NIH GUIDE

For Grants and Contracts

NOTICE OF MAILING CHANGE

☐ Check here if you wish to discontinue receiving this publication

☐ Check here if your address has changed and you wish to continue receiving this publication. Make corrections below and mail this page to:

NIH Guide
Printing & Reproduction Branch
National Institutes of Health
Room B4BN08, Building 31
Bethesda, Maryland 20892

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICIAL BUSINESS
Penalty for Private Use, $300

First Class Mail
Postages & Fees Paid
PHS/NIH/OD
Permit No. G-291

The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 20, No. 39
October 18, 1991

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

NOTICE OF POLICY CHANGE

P.T. 22; K.W. 0720005, 1014006

Alcohol, Drug Abuse, and Mental Health Administration

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) announces that effective immediately, applications for the Individual National Research Service Award (NRSA) must be accompanied by at least three completed, sealed, reference letters (as described in the instructions for application form PHS 416-1). Applications not containing these letters will be returned to the applicant without review.

The receipt and review schedule for the NIH and ADAMHA NRSA Individual Fellowship awards is unchanged. The following schedule remains in effect:

RECEIPT	INITIAL REVIEW	APPROXIMATE START DATE
Jan 10	Jun/Jul	Aug
May 10	Oct/Nov	Jan
Sep 10	Feb/Mar	May

NATIONAL WORKSHOPS ON THE PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are sponsoring a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

NORTH MIDWESTERN WORKSHOP

DATES: October 17 and 18, 1991

WORKSHOP SITE:
Westin Hotel
Renaissance Center
Detroit, MI
Telephone: (313) 568-8000

SPONSORS:
Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201

Wayne State University
4237 Scott Hall
Detroit, MI 48201

REGISTRATION CONTACT:
Mr. Jerome Wilczynski
Vice President for Operations
Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, MI 48201
Telephone: (313) 745-5450

TOPIC: Protection of Human Subjects in Research: The Vulnerable Patient

WEST COAST WORKSHOP

DATES: January 23 and 24, 1992 (REVISED DATES)

WORKSHOP SITE: Los Angeles, CA

SPONSORS:
University of Southern California
Los Angeles, CA 90089-4014

California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202

REGISTRATION CONTACT:
Ms. Lily Patterson
Assistant to the Director
Research and Sponsored Programs
California State University - Los Angeles
5151 State University Drive
Los Angeles, CA 90032-8202
Telephone: (213) 343-3820

TOPIC: Protection of Human Subjects

SOUTH MIDWESTERN WORKSHOP

DATES: February 20 and 21, 1992

WORKSHOP SITE: San Antonio, TX

SPONSORS:
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive
San Antonio, TX 78284-7972

St. Mary's University
One Camino Santa Maria
San Antonio, TX 78228-8572

REGISTRATION CONTACT:
Ms. Angie Khan
Institutional Coordinator of Research Review
University of Texas Health Science Center at San Antonio
7703 Floyd Curl Drive (Room 402L)
San Antonio, TX 78284-7972
Telephone: (512) 567-2351

TOPIC: Identifying and Assessing Risks in Human Subject Research

NORTHEASTERN WORKSHOP

DATES: April 27 and 28, 1992

WORKSHOP SITE: Philadelphia, PA

SPONSORS:
University of Pennsylvania
133 South 36th Street
Suite 300
Philadelphia, PA 19104-3246

Lincoln University
Lincoln University, PA 19352

REGISTRATION CONTACT:
Ms. Lynn Bevan
Assistant Director
Office of Research Administration
University of Pennsylvania
133 South 36th Street
Suite 300
Philadelphia, PA 19104-3246
Telephone: (215) 898-2614

TOPIC: The Shifting Ground: Current Issues for the Protection of Human Subjects on Biomedical and Behavioral Research

For further information regarding these workshops and future NIH/FDA National Protection of Human Subjects Workshops, please contact:

Ms. Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

NOTICES OF AVAILABILITY (RFPs AND RFAs)

CLINICAL TRIALS OF BIOLOGICAL RESPONSE MODIFIERS

MAA AVAILABLE: NCI-CM-27732-49

P.T. 34; K.W. 0755015, 0740015

National Cancer Institute

The National Cancer Institute (NCI), Division of Cancer Treatment (DCT), Biological Resources Branch (BRB), Biological Response Modifiers Program (BRMP), is soliciting proposals for highly innovative approaches to evaluate new agents or concepts in cancer therapy with Biological Response Modifiers (BRMs). Proposals are sought from investigators who have extensive preclinical experience in the area of the proposal and the unique technical capabilities to address the issues of mechanisms of action essential for the early clinical development of new BRM regimens. Proposals may be from single institutions, consortia, non-profit, and commercial entities.

The BRMP specifically intends to establish Master Agreements (MAs) under which MA holders will compete for subsequent Master Agreement Orders (MAOs) for novel strategies for cancer treatment with BRMs. A clinical study of BRMs consisting of at least one clinical protocol shall be conducted by the MA holder for each MAO award. Depending upon the availability of funds, a limited number of MAOs may be awarded at the time of award of MAs. Offerors competing for this MA will be required to include as part of the proposal a specific proposal for a clinical trial. The MA holder shall conduct a Phase Ia, Ib, or Phase II trial of BRMs in accordance with NCI-approved protocols that are submitted in response to individual specific MAOs issued under the MA. The objectives of a Phase Ia trial are to provide the parameters and characteristics of side effects and toxicity, and to establish the dose limiting toxicity and the maximum tolerated dose. The objectives of a Phase Ib trial are to establish the optimal biological dose, i.e., the dose that produces the optimal desired response by route and schedule of administration, for the parameters deemed important with respect to a particular biologic agent. The major objective of a Phase II trial is the determination of therapeutic efficacy in defined patient populations. This procurement is unrestricted. The Standard Industrial Classification (SIC) code is 8731.

Master Agreement Announcement (MAA) No. NCI-CM-27732-49, will be available on or about October 25, 1991, and responses will be due approximately eight weeks thereafter.

Master Agreements (MAs) will be awarded beginning approximately June 30, 1992 to all offerors determined to have submitted technically acceptable proposals. Requests for the MAA must reference the MAA number and be sent to:

Ms. Sandra G. Lehner, Contract Specialist
National Cancer Institute
Research Contracts Branch, TCS
Executive Plaza South, Room 603
9000 Rockville Pike
Bethesda, MD 20892

TUBERCULOSIS RESEARCH MATERIALS

RFP AVAILABLE: NIH-NIAID-DMID-92-05

P.T. 34; K.W. 0715165, 0710060, 1003008

National Institute of Allergy and Infectious Diseases

Proposed Receipt Date: January 9, 1992

The Bacteriology and Mycology Branch of the Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of a Request for Proposals (RFP)

from investigators having the capabilities and facilities to devise an analytical method(s) for the determination of the profile of M. tuberculosis surface antigens to be employed in biological test systems.

This NIAID project will take approximately five years to complete. One completion type contract is anticipated. RFP-NIH-NIAID-DMID-92-05 shall be issued on or about October 31, 1991, with a closing date for receipt of proposals tentatively set for January 9, 1992. To receive a copy of this RFP, please supply this office with two self-addressed labels. Requests for the RFP shall be directed in writing to:

Ann Linkins
Contract Management Branch
National Institute of Allergy and Infectious Diseases
Control Data Building, Room 3C07
6003 Executive Boulevard
Bethesda, MD 20892

SPECIALIZED CENTERS OF RESEARCH FOR ACUTE LUNG INJURY, CARDIOPULMONARY DISORDERS OF SLEEP, AND CYSTIC FIBROSIS

RFA AVAILABLE: HL-92-02-L

P.T. 04; K.W. 0715165, 0715187, 0755030, 0765033, 0745020, 0745027

National Heart, Lung, and Blood Institute

Letter of Intent Receipt Date: April 17, 1992
Application Receipt Date: August 3, 1992

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. The primary objective of the Specialized Center of Research (SCOR) program is to foster multidisciplinary basic and clinical research so that advances in the basic sciences are rapidly applied to clinical problems. It is expected that results from these SCOR grants will have an impact on the prevention, diagnosis, and treatment of acute lung injury, cardiopulmonary disorders of sleep, and cystic fibrosis.

HEALTHY PEOPLE 2000

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 RFA is related to the priority areas of maternal and infant health, chronic disabling conditions, and unintentional injuries. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017- 001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402- 9325 (telephone 202-783-3238).

MECHANISM OF SUPPORT

The support mechanism for this program will be the Specialized Center of Research grant (P50). Although the financial plans for fiscal years 1993 and 1994 include $11,000,000 for the total costs of this program, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that up to 11 grants will be awarded under this program. The specific number to be funded, however, will depend on the merit and scope of the applications received and the availability of funds.

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

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 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.

ELIGIBILITY

Applications may be submitted by domestic for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local Governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged.

METHOD OF APPLYING

Letter of Intent

To facilitate Institute planning, applicants are requested to submit a letter of intent to the NHLBI on or before April 17, 1992. The letter should indicate the SCOR's emphasis and theme, investigators who might be involved, and any participants outside the applicant institution.

The Institute requests such letters only for the purpose of providing an indication of the number and scope of applications to be received and, therefore, usually does not acknowledge their receipt. A letter of intent is not binding; it will not enter into the review of any application subsequently submitted, nor is it a requirement for submission.

The letter of intent is to be sent to:

Charles L. Turbyfill, Ph.D.
Review Branch, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 553
Bethesda, MD 20892

Format for Applications

Submit applications on form PHS 398 (rev. 10/88), the same form used for the traditional research-project grant. This form is available in an applicant institution's office of sponsored research or business office and from the Division of Research Grants, Office of Grants Inquiries, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892 (telephone: 301/496-7441). Specific instructions for preparing a SCOR application are available from Dr. Suzanne Hurd at the address below.

Submission of Application

Send or deliver the completed application and four signed exact photocopies by August 3, 1992, to:

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

In addition, two signed copies of the application must be sent directly to Dr. Charles L. Turbyfill at the address listed under Letter of Intent. Applications not received by August 3, 1992, will be considered ineligible.

INQUIRIES

Inquiries regarding this program and requests for the RFA document may be addressed to:

Suzanne S. Hurd, Ph.D.
Director, Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16
Bethesda, MD 20892
Telephone: (301) 496-7208
FAX: (301) 496-9886

For fiscal and administrative matters, contact:

Mr. Raymond Zimmerman
Section Chief, Grants Operations Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A17
Bethesda, MD 20892
Telephone: (301) 496-4970

AUTHORITY AND REGULATIONS

The programs of the Division of Lung Diseases of the National Heart, Lung, and Blood Institute are identified in the Catalog of Federal Domestic Assistance, Number 93.838. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or to Health Systems Agency review.

TUBERCULOSIS DRUG DEVELOPMENT

RFA AVAILABLE: AI-91-16

P.T. 34; K.W. 0715165, 0755025, 1002027

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: January 10, 1992
Application Receipt Date: March 10, 1992

PURPOSE

The Bacteriology and Mycology Branch (BMB) of the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of a Request for Applications (RFA) focused on the development of new drugs for the treatment of tuberculosis. The growing problems of multiple-drug resistance, patient and provider noncompliance, and actual and perceived toxicity of anti-tuberculosis agents, must be addressed. New drugs are needed to shorten current therapy, treat patients with drug-resistant disease, and provide for more effective preventive therapy. The purpose of this RFA is to solicit research applications that focus on the development of new and more effective anti-tuberculosis agents.

ELIGIBILITY REQUIREMENTS

Domestic universities, medical colleges, hospitals, and other public and private research institutions, including State and local government units, are eligible. Awards to foreign institutions under this RFA will be made only for research of unusually high merit, need, and promise, and in accordance with PHS policy governing such awards. Applications from minority investigators and women are encouraged.

BACKGROUND

Multi-drug treatment of tuberculosis requires compliance with therapy for at least six months. Many patients stop taking drugs or fail to return for appointments as soon as they begin feeling better. This may lead to treatment failure, drug resistance, and even death. The best treatment regimens are too expensive for resource-poor countries with a large tuberculosis problem. Alarmingly high rates of resistance have developed to the less expensive drugs (Isoniazid and Streptomycin) used in these countries. The situation has been further complicated by recent outbreaks of multi-drug-resistant (MDR) tuberculosis in the United States. These outbreaks involve strains of Mycobacterium tuberculosis that are resistant to both Isoniazid and Rifampin. To further complicate the problem, outbreaks of MDR-tuberculosis have occurred among persons infected with human immunodeficiency virus. It is apparent that there is a great need for the development of new and more effective drugs for the treatment of tuberculosis.

RESEARCH GOALS AND SCOPE

The purpose of this RFA is to stimulate research in the development of new drugs for the treatment of tuberculosis. The need for this research is underscored by the fact that it has been nearly two decades since the introduction of an effective new drug for the treatment of tuberculosis. There are several challenges in the treatment of tuberculosis including the length of treatment, development of resistance, lack of alternative agents, and toxicity of existing agents. The major objective of this RFA is to encourage research aimed at the development of new anti-tuberculosis agents with one or more of the following characteristics:

o bactericidal for a critical proportion of both actively growing and quiescent bacilli

o can be administered over a period of treatment not longer than eight weeks (such a short course of treatment is considered important to assuring compliance with therapy)

o possess a long half-life without toxicity

o can be administered orally

o resistance to the drug should not develop during the course of therapy.

The applicant must consider the application of molecular biology to tuberculosis drug development and the mechanisms of action and mechanisms of resistance of potential anti-tuberculosis drugs. Studies of the growth, physiology, and biochemistry of M. tuberculosis would significantly enhance the development of new drugs. New drug development must include in vitro testing, in vivo studies in suitable animal models, and lead to the initiation of clinical trials.

HEALTHY PEOPLE 2000

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 RFA, TUBERCULOSIS DRUG DEVELOPMENT, is related to the priority area of HIV infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional individual research grant (R01). Responsibility for planning, direction, and execution of the proposed project will be solely that of the applicant.

NIAID anticipates making two awards as a result of this request. However, the number of awards to be made is dependent upon receipt of a sufficient number of applications of high scientific merit and upon the availability of funds. If appropriate, collaboration with other investigators and institutions is encouraged. NIAID staff anticipates that each application would be a comprehensive single project (i.e., not a multiproject application). It is expected that the initial year's awards for successful applications will average $500,000 in total (direct plus indirect) costs for each award, although each award may be slightly higher or lower. Awards will be made for a project period of up to five years. Awards to applicant institutions outside the United States will be limited to three years. The earliest possible award date is September 30, 1992. NIAID has no plans to reissue this announcement. At the end of the initial competitive segment, awardees may apply for continuation through the competing renewal process for R01 grants.

METHOD OF APPLYING

Prospective applicants are asked to submit by January 10, 1992, a letter of intent, addressed to Dr. Olivia Preble, 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.

Format of Applications: Applications must be submitted on form PHS 398 (rev. 10/88), the application form for research grants. Application kits are available at most institutional business offices and may be obtained from the Office of Grants Inquiries, Room 449, Westwood Building, Division of Research Grants, NIH, Bethesda, MD 20892, Telephone (301) 496-7441). The format and detail applicable to research grant applications should be followed, and the requirements specified under Review Criteria must be fulfilled.

For purposes of identification and processing, mark "yes" in item 2 on the face page of the application and type in the words TUBERCULOSIS DRUG DEVELOPMENT and the RFA number AI-91-16.

The RFA label available in the form PHS-398 (rev. 10/88) must be affixed to the bottom of the face page of the original signed application. Failure to use this label could result in delayed processing of the application such that it may not reach the committee in time for review.

The research proposed must describe plans to accommodate the RFA research program requirements and NIAID staff involvement.

Application Procedure: The completed original application and four exact copies must be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892

INQUIRIES

Investigators seeking a copy of the RFA and information relevant to this RFA may contact:

Dr. Darrel Gwinn
Tuberculosis Program Officer
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
6003 Executive Blvd., Room 3A03
Bethesda, MD 20852
Telephone: (301) 496-7728

For fiscal and administrative matters, contact:

Mr. Todd Ball
Chief, Microbiology and Infectious Diseases Grants Management Section
National Institute of Allergy and Infectious Diseases
6003 Executive Blvd., Room 415P
Bethesda, MD 20852
Telephone: (301) 496-7075

For information about review procedures, contact:

Dr. Olivia Preble
Chief, Microbiology and Immunology Review Section
Program and Project Review Branch
National Institute of Allergy and Infectious Diseases
6003 Executive Blvd., Room 429P

Bethesda, MD 20852
Telephone: (301) 496-8208

AUTHORITY AND REGULATIONS

This program is supported under authorization of the Public Health Service Act, Sec. 301(c), Public Law 78-410; as amended. The catalog of Federal Domestic Assistance citation is Sec. 93.856, Microbiology and Infectious Diseases Research. Awards will be administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

RECRUITMENT AND RETENTION OF UNDERREPRESENTED MINORITIES INTO ACADEMIC RESEARCH

RFA AVAILABLE: DK-92-09

P.T. 14, 34, FF; K.W. 0710030

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: February 21, 1992
Application Receipt Date: March 20, 1992

PURPOSE

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) recognizes the need to increase the number of underrepresented minorities committed to scientific careers in research areas served by the DKUHD. This program is primarily aimed at recently trained M.D. and/or Ph.D. minority investigators. The program will enable the minority applicant to accept a tenure-earning position, gain additional research experience, and obtain preliminary data on which to base a subsequent research grant application in kidney, urologic, or hematologic research.

HEALTHY PEOPLE 2000

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 Request for Applications (RFA), Recruitment and Retention of Underrepresented Minorities in Academic Research, is related to the priority area of increasing underrepresented minority health scientists. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

The applicant must be either Black, Hispanic, Native American, Pacific Islander, or other ethnic or racial group members underrepresented in biomedical or behavioral research. The applicant must be a citizen or non-citizen national of, or have been lawfully admitted to the United States for permanent residence.

Applicants may not hold, or apply for concurrently any other PHS research project grant at the time of this application. Priority will be given to those applicants without a record of having been a Principal Investigator on a major research grant.

RESEARCH OBJECTIVES

The primary purpose of this RFA is to increase the number of underrepresented minority Principal Investigators conducting research in kidney, urologic, and hematologic diseases. This program was designed to provide an additional one or two years of research experience prior to application for R01 support but without incurring payback obligations. He/she may concurrently hold a tenure-earning position.

MECHANISM OF SUPPORT

Support will be provided through the small research grants (R03) program administered by the DKUHD in the NIDDK. Responsibility for the planning, direction, and execution of the proposed project will be that of the applicant. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the PHS Grants Policy Statement.

The total project period for applications submitted in response to the present RFA may be for one to two years. Direct costs requested may not exceed $50,000 per year. The anticipated award date will be September 1, 1992, and the anticipated number of awards is five.

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

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 for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

REVIEW CONSIDERATIONS

Applications for the small grants program will receive initial technical merit review by an initial review committee appointed by the NIDDK, and secondary review by the DKUHD. Factors to be included in the review of applications include: the applicant's previous research training, experience, and publications; ability to complete the proposed research plan; the overall scientific merit of the research plan; whether or not the aims and scope of the research plan can provide definitive data within a one- or two-year period; the potential of the proposed research to provide the bases for future studies; the willingness of the institution to commit facilities and departmental support to the applicant; the applicant's plans and career goals; and the availability of a recognized expert in the area of the proposed research for counsel and advice as attested to by a letter of agreement.

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent by February 21, 1992, that includes the RFA title, a descriptive title of the research, the address and telephone number of the Principal Investigator, his/her institution and the name and address of any other key investigators.

A letter of intent is not required, is not binding and is not considered in the review of applications. It is used by NIDDK staff to initiate planning for the review of applications, to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Robert Hammond, Ph.D.
Review Branch, Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 402
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7083

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 10/88) must be used in applying for these grants. These forms are available at most institutional business offices, and from the Office of Grants Inquiries, Division of Research Grants, NIH, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892 (telephone 301-496-7441).

The RFA label available in the 10/88-9/89 revision of the PHS 398 application form 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. In addition, on line 2 of the face page of the application check the YES box, type the RFA number and the following title: "DKUHD/NIDDK Underrepresented Minority Investigator Training Program."

Submit a signed, typewritten original of the application, including the Checklist, and four signed, exact photocopies, in one package to:

DIVISION OF RESEARCH GRANTS
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Send two additional copies of the application to:

Robert Hammond, Ph.D.
Review Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 406
5333 Westbard Avenue
Bethesda, MD 20892

Applications must be received by March 20, 1992. If an application is received after that date, it will be returned to the applicant without review.

INQUIRIES

Potential applicants and interested individuals are urged to contact the program director to obtain the RFA. Written and telephone inquiries concerning this RFA are encouraged, and are to be directed to:

Charles H. Rodgers, Ph.D.
Manpower Program Director
Division of Kidney, Urologic and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 621
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7573

Direct inquiries regarding fiscal matters to:

Nancy C. Dixon
Grants Management Branch
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 649
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7467

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.849. Awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS FOR THE TREATMENT OF OPPORTUNISTIC INFECTIONS ASSOCIATED WITH ACQUIRED IMMUNODEFICIENCY SYNDROME

RFA AVAILABLE: AI-91-15

P.T. 34; K.W. 0755025, 0715125, 0715008, 0710100

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: October 30, 1991
Application Receipt Date: January 16, 1992

The National Institute of Allergy and Infectious Diseases (NIAID) announces availability of a Request for Applications (RFA) for funding of the National Cooperative Drug Discovery Groups for the Treatment of Opportunistic Infections Associated with Acquired Immunodeficiency Syndrome (NCDDG-OI). It is the purpose of this RFA to invite applications aimed at the discovery of new, more effective, selective and diverse therapeutic agents to treat infections caused by Pneumocystis carinii, Cryptosporidium parvum, Mycobacterium avium, and human cytomegalovirus, opportunistic pathogens associated with AIDS. Applications that include research projects or core components from the private sector (e.g., pharmaceutical, chemical, or biotechnological companies) are encouraged.

Opportunistic infections are the major causes of morbidity and mortality in Human Immunodeficiency Virus (HIV) disease. Available drugs to treat the opportunistic infections have limited value because of toxicity and other adverse reactions. Prolonged immunosuppression requires treatment and prophylaxis regimens that are lengthy in duration and often expensive. There are no proven therapies effective for Cryptosporidium and M. avium infections, and limited treatment options are available for cytomegalovirus and P. carinii. The need exists for more potent and selective therapeutic agents with activity against the opportunistic infections.

HEALTHY PEOPLE 2000

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 RFA, National Cooperative Drug Discovery Groups for the Treatment of Opportunistic Infections Associated With Acquired Immunodeficiency Syndrome, is related to the priority area of HIV Infection. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 2020-783-3238).

PURPOSE

The purpose of this RFA is to encourage investigators from diverse fields and expertise to collaborate and to explore new avenues utilizing recent advances in molecular biology and biochemistry for identification of new therapeutic targets. Units in which these research talents and resources are combined are termed "NATIONAL COOPERATIVE DRUG DISCOVERY GROUPS" (NCDDGs). The NCDDG-OI program would provide a mechanism for a formalized collaboration between scientists from universities, pharmaceutical companies, and the Government. The NCDDG-OI program was conceptualized as having the capacity to generate new approaches and strategies for the treatment of opportunistic infections in AIDS patients and to rapidly translate such concepts into potentially effective treatment. Results from the research proposed should be used to identify and develop strategies for long-term planning of therapeutic approaches or to identify and develop new potential treatments worthy of further development in clinical trials.

The NCDDG-OI initiative has evolved as a part of the NCDDG program on AIDS (now referred to as NCDDG-HIV). The NCDDG-HIV program, launched in 1986, is currently funding 23 groups whose research efforts are directed towards the identification of more selective and effective agents to treat HIV infection. The studies supported by the NCDDG-HIV program have led to the identification of several potential new therapeutic agents. The NCDDG-OI initiative, launched in 1989, seeks to stimulate investigations leading to the identification and preclinical development of agents active against the various pathogens causing opportunistic infections in AIDS patients. Seven groups were funded in 1990 and four additional groups were funded in 1991. This RFA encourages participation by groups proposing to study Pneumocystis, Cryptosporidium, Mycobacterium avium, and cytomegalovirus. Applications focusing on the biochemistry and metabolic activities (other than folate metabolism) of these microorganisms or on cellular changes produced by infection are strongly encouraged. Other organisms have been excluded from this competition in order to achieve programmatic balance among Groups previously funded within the NCDDG-OI program. Scientists studying the opportunistic infections associated with AIDS and whose research does not lie within the areas defined as responsive to this RFA are strongly encouraged to apply for investigator-initiated (R01) grants.

Recent advances in molecular biology, biochemistry, and pathogenesis are creating avenues for innovative approaches. The NCDDG-OI program will provide assistance to talented scientists to interact as a unit to carry out the preclinical research essential for the realization of project objectives. An NCDDG-OI could be composed of scientists from a combination of academic, non- profit research, and commercial organizations. Each NCDDG-OI will be assembled by the Principal Investigator to form a multidisciplinary consortium representing the various skills needed to successfully design, synthesize, and evaluate, at the preclinical level, potential therapeutic agents useful in the treatment of opportunistic infections in AIDS patients. Specifically excluded from the group's activities are studies related to clinical evaluation of drugs.

Projects or cores with proposed animal model development must be integrated within the major goal of targeted drug discovery and required to attain the group's objectives. Animal model component(s) may be requested by the NIAID to evaluate in vivo compounds other than compounds generated by the group. Funds for evaluation of new agents in animal models will be withheld until compounds generated by the group or provided by the NIAID are available for animal efficacy studies. Testing of natural products, biologics and/or synthetic compounds may not exceed 25 percent of the total level of effort of the group. Random screening of compounds will not be supported under this RFA.

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

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 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.

MECHANISM OF SUPPORT

Awards will be made as cooperative agreements (U01). The cooperative agreement funding mechanism differs from the traditional research grant in that the Government component (NIAID) awarding the cooperative agreement anticipates substantial programmatic involvement during performance. The nature of NIAID staff participation is described in the RFA. However, it is the Principal Investigator who defines his/her objectives in accord with his/her own interests and perceptions of approaches to the treatment of AIDS-associated opportunistic infections.

The applicant institution and the Principal Investigator will be responsible for the group's application. Awards will be made to the applicant institution on behalf of the group as a whole and not to individual research projects within the group. The applicant institution will provide a Central Operations Office for the group. The applicant institution will be responsible for the performance of the entire group and will be accountable for the funds awarded. The participation of the Government through the NIAID extramural staff is aimed at facilitating a concerted effort by all members of the group by providing appropriate scientific input, by making available to the group biological materials for testing, by accessing appropriate data bases, by providing ancillary testing and other resources available under existing contracts. The interaction of academic and non-profit research institutions with commercial organizations and the Government is strongly encouraged

and is expected to favor expeditious discovery and preclinical development of agents active against opportunistic infections in AIDS patients and to facilitate their subsequent development for clinical trials.

AVAILABILITY OF FUNDS

NIAID anticipates making two to four awards, based on highest Program priorities, for project periods up to three years and has set aside $2.0 million total costs for first year funding. It is anticipated that no more than one new group each will be funded for P. carinii, Cryptosporidium, M. avium, and cytomegalovirus as a result of this RFA. Awards will be subject to the limitation of $550,000 in total costs for the first year with subsequent years funded at a level no greater than the first year plus 4 percent. Applications with budgets in excess of $550,000 total (direct and indirect) first year costs will be returned without review. The amount spent for this RFA will be dependent on the continuing availability of funds for this purpose and the quality and diversity of approved applications.

METHOD OF APPLYING

It is important to follow the instructions in this RFA for preparing the application. Failure to do so may result in an application with insufficient information for appropriate scientific review. The prospective applicant is also urged to carefully read the sample application that is available from:

Besita Wyche
Targeted Drug Discovery Section
Developmental Therapeutics Branch
Division of AIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Room 243P
Bethesda, MD 20892
Telephone: (301) 496-8197

If additional information on how to prepare a multi-project application is required, the applicant may request the NIAID Information Brochure on Program Project and Center Grants, available from:

Program and Project Review Branch
National Institute of Allergy and Infectious Diseases
Control Data Building
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-0123

Questions concerning review requirements of a complete application may be directed to Dr. Hortencia Hornbeak, (301) 496-0123. Questions regarding responsiveness to the RFA may be directed to Dr. Barbara Laughon, (301) 496-8197.

The deadline for receipt of applications is January 13, 1992. Applications received after this date will be returned without review.

The research grant application form PHS 398 (rev. 10/88) is available at most institutional business offices. If not available there, they may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
5333 Westbard Avenue
Bethesda, MD 20892

Submit a signed, typewritten original of the application, including the Checklist, and six signed, exact, single-sided photocopies, in one package to:

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

The RFA label available in form PHS 398 (rev. 10/88 or 9/89) must be affixed to the bottom of the face page of the original signed application. Failure to use this label could result in delayed processing of the application such that it may not reach the committee in time for review.

To assure the identification of your application with this RFA the application form must have "NATIONAL COOPERATIVE DRUG DISCOVERY GROUP FOR TREATMENT OF OPPORTUNISTIC INFECTIONS" (RFA AI-91-15) typed on item 2 of the face page of the application form; and

Submit 17 exact copies of the application directly to:

Hortencia Hornbeak, Ph.D.
Deputy Chief, Program and Project Review Branch, DEA, NIAID
Control Data Building, Room 4C19
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-0123

LETTER OF INTENT

Prospective applicants are asked to submit by October 30, 1991, a letter of intent that includes a descriptive title of the overall proposed research, the name and institution of the Principal Investigator, a title, Project Leaders, and institution for each component research project and brief descriptions of the proposed projects. Names of prospective project leaders and other key investigators and their respective responsibilities should be included (maximum of two pages). The letter of intent is requested in order to provide an indication of the number and scope of applications to be reviewed and in order to allow early preparations for review as well as promote early interactions between applicants and NIAID staff. The letter of intent does not commit the sender to submit an application nor is it a requirement for submission of an application. The letter of intent is to be sent to:

Barbara Laughon, Ph.D.
Targeted Drug Discovery Section
Developmental Therapeutics Branch
Division of AIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-8197

INQUIRIES

For a copy of this RFA, contact:

Ms. Besita Wyche
Targeted Drug Discovery Section
Developmental Therapeutics Branch
Division of AIDS
National Institute of Allergy and Infectious Diseases
6003 Executive Boulevard, Room 243P
Bethesda, MD 20892
Telephone: (301) 496-8197

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, 93.856 - Microbiology and Infectious Diseases Research and 93.855 - Immunology, Allergic and Immunologic Diseases Research. Grants are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grants policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

HEALTH EDUCATION RESEARCH FOR DIABETIC EYE DISEASE

RFA AVAILABLE: EY-92-01

P.T. 34; K.W. 0715080, 0502000, 0403004

National Eye Institute

Letter of Intent Receipt Date: December 20, 1991
Application Receipt Date: February 19, 1992

PURPOSE

The National Eye Institute (NEI) announces the availability of a Request for Applications (RFA) for cooperative agreements for applied research projects in diabetic eye disease education. These research projects must be designed to develop, implement, and evaluate innovative, cost-effective, community-based education strategies in the United States that increase awareness and knowledge of diabetic eye disease and encourage actions to prevent loss of vision. Projects may be aimed at the general population of people with diabetes or at specific segments of the population with diabetes, e.g., pregnant women, Native Americans, Hispanics, Blacks, other minorities, older Americans, residents of rural areas, and the medically underserved.

HEALTHY PEOPLE 2000

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 RFA, Health Education Research for Diabetic Eye Disease, is related to the priority area of reducing blindness among people with diabetes. Potential applicants may obtain a copy of "Healthy People 2000" (Full report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, non-profit and for-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from minorities and women are encouraged.

MECHANISM OF SUPPORT/FUNDS AVAILABLE

The cooperative agreement mechanism (U01) of support will be used because substantial NEI programmatic staff involvement with awardee(s) is expected. This RFA is a one-time solicitation. One to three applications are expected to be funded as a result of this RFA. Projects are expected to vary from one to five years. The funds available for the first year of support for the RFA are expected to total approximately $650,000. However, this support level is conditional upon the receipt of applications of high scientific merit. Awards are expected to be made in September 1992. Although the financial plans of the NEI provide for these projects, awards pursuant to this RFA are also contingent upon the availability of funds.

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

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 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

The research grant application form PHS 398 (rev. 10/88) must be used in applying for these cooperative agreements. These forms are available at institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892 (Telephone: 301-496-7441).

Applications must be received by February 19, 1992.

LETTER OF INTENT

Prospective applicants are encouraged to submit, by December 20, 1991, a letter of intent that includes a descriptive title of the proposed research, the grantee institution, the name, address, and telephone number of the Principal Investigator, the names of other key personnel, the participating institutions, if any, and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is extremely helpful in planning for the review of applications. It allows NEI staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The letter of intent is to be sent to:

Janet M. Cuca, Ph.D.
Review and Special Projects Officer
National Eye Institute
Building 31, Room 6A06
9000 Rockville Pike
Bethesda, MD 20892

INQUIRIES

Written and telephone inquires concerning the objectives and scope of this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Applicants should request a copy of the RFA. The RFA contains complete application procedures, and additional information regarding the background, research objectives, special requirements, review procedures, and schedules. The program official named below will be pleased to mail the RFA to all who request it.

Direct inquiries regarding programmatic issues to:

Donald F. Everett
Extramural Program Director
Collaborative Clinical Research Branch
National Eye Institute
Building 31, Room 6A49
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-5983

For grants administration information, contact:

Gaye Lynch
Chief, Grants Management Section
National Eye Institute
Building 31, Room 6A48
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-5884

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.867, Retinal and Choroidal Disease Research. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulation 42 CFR 52 and 45 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

DEVELOPING AND IMPROVING INSTITUTIONAL ANIMAL RESOURCES

PA: PA-92-09

P.T. 34; K.W. 1002002, 0735000

National Center for Research Resources

Application Receipt Date: December 20, 1991

PURPOSE

The National Center for Research Resources (NCRR) encourages the submission of improvement grant applications by biomedical research institutions receiving over $1,000,000 (direct costs) in the most recently completed fiscal year (October 1 to September 30), for one or more research projects supported by the U.S. Public Health Service agencies and involving the use of animals. Major objectives of this program are to upgrade animal facilities, develop administratively centralized programs of animal care, and to enable institutions to comply with the USDA Animal Welfare Act and DHHS policies related to the care and use of laboratory animals. These awards require matching funds from the awardee institution. Eligible budget categories are limited to Alterations and Renovations (A&R) to improve laboratory animal facilities and major equipment items for animal resource and diagnostic laboratory needs.

ELIGIBILITY REQUIREMENTS

Any domestic public or private institution, organization, or association with one or more research projects supported by the PHS that involve the use of laboratory animals is eligible to apply. Institutions and commercial firms providing only services or products and without a clearly defined research component are not eligible to apply. Also, this program will not support requests for A&R and equipment used for teaching purposes or for housing non-research animals. Only one application may be submitted under this program by an institution per Federal fiscal year. However, separate applications may be submitted from different colleges or schools on the same campus of a university within the same federal fiscal year. Institutions must currently have PHS research support to be eligible for an award. Applications from other Federal agencies or institutions (e.g., Veterans Administration) are limited to requests for equipment only.

A separate program announcement is available for animal facility improvement grant applications from small research institutions receiving less than $1,000,000 (direct costs) of PHS support during the most recently completed Federal fiscal year.

MECHANISM OF SUPPORT

The mechanism available for the support of improvement projects are Grants for Repair, Renovation and Modernization of Existing Research Facilities (G20). The total budget request for the improvement grant application and award is limited to $700,000. Within this limit, the equipment request may be up to $700,000, but the A&R portion may not exceed $500,000. Requests are limited to A&R to improve laboratory animal facilities and major resource equipment related to the improvement, such as animal cage systems and cage washers with a manufacturer's unit value of at least $1000. Requests for basic equipment items for centralized surgical facilities, diagnostic laboratories, transgenic animal facilities, and other similar associated activities are allowable but must be well justified. Support for new construction, including completion of shell space, and equipment intended for teaching and non-research purposes is not authorized. Matching funds from non-Federal sources, equal to or exceeding the total award, are required.

RESEARCH OBJECTIVES

Animal resource improvement grants are awarded to assist biomedical research and educational institutions in upgrading their animal facilities and in developing administratively centralized programs of animal care. Another major objective is to assist institutions in complying with provisions of the Animal Welfare Act and Public Health Service (PHS) policies related to the care and use of laboratory animals.

REVIEW PROCEDURES

All applications will be reviewed for scientific and technical merit by an appropriate review committee managed by the Office of Review, NCRR. Second level review will be provided by the National Advisory Research Resources Council (NARRC). Review of the applications will be based on scientific merit, technical soundness, and reasonableness of the budget.

APPLICATION PROCEDURES

Applications must be submitted to the Division of Research Grants (DRG) using form PHS 398, "Application for Public Health Service Grant," (rev. 10/88).

The receipt date for submission of applications is December 20, 1991. Applications received by this deadline will receive February-March initial review, May-June NARRC review, and will have an earliest possible beginning date of July 1, 1992. Subsequently, October 1 will be the annual receipt date. Applications submitted for this deadline will receive February-March initial review, May-June NARRC review, and will have an earliest possible beginning date of July 1.

Applications received late for a particular deadline will be returned to the applicant. Application kits may be obtained from most institutional business offices, and from the Division of Research Grants, NIH (see address below). The NCRR Comparative Medicine Program (address indicated below) must be contacted for information about the special instructions that apply to the format and details of applications submitted.

The completed original application and four copies, including appendix material, must be mailed or delivered to:

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

An additional two copies of the application and appendix material must be mailed to:

Dr. Arthur Schaerdel, Scientific Review Administrator
Office of Review
National Center for Research Resources
Westwood Building, Room 10A16
Bethesda, MD 20892

INQUIRIES

Inquiries about specific improvement program guidelines and instructions for completion of applications and other aspects of the program must be directed to the following address (requests for guidelines must include two self-addressed mailing labels):

Comparative Medicine Program
National Center for Research Resources
Westwood Building, Room 857
Bethesda, MD 20892
Telephone: (301) 496-5175
Facsimile: (301) 480-0868

Application forms (PHS 398) may be obtained from grantee business or sponsored projects offices and from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 449
5333 Westbard Avenue
Bethesda, MD 20892**
Telephone: (301) 496-7441

For grants administration and fiscal matters contact:

Mr. Paul Karadbil
Grants Management Specialist
Office of Grants and Contracts Management
National Center for Research Resources
Westwood Building, Room 849
Bethesda, MD 20892
Telephone: (301) 496-9840

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.306, Laboratory Animal Sciences and Primate 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 grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ANIMAL FACILITY IMPROVEMENT FOR SMALL RESEARCH PROGRAMS

PA: PA-92-10

P.T. 34; K.W. 1002002, 0735000

National Center for Research Resources

Application Receipt Date: December 20, 1991

PURPOSE

The National Center for Research Resources (NCRR) encourages the submission of individual animal resource improvement grant applications from small biomedical research institutions receiving less than $1,000,000 (direct costs) in the most recently completed Federal fiscal year (October 1 to September 30), for one or more research projects supported by the U.S. Public Health Service (PHS) agencies and involving the use of animals. Major objectives of this program are to upgrade animal facilities, develop administratively centralized programs of animal care, and enable institutions to comply with the USDA Animal Welfare Act and DHHS policies related to the care and use of laboratory animals. These awards do not require matching funds from the awardee institution. Eligible budget categories are limited to Alterations and Renovations (A&R) to improve laboratory animal facilities and major equipment items for animal resource and diagnostic laboratory needs.

ELIGIBILITY REQUIREMENTS

Any domestic public and private institution, organization, or association with one or more research projects supported by the PHS that involve the use of laboratory animals is eligible to apply. Institutions and commercial firms providing only services or products and without a clearly defined research component are not eligible to apply. Also, this program will not support requests for A&R and equipment used for teaching purposes and for housing non-research animals. An institution must have current PHS funding for research to be eligible for an award. Applications from other Federal agencies or institutions (e.g., Veterans Administration) are limited to requests for equipment only.

A separate program announcement entitled "Developing and Improving Institutional Animal Resources" is available for biomedical research institutions receiving over $1,000,000 (direct costs) of PHS support during the most recently completed Federal fiscal year.

Applicant institutions must receive less than $1,000,000 (direct costs) during the most recently completed Federal fiscal year in PHS awards for research. The $1,000,000 limit applies to all PHS research support awarded, not just that portion that can be identified with animal research. If this limit is exceeded, the program announcement mentioned above that relates to institutions receiving more than $1,000,000 annually in PHS research funding will apply and applications will be transferred by NCRR for consideration in that category. Small institutions may not submit more than one application or apply for other NCRR support for developing and improving institutional animal resources within the same Federal fiscal year of PHS funding.

MECHANISM OF SUPPORT

The mechanism available for the support of improvement projects is the Grant for Repair, Renovation and Modernization of Existing Research Facilities (G20). The total budget request for the improvement grant application and award is limited to $150,000 for equipment and $100,000 for A&R. Requests are limited to A&R to improve existing laboratory animal facilities and major resource equipment related to the improvement, such as animal cage systems and cage washers with a manufacturer's unit value of at least $1,000. Requests for basic equipment items for centralized surgical facilities, diagnostic laboratories, transgenic animal facilities, and other similar associated activities are allowable but must be well justified. Requests for new construction, including the completion of shell space, and equipment intended for teaching or non-research purposes are not allowable.

RESEARCH OBJECTIVES

Animal resource improvement grants are awarded to assist biomedical research institutions in upgrading their animal facilities and in developing administratively centralized programs of animal care. Another major objective is to assist institutions in complying with provisions of the Animal Welfare Act and PHS policies related to the care and use of laboratory animals.

REVIEW PROCEDURES

All applications will be reviewed for scientific and technical merit by an appropriate review committee managed by the Office of Review, NCRR. Second level review will be provided by the National Advisory Research Resources Council (NARRC). Review of the applications will be based on scientific merit, technical soundness, and reasonableness of the budget.

APPLICATION PROCEDURES

Applications must be submitted to the Division of Research Grants (DRG) using form PHS 398, "Application for Public Health Service Grant," (rev. 10/88). The receipt date for submission of applications is December 20, 1991. Applications received for this deadline will receive February-March initial review, May-June NARRC review, and will have an earliest possible beginning date of July 1, 1992. Subsequently, June 1 will be the annual receipt date. Applications received for this deadline will receive October-November initial review, January-February NARRC review, and will have an earliest possible beginning date of April 1.

Applications received late for a particular deadline will be returned to the applicant. Application kits may be obtained from most institutional business offices, and from the Division of Research Grants, NIH (see address below). The NCRR Comparative Medicine Program (address indicated below) must be contacted for information about the special instructions that apply to the format and details of applications submitted.

The completed original application and four copies including appendix material should be mailed or delivered to:

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

An additional two copies of the application and appendix material must be mailed to:

Dr. Arthur Schaerdel
Scientific Review Administrator
Comparative Medicine Review Committee
National Center for Research Resources
National Institutes of Health
Westwood Building, Room 10A16
5333 Westbard Avenue
Bethesda, MD 20892

INQUIRIES

Inquiries about specific improvement program guidelines and instructions for completion of the application and other aspects of the program must be directed to the following address (requests for guidelines must include two self-addressed mailing labels):

Comparative Medicine Program
National Center for Research Resources
Westwood Building, Room 857
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-5175
Facsimile: (301) 480-0868

Application forms (PHS 398) may be obtained from grantee business or sponsored projects offices and from:

Office of Grants Inquiries
National Institutes of Health
Westwood Building, Room 449
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7441

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.306, Laboratory Animal Sciences and Primate 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 the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MECHANISMS OF ACTION OF INTRAVENOUS IMMUNOGLOBULIN

PA: PA-91-11

P.T. 34; K.W. 0710070, 0745045, 0715015, 0715120

National Institute of Allergy and Infectious Diseases

The Division of Allergy, Immunology and Transplantation (DAIT) of the National Institutes of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), invites research project grant applications for support of basic and preclinical studies on the mechanisms of action of intravenous immunoglobulin (IVIG) therapy of diseases.

BACKGROUND INFORMATION

Immunoglobulin preparations from human blood were first successfully used clinically to treat immunodeficiency conditions. Lately however, improved IVIG preparations have been used with varying degrees of success for the treatment of several diseases including infections in low birth weight infants, graft versus host disease (GVHD), idiopathic thrombocytopenic purpura (ITP), Kawasaki syndrome, and demyelinating polyneuropathies. At a conference entitled "Consensus Development Conference on Intravenous Immunoglobulin: Prevention and Treatment of Disease," held on May 21-23, 1990 at the National Institutes of Health (NIH), the consensus panel concluded, "There is a great need for an understanding of the mechanisms of action of IVIG in the various conditions in which it is employed. Without knowledge of specific mechanisms, progress in this area will be slow. This should be a major focus of future efforts."

The mechanisms of action and the effectiveness of IVIG therapy used in treating primary and presumably secondary immunodeficiencies appear related to replacement of antibodies directed against environmental pathogens such as group B streptococci and cytomegalovirus. However, the need for massive doses of IVIG suggests that the relevant antibodies may be present at very low concentrations in the pooled immunoglobulin preparations. In contrast, little information exists regarding the mechanisms involved in reversion of symptomatology induced by IVIG in patients with ITP, GVHD, polyneuropathies, and Kawasaki syndrome.

RESEARCH GOALS AND SCOPE

The NIAID believes that the elucidation of the mechanism of action of IVIG will lead to a better rationale and improved strategies for its application to the therapy of disease. Areas of interest on the mechanisms of action of IVIG administration include but are not limited to:

o Analysis of the effects of IVIG on the induction and development of cellular and humoral immune responses in the normal and immunodeficient host.

o Effects of IVIG on the number and function of natural killer and T suppressor/cytotoxic cells.

o Effects of IVIG on the clearance of immune complexes by the reticuloendothelial system.

o Effects of IVIG on the initiation and evolution of autoimmune responses, particularly pertaining to the induction of tolerance and of antiidiotypic antibodies.

o Determination of the effects of IVIG on the levels and activities of complement activation products.

HEALTHY PEOPLE 2000

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,

Mechanisms of Action of Intravenous Immunoglobulin, is related to the priority areas of immunization and infectious diseases, and diabetes and chronic disabling diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone: 202-783-3238).

MECHANISM OF SUPPORT

The support mechanism for this research will be the individual research grant (RO1) and the First Independent Research Support and Transition (FIRST) Award (R29). Applications from women and minority individuals are encouraged.

GENERAL REQUIREMENTS

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/offerors 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.

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 Principal Investigator must be included with the application.

METHOD OF APPLYING

Applicants must use the research grant application form PHS 398 (rev. 10/88). For purposes of identification and processing, check yes on item 2 of the face page and enter the title: "MECHANISMS OF ACTION OF INTRAVENOUS IMMUNOGLOBULIN PA-91-11". Applications will be accepted in accordance with the standard submission dates for new applications: February 1, June 1, and October 1.

The original and six copies of the application should be submitted to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**
**20816 if using overnight delivery services

REFERRAL AND REVIEW PROCEDURES

Applications will receive Institute and Study Section assignment on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by Study Sections convened by the Division of Research Grants, NIH. Following Study Section review, the applications will receive a second-level review by an appropriate council/board.

REVIEW CRITERIA

The standard review criteria will be used to assess the scientific merit of applications. The Study Section will be reviewing the adequacy of protection of human subjects, the humane care of animals, and biosafety conditions. In clinical research studies, reviewers also will be evaluating the adequacy of the inclusion of women and minorities in the study populations.

AWARD CRITERIA

Applications will compete for available funds with all other approved applications assigned to the institute. The number of awards to be made is dependent upon receipt of a sufficient number of applications of high scientific merit and upon availability of funds.

STAFF CONTACT

Requests for additional information or questions regarding this program may be directed to:

Susana A. S. Sztein, M.D.
Chief, Autoimmunity Section
Division of Allergy, Immunology and Transplantation
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 755
Bethesda, MD 20892
Telephone: (301) 496-7985
FAX Number: (301) 402-0175

For fiscal and administrative matters contact:

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

AUTHORITY AND REGULATIONS

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 grants 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.