

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific
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NOTICES

REPRODUCIBILITY OF PAGES IN APPLICATION FORM PHS 398 WITH ORANGE PRINT

P.T. 34: K.W. 1014002

National Institutes of Health

In the new edition of the Application for Public Health Service Grant Form PHS 398, revised 9/86, the original form pages are printed using orange ink. Orange print is transparent to optical scanning systems and therefore this color print was chosen because the ability to automatically transfer information into the NIH computer will be important to NIH in the future. It was recently learned, however, that this color is not reproduced by some duplicating machines and especially machines in which the toner is not fresh.

Applicants are reminded of the importance of submitting legible copies of the application. An application may be considered incomplete and returned if the original and all copies are not legible.

PHS 398 MISCONDUCT IN SCIENCE ASSURANCE

P.T. 34; K.W. 0710030, 1014002

National Institutes of Health

Applicant organizations should note that a new assurance related to misconduct in science has been added to the Public Health Service grant application form 398 (rev.9/86). This assurance is required under section 493 of the PHS Act as amended by P.L. 99-158, the "Health Research Extension Act". That statute requires the Department of Health and Human Services (DHHS) to issue regulations requiring applicant organizations to establish an administrative process for reviewing reports of scientific fraud and to report to the Secretary any investigation of alleged scientific fraud that appears substantial.

PHS expects to publish a notice of Proposed Rulemaking (NPRM) implementing this requirement in the near future. It is important to note that the legislation does not require, and PHS does not intend to require, agency approval of institutional procedures, nor is it intended that the regulations will spell out in detail the administrative requirements for institutional procedures. Thus it would be quite appropriate for you to check "yes" if your institution has procedures in place now. However, applicants will not be required to provide this certification until the regulation becomes final. Future announcements in the GUIDE will note the dates of the proposed and final regulations.

DATED ANNOUNCEMENTS (RFPs AND RFAs AVAILABLE)

PRODUCTION AND DELIVERY OF SCHISTOSOMA MANSONI

RFP AVAILABLE: NIH-NIAID-IRP-88-17

P.T. 34; K.W. 0780000, 1002002

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases has a requirement for the production and delivery of adult worms and cercariae of *Schistosoma mansoni*. The successful offeror must be able to deliver worms and cercariae to the NIH within an hour after they have been harvested. Approximately 10,500 mature *S. mansoni* shall be required each week. When different isolates are requested at the same time, the total number of worms and/or mice perfused per week for the worms will not exceed 10,500 worms or the number of mice needed to obtain 10,500 adult worms (100 mice).

Approximately 1,000,000 cercariae shall be required each week. Cercariae must be live upon receipt. A fixed-priced award is contemplated. It is anticipated that this contract will be awarded for one year with 2 one-year options to continue the contract. Any contract awarded will be subject to DHHS regulations regarding the use of animals in research. Any responsible source may submit a proposal which will be considered by the Government.

RFP NIH-NIAID-IRP-88-17 will be available on October 19, 1987. Proposals will be due by close of business November 30, 1987.

To receive a copy of this RFP, please supply this office with two self-addressed mailing labels. Telephone inquiries will not be honored and all inquiries must be in writing and addressed to the office below.

Ms. Rosemary L. McCabe
National Institute of Allergy and Infectious Diseases
5333 Westbard Avenue, Room 707
Bethesda, Maryland 20892

This advertisement does not commit the Government to make an award.

CONFERENCE AND SUPPORT SERVICES FOR THE NATIONAL ADVISORY BOARDS
AND COMMITTEES

RFP AVAILABLE: NIH-NIDDK-87-14

P.T. 01; K.W. 1014002, 0780000

National Institute of Diabetes and Digestive and Kidney Diseases

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is seeking an organization to provide logistical and technical support for the National Diabetes Advisory Board, National Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board in carrying out their mandated functions which include the formulation of national plans for research and public health policy, the convening of related workshops and conferences, the collection and analysis of data, the preparation of their annual reports for the Secretary, Department of Health and Human Services (DHHS), and the presentation of recommendations to the Congress and the Heads of other agencies.

This acquisition is under a 100 percent Small Business Set-Aside.

This Request for Proposals, RFP No. NIH-NIDDK-87-14, will be issued on or about October 8, 1987, with a closing date set for December 18, 1987. It is expected that the contract will have a five-year period of performance. To receive a copy of this RFP, please supply this office with two self-addressed mailing labels and cite the RFP number referenced above. Requests must be in writing and addressed to:

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

Telephone requests will not be honored. A reasonable number of the RFPs has been prepared and will be issued on an as-available basis.

This advertisement does not commit the Government to make an award.

COOPERATIVE AGREEMENTS FOR PREVENTION CLINICAL TRIALS
UTILIZING INTERMEDIATE ENDPOINTS AND THEIR MODULATION BY
CHEMOPREVENTIVE AGENTS

RFA AVAILABLE: 88-CA-01

Division of Cancer Prevention and Control

National Cancer Institute

P.T. 34; K.W. 0755015, 0740015, 0715035, 0745055, 0710095

Application Receipt Date: December 10, 1987

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support clinical trials which are directed toward examining the role of various chemopreventive agents and/or diet in the prevention of cancer. This is a follow-up to earlier RFAs which had requested grants, and then later, cooperative agreement proposals in this area.

The major objective of this solicitation is to encourage cancer chemoprevention clinical trials which utilize biochemical and biological markers to identify populations at risk and/or to provide intermediate endpoints that may predict later reduction in cancer incidence rates.

These studies may be developed in phases, including a pilot phase, which could later proceed to a full scale intervention. The main emphasis should be on small, efficient studies aimed at improving future research designs of chemoprevention trials, providing biologic understanding of what is happening in the trials, or providing better, more quantitative and more efficient endpoints for these trials. After successful completion of the pilot phase; (i.e. demonstrated modulation of marker endpoints by the intervention), subsequent studies can include Phase III clinical trials involving the designated agent, the utilization of the monitoring test system and a cancer incidence or mortality endpoint may be implemented.

Investigators may apply at this time for the pilot phase, or submit an application for both phases. However, if the application is for the pilot phase only, the proposed study must be relevant to a clinical application and utilize a chemopreventive agent, marker test system, and study population which could later be the subject of a full scale, double-blind, randomized, risk reduction, clinical trial.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. The recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to (1) assistance securing an Investigational New Drug (IND) approval from the Food and Drug Administration (FDA), (2) monitoring of safety and toxicity and, (3) coordination and assistance in obtaining the chemopreventive agent, (4) quality assurance with regard to the clinical chemistry aspects of the study. Awards will not be made until all arrangements for obtaining the IND, agent, and its delivery are completed. Final awards will also consider not only the cost of the clinical trial but also the cost of the agent and its formulation if necessary. This RFA solicitation represents a single competition, with a specified deadline December 10, 1987, for receipt of applications. All applications received in response to the RFA will be reviewed by the same National Cancer Institute Initial Review Group (IRG). The intent is to fund four to six projects of high scientific merit.

To ensure their review, applications should be received by December 10, 1987. Applications received after that date will not be considered under this RFA.

The RFA label available in the 9/86 revision of Application Form 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.

Inquiries may be directed to:

Andrew J. Vargosko, Ph.D. or
Marjorie Perloff, M.D.
Chemoprevention Branch
Blair Building - Room 616
National Cancer Institute
Bethesda, MD 20892-4200
Telephone: (301) 427-8680

ISCHEMIA-REPERFUSION INJURY IN THE LUNG

RFA AVAILABLE: 88-HL-2-L

P.T. 34; K.W. 0715165, 0765035

National Heart, Lung, and Blood Institute

Application Receipt Date: March 15, 1988

The Division of Lung Diseases invites grant applications for support of research on studies aimed at understanding the mechanisms of ischemia-reperfusion injury in the lung. The primary objective of this program is to encourage research on the pathophysiology and pathogenesis of ischemia-reperfusion injury in the lungs and to develop interventions which can protect the lungs from such injury. Applications received in response to this request will be considered for a single competition.

BACKGROUND

Responses of several organs, including the heart, kidneys, and intestine, to reperfusion following periods of reduced or absent blood flow have been studied in some detail. The delineation of the physiologic, pathologic, and biochemical aspects of the response has produced innovative pathogenetic concepts and led to identification of pharmacologic interventions which have promise in prevention of ischemia-reperfusion injury. Ischemia-reperfusion injury has also been described in the lungs, but the pathogenetic mechanisms have not been defined. The relative susceptibility of the many different cell types in the lung to this response has not been determined and the pathophysiology of the injury is not well-defined. Neither is there information relating specific cellular responses to alterations in lung function. Many forms of acute lung injury appear to involve both humoral and cellular components of the inflammatory response, but these systems have not been investigated relative to reperfusion injury in the lungs.

OBJECTIVES AND SCOPE

The primary objectives of this program are to encourage studies which will define the pathophysiology and pathogenesis of ischemia-reperfusion injury in the lungs, to determine the cellular and biochemical mechanisms involved in reperfusion injury, and to develop interventions with potential for use in humans which can prevent reperfusion injury. Applicants should clearly define the rationale, background, and specific aims of the proposed studies and relate them to the problem of ischemia-reperfusion injury in the lung.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional, individual research grant. All current policies and requirements that govern the research grant programs of the National Institutes of Health will apply to grants awarded under this RFA. Applications must be received by March 15, 1988. An application not received by this date will be considered ineligible. Awards will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service Policy governing such awards. It is anticipated that five grants will be awarded under this program.

The RFA label available in the 9/86 revision of Application Form 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.

REVIEW PROCEDURES

All applications submitted in response to this RFA will be evaluated for scientific and technical merit by an initial review group, which will be convened for this purpose, by the Division of Extramural Affairs, NHLBI.

METHOD OF APPLYING

Prospective applicants are asked to submit a letter of intent and include the names of any other participating institutions or investigators. This letter should be received no later than January 15, 1988. Requests for copies of this announcement may be directed to:

Carol E. Vreim, Ph.D.
Interstitial Lung Diseases Branch
Division of Lung Diseases, NHLBI
National Institutes of Health
Westwood Building, Room 6A09
Bethesda, Maryland 20892
Telephone: (301) 496-7034

BASIC BIOLOGY OF CARDIAC DEVELOPMENT

RFA AVAILABLE: 88-HL-4-H

P.T. 34; K.W. 0705015, 0715040, 0755030, 1002059, 0775015, 0710050

National Heart, Lung and Blood Institute

Application Receipt Date: April 12, 1988

The Division of Heart and Vascular Diseases of the National Heart, Lung and Blood Institute invites grant applications to be considered in a single

competition for support of fundamental studies of cardiac development. The emphasis of this program is on growth and functional maturation of the heart during and following the period of septation up until birth.

BACKGROUND

Current research on cardiac development is mostly oriented toward understanding of the processes of cell migration, proliferation and differentiation, and of the mechanisms of assembly into tissue. There is a paucity of research on functional development, particularly during and following septation. Knowledge is needed regarding the conduction system and the establishment of intercellular communication, the coordination of electrical and contractile events, the development of the coronary circulation, innervation of the heart and other processes of growth and maturation prior to birth. Little is known about how perturbations of these developmental processes contribute to congenital cardiac defects and dysfunction.

OBJECTIVES AND SCOPE

The overall goal is to develop knowledge which will contribute to understanding of the etiology, diagnosis, treatment and prevention of congenital heart disease. The research solicited in this RFA concerns the developmental events occurring during and after septation and mechanisms whereby perturbations of these events can lead to congenital heart disease. Of special interest are investigations correlating structural development and growth with physiologic function. Applications should not include human studies.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional, individual research grant. All current policies and requirements that govern the research grant programs of the National Institutes of Health will apply to grants awarded under this RFA. Awards will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards. It is anticipated that approximately eight grants will be awarded under this program.

REVIEW PROCEDURES

All applications submitted in response to this RFA will be evaluated for scientific and technical merit by an initial review group, which will be convened for this purpose, by the Division of Extramural Affairs, NHLBI.

METHOD OF APPLYING

Potential applicants should write or phone the individual listed below for the full RFA document, which includes instructions for the submission of applications:

Constance Weinstein, Ph.D.
Deputy Chief, Cardiac Diseases Branch, DHVD
National Heart, Lung and Blood Institute, NIH
Federal Building, Room 3C06
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-1081

The RFA label available in the 9/86 revision of Application Form 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.

ONGOING PROGRAM ANNOUNCEMENTS

MINORITY TRAVEL AWARD PROGRAM

P.T. 42, 48, FF; K.W. 0710030

National Institute of Diabetes and Digestive and Kidney Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases

DESCRIPTION

The Minority Travel Award Program (MTAP) provides support for minority students and faculty members of minority institutions to allow them to attend national scientific meetings.

Any NIDDK/NIAMS grantee wishing to include travel funds for minority students and/or faculty may submit a supplemental grant application for this purpose. Minority students may be from any domestic institution. Faculty must be from a minority institution. Approved applications will be funded as supplements to active grants. Such grants include individual projects (R01, R29, R37), program projects (P01), and center grants (P30, P50, P60).

OBJECTIVES

The MTAP is a component of the overall NIDDK/NIAMS program to strengthen biomedical research and training in institutions with significant commitments to minorities and to increase the awareness and participation of minority scientists in biomedical research. The MTAP supports minority students and faculty from minority institutions to accompany principal investigators currently funded by NIDDK/NIAMS grants to scientific meetings. The MTAP is targeted at minority students at various stages of academic development and at faculty at minority institutions who have not been supported on NIH regular research grants. The MTAP is intended to enhance awareness of biomedical research opportunities and to influence more minority students/faculty to become interested and involved in research and research training.

DEFINITIONS, ELIGIBILITY AND TERMS OF AWARD

1 Minority Institution

A minority institution is defined as a medical or non-medical college, university, or equivalent school in which students of underrepresented minorities (including, but not limited to Blacks, Hispanics, American Indians, and Asian and Pacific Islanders) comprise the majority or significant proportion of the school enrollment and which has a commitment to the special encouragement of minority faculty, students, and investigators.

2 Minority Student

A minority student is defined as anyone of the underrepresented minorities, as defined above, at any stage of academic achievement (including, but not limited to undergraduate, predoctoral, and postdoctoral students).

3 Minority Faculty

A minority faculty is defined as a full-time faculty member of a minority institution who is interested or engaged in biomedical research. The minority investigator should not have been a principal investigator on any traditional grant mechanism from NIH. This does not exclude from candidacy minority faculty who have been supported by the NIH Minority Biomedical Research Support (MBRS) Program or the Minority Access to Research Careers (MARC) Program.

4 Principal Investigator

All principal investigators of active NIDDK/NIAMS grants are eligible to submit supplemental applications on behalf of a minority student and/or faculty member. Principal investigators are expected to serve as a guide or mentor for the student or faculty member while at the scientific meeting.

5 Travel Funds

Funds requested in the supplemental application are intended to support the minority student and/or faculty member while accompanying the principal investigator or other senior investigator to a national scientific meeting. Travel funds can include air and ground transportation, a per diem allowance, and registration fees associated with the meeting.

6 Scientific Meeting

A scientific meeting in the context of this program is defined as any national scientific meeting of a specialty nature related to the interests of NIDDK and NIAMS.

7 Other Considerations

In general, applications and awards are limited to travel to one meeting per student and/or minority faculty member per year. Supplemental applications should be submitted for a duration to coincide with the end of the appropriate budget period. An amount not to exceed \$1,000 travel expenses per individual may be requested. The specific dollar amount requested should be justified in the application. If circumstances indicate that these limitations should be exceeded, a special justification should be included in the application.

8 Travel Report

In order to properly evaluate the effectiveness of this program, the minority student or faculty member is requested to prepare a brief report for submission through the principal investigator to the NIDDK/NIAMS Program Director, which is due 30 days after returning from a meeting. The report should include but not be limited to the following elements:

Name, location, and general indication of the type of meeting and subject matter covered.

A listing of papers and symposia of special interest.

Tangible and intangible benefits derived from attendance.

Suggestions for improvement of the MTAP to make the meeting experience more rewarding for the individual and his/her biomedical research goals.

PROJECT EVALUATION AND REVIEW CRITERIA

Applications submitted in response to this announcement will be reviewed for eligibility by the NIDDK/NIAMS Minority Affairs Advisory Committee, a staff committee of intramural and extramural scientists, using the following criteria:

1 For Minority Students:

Completion of the sophomore year in college, or enrollment in a predoctoral program (exceptions will be considered if justification is furnished);

Overall grade point average of at least 3.0 on a 4.0 scale;

Recommendation from one science faculty member or researcher other than principal investigator;

Completion of a brief written statement of interest in attending the meeting, benefits to be derived, and long-range professional plans.

2 For Faculty at Minority Institutions:

Provision of an up-to-date resume;

A written statement indicating research interests and benefits to be derived by attendance at the meeting;

Two letters of recommendation from the institution, including the Dean or Department Chairperson.

FUNDING

Successful applications will be funded as administrative supplements to the NIDDK/NIAMS investigator's grant. Funds awarded under this program are for the sole purpose of facilitating participation of minority students and faculty as described above.

HOW TO APPLY

All potential applicants are encouraged to contact the NIDDK/NIAMS Division of Extramural Activities at (301) 496-7277 prior to preparing an application.

The principal investigator must submit a supplemental grant application through his/her institution on the standard PHS 398 (Rev. 9/86), and should include only the following: (1) face page--item 2 should give the grant number of the active grant and specifically state "Minority Travel Award Program;" (2) budget page; (3) complete curriculum vitae; and (4) information addressing the review criteria described in a previous section.

Applications may be submitted at any time; however for a more expeditious review, they should be submitted no later than the 15th of any month.

The original and 5 copies of the application should be sent to:

Division of Extramural Activities
NIDDK/NIAMS/NIH
Westwood Building, Room 657
Bethesda, MD 20892**
Telephone: (301) 496-7277

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS 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