Basic laboratory research has developed favorably in settings where there have been facilities and resources in which experienced investigators could work collaboratively and also with research trainees. The combination of facilities, resources, and scientists constitutes what might be designated a "laboratory research center."

The Council also observed that there are currently established laboratories, or "centers," for the conduct of clinical investigations. The settings for these investigations are mostly hospitals, patient-care facilities, and academic medical centers specially designed or adapted for the acquisition of clinical data; these settings involve a large variety of laboratories that aid clinical studies. These "clinical research centers" are the source of very productive biomedical research.

Although less numerous than laboratory or clinical research activities, there are also research projects or programs in demonstration and education for investigating the maintenance of health and the prevention of disease by the application of knowledge already acquired and validated. It is this type of demonstration and education research that is the subject of this RFA. Just as basic research and clinical research have their laboratories, these demonstration and education activities involve populations, investigators, and basic facilities for conducting research and for evaluating results.

Thus, demonstration and education research programs, as defined in this RFA, may be directed toward health-care professionals, the community, or the general population and would be staffed by scientists and physicians whose expertise may include, but not be limited to, medical disciplines, health education, epidemiology, biostatistics, and behavioral and social science.

This RFA invites applications for research in demonstration and education that the applicant institution plans to eventually incorporate into a National Research and Demonstration Center.

*Eligibility for eventual designation as a National Research and Demonstration Center does not require participation in this first-phase RFA. If meritorious demonstration and education research, regardless of its source of support, is already ongoing, and if there is corresponding excellence in basic and clinical research, applicants will be able to compete for designation as a National Research and Demonstration Center in response to the second-phase RFA.
To be eligible for competition under this RFA, an applicant must:

- describe the institution's plans for developing a National Research and Demonstration Center;

- explain how these proposed research projects would fit with ongoing basic and clinical research in the future Center both administratively and scientifically; and

- include any letters of agreement from other participating groups.

Thus, the proposed demonstration and education research solicited by this RFA must relate scientifically (thematic ally) to other research activities that are also potential components of a National Research and Demonstration Center. Submission of the application for designation as a National Research and Demonstration Center must await the announcement of that future competition. Investigators who wish to compete for funding for demonstration and (or) education projects independent of National Research and Demonstration Centers, however, may do so at any time through the usual grant mechanism and should not respond to this RFA. Applications for such independent demonstration and (or) education projects are still encouraged and are unaffected by this announcement.

RESEARCH GOALS AND SCOPE

The application for a demonstration and education research grant may include a research effort that is only a demonstration project, only an education project, or some combination of both. An application for a demonstration and education program may consist of more than one project. If there is more than one project, the projects must be developed around a central theme. The following sections define demonstration research and education research within the context of this announcement.

Demonstration Research

Demonstration research, as defined for the purpose of this RFA, is a project designed to test the applicability, in an appropriate setting, such as the community, physicians' offices, or work settings, of new approaches to the prevention, diagnosis, or control of diseases that have been shown to be effective in controlled laboratory or clinical investigation. The specific aims must be defined. An evaluation plan must be included.

The development of health-significant demonstration research relevant to the goals of the NHLBI should include the following considerations:

- significance of the problem and anticipation of the expected gains in terms of health promotion, prevention, extension of health-care services in the community, improvement of community health delivery, effective use of health personnel, and enhancement of cost effectiveness;

- utilization of special features of the specific setting, such as prevalence of a particular disease, unique research resources, specific population
groups suitable for the project, special health delivery facilities, and local health organizations; and

- evidence that the participating investigators have the experience, competence, and commitment necessary for the successful implementation of the program, the applicant institution has the resources necessary and is committed to the proposed study, and the local groups that would participate have indicated their commitment to the study as proposed.

**Education Research**

As defined for the purpose of this RFA, an education research project is one designed to use education methods for the maintenance of health, prevention of disease, or the delivery and utilization of health-care services. The development of health-significant education research relevant to the goals of the NHLBI should include the following considerations:

- clear identification of the need for a change in health behavior, including a description of the existing health behavior addressed, the anticipated course if no program is instituted, and the significance of attempting to alter cognition and behavior;

- definition of the objectives in terms of the behavioral change desired, the intervention strategies to be used, and the criteria by which change is to be measured; and

- careful definition of the study population, including plans for recruitment of participants and maintenance of the study population, any anticipated changes in the composition of the study population, and plans for measuring the impact of these changes on a project.

Projects with the goal of information dissemination alone do not fit these criteria.

**General Considerations**

An application for support of demonstration research or education research must include:

- a description of the theoretical and factual basis or framework for the proposed study, the research questions or hypotheses to be tested, the research design to be used, procedures for sample selection, variables to be observed, methods and materials to be used, instruments and procedures to be used for measurement, approaches to data management and analysis, and plans for dissemination of the results and its potential for replication in other settings; and

- an overall evaluation plan that includes specific procedures for evaluation during the course of the project (formative evaluation) and at its end (summative evaluation) and instruments and methods to be used in determining whether the objectives have been met.
The following list includes major areas of interest to the Divisions of the NHLBI. The proposed demonstration and education research projects must be related to the programs of the NHLBI, as exemplified in this list, and should capitalize on the strengths of the applicant institution. The list is neither all-inclusive nor exclusive, nor is it in an order of priority of interest.

**Heart and Blood Vessel Diseases:** risk factor or factors for coronary heart disease in children and (or) adults, including diabetes, overweight, and lack of exercise; nutrition as it affects the cardiovascular system; rehabilitation after a myocardial infarct; prosthetic devices related to heart and vascular diseases; atherosclerosis; hypertension; coronary heart disease; arrhythmias; heart failure and shock; cerebrovascular disease, excluding the neurological components of completed stroke; peripheral vascular disease; congenital and rheumatic heart disease; cardiomyopathy; and infections of the heart.

**Lung Diseases:** obstructive diseases of the airways (emphysema, chronic bronchitis, asthma, cystic fibrosis), respiratory distress of the newborn, fibrotic and immunologic diseases of the lung, respiratory failure, pulmonary vascular diseases, risk factors for lung disease (smoking, occupational exposure, environmental exposure), and maintenance of respiratory health. (Cancer of the lung, upper respiratory infections, and tuberculosis are covered by other programs of the National Institutes of Health and are, therefore, not included as major problem areas for the NHLBI.)

**Blood Diseases and Blood Resources:** thromboembolic disorders, the hemophilies, and other conditions related to the plasma clotting factors; platelet abnormalities; microcirculatory thrombosis; bone marrow physiology and dysfunction; diseases and disorders of the red blood cell, including sickle cell disease, the thalassemias, and similar disorders; optimal utilization of the national blood resource; blood and blood-component therapy; and blood banking functions. (Malignancies of the blood and white blood cell disorders are the responsibility of other components of the National Institutes of Health and are not included in this program.)

**Period of Support**

Generally, each project should be designed so that it can be implemented and evaluated within a maximum of five years.

**Collaboration With National Heart, Lung, and Blood Institute**

While each applicant institution is expected to develop its own program in accordance with local expertise, interests, and resources, each must be willing to work with the NHLBI in furthering its goals. If a grant is awarded, the NHLBI will designate a member of its staff to work closely with the staff of the applicant institution on scientific, fiscal, and administrative matters and to facilitate coordination between relevant programs of the NHLBI.

**MECHANISM OF SUPPORT**

Grants for the Demonstration and Education Research Programs of the NHLBI will be awarded under the authority of the Public Health Service Act, Title III,
Section 301, and Public Law 95-622, Section 415, and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. Support may also be derived in part from other sources—Federal, local, public, and private. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

The total amount of funds that will be set aside will be determined at the November 1981 meeting of the National Heart, Lung, and Blood Advisory Council. It is currently anticipated that there may be from ten to fifteen projects awarded at a total cost of about $2,500,000. The specific amount to be funded will, however, depend on the merit of the applications received and the availability of funds.

ELIGIBILITY

To be eligible for competition under the RFA, applicants must:

- describe the institution's plans for developing a National Research and Demonstration Center;
- explain how the proposed research projects would fit with ongoing basic and clinical research in the future Center both administratively and scientifically; and
- include any letters of agreement from other participating groups.

REVIEW PROCEDURES AND CRITERIA

The Division of Extramural Affairs, NHLBI, will manage the scientific and technical merit review of applications. The initial peer review will be conducted by consultants who have expertise in each area of the proposed program. The subsequent review will be by the National Heart, Lung, and Blood Advisory Council.

Review of Demonstration Projects

The peer review criteria include assessment of:

- the scientific merit of the research project, the importance of the underlying disease or health-related issue, the relevance to the

*The demonstration and education programs that the NHLBI intends to support are related to the provisions of the National Heart, Blood Vessel, Lung, and Blood Act of 1972 (Public Law 92-423), as extended by the Health Research and Health Service Amendments of 1976 (Public Law 94-278), the Biomedical Research Extension Act of 1977 (Public Law 95-83), and subsequent reauthorizations through 1980, and are described in the 1980 Catalog of Federal Domestic Assistance, program numbers 13.837, 13.838, and 13.839, Heart and Vascular Diseases Research, Lung Diseases Research, and Blood Diseases and Resources Research.*
objectives of the NHLBI, the relation of multiple projects to a central theme, the soundness of research design, and the qualifications and experience of the responsible investigators;

- the availability of necessary resources and a commitment of local groups to participate; and

- a plan for evaluation of the progress and the effect of a demonstration project.

**Review of Education Projects**

The peer review criteria include assessment of:

- the scientific merit of the research project, the importance of the underlying disease or health-related issue, the relevance to the objectives of the NHLBI, the relation of multiple projects to a central theme, the soundness of the project design, and the qualifications and experience of the responsible investigators;

- the reasons for selection of the study population, or populations, and the significance of attempting to alter existing health-related behavior;

- the availability of necessary resources and the commitment of local population groups to cooperate and participate; and

- a plan for evaluation of the progress and the effect of an education project.

**Other Criteria**

The peer review of demonstration and education research projects will also include assessment of:

- the experience, commitment, and leadership ability of the principal investigator and, where appropriate, the participation of experienced investigators in all aspects of a project;

- the strength of the management plan for assuring the smooth functioning of a project, including:
  - an administrative and organizational structure that would facilitate attainment of the proposed objectives of the project,
  - the availability of appropriate consultants, or, if multiple projects are involved, advisory committees, including definitions of their functions,
  - a plan for the day-to-day management, for the allocation and management of funds, for the decision-making processes, and for the maintenance of quality control in all aspects of the proposed projects, and
- the plans for the collection, storage, retrieval, and analysis of data related to all projects;

- the availability of necessary physical, professional, and community resources to support a project and to successfully develop and maintain working relationships with the relevant segments of the community; and

- a willingness to work cooperatively with other demonstration and education projects, if appropriate, and with the NHLBI.

METHOD OF APPLYING

Note: Applicant institutions are urged to consult with appropriate members of the staff of the NHLBI before and during the preparation of their applications regarding questions of policies, procedures, and guidelines.

Letter of Intent

Applicants should submit a letter of intent to the NHLBI not later than June 1, 1981. The NHLBI requests such letters so that the staff can plan for the review. A letter of intent is not binding and will not be considered in the review of any application submitted subsequently.

The letter should be addressed to:

Jerome G. Green, M.D.
Director, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building, Room 7A17
Bethesda, Maryland 20205

Format for Applications

Applications for the Demonstration and Education Research Programs of the NHLBI should be submitted on Form PHS 398, the application form for the traditional research-project grant. This form is available from most institutional business offices or from the Division of Research Grants, NIH.

Applications must be received by August 1, 1981.

Label the outside of the mailing package and the top of the face page of the application "Response to RFA, NIH, NHLBI: Demonstration and Education Research Programs." Send six copies of the application to the Division of Research Grants and eighteen copies to the Review Branch, Division of Extramural Affairs, NHLBI. Indicate in a brief covering letter that the application is being submitted in response to this RFA: "Demonstration and Education Research Programs in Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources." Send a copy of the letter to Dr. Jerome G. Green at the address given under the section entitled "Letter of Intent."
Inquiries

Information about demonstration and education research in heart and blood vessel diseases and a complete copy of the RFA may be obtained from:

Dr. Barbara Packard  
Director  
Division of Heart and Vascular Diseases  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Federal Building, Room 416  
Bethesda, Maryland 20205  
Telephone: (301) 496-2553

Information about demonstration and education research in lung diseases and a complete copy of the RFA may be obtained from:

Dr. Suzanne Hurd  
Acting Director  
Division of Lung Diseases  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Westwood Building, Room 6A15  
Bethesda, Maryland 20205  
Telephone: (301) 496-7440

Information about demonstration and education research in blood diseases and blood resources and a complete copy of the RFA may be obtained from:

Dr. Amoz I. Chernoff  
Director  
Division of Blood Diseases and Resources  
National Heart, Lung, and Blood Institute  
National Institutes of Health  
Federal Building, Room 516  
Bethesda, Maryland 20205  
Telephone: (301) 496-4868
ANNOUNCEMENT

ACADEMIC AWARD

NATIONAL INSTITUTE ON AGING

PROGRAM GUIDELINES

I. OBJECTIVES

The purpose of the Academic Award Program is the recruitment and preparation of future academic investigators for careers in research and teaching with special emphasis upon geriatric medicine and related clinical disciplines.

This award, made to an institution, provides a superior candidate with opportunity for five years of special study and supervised experience to further his/her individual needs.

The Academic Award is designed to provide support for individuals with high potential for academic and/or research careers in clinical areas; it bridges the gap between the initial period of postdoctoral study and a formal academic appointment. The Academic Award differs from the Individual National Research Service Award in that the Academic Award provides a continuing five-year period of support for the future teacher-clinical researcher. This Academic Award differs from the Research Career Development Award in that it seeks to identify academic potential as differentiated from research achievement, and it emphasizes expertise in research, curriculum development, and teaching in clinical areas.

II. ELIGIBILITY OF CANDIDATE

A. Acceptance by Sponsoring Institution

The candidate must be nominated for the program by a non-Federal public or private non-profit institution located in the United States, its possessions, or territories.

B. Previous Training and Experience

Candidates are restricted to those holding health-professional degrees in the clinical sciences (M.D., D.O., or equivalent). At the time of receiving the award the candidate must have completed at least three years of postdoctoral training and/or experience. For example, at the

1This program will be administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74.
time of application the candidate should have completed at least an internship and two years of residency training or experience. The most competitive candidate in the clinical sciences is one who has either just completed or is in the final year of residency training or, in the basic sciences, is just completing three years of postdoctoral training and experience and now wishes additional training to become more skilled as a teacher-investigator in a clinical research area.

The candidate should have demonstrated potential for excellence in research, teaching, and evidence a serious intent for an academic and/or research career. Individuals holding senior academic positions such as that of associate professor or professor at the time the award would be activated are not eligible for an Academic Award.

C. Citizenship

Academic Awards will be made only to citizens or non-citizen nationals of the United States, or individuals who have been lawfully admitted to the United States for permanent residence at the time of application.

III. CONDITIONS OF THE ACADEMIC AWARD

A. Program

The application will describe a five-year plan for the candidate's development. This should include research and appropriate clinical and teaching experiences necessary to gain his/her career objectives. It is expected that the plan will be carried out at the sponsoring institution. However, short periods of special emphasis experience may be authorized and may be included in the program design in the original application.

B. Relationship Between Applicant Institution and Candidate

The applicant institution is responsible for providing facilities for the candidate. The sponsor is responsible for advising the candidate in planning and carrying out the program and for assuring that appropriate space and facilities involved in the candidate's activities are available.

It is of utmost importance that the applicant's sponsor or preceptor be selected with considerable care by the institution. In most cases the sponsor will be a member of the senior faculty who is capable and willing to devote an appropriate amount of time, effort, and professional expertise to insure an excellent career program for the young physician.

The candidate is expected to devote full time to the proposed research, teaching, and related clinical activities. Although no exact apportionments of time are specified, it is expected that the total program will be well-balanced and that no one activity will be followed to the exclusion of others.
If the administrative duties are included, they should constitute only a minor part of the total program. Clinical activities are appropriate to the extent that they are a necessary part of the total program or are an integral part of the candidate's research and teaching responsibilities.

C. Amount of the Award

1. Salary

The Academic Award will provide the grantee institution with support for the candidate's efforts which, under the terms of the award, are devoted essentially to full-time academic activities, but only up to a maximum base salary of $30,000 for each budget period.

The grantee institution may supplement the awarded salary consistent with the institution's salary scale. No supplementation may be provided from Federal funds unless explicitly authorized by the program from which such funds are to be derived. In no case may other NIH funds be used as a means of additional salary support.

2. Fringe Benefits

When requested, the grantee institution's share of the fringe benefits, which is in keeping with those paid to comparable individuals under established grantee institution policies, will be paid as a direct cost on the portion of the candidate's salary provided from NIH funds. Fringe benefits, where calculated as part of an indirect cost pool, will not be allowed as a direct cost.

3. Research Allowance

A $5,000 research allowance will be provided for each year of the award to be used for such ancillary support as supplies, equipment, and travel essential to fulfill the objectives of the award.

4. Indirect Costs

Funds will be provided for the reimbursement of indirect costs at 8% of the total direct costs or actual, whichever is less.

D. Concurrent Applications and Concurrent Awards

An Academic Award application may not be submitted concurrently with an application for a Research Career Development Award, a Clinical Investigator Award, an individual National Research Service Award or other career development type award. Nor may an Academic Award be held concurrently with any of the above awards. This does not preclude holding a regular research project grant.
E. Duration of the Award

The Academic Award is made on an annual basis with additional years of recommended support for a total of five years. It is not renewable. Support for the second and third year of the award is contingent upon receipt of a completed application annually which provides a summary report of the progress to date, plans for the next year, and appraisal of the awardee's progress submitted by the sponsor. The fourth year application must contain specific program plans for both the fourth and fifth years, in order to assess the plans for the orderly completion of the program objectives. This application will receive technical merit review by Institute committees. If it is determined that an awardee's progress has been unsatisfactory and/or that the plans for the final two years are not appropriate, the Academic Award may be terminated.

F. Vacations

Awardees may take vacations in accordance with the established policies of the grantee institution consistently applied, and with the approval of the sponsor.

IV. REVIEW OF APPLICATIONS

A. Timing of Applications

Receipt dates for new applications are February 1, June 1, and October 1. Continuation applications are due 60 days before the termination of the active award period except for the -04 year application which is due three months after the beginning of the -03 year award.

B. Review Criteria

The evaluation by a technical merit review committee will include the proposed five-year plan and material pertinent to the candidate's qualifications for the award, such as academic records, professional references, and bibliography. Key factors in the review process are details of the proposed research and teaching program in which the applicant will participate.

V. OTHER CONDITIONS OF THE AWARD

A. Human Subjects and Animal Welfare

No award may be made unless the grantee institution has complied with (1) 45 CFR Part 46 and any other applicable requirements pertaining to the protection of human subjects and (2) Chapter 1-43 of the DHHS Grants Administration Manual and any other applicable requirements concerning animal welfare.
B. Non-Discrimination

Institutions administering Academic Awards are subject to (1) the prohibition against discrimination on the basis of race, color, or national origin imposed by Title VI of the Civil Rights Act of 1964 and the implementing regulation of DHHS (45 CFR Part 80); (2) the prohibition against discrimination on the basis of sex imposed by Title IX of the Education Amendments of 1972 and in particular Section 901 of such Act; and (3) the prohibition of discrimination against the handicapped imposed by Section 504 of the Rehabilitation Act of 1973 amended. Every applicant organization is required to have an Assurance of Compliance (Form DHHS 441 or 441B) or any other required assurances on file with the Office of Civil Rights, Office of the Secretary, DHHS, before a grant may be made to that institution.

C. Publications

Awardees are free to submit for publication reports of their findings to the journals of their choice. Responsibility for direction of the project must be acknowledged by a footnote in language similar to the following:

The investigation was supported by an Academic Award #___ from the National Institute on Aging.

Copyright: Except as otherwise provided in the conditions of the award, when publications or similar materials are developed from work supported by the NIH, the author is free to arrange for copyright without approval. Any such copyrighted material shall be subject to a royalty-free, non-inclusive, and irrevocable license to the Government to reproduce, translate, publish, use and dispose of such material, and to authorize others to do so. Two copies of each publication should be sent to the Grants Management Officer, National Institute on Aging.

VI. HOW TO APPLY

Applications shall be submitted on application form PHS 398. Special instructions for preparing an Academic Award application and other additional information should be requested from:

Associate Director
Biomedical Research and Clinical Medicine
National Institute on Aging
National Institutes of Health
Bethesda, Maryland 20205
Telephone: (301) 496-6761 or 496-4996
ANNOUNCEMENT

CLINICAL INVESTIGATOR AWARD

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

PURPOSE

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of Clinical Investigator Awards. The clinical investigator award program is intended to:

- encourage newly trained clinicians to develop clinical and basic research interests and skills in the areas of cardiovascular, pulmonary, or blood diseases and the blood banking sciences;

- increase the pool of physician investigators in the areas of cardiovascular, pulmonary, or blood diseases and the blood banking sciences.

These awards provide the opportunity for clinically-trained physicians with a commitment to research to develop into independent biomedical research investigators.

The award will enable candidates to undertake up to five years of special study and supervised experience tailored to individual needs with a sponsor (or sponsors) competent to provide research guidance. This award is intended to cover the transition between postdoctoral experience and a career in independent investigation. The clinical investigator award differs from the NIH Research Career Development Award (RCDA) in that it seeks to develop research ability in individuals with a clinical background early in the candidate's career rather than to promote the further development of research skills of individuals already demonstrating significant research achievement.

BACKGROUND

Despite a recent decline in the death rate from coronary heart disease, cardiovascular disease continues to be the number one cause of death in the United States. Arteriosclerosis and hypertension account for almost one million deaths annually. An estimated 40 million Americans have diseases of the heart

This program is described in the Catalog of Federal Domestic Assistance numbers 13.837, 13.838, and 13.839, Heart and Vascular Diseases Research, Lung Diseases Research, and Blood Diseases and Resources Research. 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 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.
and blood vessels, resulting in a large burden of acute and chronic illness and disability. Heart and blood vessel diseases cost the economy more than $50 billion per year in wages, lost productivity, and expenses for medical care.

Diseases of the lung constitute a major national health problem. An estimated 10 million Americans, both young and old, are currently affected by these diseases with an annual estimated cost to the nation of over $17 billion. In the newborn, the most common cause of death is neonatal respiratory distress syndrome. Neonatal RDS is implicated in the development of adult respiratory diseases as well. Fibrotic and immunologic lung diseases are major causes of lung problems in the young adult and may cause chronic obstructive pulmonary diseases. Of the adult respiratory diseases, emphysema and chronic bronchitis are the major causes of death.

Asthma, emphysema and chronic bronchitis represent particularly pressing health problems, since the death rate and prevalence of these conditions have increased at an alarming rate over the past 15 years. As a disabling disease, emphysema is the third leading cause of worker retirement on Social Security disability payments.

Diseases of the blood underlie, or are critical contributors to, many disorders affecting mankind. As a consequence, they are major causes of death and disability in the United States. Nevertheless, no valid estimate of their adverse economic impact can be realistically made since disorders of the blood not only affect the blood itself, but all the organs and tissues through which it flows. Platelet and clotting disorders affect large numbers of individuals suffering from hemorrhagic or thrombotic episodes. Significant segments of the population have sickle cell disease, Cooley's anemia, or other hemolytic disorders. Anemias due to other mechanisms affect smaller numbers of patients. Furthermore, it is difficult to estimate the economic consequences of an inadequate blood banking and blood resource system, since the supply and management of blood and blood products underlie much routine and emergency medical practice.

The clinical investigator award program is designed to encourage recently trained physicians to develop their clinical and basic research interests and research capabilities in heart, lung, or blood disease* areas. To help support the transition from clinical training status to that of a productive research investigator, the clinical investigator award will provide early support for clinicians with potential for developing into independent researchers.

*The term "blood disease" covers research into many aspects of bone marrow function and disorders of red cells, megakaryocytes, platelets, and the coagulation system. Research on disorders of white cells, including the leukemias and other blood malignancies, is the responsibility of other Institutes of the NIH and is not supported through this mechanism.
IMPLEMENTATION

Beginning in Fiscal 1980, under the authorizations in Public Health Service Act, Section 301(c) and Section 413(a), the National Heart, Lung, and Blood Institute has funded clinical investigator awards. Each grant has a duration of five years. Funding beyond the first year of the grant is contingent on satisfactory progress during the preceding year.

The status of the clinical investigator award program will be reviewed four years from the date of the first awards to determine whether the program should be continued. In addition, to assess the effectiveness of the program in fulfilling its objectives, the Institute intends, after completion of each grant, to follow the progress of the recipient for a period of five years to determine: (1) the investigator's professional affiliation(s); (2) his/her record of subsequent grant or contract support; and (3) his/her record of scientific publications. It is anticipated that the experience and results achieved by the awardee from this special grant program, in the majority of cases, will provide the basis for successful competition in the regular research support programs of the Institute.

The receipt date for applications will be August 3, 1981 and August 1 each year thereafter. They will be evaluated by an initial review group and by the National Heart, Lung, and Blood Advisory Council. The earliest start date for successful applications will be on July 1 of each subsequent year.

PROVISIONS OF THE AWARD

The clinical investigator awardee will be supported for a maximum of five years. All funds must be used to support the original awardee. Support is based on a full-time, twelve-month appointment. The awardee will be provided salary support of up to $25,000 in the first year with subsequent years up to a ceiling of $30,000, plus fringe benefits. The actual salary must be consistent with the established salary structure of the institution for persons of equivalent qualifications, experience, and rank.

Up to a total of $10,000 annually may be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the awardee's research program. An appropriate sponsor must assume responsibility and provide guidance for the development of the candidate's research program.

Institutions may apply for awards on behalf of named individuals meeting the criteria for this award. Evidence of the commitment of the institution and sponsors to the candidate's research and career development is to be included in the application.

The grant will be made annually to the awardee's parent institution for each of the five annual budget periods. Costs allowed may include:

1. Awardee's Salary

   Up to a maximum of $25,000 in the first year with subsequent years up to a ceiling of $30,000 for full-time support; in addition, fringe benefits will be provided. Institutional supplementation is permitted.
2. **Research Support**

   Up to a maximum of $10,000 per year.

   - **Equipment:** specialized research equipment essential to the proposed program. The available facilities should include most of the necessary equipment;
   
   - **Supplies:** consumable supplies essential to the proposed program;
   
   - **Travel:** domestic travel essential to the proposed program;
   
   - **Tuition for training courses:** if essential to the awardee's individual research development program; and
   
   - **Other:** publication costs, patient costs, etc., necessary for the research program.

3. **Indirect Costs**

   Funds will be provided for the reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees, and expenditures for equipment.

**ELIGIBILITY**

1. The award is designed to provide intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health-professional degrees in the clinical sciences (M.D., D.O., or equivalent). Candidates ordinarily will have completed their clinical experience by the time the award can be made. Ordinarily a candidate in the following categories will not qualify:

   a) with more than 6 years of postdoctoral experience at the time of award;
   
   b) with previous independent NIH research support or its equivalent;
   
   c) with less than three years total postdoctoral clinical experience at the time of the award.

   In exceptional circumstances, individuals in one or more of the above categories may qualify for the award. However, the applicant must provide sufficient justification for such an exception.

   Candidates should have broad clinical training, should demonstrate individual competence in clinical activities, and should show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for research and academic careers.
2. Applicants for a Clinical Investigator Award may not submit a concurrent application for an NIH Research Career Development Award, Academic Award, or for a New Investigator Research Award. A Clinical Investigator Awardee may subsequently apply for a research project grant.

3. The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic departments, and commitment and capability to provide guidance to clinically oriented individuals in the development of independent research careers.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for a research career. Evidence of the commitment of the institution to the candidate's research and development must be provided.

4. Candidates must have one or more sponsors or advisors who are recognized as accomplished investigators in the research proposed at the applicant's institution. The sponsor must provide: 1) his/her concept of a development and research plan for the awardee; 2) his/her curriculum vitae (updated) with complete bibliography and research support; and 3) a letter indicating his/her evaluation of the proposed awardee and his/her willingness to provide guidance and support.

5. Candidates must provide a description of the proposed research and career development plan for the five-year period of the award. The candidate must be prepared to commit full-time effort to the objectives of this award. It is required that a minimum of 75 percent effort be devoted to the research program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals, i.e., the awardee's development into an independent biomedical research investigator.

6. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of their third year of support. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed research plan and protocol.

7. Candidates must agree to inform the National Heart, Lung, and Blood Institute annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.

8. Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.
APPLICATION

Detailed instructions for completion of applications should be requested from the NHLBI staff contacts shown on page 7.

Applications must be submitted on form PHS 398 which is available at the grantee institution, or from the Division of Research Grants, NIH. The original and six (6) copies of the application should be clearly labeled "NHLBI CLINICAL INVESTIGATOR AWARD PROGRAM."

The chairperson of the department sponsoring the candidate should submit a signed statement, as part of the application, detailing the department's commitment to the candidate.

Completed grant applications should be mailed to the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205. Upon receipt of each application at NIH, a postal card acknowledging receipt will be mailed to the applicant.

The applicant should ask three present or former supervisors or preceptors to send a letter to the Review Branch, Division of Extramural Affairs, NHLBI, attesting to his/her potential for conducting independent research. The applicant is responsible for making necessary arrangements to ensure that the reference letters are mailed by the supervisors/preceptors directly to the Review Branch.

Applications for this award are due August 3, 1981. The earliest start date for awards is July 1, 1982.

Subsequent competitions will occur on a once-a-year basis and the receipt dates will be August 1 of each year.

REVIEW CRITERIA

Applications for clinical investigator awards will undergo initial merit review in the Review Branch, Division of Extramural Affairs, NHLBI. Secondary review will be by the National Heart, Lung, and Blood Advisory Council. Criteria for review include:

- The candidate's potential for a career in independent research;
- The candidate's commitment to a research career;
- The eligibility of the candidate as defined in the program announcement;
- The overall merit of the candidate's five-year plan for research and the development of research skills;
- The quality of the candidate's clinical training and experience;
- The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development;

- Presence of highly trained faculty in clinical and basic departments relative to the area of study; and

- The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

NHLBI STAFF CONTACTS

Inquiries about the program should be directed to:

Research Training and Development Officer
DIVISION OF BLOOD DISEASES AND RESOURCES
National Heart, Lung, and Blood Institute
Federal Building, Room 514A
Bethesda, Maryland 20205
Telephone: (301) 496-1817

Research Training and Development Officer
DIVISION OF HEART AND VASCULAR DISEASES
National Heart, Lung, and Blood Institute
Federal Building, Room 3A-08
Bethesda, Maryland 20205
Telephone: (301) 496-1724

Research Training and Development Officer
DIVISION OF LUNG DISEASES
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A-05
Bethesda, Maryland 20205
Telephone: (301) 496-7668

Letters of reference and inquiries regarding review procedures should be directed to:

Centers and Special Projects Review Section
Review Branch, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 553
Bethesda, Maryland 20205
Telephone: (301) 496-7351
ANNOUNCEMENT

SPECIAL EMPHASIS RESEARCH CAREER AWARD:

DIABETES MELLITUS - OBSTETRICAL, PERINATAL, AND PEDIATRIC ASPECTS

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

This is to announce the annual receipt date of June 1 for applications for the SERCA: Diabetes Mellitus - Obstetrical, Perinatal, and Pediatric Aspects. Applications received on or before June 1, 1981 should specify a project start date of July 1, 1982. The next receipt date will be June 1, 1982 for a possible start date of July 1, 1983.

The award is intended to:

- encourage qualified individuals in the early stages of their post-graduate medical and scientific careers to develop research interests and skills in the obstetrical, perinatal, and pediatric aspects of diabetes mellitus;

- provide support for individuals to pursue a program of research in various fundamental and clinical research disciplines related to diabetes mellitus during pregnancy and its associated neonatal morbidity and mortality; and

- create a pool of highly qualified investigators with experience and skills in the obstetrical, perinatal, and pediatric aspects of diabetes mellitus for a future role in research, teaching, and clinical care.

The Special Emphasis Research Career Award provides the opportunity for an obstetrician or pediatrician with developing research interests to acquire experience and skill in the broad fundamental and clinical scientific disciplines essential for a multidisciplinary approach to the endocrinologic and metabolic aspects of diabetes mellitus in obstetrical, perinatal, and/or pediatric contexts. This SERCA emphasizes in-depth experience in several fundamental and clinical scientific disciplines which are not dependent upon a single laboratory or institution.

PROVISIONS OF THE AWARD

This nonrenewable award provides support for a five-year period of full-time research and related activities. The latter may include research development activities as well as involvement in patient care to the extent that it will strengthen research skills. The SERCA grant made to the awardee's parent institution provides up to $30,000 per year for full-time salary support plus fringe benefits. A maximum of $8,000 per year during the first three years and up to $20,000 per year during the last two years will be provided for necessary research costs including technical assistance, equipment, supplies, consultant costs, domestic travel, patient care costs, publication, and other costs.
Working closely with an advisor, the candidate is expected to develop capabilities in fundamental, applied, or clinical research in the metabolic and endocrinologic aspects of diabetes in gestational, perinatal, or pediatric contexts. These activities should be oriented around the initiation of a specific research program of the applicant's own design. Exposure to multiple disciplines, such as physiology, biochemistry, biophysics, pharmacology, nutrition and epidemiology should be included in the candidate's plans. Investigators are encouraged to pursue these activities in more than a single laboratory. At the completion of this five-year award, the individual should be in a position to compete in regular NIH research grant award programs.

ELIGIBILITY REQUIREMENTS

Candidates for the SERCA Award must: (1) hold an M.D. or equivalent professional degree (e.g., D.D.S., D.O., D.V.M., etc.); (2) have a minimum of three years post-M.D. experience, including one year of clinical training in obstetrics, pediatrics or endocrinology-metabolism, or two years post-M.D./Ph.D. experience or equivalent. M.D./Ph.D. applicants should possess significant experience in metabolism, endocrinology, obstetrics, pediatrics, physiology, biochemistry, pharmacology, or other relevant areas of interest, such as epidemiology; (3) be citizens or noncitizen nationals of the United States or its possessions or territories or must have been lawfully admitted to the U.S. for permanent residence at the time of application; (4) meet certain other eligibility requirements specified in the SERCA Program Guidelines (See "For Additional Information").

DEADLINE FOR RECEIPT OF APPLICATIONS

SERCA applications will be received once a year according to the following schedule:

<table>
<thead>
<tr>
<th>Application Date</th>
<th>Council Review</th>
<th>Start Date</th>
</tr>
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<tbody>
<tr>
<td>June 1</td>
<td>Jan/Feb*</td>
<td>July 1*</td>
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</table>

*of the year following application receipt.

FOR ADDITIONAL INFORMATION

Prospective applicants are encouraged to review the SERCA Guidelines which detail eligibility requirements and application procedures. In addition, prior to preparing an application, individuals are strongly encouraged to discuss their potential eligibility as well as their areas of research interest with the Program Director listed below. Requests for copies of the SERCA Guidelines as well as questions related to eligibility, etc., should be directed to:

Chief, Endocrinology, Metabolic Diseases, and Resources Programs Branch
Diabetes, Endocrinology, and Metabolic Diseases
National Institute of Arthritis, Metabolism, and Digestive Diseases
Westwood Building, Room 626
Bethesda, Maryland 20205
Telephone: (301) 496-7851
ANNOUNCEMENT

SPECIAL EMPHASIS RESEARCH CAREER AWARD:

DIABETES MELLITUS - CARDIOVASCULAR, METABOLIC, AND
ENDOCRINOLOGIC ASPECTS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM AND DIGESTIVE DISEASES

This is to announce the regular annual receipt date of June 1 for applications for the SERCA: Diabetes Mellitus - Cardiovascular, Metabolic, and Endocrinologic Aspects. Applications received on or before June 1, 1981 should specify a project start date of July 1, 1982. The next receipt date will be June 1, 1982 for a possible start date of July 1, 1983.

The award is intended to:

- encourage qualified individuals in the early stages of their post-graduate medical and scientific careers to develop research interests and skills in the metabolic, endocrinologic, and cardiovascular aspects of diabetes mellitus;

- provide support for individuals to pursue a program of research in various fundamental and clinical research disciplines related to diabetes mellitus and its sequelae, at one or more domestic institutions which offer superior opportunities in these areas; and

- create a pool of highly qualified investigators with experience and skills in the cardiovascular, metabolic, and endocrinologic aspects of diabetes mellitus for future roles in related areas of research.

The Special Emphasis Research Career Award (SERCA) provides the opportunity for an individual with developing research interests to acquire experience and skill in the broad fundamental and clinical scientific disciplines essential for a multidisciplinary approach to the study of the metabolic, endocrinologic, and cardiovascular aspects of diabetes mellitus. This award emphasizes in-depth experience in several fundamental and clinical scientific disciplines which are not necessarily dependent upon a single laboratory institution.

PROVISIONS OF THE AWARD

This non-renewal award provides support for a five-year period of full-time research and related activities. The latter may include research development activities as well as involvement in patient care to the extent that it will strengthen research skills. The SERCA grant made to the awardee's parent institution provides up to $30,000 per year full-time salary support plus fringe
benefits. A maximum of $8,000 per year during the first three years and $20,000 per year during the last two years will be provided for necessary research costs including technical assistance, equipment, supplies, consultant costs, domestic travel, patient care costs, publication, and other costs.

While working closely with an advisor, the awardee is expected to develop capabilities in fundamental, applied, and/or clinical research in the cardiovascular, metabolic, and endocrinologic aspects of diabetes. This should include exposure to multiple disciplines, such as physiology, biochemistry, biophysics, pharmacology, nutrition, and/or epidemiology. Investigators are encouraged to pursue these activities in several laboratories, and if appropriate, at more than one institution. In addition, an applicant must propose a research project of his/her own design which focuses on the cardiovascular, endocrinologic, and metabolic aspects of diabetes and which is of such scope that, within three years, evidence of independent investigative capability will be present. At the completion of this five-year award, the individual should be in a position to compete in regular NIH research grant award programs.

ELIGIBILITY REQUIREMENTS

Candidates for the SERCA Award must: (1) hold an M.D. or equivalent professional degree (e.g., D.D.S., D.O., D.V.M., etc.); (2) have a minimum of three years post-M.D. experience, including one year of clinical training in the sub-specialties of either cardiovascular disease or endocrinology-metabolism, or two years post-M.D./Ph.D. experience or equivalent. M.D./Ph.D. applicants should possess significant experience in metabolic, endocrine, or related areas, cardiovascular physiology, biochemistry, pharmacology, or other relevant areas of interest, such as epidemiology; (3) be citizens or noncitizen nationals of the United States or its possessions or territories or must have been lawfully admitted to the U.S. for permanent residence at the time of application; (4) meet certain other eligibility requirements specified in the SEP.CA Program Guidelines.

FOR ADDITIONAL INFORMATION

Prospective applicants are encouraged to review the SERCA Guidelines which detail eligibility requirements and application procedures. In addition, prior to preparing an application, individuals are strongly encouraged to discuss their potential eligibility as well as their areas of research interest with the Program Director listed below. Requests for copies of the SERCA Guidelines as well as questions related to eligibility, etc., should be directed to:

Chief, Endocrinology, Metabolic Diseases and Resources Programs Branch  
Diabetes, Endocrinology, and Metabolic Diseases  
National Institute of Arthritis, Metabolism, and Digestive Diseases  
Westwood Building, Room 626  
Bethesda, Maryland 20205  
Telephone: (301) 496-7851
ANNOUNCEMENT

NIH NEW INVESTIGATOR RESEARCH AWARD (NIRA) IN NUTRITION

ADAMHA SPECIAL NOTIFICATION FOR RESEARCH ON NUTRITION AND

BEHAVIOR

March 1981

The National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration, through the individual Bureaus and Institutes shown below, are encouraging the submission of applications for specifically described awards in support of research in areas related to human nutrition. The NIH program is described below; the ADAMHA program is described on page ten and eleven.

NIH - NEW INVESTIGATOR AWARDS IN NUTRITION

I. PURPOSE

The New Investigator Research Award program is designed to encourage new investigators (including those who have interrupted early promising research careers) in basic or clinical science disciplines to develop their research interests and capabilities in biomedical and behavioral research within the program interests of the National Institutes of Health. To help bridge the transition from training status to that of established investigator, this special grant supported program provides research grant funds for relatively inexperienced investigators with meritorious research ideas. Funds for this program are being allocated from appropriations made to the participating NIH awarding units to fulfill their legislatively mandated missions.

Under the authorizations in the Public Health Service Act (Section 301 and applicable sections pertaining to individual Institutes and Bureaus of Title IV) the Bureaus, Institutes and Divisions (BIDS) of the National Institutes of Health (NIH) may make New Investigator Research Awards (NIRAs), formerly known as Young Investigator Research Grants (NCI, NHLBI), Special Research Award Program (NIA), Special Dental Research Award, Young Environmental Scientist Health Research Grant Program, Special Visual Science Research Awards, NIRA in Diabetes, Special Grants for New Investigators in Anesthesiology, Special Grants for New Investigators in Trauma and Burn Research, New Investigator Research Grant in Medical Informatics.

Funds for this program are being allocated from appropriations made to the participating NIH awarding units to fulfill their legislatively mandated missions.

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 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.
II. ELIGIBILITY

A. Applicant Institutions

Only domestic nonprofit organizations and institutions, qualified entities of State and local governments and their agencies and Federal institutions may apply.

B. Principal Investigator

These awards are restricted to individuals who have not previously been principal investigators on a PHS supported research project. Exceptions may be granted to individuals who are changing their field of scientific endeavor. If there are questions, applicants should consult with NIH staff concerning the choice of application best suited to their needs.

The principal investigator must ordinarily have a doctorate degree or its equivalent. The applicant should have completed his/her formal professional education. In most instances the principal investigator will have no more than five years of research experience after completion of formal training at the time the award is made. Under unusual circumstances, if clearly justified, there may be an exception to this five year limitation.

C. Concurrent Applications

The requirement for eligibility for an NIRA precludes concurrent application for a Research Career Development Award, Clinical Investigator Award, Academic Award, Teacher Investigator Award, or National Research Service Award from the Public Health Service. A New Investigator Research Award recipient may apply for a research project grant provided the second award does not conflict with the time or other commitments to the NIRA.

III. REVIEW

Initial review of applications for scientific merit will be managed by the Division of Research Grants. Particular attention will be given to the following:

A. The adequacy of the applicant's research and research training background as a guide to future development into a creative independent investigator will be evaluated. The quality of the individual's past education, scientific training and commitment to a health-related research career will be taken into account along with the research proposal. Letters of reference are particularly valuable when the investigator's research originality and potential for independent investigation are not reflected in his/her past research experience.
B. The principal investigator's research proposal will be evaluated for scientific merit, originality, feasibility, adequacy of design and plans for analysis and evaluation of data. It is recognized that an investigator of limited experience is less likely to be able to submit an application with the same breadth and depth as an experienced investigator. The application must, however, give clear evidence of the investigator's ability to develop a sound research plan.

IV. TERMS OF THE AWARD

A. Principal Investigator

Principal investigators are directly responsible to the grantee institution to which the awards are made. The employment status, salary, title, and staff privileges are determined by the grantee institution in accordance with its established policies for other individuals of the same rank, faculty or employment status without regard to source of support.

Principal investigators must make a truly significant commitment of time or effort to the research project proposed; while in no case can this be less than 50%, for most applicants a larger commitment is encouraged. Salary support can be provided from the award up to $25,000 plus fringe benefits according to the time or effort devoted to the project.

B. Duration

NIRA awards are made for periods up to three years and are not renewable. A continuation of research support beyond the NIRA award may be sought as a regular research grant.

C. Follow-up Information

The principal investigators, upon request, are expected to provide the NIH with information about their scientific accomplishments, changes in professional status or institutional affiliation for a period of six years subsequent to termination of the award.

V. APPLICATION PROCESS

A. The regular research grant application form PHS 398 must be used in applying for these awards. Application material may be obtained from the institution's application control office or from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205.

B. The title of the program, "New Investigator Research Award," should be typed on Line 2, face page of the application form PHS 398.

C. Direct costs may be requested for up to three years of support. The total direct costs requested must not exceed $107,500 for the three-year period; no more than $37,500 may be requested in any one year.
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1. Up to $25,000 salary plus applicable fringe benefits may be requested for the principal investigator. The amount requested should reflect the time and effort to be directed to the project and must be consonant with the policies of the grantee institution governing salary for other individuals of similar rank.

2. Technical support, supplies, publication costs and limited equipment, as well as necessary travel, may be requested within the direct cost budget.

3. Requested funds may not be used to supplement a project supported by other funds.

D. Indirect costs are allowable in accordance with DHHS policies for research grants.

E. Because many new investigators may not have developed a significant bibliography of research accomplishments, principal investigators may request present or former supervisors to submit letters attesting to their potential for conducting independent research.

VI. GENERAL INFORMATION

A. Review Cycle

Receipt date for applications and review schedules are the same as for regular research grant applications.

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VII. RESEARCH AREA LIST FOR NIRA IN NUTRITION

For the purposes of assignment to the appropriate NIH Institute, applications must be identified as responding to one or more of the research areas listed below. Therefore, all applications submitted in response to this announcement should include the word "Nutrition" and the name of the relevant Institute on the first page.

NATIONAL INSTITUTE ON AGING

The NIA provides support for biomedical, social, and behavioral research and research training in the areas of diet and nutrition (both basic and clinical) as these relate to the aging process and the problems and needs of the aged individual. Examples of research areas of interest are:
1. Investigations on the effects of aging on nutrient digestion, absorption, and utilization, and the relationship of these effects to nutrient requirements.

2. Studies on special nutrition-related problems in the aged individual. Examples of such studies include: the role of nutrition in preventative and therapeutic regimens; the effects of specific diseases on nutritional status; interactions of nutrients and therapeutic agents as well as the effects of nutritional status on the efficacy of therapeutic agents and vice versa; and the role of nutrition in tolerance to, and recovery from surgery.

3. Clinical or epidemiological research on the relationship between aging, nutritional status, dietary intake, and health status of the aged adult.

4. Basic and clinical nutrition studies of the interrelationships between aging and:
   a. factors which may regulate changes that occur in body composition, including lean body mass and other musculoskeletal changes, energy balance, and regulation of metabolic processes, as well as disease susceptibility with increasing age. This includes studies on effects of diet, weight, and physical exercise in modifying immune, endocrine, and metabolic processes with age, as well as the effects of excessive caloric intake and levels of obesity on the health of the aged adult;
   b. the effects of nutritional deficiencies of essential nutrients, vitamins, minerals, and trace elements on long-term health and longevity, including the effects of protein and ascorbic acid intake on the absorption and utilization of heavy metals and trace minerals, such as iron and calcium, zinc, and chromium;
   c. nutrition as it relates to age-associated mental deterioration and loss of neural function, particularly senile dementia, and including decline in the sensations of taste and smell, in motor coordination, and in cognition.

5. Studies on psychological, social, and economic factors which affect the dietary patterns of the aging individual.

The areas of emphasis listed above are examples. They are not intended to be all inclusive.

Contact Person:

Elizabeth A. McGuire, Ph.D.
Physiology of Aging Branch
Biomedical Research and Clinical Medicine
National Institute on Aging
Building 31, Room 5C-25
Bethesda, MD 20205
Telephone: (301) 496-9350
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM, AND DIGESTIVE DISEASES

The Nutrition Program, NIAMDD, provides support for research in basic, clinical, and behavioral science areas related to human nutrition. Other programs of the Institute, especially the Digestive Diseases, Diabetes, Hematology, Endocrinology, and Metabolism Programs also support relevant nutrition research. The following are examples of emphasis areas:

1. Human nutritional requirements for all healthy individuals as well as for various disease conditions; factors that may influence dietary needs such as bioavailability, nutrient imbalance, activity level, stress, drugs, and environmental toxicants. Of special interest are studies on the need for trace elements, dietary fiber, and vitamins.

2. Study of the metabolic function of nutrients and the role of nutrients as metabolic regulators.


4. Nutritional support of patients, with efforts aimed toward the development of improved methodologies for the assessment of nutritional status, and the delivery of the proper amounts of the essential nutrients in the prevention and treatment of specific disease states.

5. Nutritional aspects of digestive diseases, diabetes, anemias, and other metabolic diseases.

Contact Person:

Dr. Gerald F. Combs
Director, Nutrition Program
National Institute of Arthritis, Metabolism, and Digestive Diseases
National Institutes of Health
Room 606, Westwood Building
Bethesda, MD 20205
Telephone: (301) 496-7823

NATIONAL CANCER INSTITUTE

The Diet, Nutrition, and Cancer Program of the NCI supports broad areas of diet and nutrition research as they may relate to cancer. The following areas of emphasis are examples:

1. Nutritional biochemistry.

3. Nutritional microbiology - Dietary influences on gastrointestinal microbial populations, both aerobic and anaerobic. Effects of nonnutritive substances (e.g. fiber), vitamins, minerals, as well as nutrients in various combinations, in the formation of bacterial degradation products.

4. Nutritional immunology - Effects of specific nutrients on cell mediated and humoral defense systems as they may be related to inhibition of carcinogenesis.

5. Nutritional epidemiology - Biostatistical and epidemiological methods pertinent to dietary studies. Metabolic and biochemical characterization of body fluids, foods, etc., from populations at low or high risk of cancer.

6. Nutritional endocrinology - The role of diet to various endocrine responses as involved in the initiation or inhibition of carcinogenesis.

The above listed areas are given as examples of project interest. They are by no means meant to be all inclusive.

Contact Person:

Dr. Gerald Liddel  
Division of Extramural Activities  
National Cancer Institute  
National Institutes of Health  
Westwood Building, Room 826  
Bethesda, Maryland 20205  
Telephone: (301) 496-7575

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

The Nutrition Program of the NICHD provides support for research that deals with developmental aspects of nutrition, particularly in regard to reproduction, lactation, infancy, childhood, and adolescence. The following are research areas of emphasis:


2. Developmental Nutrition - Effects of normal, excessive or deficient amounts of nutrients during pregnancy, fetal development, and post-natal life including the roles played by nutrition in physical, physiological, and behavioral development.

3. Infant Nutrition - Nutritional composition of colostrum and human milk and the functional roles played by components of these fluids. The effects of nutrients on infant development as well as the effects on development of chronic diarrhea and malnutrition. Nutritional therapy for these conditions. Nutritional therapy of inborn errors of metabolism.
4. Nutritional Aspects of Gastrointestinal Development - Nutrient transport studies, including absorptive capabilities and capacities, intestinal flora-nutrient relationships; the influence of nutrients on gastrointestinal development; and local immunological reactions to nutrients.

5. Obesity and Nutritional Antecedents of Adult Disease - The origins of obesity and its attendant morbidity, including the influences in adulthood of dietary intake and patterns of food consumption during infancy and childhood. Studies are sought that address behavioral, genetic, metabolic, neurochemical, and other factors present during infancy and childhood that may contribute to the development of obesity, insulin resistance, glucose intolerance, and diabetes mellitus later in life.

6. Nutritional Individuality - Interactions of nutrition and the genome; historical, geographical, and evolutionary factors that contribute to individual nutrient requirements; evolutionary modification of digestive processes under selective pressure of certain foods; and the relationships of geophysical environments to local cuisines, food preparation, and nutritional status.

7. Cultural and Behavioral Aspects of Nutrition - Cultural, social and psychological aspects of nutrition during pregnancy, infancy, childhood, and adolescence; determinants and control of food intake during critical stages of the life cycle; effects of malnutrition on behavior; behavior modification of deleterious dietary habits, in regard to obesity and in regard to correction of unbalanced diets during pregnancy, infancy and childhood.


Contact Person:

Gilman D. Grave, M.D.
Head, Nutrition and Endocrinology Section
National Institute of Child Health and Human Development
National Institutes of Health
Landow Building, Room 7C-17
Bethesda, MD 20205
Telephone: (301) 496-5575

NATIONAL INSTITUTE OF DENTAL RESEARCH

Examples of areas in which applications dealing with nutrition research will be accepted by NIDR include:

1. Dental caries - Studies of nutritional deficiencies relating to tooth development and caries resistance; laboratory and behavioral studies of diet preference; development of noncariogenic sugar substitutes and assessment of the cariogenicity of foods.
2. Periodontal disease - Studies of the need for trace elements to prevent oral disease; studies of the role of nutrition on oral immune systems including cell mediated and secretory immune mechanisms.

3. Oral soft tissues diseases - Effects of nutrition on epithelial integrity and function, secretory cell function, ulcerative and other oral diseases, and the possible deleterious effects of subclinical deficiencies on general oral health.

4. Craniofacial anomalies - Studies dealing with nutritional requirements as well as biochemical and/or metabolic effects of nutrient variables which may cause aberrations in growth and development of the face and jaws including developmental anomalies.

Contact Person:

David A. Wolff, Ph.D.
Soft Tissue Stomatology and Nutrition Program Branch
National Institute of Dental Research
National Institutes of Health
Westwood Building, Room 510
Bethesda, MD 20205
Telephone: (301) 496-7807
ADAMHA - SPECIAL NOTIFICATION FOR RESEARCH ON NUTRITION AND BEHAVIOR

Although the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) does not have a specific NIRA program in nutrition, ADAMHA is interested in stimulating research in the area of nutrition and behavior through its regular research grant programs. Specific areas of interest relevant to the National Institute of Alcohol Abuse and Alcoholism (NIAAA) and the National Institute of Mental Health (NIMH) are described below.

NATIONAL INSTITUTE OF ALCOHOL ABUSE AND ALCOHOLISM

Through the regular research program, including the Small Grants Program and the Research Scientist Development Program, NIAAA provides support for research in areas of nutrition which are of importance to the subject of alcoholism and alcohol abuse. Examples of alcoholism relevant nutrition research include the following:

1. The effect of alcohol as a nutrient, as distinct from a pharmacologic agent, on central nervous system functions. This may encompass any or all of the disciplines of the neurosciences.

2. Alcohol as a nutrient, as distinct from a pharmacologic agent, and its actions on metabolism and physiology.

3. The effects of alcohol on vitamin and mineral metabolism.

4. Primary and secondary malnutrition from alcohol -- the mechanisms of action which underlie the pathology of alcoholism.

The above research areas are not meant to be all inclusive.

Contact Person:

Kenneth R. Warren, Ph.D.
Chief, Biomedical Research Branch
National Institute on Alcohol, Alcohol Abuse, and Alcoholism
Alcohol, Drug Abuse, and Mental Health Administration
Parklawn Building, Room 1-27
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4223

NATIONAL INSTITUTE OF MENTAL HEALTH

NIMH provides support for research in the area of mental health and nutrition through its regular research grant programs, the Small Grants Program and the Research Scientist Development Program.
NIMH - Research Areas in Nutrition

The NIMH supports biological, behavioral, and psychosocial research related to mental health and mental illness. The following areas of emphasis are examples of areas of interest relevant to nutrition.

1. Clinical and applied studies of the relationship of eating behavior, and nutritional status on mental disorders.

2. Research to assess the interactions between psychotherapeutic drugs and treatments and the nutritional status of psychiatric patients.

3. Basic studies designed to understand the biological, behavioral, and social processes which underlie the motivation for eating behavior and nutritional status including studies to understand the psychological and biological mechanisms involved in the prevention, development and treatment of obesity and anorexia nervosa.

4. Studies involving the use of nutrients or other dietary substances as part of a therapeutic regimen for behavioral disorders.

Contact Person:

Ellen Simon Stover, Ph.D.
Division of Extramural Research Programs
National Institute of Mental Health
Alcohol, Drug Abuse, and Mental Health Administration
Parklawn Building, Room 10-104
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4337

GENERAL INFORMATION

It is recommended that applicants consult with the individuals listed in this announcement for additional information concerning specific mechanisms, application procedures, etc.

Review Cycle

Receipt date for applications and review schedules for regular research grant applications are provided below:

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Small grants are reviewed five times a year and may be submitted at any time without regard to the receipt dates that pertain to the regular research grant program. However, applications requesting June 1 starting dates must be received no later than December 1 and applications with July 1 or August 1 starting dates must be received no later than February 1.

Receipt dates for the submission of the Research Scientist applications and the review cycle are as follows:

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