

# NIH GUIDE

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The NIH Guide announces scientific  
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NOTICES

COOPERATIVE AGREEMENTS AS THE AWARD INSTRUMENT FOR CERTAIN NHLBI CLINICAL  
TRIALS AND LARGE-SCALE EPIDEMIOLOGICAL STUDIES

P.T.

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) announces that any new investigator-initiated clinical trial or epidemiological study in which direct costs exceed \$500,000 in any year (at a single institution or in the aggregate for multi-institutional collaborative studies) will usually be awarded only as a cooperative agreement.

The cooperative agreement is an assistance instrument similar in most ways to a grant. It differs in that in addition to the standard stewardship role, an Institute program scientist is expected to have a continuing substantive role in one or more programmatic aspects of the study, in an assisting, not a directing, relationship. The type and degree of such involvement is to be appropriate to the specific cooperative agreement and is described in a document accompanying the award statement. When an investigator-initiated application results in a cooperative agreement, the awardee will have lead responsibilities in all aspects of the study, including any modification of study design, conduct of the study, quality control, and analysis of results. The Institute program scientist may have assistance roles in one or more of these areas and will have a shared lead responsibility in facilitating the interim data and safety monitoring.

As in the past, potential applicants for research of this scope and scale are encouraged to contact NHLBI staff prior to making detailed plans for their application or submitting their application.

Questions regarding this notice may be directed to:

Peter Frommer, M.D.  
Deputy Director  
National Heart, Lung, and Blood Institute  
Building 31, Room 5A-49  
Bethesda, MD 20892  
Telephone: (301) 496-1078

NOTICES OF AVAILABILITY (RFPs AND RFAs)

PROGRAM PROJECTS ON NEW METHODS OF IMMUNE INTERVENTION

RFA AVAILABLE: AI-91-11

P.T.

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: August 22, 1991

Application Receipt Date: November 19, 1991

**BACKGROUND**

The Basic Immunology Branch, Division of Allergy, Immunology and Transplantation, of the National Institute of Allergy and Infectious Diseases (NIAID) supports fundamental research that expands recent, major advances in the field of immunology and leads to the clinical application of those advances. The remarkable progress in understanding the immune system in health and disease has created a wealth of potential for the treatment and prevention of human illness. It is also evident that a void exists between the new information and new experimental approaches generated by basic research and the effective use of recent information to develop methods and procedures for clinical application. This Request for Applications (RFA) is intended to encourage the submission of applications from collaborating investigators that include prospective clinical significance as a factor in the design and execution of the research. The ultimate goal of these program project grants is to develop new approaches to the treatment and/or prevention of human autoimmune, allergic, and inflammatory diseases.

**RESEARCH GOALS AND SCOPE**

Major, recent advances in our knowledge have indicated that, for example, immunodominant (Class I- and Class II-reactive) peptides and idiotypes of T-cell receptors (prospective "vaccines"), and cell adhesion molecules and lymphocyte homing receptors may be valuable tools in treating illness. The prospects for the use of immunodominant major histocompatibility complex peptides, idiotypic peptides, and anti-idiotypic monoclonal antibodies or T-cell clones to treat autoimmune diseases are particularly promising. The reason for optimism is that, in several experimental autoimmune disease models, the disease results from the autoaggressive actions of a highly restricted number of T-cell clones. There likewise appear to be opportunities to employ cell adhesion molecules and lymphocyte homing receptors to treat inflammation, various infections, and asthma. An approach that appears unusually promising in altering the course of autoimmune and allergic diseases is the induction of oral tolerance by appropriate tolerogenic substances. The scope of these program project grants includes all aspects of research concerned with the treatment or prevention of model experimental autoimmune, allergic, and inflammatory disorders. Studies involving valid in vitro models are appropriate. Investigations that involve human subjects or human materials are welcome.

**SPECIAL INSTRUCTIONS FOR THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES**

The following is a brief statement of the NIH and ADAMHA policy regarding the inclusion of women and minorities in study populations. The inclusion of women and minorities must be addressed in clinical applications submitted in response to this RFA.

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

## MECHANISM OF SUPPORT

Program project (P01) grants are awarded to an institution on behalf of a program director for the support of a broadly based, multidisciplinary, long-term research program that has a specific major goal or basic theme. A program project involves the organized efforts of groups of investigators who conduct research projects related to the overall program goal. The grant can provide support for the projects and for certain basic resources shared by individuals in the program project if sharing facilitates the total research effort. Each project supported by a program project grant is expected to contribute to and be directly related to the common theme of the program. The projects, under the direction of a Principal Investigator, must demonstrate an essential element of unity and interdependence. In Fiscal Year 1992, the NIAID plans to award at least two program project grants submitted in response to this RFA and, depending on availability of funds and scientific merit, more than two. Budgetary requests must be limited to no more than \$500,000 direct costs per year.

## ELIGIBILITY

Only domestic institutions are eligible to apply.

## METHOD OF APPLYING

Applications may be submitted by any domestic, public or private, nonprofit or profit-making, organizations. Before preparing an application, the prospective applicant should request a copy of the NIAID Information Brochure on Program Project and Center Grants from:

Olivia Preble, Ph.D.  
Allergy, Immunology and Transplantation Research Committee  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
Westwood Building, Room 3A-07  
Bethesda, MD 20892  
Telephone: (301) 496-3528

## STAFF CONTACT

A more detailed RFA may be obtained from:

Joseph F. Albright, Ph.D.  
Chief, Basic Immunology Branch  
Division of Allergy, Immunology and Transplantation  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health  
5333 Westbard Avenue, Room 757  
Bethesda, MD 20892  
Telephone: (301) 496-7551  
Telefax: (301) 402-0175

Inquiries regarding fiscal matters may be addressed to:

Mr. Jeffrey Carow  
Chief, Immunology Grants Management Section  
GMB, DEA  
National Institute of Allergy and Infectious Diseases  
Westwood Building, Room 726  
Bethesda, MD 20892  
Telephone: (301) 496-7075

Prospective applicants are asked to submit by August 22, 1991, a letter of intent that includes a descriptive title of the overall proposed research, the name of the Principal Investigator, and a list of the names of key investigators and their institution(s). The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed to allow early preparations for review, as well as to promote early interactions between applicants and NIAID staff. The letter of intent is not binding and does not commit the sender to submit an application, nor is it a requirement for submission of an application.

THE RFA LABEL AVAILABLE IN THE 10/88 REVISION OF APPLICATION FORM PHS 398 MUST BE AFFIXED TO THE BOTTOM OF THE FACE PAGE. FAILURE TO USE THIS LABEL COULD RESULT IN DELAYED PROCESSING OF THE APPLICATION SUCH THAT IT MAY NOT REACH THE REVIEW COMMITTEE IN TIME FOR REVIEW.

This program is described in the Catalog of Federal Domestic Assistance No. 93.855, 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 Regulation 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

#### ONGOING PROGRAM ANNOUNCEMENTS

#### RESEARCH ON RELATIONSHIPS BETWEEN ALCOHOL USE AND SEXUAL BEHAVIORS ASSOCIATED WITH HIV TRANSMISSION

PA: PA-91-75

P.T. 34; K.W. 0404003, 0715008, 0715182, 0404000

National Institute on Alcohol Abuse and Alcoholism

Application Receipt Dates: January 2, May 1, September 1

#### PURPOSE

The primary purpose of this program announcement is to encourage in-depth research on the linkage between unprotected sexual behaviors and alcohol use or misuse in order to inform and improve the design and implementation of programs to prevent HIV transmission.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement for Research on Relationships Between Alcohol Use and Sexual Behaviors Associated with HIV Transmission is related to the priority area of reducing the incidence and prevalence of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone: 202-783-3238).

#### RESEARCH OBJECTIVES

The research envisioned will study possible relationships between alcohol use and unsafe sexual practices; determine whether associations are causal or correlative; and identify specific components of the causal or correlative process, particularly those that have implications for prevention and relapse prevention programs. The objective of this research is to gain a better understanding of the relationship between alcohol use and sexual risk taking as well as the individual and environmental determinants of risky sexual practices enacted in the context of alcohol use.

Research called for under this announcement could span a range of prevention-related activities, from social epidemiology used to describe the nature and scope of the problem, to basic research needed to develop hypotheses and theories regarding potential for behavioral change, to applied research required to intervene effectively in the problem. Applied research may involve pilot tests of possible strategies to change alcohol-related behaviors that increase the risk of HIV exposure (in laboratory and real world environments), small-scale trials building to larger-scale controlled trials, or technology transfer studies (i.e., tests of dissemination strategies affecting the adoption of approaches that have proven to be effective). In addition, research on methodological issues and techniques is also needed.

Examples of possible research topics relevant to this announcement include:

- o studies to elaborate on the existing descriptions of relationships between alcohol use and unsafe sex, such as (1) the role of the environment in which alcohol is used (e.g., singles and gay bars, cocktail parties, the home) as a contributor to sexual risk taking, (2) the contribution of particular alcohol consumption patterns (e.g., binge drinking) to unsafe sexual practices, (3) possible variations in linkages between alcohol consumption and sexual risk taking across various types of couples (e.g., monogamous couples, extramarital coupling, sex between strangers, and others) and across different subpopulations (e.g., by gender, race, ethnicity);
- o methodologic studies to identify innovative, appropriate techniques (e.g., the use of diaries) for gathering data and probing the strength and stability of associations over time and to ascertain

the strengths and weaknesses of different measures of pertinent variables;

- o ethnographic research to provide detailed descriptions of norms governing sexual behavior while drinking and not drinking and to provide detailed information on what makes condom use difficult or appealing in different contexts and how alcohol may affect perceptions of condom usage;
- o prospective, longitudinal studies to examine the stability and variability of key behaviors over time and to establish the temporal relationships between a range of critical variables that address alcohol use and sexual behaviors known to transmit HIV infection;
- o studies leading to multivariate analyses that may identify direct, indirect, and interactive effects of a range of variables contributing to sexual risk taking (including the use and misuse of alcohol; expectancies about alcohol; sexual norms, roles, and orientation; impulsivity; perceived vulnerability; and risk taking related to other behaviors);
- o the design, implementation, and evaluation of intervention programs that seek to prevent risk taking and promote condom use among individuals who use alcohol in the context of sexual activity.

Although the National Institute on Alcohol Abuse and Alcoholism (NIAAA) has particular interest in behaviors that increase the risk of HIV infection, it is also important to understand the behaviors that reduce that risk. Thus, researchers alternatively might study drinking and non-drinking populations that protect themselves against exposure to HIV.

#### SUPPORT MECHANISMS

Research support may be requested through applications for a research grant (R01), small grant (R03), and First Independent Research Support and Transition (FIRST) Award (R29). Specialized announcements for the FIRST Award program (R29) and the small grant program (R03) are available from: The National Clearinghouse for Alcohol and Drug Information (NCADI), P.O. Box 2345, Rockville, Maryland 20852, telephone (301) 468-2600.

Applications may request support for up to five years. Small grants are limited to two years. It is recognized that applicants may want to extend the time to continue a longitudinal study of subjects. When such a design is considered, applicants should outline the full scope of the project in the current application and propose to reapply for competitive continuation funding at a later date. FIRST and small grants can not be renewed.

Annual awards will be made, subject to continued availability of funds and progress achieved.

#### CONDITIONS OF SUPPORT

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

#### ELIGIBILITY

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

#### REVIEW PROCEDURES

The Division of Research Grants, NIH, serves as the central point for receipt of applications under this program announcement. Applications received will be assigned to an Initial Review Group (IRG) in accordance with established Public Health Service Referral Guidelines. The IRG, consisting primarily of

non-Federal scientific and technical experts, will review applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate National Advisory Council, where reviews may be based on policy considerations as well as scientific merit considerations. Only applications recommended for approval by these advisory bodies will be considered for funding.

#### INCLUSION OF WOMEN AND MINORITIES IN STUDY POPULATIONS

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

#### APPLICATION PROCEDURES

Applicants must use the grant application form PHS 398 (rev. 10/88). Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities, or from the following office:

National Clearinghouse for Alcohol and Drug Information  
P.O. Box 2345  
Rockville, MD 20852  
Telephone: (301) 468-2600

The number and title of this program announcement, "PA-91-75, Research on the Relationships Between Alcohol Use and Sexual Behaviors Associated with HIV Transmission," must be typed in item number 2 on the face page of the PHS 398 application form.

The signed original and 24 permanent, legible copies of the completed application must be sent to the address listed below. The number of copies of appendix materials to be sent is six.

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

#### INQUIRIES

For a copy of the complete program announcement and preapplication consultation, contact:

Heather G. Miller, Ph.D.  
Prevention Research Branch  
Division of Clinical and Prevention Research  
National Institute on Alcohol Abuse and Alcoholism  
5600 Fishers Lane, Room 13C-23  
Rockville, MD 20857  
Telephone: (301) 443-1677

For fiscal and administrative matters, contact:

Ed Ellis  
Office of Grants Management  
National Institute on Alcohol Abuse and Alcoholism  
Parklawn Building, Room 16-86  
5600 Fishers Lane  
Rockville, MD 20857  
Telephone: (301) 443-4703

Applications submitted in response to this announcement are not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through the Department of Health and Human Services' regulations at 45 CFR Part 100, and are not subject to Health System Agency review.

THE STUDY OF THE ETIOLOGY AND PATHOGENESIS OF CELIAC DISEASE, GLUTEN SENSITIVE ENTEROPATHY

PA: PA-91-76

P.T. 34; K.W. 0715085, 0765033, 0710095, 0710065, 1002008, 1003018

National Institute of Diabetes and Digestive and Kidney Diseases  
National Institute of Allergy and Infectious Diseases

Application Receipt Dates: October 1, February 1, and June 1

**BACKGROUND**

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institute of Allergy and Infectious Diseases (NIAID) invite applications from researchers to investigate the etiology, pathogenesis, immunogenetics, and biological aspects of intestinal injury of celiac disease also known as gluten sensitive enteropathy. At a Celiac Educational Conference held on May 7, 1990, concern was expressed about the paucity of the research activities in this disease that affects about 130,000 Americans.

Celiac disease, also known as gluten sensitive enteropathy, is an autoimmune disease induced by the ingestion of proteins derived from wheat, rye, barley, and possibly oats in genetically predisposed individuals. Symptoms of celiac disease usually occur during the first three years of life after the introduction of cereals into the diet. The typical child with celiac disease presents with malabsorption symptoms, anorexia, failure to thrive and short stature. During the third decade of life, a second peak in incidence of the disease is observed. The disease is more prevalent in individuals of Irish decent and of North European extraction. Family studies have demonstrated a two to five percent prevalence of celiac disease in first degree relatives of persons with celiac disease. Genetic markers, HLA-B8, DR3, and DR7, are found in as many as 60-90 percent of patients with celiac disease.

Our understanding of the nature and epidemiology of celiac disease was greatly enhanced by the development of the small intestinal biopsy during the 1950s and 1960s. More recently, the development of tests for antigliadin antibodies has been helpful for screening patients suspected of celiac disease. The use of gluten-free diets to normalize the biopsy findings in patients with suspected disease has been the standard means of establishing the diagnosis. The absence of a simple diagnostic or screening assay for this disease and the lack of knowledge about the fundamental underlying pathogenesis have delayed progress in identification, treatment, and prevention of this disease.

Several studies have suggested that cell-mediated immunity plays an important role in the pathogenesis of celiac disease. Responses to mitogenic stimulation of peripheral blood lymphocytes with phytohemagglutinin have been reported to vary in celiac disease. In addition, an increased percentage of intra-epithelial lymphocytes from patients with celiac disease has been shown to bear the CD8 (cytotoxic/suppressor cell) surface marker. Whether or not these cells are responsible for epithelial damage in celiac disease is unclear. Further studies of cell-mediated immune reactions in celiac disease are needed.

NIDDK and NIAID encourage collaborative research among the multiple disciplines of epidemiology, gastroenterology, pediatrics, pathology, nutrition, immunology, immunogenetics, molecular biology, and protein chemistry to pursue research in celiac disease. Institutions with demonstrated expertise in both clinical and basic sciences that can mount multidisciplinary and collaborative efforts will be considered most favorably for research support. Applications must be aimed at obtaining information needed to fill gaps in our knowledge regarding the mechanisms and etiology of celiac disease/gluten sensitive enteropathy.

Research areas of interest include, but are not limited to:

- o Biomedical, molecular, and biologic characterization of the injurious nutrients in celiac disease, gliadin and related molecules.
- o Studies of the genetics and genetic markers in celiac disease, especially in extended families with more than one member affected.
- o Phenotypic and functional characterization of intraepithelial lymphocytes in celiac disease using state-of-the-art techniques.



- o Studies of the specificity of autoantibodies found in celiac disease patients.
- o Research on the potential role of autoantigens in celiac disease.
- o Development of animal models or in vitro systems of celiac disease and gliadin sensitivity.
- o Studies of mucosal permeability, biology of enterocytes, and primary cell culture techniques in propagating enterocytes, as they apply to celiac disease.
- o Epidemiologic and natural history studies on celiac disease aimed at identifying potential environmental factors related to expression, outcome, and complications of disease.

#### MECHANISMS OF SUPPORT

The mechanisms of support for this program will include the individual research project grant (R01), and the First Independent Research Support and Transition (FIRST) Award (R29). The award of grants pursuant to this announcement is contingent upon both the receipt of proposals of high scientific merit in response to this announcement and the availability of appropriated funds.

Applications will be received by the NIH Division of Research Grants (DRG), referred to appropriate Study Sections for scientific merit review, and assigned to appropriate Institutes for possible funding. Referral decisions will be governed by the programmatic considerations specified in the Referral Guidelines of the Public Health Service.

Applications submitted in response to this announcement will be reviewed in competition with other applications and in accordance with the usual NIH peer review procedures. Applications will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (study section), and then by the National Advisory Council of the appropriate Institute(s). The review criteria customarily employed by the NIH will prevail.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or a Principal Investigator must be included with the application.

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

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/officers are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive

strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

#### APPLICATION PROCEDURES

Applications must be submitted on form PHS 398 (rev. 10/88) that is available in the business or grants and contracts office at most research and academic institutions and from the Office of Grants Inquiries, Division of Research Grants, NIH, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

In item #2 on the face page of the application, the phrase, "Etiology and Pathogenesis of Celiac Disease, PA-91-76," must be inserted.

The original and six copies of the application must be sent or delivered to:

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

For further information concerning the announcement and mechanisms of support for research, investigators are encouraged to contact:

Frank A. Hamilton, M.D., MPH  
Director, Gastrointestinal Mucosal and Immunology Program  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 3A15  
5333 Westbard Avenue  
Bethesda, MD 20892  
Telephone: (301) 496-7821

Susana A. Serrate-Sztejn, M.D.  
Chief, Autoimmunity Section  
Division of Allergy, Immunology and Transplantation  
National Institute of Allergy and Infectious Diseases  
Westwood Building, Room 755  
5333 Westbard Avenue  
Bethesda, MD 20892  
Telephone: (301) 496-7985

For fiscal and administrative matters, contact:

Thelma Jones  
Grants Management Specialist  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 630  
Bethesda, MD 20892  
Telephone: (301) 496-7467

This program is described in the Catalog of Federal Domestic Assistance No. 93.848, Research on Digestive Diseases and Nutrition. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241), and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review requirements of Executive Order 12372 or Health Systems Agency review.

#### FOGARTY INTERNATIONAL RESEARCH COLLABORATION AWARD

PA: PA-91-77

P.T.

Fogarty International Center

Application Receipt Dates: October 1, February 1, and June 1 of each year

#### PURPOSE

The Fogarty International Center (FIC), under a program of Central and Eastern European (including the USSR) and Latin American and Caribbean Initiatives, is providing small grants to U.S. grantee institutions to facilitate cooperation and collaboration between U.S. scientists and scientists in these regions. These small grants will provide funds to the foreign collaborators, through the U.S. grantee institution, for equipment and supplies at their home institution, and for travel expenses for both the U.S. Principal Investigator and the foreign collaborator. These awards are intended to support the new and expanded research efforts of U.S. scientists who are Principal Investigators of currently funded NIH research project grants on the general scientific subject of the proposed collaboration.

#### RESEARCH OBJECTIVES

The main objective of this program is to facilitate collaborative research efforts between U.S. and foreign scientists that will expand and enhance the NIH-supported research program of the U.S. Principal Investigator, while at the same time benefiting the scientific interests of the collaborating foreign scientist. These small grants will provide funds to purchase supplies, materials, and small equipment items necessary to conduct the collaborative research in the foreign scientist's research laboratory at a non-profit public or private institution in the eligible countries. These awards will also provide travel support, as necessary to conduct the collaborative research effort, for the U.S. and/or the foreign collaborator(s). All biomedical and behavioral research topics supported by the NIH are eligible for inclusion under this program. The U.S. Principal Investigator must show evidence of ongoing NIH research support in areas related to the small grant application, and this support must be available during the entire small grant award period. The application must demonstrate that the effort will enhance the scientific contributions of both the U.S. and foreign scientists and strengthen the contribution to the NIH-sponsored research effort.

#### MECHANISM OF SUPPORT

The small grants will provide up to \$20,000 per year for up to three years in direct costs. Funds may be used for materials, supplies, and equipment for the foreign scientist's research laboratory and for travel expenses for the Principal Investigator and/or the foreign collaborator, and their research associates, as justified by the scientific needs of the project. No salaries or stipends for any of the collaborators, students, or technical assistants will be offered under these awards. Applicants must request support to conduct research not already being supported by the U.S. investigator's research grant; however, the research proposal must be an extension of or related to the currently funded research project. The awards will be made to U.S. institutions that will be responsible for the expenditures. The minimum small grant project period will be for one year; the maximum will be for three years. Indirect costs will be calculated on the basis of the off-site rates of the U.S. sponsoring institution. The award of this small grant is non-renewable, and the NIH awarding unit of the "parent" grant is under no obligation to continue support for the foreign grant as a component of a recompeting "parent" grant.

#### ELIGIBILITY

U.S. scientists who are Principal Investigators of NIH research project grants (R, P, or U-01 series) that will be active and funded during the proposed grant award period (up to three years) are eligible. The small grants will be made for work conducted in cooperation with scientists only in countries

located in the geographical regions commonly known as Central and Eastern Europe (including the USSR), Latin America, and the non-U.S. Caribbean. The foreign collaborator must hold a position at a public or private non-profit institution that will allow him or her adequate time and provide appropriate facilities to conduct the proposed research.

#### SPECIAL REQUIREMENTS

Applicants should be aware that applicable provisions for protections of human research subjects and laboratory animals must be met in domestic and foreign settings. See Title 45 CFR Part 46 for information concerning the Department of Health and Human Services regulations for the protection of human subjects and the PHS Policy on Humane Care and Use of Laboratory Animals. These are available from the Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 5B59, Bethesda, MD 20892.

#### APPLICATION PROCEDURES

Applications will be assigned for review to, and awards will be made by, the Fogarty International Center, utilizing the customary NIH peer review process. Scientific and technical merit will be evaluated by a Fogarty International Center initial review group. Second level review will be provided by the Fogarty International Center Advisory Board. Award decisions will be announced within a month following each board meeting and will be based on the scientific merit of the applications and the availability of funds.

#### METHOD OF APPLYING

Applications must be submitted by the U.S. Principal Investigator on the grant application form PHS 398 (rev. 10/88) that is available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, NIH, telephone (301) 496-7441. The deadlines for receipt of applications are October 1, February 1, and June 1 of each year. Special instructions are necessary and are available from the address below. Credentials for the foreign collaborators must be included with the application and the collaborative arrangements described in a letter signed by both investigators. Applicants must list the active NIH research grant(s) that will be held during the proposed project period of this award. The foreign laboratory collaborating with the Principal Investigator of the small grant must be located in the countries of Central and Eastern Europe (including the USSR), Latin America, and the non-U.S. Caribbean.

To obtain further information on this program and to request the necessary special application instructions, write, fax, or phone:

Dr. David A. Wolff or Dr. Danuta Krotoski  
International Research and Awards Branch  
Fogarty International Center  
National Institutes of Health  
Building 31, Room B2C21  
Bethesda, MD 20892  
Telephone: (301) 496-1653  
FAX: (301) 402-0779

For grants management and fiscal matters, contact:

Ms. Silvia Mandes  
Grants Management Officer  
Fogarty International Center  
National Institutes of Health  
Building 31, Room B2C21  
Bethesda, MD 20892  
Telephone: (301) 496-1653  
FAX: (301) 402-0779

The Fogarty International Center has authority to award grants under Section 307 of the Public Health Service Act.

**\*\*THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:**

5333 Westbard Avenue  
Bethesda, Maryland 20816