

NIH GUIDE

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HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Room 2A14, 5333 Westbard Avenue, National Institutes of Health, Bethesda, Maryland 20014, and attach your address label to your letter. Prompt notice of your change of address will prevent your name being removed from our mailing list.

The GUIDE is published at irregular intervals to provide policy and administrative information to individuals and organizations who need to be kept informed of requirements and changes in grants and contracts activities administered by the National Institutes of Health.

Supplements, printed on yellow paper, are published by the respective awarding units concerning new projects, solicitations of sources, and requests for proposals.

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YOUNG INVESTIGATOR RESEARCH GRANT,

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INFECTIOUS DISEASES

A N N O U N C E M E N T

I. OBJECTIVES

The National Institute of Allergy and Infectious Diseases (NIAID) Young Investigator Research Grant Program is intended to encourage young investigators to develop independent original research projects in immunology and virology with clinical relevance. The NIAID Young Investigator Research Grant Program provides initial independent support for a designated research project developed by the young investigator. It is designed to encourage young investigators in the disciplines of immunology and virology to develop their research interests and capabilities in clinically important aspects of these areas. To help bridge the transition from training status to that of a productive investigator, this special grant program provides support for young scientists and physicians with meritorious research ideas of their own design. Women and members of minority groups are invited to consider this program, as is the case for all NIAID programs.

II. BACKGROUND AND RATIONALE

Immunologically mediated diseases cover a spectrum of illnesses that are important for their prevalence and disabling effects among all age groups. Included among these are disorders that involve multiple body systems, e.g. the respiratory and gastrointestinal tracts, skin and connective tissue, kidney, thyroid, nervous system, blood vessels and cellular elements of the blood. Statistical surveys reveal that asthma and allergic diseases alone affect between 30 and 35 million Americans each year. As such, they are leading causes of economic loss and morbidity in terms of restricted activity and days lost from work and school. Additionally, it is becoming increasingly clear that reactions to drugs and bee stings and such serious illnesses as systemic lupus erythematosus, glomerulonephritis, hypersensitivity pneumonitis, rheumatic fever, rheumatoid arthritis and ulcerative colitis have demonstrably immunologic etiologic components. Thus, if we are to reverse the trends of increasing incidence of severe illness, disability, and fatal outcomes in these situations, correspondingly increased research efforts must be mounted to bring in information on relevant sensitization and immune mechanisms and on correcting deficiencies of the immune system that can be meaningfully applied to diagnosis, prevention, control, and treatment of allergic and immunologic diseases.

Viral diseases are believed to be implicated in more than 60 percent of all human illnesses and have an economic impact of billions of dollars annually in morbidity and mortality. Many viral plagues of historical significance like smallpox and yellow fever are now preventable or controlled by vaccines but many other viral diseases

such as acute and recurrent herpes infections, influenza, and viral diarrheas remain unconquered. Insidious diseases like spongiform and sclerosing encephalitides, acute and chronic hepatitis, and multiple sclerosis are known or thought to be caused by viral agents but these are not yet well characterized and difficult to detect early. Likewise, much remains to be known about host factors controlling susceptibility to viral infections and mechanisms which permit: (1) acute disease with complete recovery; (2) latent infection with recurrent disease, or; (3) persistent infections leading to slowly progressive or chronic disease.

III. IMPLEMENTATION

Beginning in fiscal year 1977, the National Institute of Allergy and Infectious Diseases plans to award 12-14 new Young Investigator Research Grants. Each grant will have a duration of not more than three years. Funding beyond the first year of the grant will be contingent on satisfactory progress during the preceding year.

The status of the Young Investigator Research Grant Program will be reviewed four years from the date of the first awards to determine whether or not the program should be continued. To assess the effectiveness of the program in fulfilling its objectives, the Institute intends, after termination of each grant, to follow the progress of the recipient for a period of six years to determine (1) the investigator's professional affiliation(s), (2) his/her subsequent research grant or contract support, and (3) his/her scientific publications. It is anticipated that the results achieved with this grant will, in a majority of cases, provide the basis for successful competition in the regular research support programs of the Institute.

The first receipt date for applications will be November 1, 1976. They will be reviewed by study sections in February-March and by the National Advisory Allergy and Infectious Diseases Council in May 1977. July 1, 1977, will be the earliest starting date for successful applicants.

IV. CRITERIA FOR ELIGIBILITY

The project proposed in a Young Investigator Research Grant Application must be:

- relevant to clinical problems of immunology and virology such as are described in the BACKGROUND AND RATIONALE section above;
- a well-defined project to answer a specific scientific question, or a pilot study, but not supplemental to a project supported by other funds;
- designed for completion within a 3-year period; and
- acceptable in accordance with the customary criteria of scientific merit.

The investigator must:

- provide a satisfactory plan for completing the project within 3 years;
- submit with the application the names of three persons who are present or past supervisors or preceptors and who will forward letters attesting to his/her ability to undertake the project;
- have completed a two-year period of postdoctoral laboratory training by the time of the award;
- present evidence of prior research experience;
- not be or have been the recipient of an NIH Special Fellowship, Research Career Development Award, nor the principal investigator on a research grant, research contract, or the equivalent, either at present or in the past; however, trainees or regular research fellows are not excluded;
- be a citizen or a non-citizen national of the United States or its possessions and territories, or have been lawfully admitted to the United States for permanent residence at the time of submitting the grant application;
- agree to keep the National Institute of Allergy and Infectious Diseases informed about scientific accomplishments, change in professional status, and change in institutional affiliation for a period of six years after the grant terminates;
- agree to devote at least 70 percent of his/her time to the project.

The applicant institution, through the chairperson of the sponsoring department, must:

- indicate its commitment to the project,
- provide space and facilities necessary to pursue the project,
- release the principal investigator from other responsibilities for the proportion of time or effort to be devoted to the project.

Institutions may submit more than one application. Only domestic institutions may apply.

V. SUPPORT PROVIDED BY THE GRANT

Except where otherwise indicated in this announcement, the policies which apply to research project grants apply also to the NIAID Young Investigator Research Grant Program. The Young Investigator Research Grant will provide support for a period of up to three years in an amount not to exceed \$90,000 direct costs, of which no more than

\$30,000 may be requested for any 12-month period. These grants are not renewable and because of their special nature, certain limitations are placed on the items which can be supported, as specified below.

Personnel

- salary and fringe benefits for the principal investigator may be requested to the extent that they reflect the time or effort devoted to the project. In no event, however, will the salary support of the investigator exceed \$21,000 per year from this grant. The effort of one part-time technical assistant may also be supported, if justified in terms of the research.

Equipment

- the facilities available should include most of the necessary equipment. Some specialized equipment essential to the specific research effort may, however, be justified. Only in unusual circumstances will equipment purchases be allowed during the third year of the award.

Supplies

- the cost of necessary supplies must be detailed and justified.

Travel

- expenses to attend one national meeting closely related to the project may be requested for each 12-month period.

Hospitalization

- support for patient expenses may be requested but must be strongly justified if needed for the project.

Publication Costs

- since publishable results are seldom expected in the first 12 months, publication costs will be approved only for subsequent portions of the project period.

Other Expenses

- if other items are necessary for performance of the research effort, these must be clearly justified in terms of that need.

Indirect Costs

- will be provided in accordance with established DHEW policies for regular research grants.

VI. APPLICATION

Applications must be submitted on form NIH 398. The original copy and the folder in which it is submitted should be clearly labeled (in red ink) NIAID Young Investigator Research Grant. The proposed project should be presented using the format described in the "Instructions" in the application kit.

The chairperson of the department sponsoring the research should submit a signed statement, as part of the application, detailing the commitments made to the project.

The completed grant application should be mailed to the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20014. Upon receipt of each application at NIH, a postal card acknowledging receipt will be mailed to the investigator. When the application has been assigned to an initial review group (study section) the applicant will again be notified by mail.

The applicant must ask three present or former supervisors or preceptors to send a letter to the review group in the Division of Research Grants attesting to his/her potential for conducting research but these need not comment on the merit of the specific project. These reference letters should not be mailed to NIH until the applicant has received the middle part of the Receipt Card indicating the review group (study section) and its address. The applicant is responsible for making the necessary arrangements to insure that the reference letters are mailed by the supervisors/preceptors directly to the review group. (NIH staff is unable to respond to individual inquiries concerning the receipt of these reference letters.)

Applications may be submitted on the regular new research project grant receipt dates (November 1, March 1, July 1). Applications received too late for one round of review will be considered in the next round. They will be screened for relevance to the programs of the Institute in the clinical aspects of immunology and virology. The initial scientific and technical merit review of these proposals will be conducted by the Division of Research Grants. Applicants will be informed of the results of the review shortly after final consideration by the National Advisory Allergy and Infectious Diseases Council. Successful applicants may plan to initiate their research efforts as early as the first of the month which follows their notification.

Questions or requests for further information should be directed to the staff of the NIAID program area to which the research will be related. For other information and appropriate referral, call (301) 496-7820.

DIABETES RESEARCH AND TRAINING CENTERS,

NATIONAL INSTITUTE OF ARTHRITIS,

METABOLISM, AND DIGESTIVE DISEASES

A N N O U N C E M E N T

The National Institute of Arthritis, Metabolism, and Digestive Diseases announces its intent to establish a number of Diabetes Research and Training Centers under authority Part D of Title IV of the Public Health Service Act as amended by the National Diabetes Mellitus Research and Education Act of 1974 (PL 93-354) (42 USC 289c-2). Copies of the Diabetes Research and Training Centers Guidelines are now available.

A Diabetes Research and Training Center is defined as a resource formed within a single university center, or through a consortium of cooperating institutions including a university-affiliated center, dedicated to conducting research and programs for training in diabetes mellitus and related endocrine and metabolic disorders. Specifically, each Diabetes Research and Training Center is charged by the National Diabetes Mellitus Research and Education Act with conducting "A) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic disorders and the complications resulting from such disease or disorders, B) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such disease, disorders, and complications, and C) information programs for physicians and allied health personnel who provide primary care for patients with such disease, disorders, or complications." It is the inclusion of training and education efforts with the research program efforts that distinguishes the Diabetes Research and Training Centers from the presently supported "Diabetes-Endocrinology Research Centers" which are specifically oriented toward research goals.

The Diabetes Research and Training Centers will be funded by the grant mechanism, but under conditions that will require close coordination with the National Institute of Arthritis, Metabolism, and Digestive Diseases.

The implementation of this program is integral to the Institute's plans for fiscal year 1977. However, the number of Diabetes Research and Training Center grants to be awarded will be contingent upon the appropriation and apportionment of funds for this purpose. Institutions receiving awards will be selected on the basis of national competition.

Applications for Diabetes Research and Training Center grants must be submitted, in accord with the required format, prior to January 15, 1977. It is important that potential applicants consult with staff of the National Institute of Arthritis, Metabolism, and Digestive Diseases prior to the submission of an application, to determine if the proposed program meets the criteria of a Diabetes Research and Training Center. Therefore, potential applicants are asked to submit letters of intent, prior to November 30, 1976. In addition, the Institute will hold an orientation

session for the representatives of potential applicant institutions on or about November 1, 1976. Further information, copies of the Guidelines, and application materials may be obtained from:

Office of the Associate Director
for Extramural Program Activities
National Institute of Arthritis,
Metabolism, and Digestive Diseases
Bethesda, Maryland 20014

TREATMENT OF RELEASED FUNDS RESULTING FROM
ISSUANCE OF RESEARCH DEVELOPMENT OR
ACADEMIC CAREER AWARDS

POLICY

Background Since 1962 the National Institutes of Health has had a policy that grantee institutions may not automatically retain grant funds freed as a result of providing salary for an individual through an NIH research development or academic career award and use them for other project-related purposes. Grantee institutions have been required to seek prior approval from awarding units to retain such funds.

At various times questions are raised as to what NIH considers appropriate circumstances for allowing retention of such funds within the affected NIH research or training grant(s). Following is a statement of NIH's policy on this subject.

Policy Funds budgeted in an NIH-supported research or training grant for an individual's salary and/or fringe benefits, but freed as a result of funding a research development or academic career award for that individual may not be used for any other purpose except when the career award recipient no longer participates in the grant-supported activity and another individual replaces him/her and requires comparable remuneration. Only under some highly unusual circumstance will consideration be given to approval for use of released funds for any other reason than the one described above. In any event, the proposed retention of funds released in this manner must receive prior written approval of the NIH awarding unit.

APPLICATION ASSIGNMENT INFORMATION

MAILED TO BUSINESS OFFICES

PROCEDURE NOTICE

Effective October 1, 1976, the Division of Research Grants will cease mailing three copies of duplicated research, training, and Research Career Development applications to the business office indicated on the face page of the application. This had been done to provide the applicant institution with information concerning the initial review group and Bureau, Institute, or Division assignment.

Such assignment information, previously provided through the duplicated application, will henceforth be provided by form PHS 3830 (three-part post card) which acknowledges receipt of the application and subsequently the assignment to an initial scientific merit review group and a council.

EXTENSION OF APPLICATION RECEIPT DATE,

MINORITY HYPERTENSION RESEARCH

DEVELOPMENT SUMMER PROGRAM

NOTICE

The receipt date for applications for the Minority Hypertension Research Development Summer Program, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute has been extended from October 15, 1976, to November 1, 1976. The announcement of this program is contained in Vol. 5, No. 10, July 12, 1976.

NOTICE

PROHIBITED OR RESTRICTED RESEARCH

Following is a revision of the notice published in the *NIH Guide for Grants and Contracts*, Vol. 5, No. 15, September 15, 1976.

"Certain types of activities involving human subjects may not be supported or conducted with the aid of National Institutes of Health or Public Health Service or Department of Health, Education, and Welfare funds regardless of the type of grant, contract, or other support mechanism involved:

1. Any research whatsoever involving in vitro fertilization of human ova, unless previously approved by the DHEW Ethical Advisory Board, NIH, Bethesda, Maryland 20014. [Authority: 45 CFR 46.204(3)]
2. Any research involving pregnant women or fetuses, not strictly in compliance with the provisions of Subpart B of Part 46 of Title 45 of the Code of Federal Regulations. (Authority: CFR 46.201)
3. Any research in the biomedical, contraceptive development, behavioral and program implementation fields, relating to family planning or population research, where abortion is a method of family planning. [Authority: 42 U.S.C. Ch. 6A, Sections 1004(b) (2) and 1008] This prohibition should not be construed so as to prevent scientific research into the causes of abortion and its effects. (H.R. Report 92-461 accompanying Public Law 92-80)
4. Any research program or project, or program, project or course which is of an experimental nature, without the written informed consent of each participant or subject, or if the participant or subject is under 18 years of age, the written informed consent of his parents or legal guardian. (Authority: Public Law 94-206, Section 411; applicability: DHEW grants, contracts, and intramural activities)

"These prohibitions and restrictions extend to activities supported by research grants (including program project grants, center grants, and other types of grants directly supporting research), biomedical research support grants, categorical clinical research center grants, general clinical research center grants, National Research Service Awards, research career awards, similar types of grants and contracts as applicable."

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