NIH GUIDE for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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IN THIS ISSUE:

HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

ANNOUNCEMENT

CONTROLLED CLINICAL TRIALS FOR PROPHYLAXIS OR IMPROVED ANTIMICROBIAL THERAPY OF SELECTED BACTERIAL AND MYCOTIC INFECTIONS

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

PURPOSE

One of the objectives of the Clinical Studies Branch of the Microbiology and Infectious Diseases Program of the National Institute of Allergy and Infectious Diseases is to foster innovative clinical studies whereby efficacy of antimicrobial drug regimens are compared in selected infections by carefully controlled randomized trials. The primary goal of this program on Clinical Trials of Antibiotic Treatment Regimens is to sponsor studies that are targeted to improve care of patients with severe infections due to bacterial and mycotic agents. The purpose of the program is to extend clinical research of the NIAID closer to the needs of the practicing physicians in the community; establish utilization patterns that decrease the over use and misuse of antibiotics; and reduce health care costs by limiting the duration of chemotherapy and hospitalization where possible. A variety of clinical situations that would be amenable to improved antibiotic therapy were discussed at the NIAID "Symposium on the Impact of Infections on Medical Care in the U.S." May 30-31, 1978.[1]

The applicant is encouraged to consider promising areas of research that may have significant clinical and scientific merit and do not compete with the area of interest of the pharmaceutical industry.

INSTRUCTIONS FOR PREPARING APPLICATIONS

The application should deal with an innovative clinical study whereby efficacy of antimicrobial drug regimen for prophylaxis or treatment of selected infections (bacterial or mycotic) are compared by a randomized controlled trial. In addition

[1] Annals of Internal Medicine. Vol. 89, No. 5 (Part 2), November, 1978.

This program is described in the Catalog of Federal Domestic Assistance Number 13.856, Microbiology and Infectious Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. Applications responding to this Announcement are not subject to OMB Circular A-95 Clearinghouse or Health Systems Agency review.

to equal or improved efficacy and less toxicity, the proposed clinical trial should have the potential to demonstrate a reduction of medical care cost associated with management of the selected infection. Prophylactic or treatment regimens may include single or combination antimicrobial drugs that are licensed and approved, as well as new antimicrobial agents which show clinical promise after phase II testing, but because of low disease prevalence are not widely used and are thus unlikely to be marketed by the pharmaceutical industry. For selected infections of low frequency it may be necessary to establish a multicenter project employing a common clinical protocol.

Applicants are reminded that the study design should be of the best quality and address basic features that include: specific objectives of the trial; estimated sample size; randomization procedures; and acceptable procedures for statistical analysis of the data.

APPLICATION PROCEDURE

The NIAID is requesting submission of research grant proposals for initiation of clinical research in the areas mentioned above.

Research proposals should be submitted on application form PHS 398 available from institutional application control offices or from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 448
Bethesda, Maryland 20205
Telephone: (301) 496-7441

Receipt dates for research grant applications are October 1, February 1, and June 1 of each year. This program announcement has no specified termination date.

REVIEW

Review of research proposals will be by a peer review group with special expertise in clinical trials and antibiotic studies, with final review by the National Advisory Allergy and Infectious Diseases Council at its regularly scheduled meeting. Applicants will be notified by mail, shortly after final review of the outcome of their proposals. Support for these proposals will be on a competitive basis and will depend on the availability of funds.

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

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

For further information contact:

Richard E. Horton, M.D.
Medical Officer, Clinical Studies Branch
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A49
Bethesda, Maryland 20205

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NEI-80-1

NATIONAL EYE INSTITUTE

TITLE: NATIONAL EYE INSTITUTE CONSTRUCTION PROGRAM

Application receipt date, May 1, 1981

The National Eye Institute announces a construction grant program to expand the vision research facilities of organizations engaged in eye research.*

I. PROGRAM GOAL AND DESCRIPTION

The National Eye Institute Construction Program is administered by the National Eye Institute, National Institutes of Health, Department of Health and Human Services. Grants are awarded under this program for the purpose of building or renovating physical facilities dedicated to eye research. A total of $3,000,000 is available for this program.

An organization applying for construction funds must clearly show that the facilities to be constructed will be used to expand an existing eye research program. Facilities constructed under this program may not be used to replace existing eye research facilities, (e.g., so that the latter could be used for purposes other than eye research).

The main objective of this program is to increase the quantity and improve the quality of clinical vision research by supporting an expansion of clinical vision research facilities. In this instance, clinical research is defined as research involving patients, normal human subjects, animals, tissues, cells, or cellular components which has potential for adding to an understanding of the etiology, pathogenesis, and epidemiology of human eye diseases and visual disorders thereby improving the prevention, diagnosis and treatment of these conditions. Thus, a construction grant application might propose the development or expansion of a clinical research facility and/or integration of "wet" laboratories (e.g., biochemistry), with "dry" laboratories (e.g., visual psychophysics), if these facilities are to be dedicated to clinical research as defined above.

*This program is described in the Catalog of Federal Domestic Assistance, 13.985, National Eye Institute Construction Program. Grants will be awarded under the authority of the Public Health Service Act, Section 453 (Public Law 78-410, as amended; 42 USC 289k) and administered under 45 CFR Part 74. This program is subject to A-95 Clearinghouse and Health Systems Agency Review.

II. TYPES OF FACILITIES

Facilities eligible for support under this program include:

* Completion of "shell" space in new or existing buildings. (The building of new "shell" space is not allowed.)

* Additions to existing buildings

* Construction of new buildings

* Renovations or alterations which exceed $100,000. (Proposals requiring lesser grant amounts are eligible for funding by the individual NIH Research Project Grant.)

III. ELIGIBILITY

Any public or non-profit institution, organization, corporation or association is eligible to apply for a grant for the construction of eye research facilities provided the institution is authorized by its governing body to conduct eye research and is located in a State, the District of Columbia, the commonwealth of Puerto Rico, the Virgin Islands, the Canal Zone, American Samoa, the Trust Territory of the Pacific Islands, or Guam.

IV. FUNDING PARTICIPATION

The National Eye Institute will provide up to 50% of the total allowable costs of a project up to a maximum of $500,000. At least 50% of the costs for an approved project must be provided from non-Federal sources. Prior to a grant award, the applicant must provide assurance that matching funds have been secured.

V. APPLICATION RECEIPT

Construction grant applications should be submitted to the Division of Research Grants, National Institutes of Health. A one time receipt date of May 1, 1981 has been established. Applications received after May 1, 1981 will not be accepted for review in this competition.

VI. APPLICATION REVIEW

Applications will be reviewed for technical merit by a special peer group convened by the National Eye Institute. The National Advisory Eye Council will conduct a final review in January, 1982, and awards may be made as early as March, 1982. In addition, each application will be reviewed by National Eye Institute engineering consultants for adherence to sound engineering practices and government regulations.

VII. TECHNICAL REVIEW CRITERIA

Applications will be evaluated on the basis of:

* The soundness and comprehensiveness of the proposed construction plan including its potential for meeting specific vision research needs, proposed time course for construction, and guarantee of eye research use commitment;

* The scientific merit of the vision research program proposed to be housed in the new facility;

* The scientific and professional expertise of the institution's existing or proposed research staff and officers;

* The applicant's demonstrated potential for outstanding clinical research.

VIII. FUNDING CRITERIA

In making funding decisions, the National Eye Institute will be guided by the recommendations of the National Advisory Eye Council, and the proposal's potential for meeting National Eye Institute program needs. Geographic location will also be considered.

IX. APPLICATION PROCEDURE

Prospective applicants are advised first to contact the National Eye Institute before any application procedures are initiated to discuss the feasibility of the proposal.

Application forms and further information and assistance may be obtained by telephone (301-496-4903) or by writing to the following address:

Associate Director
Extramural and Collaborative Programs
National Eye Institute
Building 31, Room 6A-03
Bethesda, Maryland 20205

ANNOUNCEMENT

HEALTH SCIENTISTS EXCHANGE PROGRAMS WITH

*POLAND

*ROMANIA

*UNION OF SOVIET SOCIALIST REPUBLICS

FOGARTY INTERNATIONAL CENTER

The Fogarty International Center, NIH, administers joint cooperative programs involving short- and long-term exchange of health and biomedical scientists with the above countries. An intergovernmental agreement covers the terms of the particular program with each country, such as the number of persons to be exchanged each year, duration of visits, elements of support, and areas of program interest. There are differences of terms among the individual programs but, in general, costs are shared through support of international travel by the sending side and in-country costs by the receiving side. Duration of visits may be from one to twelve months, depending on the program and nature of the work to be accomplished.

U.S. health and biomedical specialists who have particular scientific interests with respect to any of these countries for which a period of work, observation, or consultation in that country would be of mutual benefit may submit a proposal for consideration as an exchange visitor under one of these programs. In addition to such special requirements as may pertain to a particular country program, the general eligibility requirements specify that a participant must:

*be a U.S. citizen or a permanent U.S. resident,

*hold an advanced degree (normally doctorate) in one of the health sciences or related fields,

*have had professional experience in health or biomedical fields appropriate to the proposed study,

*be affiliated with a U.S. public or private nonprofit educational, research, or clinical institution.

Those considering the submission of a proposal should first contact the Fogarty International Center for further information with respect to the terms and requirements of the particular country program of interest.

Inquiries should be addressed to:

Chief, International Cooperation and
Geographic Studies Branch
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20205
Telephone: (301) 496-5903

NOTICE

NIH CONTRACT COMPLIANCE PROGRAM

As a result of the announcement of the NIH Contract Compliance Program in the NIH Guide for Grants and Contracts, Volume 9, No. 6, dated April 25, 1980, NIH has received several questions concerning the overall goals and objectives of the program. The compliance program was initiated in May, 1976, under guidelines developed by the Public Health Service. The NIH program was developed in two phases. The first phase, involving NIH contract specialists, began in November, 1977. The second phase, involving project officers, began July 1, 1980. Both phases of the program were fully discussed and developed by committees of NIH contract specialists and project officers.

In the first phase, contract specialists were trained to understand the basic contract compliance laws, executive orders, and regulations. Upon completion of their training, NIH contract specialists now are required to ask five (5) elementary questions of the contractor's Affirmative Action Officer concerning the contractor's Affirmative Action Program (AAP). These questions are asked orally during contract negotiation site visits. The second phase involved the training of NIH project officers and requires that they ask seven (7) elementary questions of the contractor's principal investigator during the first site visit after the award of a new contract. The NIH contract specialist's questions are designed to determine if the contractor's AAP has been approved by the Office for Federal Contract Compliance Programs (OFCCP), Department of Labor, and disseminated to appropriate persons within and outside the institution, organization, or corporation. The NIH project officer's questions are designed to determine if the contractor's first line supervisors (principal investigators) are aware of the AAP and generally familiar with its provisions. The specific oral questions to be asked by NIH contract specialists and project officers were included in the April 25, 1980 NIH Guide for Grants and Contracts.

The NIH Contract Compliance Program is a positive initiative intended to provide early identification of any obvious problems with a contractor's Affirmative Action Program. If problems appear to exist in a contractor's implementation of an AAP, the NIH will arrange to provide technical assistance through appropriate contractor management channels. The NIH's responsibility as a funding agency does not include EEO enforcement and is solely restricted to limited monitoring of a contractor's AAP. The Department of Labor has the responsibility of enforcing the Civil Rights executive orders, laws, and regulations applicable to Federal contractors. The NIH Contract Compliance Program has been developed in consultation with the Department of Labor to ensure that the NIH Program is consistent with and complementary to the efforts of the Office for Federal Contract Compliance Programs.

If, during a site visit, either a contract specialist or project officer observes a circumstance that seems to indicate an obvious problem with a contractor's Affirmative Action Program, he/she will bring the matter to the attention of either an Institute Contract Compliance Coordinator or the NIH Contracts and Grants Compliance Officer, Ms. Maureen Miles. One of these individuals, in turn, will contact the contractor's Affirmative Action Program Officer to discuss the apparent

problem. If, in fact, the NIH site visitor's concern is found to be valid, the NIH Institute Coordinator and/or Ms. Miles will work closely with the appropriate contractor's staff, and OFCCP when appropriate, to eliminate the problem.

The goal of the NIH Contract Compliance Program is the early identification of obvious problems NIH contractors might be encountering in establishing effective Affirmative Action Programs. Early identification and the provision of technical assistance by NIH may prevent a contractor from being found to be out of compliance by OFCCP during a subsequent enforcement review. If a contractor is found to be out of compliance, interruption in NIH contract support might be required by OFCCP.

Staff Contact

For further information contact:

Ms. Maureen B. E. Miles
9000 Rockville Pike
Room 1B50, Building 31
Bethesda, Maryland 20205
Telephone: (301) 496-2973

NOTICE

AVAILABILITY OF NEI DOCUMENTS RELATED TO RESEARCH GRANTS

The National Eye Institute announces the availability of the following documents:

1. Revised Guidelines for Core Grants for Vision Research, June 1980

   These revised guidelines include the goals of the core grants program, the eligibility criteria, direct costs which may be requested, and review criteria.

2. Criteria for Review of Research Grant Applications Involving Clinical Trials

   This announcement stipulates the criteria by which all clinical trial research proposals will be reviewed and invites potential applicants to communicate with NEI staff prior to submission of a clinical trial application.

3. National Advisory Eye Council Statement on Research Supported by the National Eye Institute: Program Relevance Judgments and Choice of Animal Species

   This statement, prepared by the National Advisory Eye Council, discusses the role of the Institute, the Council, and the initial review groups in applying program relevance judgments, evaluating scientific merit of research grant applications, and relating the choice of animal species to the nature of the research proposed.

Copies may be obtained by writing to:

Grants Management Officer
National Eye Institute
National Institutes of Health
Building 31, Room 6A52
9000 Rockville Pike
Bethesda, Maryland 20205
Telephone: (301) 496-5884

*U.S. GOVERNMENT PRINTING OFFICE: 1980 311-215/7 1-3