NIH GUIDE for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Vol. 10, No. 8, June 26, 1981

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HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: 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.

Index (continued)

NOTICE

SPECIAL APPROVAL PROVISION FOR TRAVEL TO SCIENTIFIC MEETING

The VII International Biophysics Congress and III Pan-American Biochemistry Congress have scheduled a Joint Symposium to be held in Mexico City, August 23-29, 1981. It is expected that a large number of NIH grantee investigators will be justified in seeking approval for use of existing grant funds for attendance. Ordinarily each investigator would be required to solicit prior approval from the NIH awarding component. In order to minimize the administrative burden for both the investigator and the NIH awarding component, and to expedite the approval process, the following special provisions will apply to travel to this particular Seminar only.

1. Each trip to Mexico City for this Congress (and the dollars involved) must be specifically approved in advance in writing by an appropriate grantee institution official. The NIH awarding component shall be notified of the travel for information only. The institution's approval document shall be retained with grant expenditure records.

2. Existing grant funds may be used. No supplemental funds will be provided for this purpose.

3. No precedent is being established for other meetings involving foreign travel.

NOTICE

NEW LAW ON PATENTS

On July 1, 1981, P.L. 96-517 (an amendment to Title 35 of the United States Code, entitled "Patents") will be effective.

The amendment adds to the Code a new Chapter 30, the major provisions of which are as follows:

- In effect, the Act codifies and extends many past DHHS policies on patents under the Institutional Patent Agreements.
- All non-profit and small business grantees and contractors will have the option of obtaining title to patents resulting from federally sponsored research.
- As in the past, all inventions must be reported to the funding agency.
- The Government will retain a royalty-free license to the inventions and, if it deems necessary, may exercise march-in rights.
- Exclusive licenses may be negotiated.
- The individual inventor must share in the royalties.
- The Office of Management and Budget will soon publish in the Federal Register a notice which solicits comments on its proposed implementation of this Act. Members of the public will be invited to comment. This will be followed by issuance of NIH guidelines implementing the Government-wide regulations as they apply to NIH programs.

NOTICE

NEW NIH CATALOGUE OF RODENTS AVAILABLE

This edition of the catalogue replaces the 1974 edition, and has been expanded to reflect the increased number of animal strains and stocks contained in the NIH Genetic Resource. Characteristics of the 209 strains and stocks of rodents and rabbits listed in the catalogue are fully referenced. The format, which includes subject and animal indexes, has been designed to facilitate its use in identifying potential animal models for research. Detailed descriptions of the management and microbiological definition of the Resource colonies, including their nutrition and associated quality assurance programs, are provided to better inform readers about the conditions under which the animals are maintained.

Information is also provided which describes the procedures for obtaining animals from the Genetic Resource for establishing colonies outside of the National Institutes of Health.

Requests for copies of the catalogue may be directed to:

Office of the Chief
Veterinary Resources Branch
Division of Research Services
Building 14G, Room 102
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIEHS-EP-81-4

BIOLOGICAL EFFECTS OF CHEMICAL INTERACTIONS

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Application receipt date: October 15, 1981

BACKGROUND

Approximately 30,000 chemical waste dumps containing hazardous materials are estimated to pose a significant health risk in the United States. The degree of magnitude of the health risk is not known, however the sites are known to contain chemicals which may produce a variety of toxic effects, including disorders of the nervous and reproductive systems and other illnesses. In one such site which serves to illustrate the magnitude of the problem, the Environmental Protection Agency has identified more than 200 chemicals (Love Canal). For the large majority of chemicals, those which are not the final commercial products but rather precursors, by-products or process intermediates, toxicological information may be missing or incomplete.

Laboratory studies with rodents have shown that several of the chemicals identified in the Love Canal dump can interact resulting in potentiation of toxic effects, or enhancement of latent neoplastic changes, via promotion or co-carcinogenesis. Although there are numerous examples in the literature of interactions of chemical-chemical (including drugs) and chemical-physical agents which affect biological systems, almost nothing is known concerning the potential for interactions of the multitude of chemicals contained in waste dumps which may pose a serious toxicological problem for humans. Until more information is available concerning the propensity for interaction of mixtures to affect biological systems, the extent of the hazard cannot be properly assessed.

GOALS AND SCOPE

This announcement indicates that the NIEHS has an interest in supporting high quality research in the area of chemical interactions which affect biologic

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This program is described in the Catalog of Federal Domestic Assistance number 13.892, Prediction, Detection and Assessment of Environmentally Caused Diseases and Disorders; and 13.893, Mechanisms of Environmental Diseases and Disorders. 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 A-95 Clearinghouse or Health Systems Agency Review.

systems and may have significance for human health. Although the announcement cites potential interactions of chemicals which are associated with waste dumps and pose a health hazard to man, other factors in the general environment to which man is exposed are not excluded from consideration. All facets of biological effects of interactions are of interest to this announcement and may include single or diverse agent sources, dose response relationships, time factor with respect to exposure and injury; additive, synergistic or antagonistic toxic effects, effects on organ systems, enzyme induction, fetal development, inhibition of DNA repair, mutagenesis and teratogenesis among others.

Since the state-of-the-art technology for testing interactions in simple and complex mixtures is time consuming or undeveloped, proposals which purport to develop new methods for study of interactions will be of interest.

Interactions for the purpose of this announcement should not be construed to mean reactions which occur between two or more chemicals external to the organism or when a single exogenous agent reacts with a biological constituent as might occur between an agent and cell constituents, such as DNA, RNA or protein.

The intent of this announcement is to encourage research proposals which focus on the study of the mechanisms and methodology involved in the interaction of chemical and/or physical agents on biological systems such as to produce synergistic effects resulting in potentiation of toxic effects.

MECHANISM OF SUPPORT

The support mechanism for this program will be the NIH research project grant. This type of announcement (the RFA) is used when an Institute--with the concurrence of its National Advisory Council or another appropriate advisory group--wishes to stimulate investigator interest in a particular research problem that is important to its program. The RFA solicitation represents a single competition with usually one specified deadline for receipt of applications. All applications in response to an RFA are reviewed by the same initial review group in competition with each other, usually for a designated amount of funds or number of awards.

The RFA identifies the scope of the Institute's interest but does not require that the proposal conform to a specific research protocol. Thus it is expected that each successful applicant will plan, direct, and carry out the research program. As with any research grant, the recipient must obtain prior approval for any major change in the scope or objectives of the approved project. Applicants should be aware that this general requirement is particularly pertinent when, as in the case of RFA solicitations, the awarding Institute has committed funds in response to a specific program need.

It is anticipated that $600,000 will be allocated for this program during the first year; however, award of grants is contingent upon the availability of funds. The project period should adequately reflect the time required to accomplish the stated goals and be consistent with the NIH policy for grant support.

REVIEW PROCEDURES AND CRITERIA

A. Review Procedure

Proposals in response to this solicitation will be reviewed in competition with each other on a nationwide basis. The initial review will be for scientific merit and will be carried out by an appropriate peer review group. The secondary review for relevance and responsiveness to the announcement will be made by the National Advisory Environmental Health Sciences Council. Applicants will be informed of the results of the competition as soon as possible after the May, 1982 meeting of the Council.

B. Review Criteria

Applications should be responsive to the RFA and, therefore, relevant to the program goals of the sponsoring Institute. Those factors considered to be important for review include a demonstrated knowledge of the applicable science, adequacy of facilities and commitment, availability of subject population when applicable and in-depth knowledge of the state-of-the-art to which the RFA is directed. The application will be judged upon the overall scientific merit, adequacy of methodology, facilities and resources, commitment of time and cost effectiveness of the proposal. The sponsoring institution should indicate a commitment of facilities and resources to the program. Applications judged to be non-responsive to the RFA will be considered along with other non-solicited applications by the NIH for the appropriate review cycle.

METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division of Research Grants, NIH. The original and six copies of the application must be received by October 15, 1981. Applications must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The face page of the application should be labeled "In response to RFA# NIH-NIEHS-EP-81-4." One copy of the application should be sent to:

Dr. Edward Gardner, Jr.
Program Director
Regular Research Programs Section
Scientific Programs Branch
Extramural Program
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, North Carolina 27709

STAFF CONTACT

Questions relating to this announcement may be directed to Dr. Edward Gardner, Jr. (address above) or (919)755-4021.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DCCP-CPCB-81-2

ROLE OF TUMOR PROMOTERS, HORMONES, AND OTHER COFACTORS IN HUMAN CANCER CAUSATION

NATIONAL CANCER INSTITUTE

Application receipt date: December 1, 1981

The Division of Cancer Cause and Prevention (DCCP) of the National Cancer Institute (NCI) invites grant applications from interested investigators for both basic and applied studies intended to provide insights and approaches to an understanding of the role of tumor promoters, hormones, and other cofactors in human cancer causation. As pertains to tumor promoters, the intended emphasis is on the use of non-phorbol agents.

Grants are awarded to nonprofit organizations and institutions, governments and their agencies, and occasionally to individuals. This type of grant solicitation (the RFA) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Program. Applicants funded under the RFA are supported through the customary NIH grant-in-aid, in accordance with PHS policies applicable to Research Project Grants including cost-sharing. However, the RFA solicitation represents a single competition, with a specified deadline for receipt of applications. All applications received in response to the RFA will be reviewed by the same National Institutes of Health (NIH) Initial Review Group.

The present RFA announcement is for a single competition with a specified deadline of December 1, 1981, for receipt of applications. Applications should be prepared and submitted in accordance with the aims and requirements described in the following sections:

This program is described in the Catalog of Federal Domestic Assistance number 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

I. BACKGROUND INFORMATION

Experimental tumor promotion, originally demonstrated in mouse skin, has been analogously modeled in organs of laboratory animals, notably the liver, and in culture systems. It has been widely postulated that the phenomenon of tumor promotion may also apply to people and may constitute an important consideration relative to the occurrence of cancer in humans.

At the present time, tumor promotion research, involving the use of the highly reactive phorbol esters, is receiving a considerable amount of interest and attention. However, the research effort devoted to non-phorbol tumor promoters, hormones, and other cofactors present in the human environment, appears to be of relatively modest proportions.

II. OBJECTIVES AND SCOPE

The research encompassed by this RFA relates to both basic and applied studies which seek to achieve insights and approaches to an understanding of the role of tumor promoters, hormones, and cocarcinogens in human cancer causation.

Applications submitted in response to the RFA should be responsive to one or more topics selected from any one or from a combination of the following categories:

Category 1. Development of non-phorbol tumor promotion models in experimental animals, in one or more of the following: breast, colon, lung, prostate, stomach, urinary bladder, and/or uterus. Development of cocarcinogenesis models in experimental animals in one or more of the same organs.

Category 2. Development of non-phorbol tumor promotion models and/or cocarcinogenesis models in human and/or non-human cell culture and/or organ culture systems.

Category 3. Studies to test the possibility that hormones may serve a tumor promotion role or other cofactor role in carcinogenesis in experimental animals. Studies to test the existence of a tumor promotion role or other cofactor role with respect to one or more of the following: bile acids, saturated/unsaturated dietary fat, alcohol abuse, salt abuse, and/or free oxygen radicals.

Category 4. Identification of non-phorbol tumor promoters and/or cocarcinogens present in the human environment. Elucidation of mechanisms of action of non-phorbol tumor promoters and/or cocarcinogens present in the human environment. Dose-response studies on non-phorbol tumor promoters in experimental animals.

Category 5. Interdisciplinary studies involving epidemiologists and experimentalists, to test hypotheses concerning tumor promoters generated by either.

In studies involving the use of one or more chemical carcinogens, the agent(s) used should be chosen from among those which are organic compounds, are present in the human environment, and are known to be carcinogenic for humans or for experimental animals, or for both. The choice of cocarcinogen(s) and/or non-phorbol tumor promoter(s) should be from among those present in the human environment. The choice of experimental animal(s) should be from among those commonly used in carcinogenicity testing

III. MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health grant-in-aid. Responsibility for the planning, direction, and execution of the proposed research will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should not exceed four years. The intent is to fund multiple projects, with total costs amounting to approximately $2.5 million for the first year. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. Also, although this program is provided for in the financial plans of the National Cancer Institute, the award of grants pursuant to this RFA is contingent upon the availability of funds for this purpose.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

Each application submitted in response to the RFA will be reviewed by: (1) an appropriate review panel of the Division of Research Grants, National Institutes of Health, and (2) the National Cancer Advisory Board. All applications will be evaluated on a competitive basis.

B. Review Criteria

Applications must be responsive to this RFA, in the sense of being directed towards the attainment of the stated programmatic goals and fall within one or more of the specified research categories (see II. OBJECTIVES AND SCOPE). If the application is judged by the National Cancer Institute not to be responsive, the applicant will have the opportunity of having the application considered, along with other unsolicited applications, in the next regular review cycle.

The factors considered in evaluating each response to this RFA will be:

1. Scientific merit of research approach, design, and methodology.

2. Research experience and competence of the Principal Investigator and staff to conduct the proposed studies.

3. Adequacy of time (effort) which the Principal Investigator and staff would devote to the proposed studies.

4. Adequacy of existing/proposed facilities and resources. Applications which specify a proposed use of cultures of specimens derived from humans, need to provide assurance and details concerning the nature, source, and availability of those specimens.

5. Adequacy of practices, procedures, and facilities relative to the safe handling and use of chemical carcinogens, if applicable.

V. METHOD OF APPLYING

A. Format of Applications

Applications must be submitted on form PHS 398, the application form for research project grants. Application kits are available at most institutional business offices, or may be obtained from the Division of Research Grants, NIH. The conventional presentation in format and detail applicable to regular research grant applications should be followed, and the requirements specified under Review Criteria (IV. B.) must be fulfilled. The words "PROPOSAL IN RESPONSE TO RFA NIH-NCI-DCCP-CPCB-81-2, ROLE OF TUMOR PROMOTERS, HORMONES, AND OTHER COFACTORS IN HUMAN CANCER CAUSATION" must be typed in bold letters across the face page of the application.

B. Application Procedure

The completed original application and six (6) copies should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Room 240, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications should be received by December 1, 1981. If applications are received after that date, the applicant will have the opportunity of having them considered, along with other unsolicited applications, in the next regular review cycle. Also, the Division of Research Grants (DRG) will not accept any application in response to this announcement, that is the same as one currently being considered by any other NIH awarding unit. A copy of the applications should also be sent to Dr. Domanski at the address shown below.

VI. INQUIRIES

Inquiries may be directed to:

Dr. Thaddeus J. Domanski
Chemical and Physical Carcinogenesis Branch
Division of Cancer Cause and Prevention
National Cancer Institute
Room 8C-29, Landow Building
Bethesda, Maryland 20205

Telephone: (301) 496-9448

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NCI-DCT-CTEP-CIB-81-3

SURGICAL ONCOLOGY RESEARCH

NATIONAL CANCER INSTITUTE

Application receipt date: October 15, 1981

I. INTRODUCTION

The National Cancer Institute's Division of Cancer Treatment desires to expand support of surgical oncology research. This announcement solicits applications for exploratory studies grants (P20s), contains specific instructions for P20 applications, establishes a single initial deadline for the P20 awards. A separate program announcement invites applications for individual research project (RO1) and program project (PO1) grants on an ongoing basis.

II. BACKGROUND

The treatment of cancer has evolved as a multidisciplinary effort involving (but not limited to) the disciplines of medical oncology, pediatric oncology, surgical oncology, and radiation oncology. The disciplines of medical oncology, pediatric oncology, and radiation oncology have developed strong cadres of academic investigators but academic development in surgical oncology has often not kept pace. It is felt that surgical oncology is not keeping pace in recruiting new young investigators. Continued development of multidisciplinary treatment of cancer is the long range objective of the Division of Cancer Treatment and the attainment of this goal requires sufficient academic strength in surgical oncology.

III. GENERAL CONSIDERATIONS

Exploratory studies must include the definition of the missions and objectives, organizational structure, program development, personnel, facilities, equipment, costs, and sources of funds. Examples of exploratory studies that NCI considers for support include:

This program is described in the Catalog of Federal Domestic Assistance number 13.395, Cancer Treatment Research. Awards will be made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

- Planning the establishment of specialized resources and facilities oriented to the problem of cancer in man.

- Feasibility studies that permit the applicant to gather data to determine the potential of an idea, and to explore the validity of various approaches to a problem.

It is important to note that the award of an Exploratory Studies Grant does not imply a commitment by NCI to future funding of any program planned and developed with the support of such a grant. Separate applications must be submitted for such projects which are then reviewed on the basis of merit.

IV. APPLICATION PROCEDURES

The title of the grant application should be "Exploratory Studies in Surgical Oncology Research." The applications must be submitted on form PHS 398 and should follow the instructions included with that form. The proposal should contain information on the following points:

- Planning mission - its goals and objectives
- Relevance of the program to the National Cancer Program
- Institutional organization to implement the goals of the planning mission
- Description of the programs to be included
- Interrelationship with other institutions and the scientific and medical communities

Although there is no specific limitation on the amount of a grant request, NCI program staff anticipate that awards will not exceed $100,000 direct costs per award. It is the intent of DCT to make approximately five awards if sufficient meritorious applications are received. This number may be increased depending on the availability of resources and applications.

Allowable Direct Costs may include:

a. Salaries for planning staff.
b. Travel required to carry out the approved project. This should include an annual trip to Bethesda for a principal investigators' meeting with the NCI surgical oncology program director.
c. Supplies relative to the planning effort.
d. Costs of alteration and renovation are <u>not</u> allowed.
e. Other related costs.
f. Payment of consultation and technical assistance needed for feasibility surveys and identification of special problems and alternatives. The applicant must include the following information when applying for consultant services in an Exploratory Grant. It should be emphasized that the applicant must not enter into a binding agreement with a consultant for expenditure of these grant funds prior to an award.

1) Evidence that the services to be provided are essential and cannot be provided by persons receiving salary support or otherwise compensated for their services under the grant.

2) Evidence that a selection process has been or will be employed to secure the most qualified consultant available, considering the nature and extent of services required.

3) Evidence that the proposed charges are appropriate, considering the qualifications of the consultant and normal charges for this type of service.

Consultant fees should not be paid to an employee of the United States Government. Further information regarding the use of consultants or consulting firms is included in "Guidelines for Obligating Grant Funds for Consultants through Contracts." This publication may be obtained from:

Grants Administration Branch, DEA
National Cancer Institute, NIH
Westwood Building
Bethesda, Maryland 20205

Expenditures under these grants are subject to policies applicable to research project grants supported by the National Institutes of Health as described in the current PHS Grants Policy Statement.

V. METHOD OF APPLYING

Applications should be submitted on Form PHS 398. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division of Research Grants, NIH. The original and six copies of the application must be sent to: Division of Research Grants, National Institutes of Health, Westwood Building, Room 240, 5333 Westbard Avenue, Bethesda, Maryland 20205. The face page of the application should be labeled, "In response to program announcement on surgical oncology research, RFA NIH-NCI-DCT-CTEP-CIB-81-3." An additional copy of the application should be sent to:

Dr. Bimal C. Ghosh, M.D., F.A.C.S.
Head, Surgery Section
Clinical Investigations Branch
Division of Cancer Treatment
National Cancer Institute
National Institutes of Health
Landow Building, Room 4C29
Bethesda, Maryland 20205

Applications received after October 15, 1981 will not be accepted.

ANNOUNCEMENT

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANTS

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: October 15, 1981

I. BACKGROUND

As part of its mission to create, develop, and maintain research resources needed by NIH-supported biomedical investigators throughout the nation, the Division of Research Resources (DRR) is initiating a competitive biomedical shared instrumentation grant program. The program is being established in recognition of the long-standing need in the biomedical research community to cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment. The objective of the program is to make available, to institutions with a high concentration of NIH extramural research awards, research instruments which can only be justified on a shared use basis and for which meritorious research projects are described.

II. RESEARCH GOALS AND SCOPE

This program is designed to meet the special problem of acquisition and updating of expensive shared-use instruments which are not generally available through other NIH mechanisms, such as the regular research, program project and center grant programs, the (BRS) Grant Program and other DRR programs such as the Animal Resources and the Biotechnology Resources Program. The latter program emphasizes development of the instrument and associated research methodology, research aspects which are not required in the new BRS Shared Instrumentation Program. The National Institute of General Medical Sciences (NIGMS) Shared Instrumentation Grants provide an instrument sharing program primarily for NIGMS grantees. The BRS Shared Instrumentation Program is intended for a broader community of NIH-supported investigators.

III. ELIGIBILITY

The shared instrumentation grant program is a subprogram of the Biomedical Research Support (BRS) Grant Program of DRR. Awards are made under the

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This program is described in the Catalog of Federal Domestic Assistance number 13.337, Biomedical Research Support. Awards will be made under the authority of the Public Health Service Act, 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 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

authority of the BRS program and are made to institutions only, not to individuals. In FY 1982, eligibility is limited to 527 institutions[1/] which received a BRS grant award in FY 1981. NIH records will be used to verify eligibility. Only one application for a single shared instrument may be submitted by an eligible institution in a review cycle. Applications will be received only once per year. The program is highly competitive. Approximately $3.7 million has been requested for the program in FY 1982. At this funding level, it is expected that a minimum of 14 and a maximum of 49 awards would be made in 1982. Future funding is contingent on the availability of appropriated funds.

IV. MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants provide support for expensive state-of-the-art instruments utilized in biomedical research. Applications are limited to instruments that cost at least $75,000 per instrument or system. Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers and cell sorters. Support will not be provided for general purpose equipment or "stand alone" computer systems.

Awards will be made for the direct costs of acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the normal purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is $250,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. If the amount of funds requested does not cover the total cost of the instrument, an award will not be made unless the remainder of the funding is assured. Description of the proposed co-funding must be presented with the application. Assurance of co-funding, signed by an appropriate institutional official, must be presented to DRR prior to the issuance of an award. The shared instrument will not be transferable outside of the institution to which it is awarded.

A major user group of three or more investigators should be identified. Each major user must have NIH peer-reviewed research support at the time of the award. The application must show a clear need for the instrumentation by projects supported by multiple NIH research awards and demonstrate that these projects will require at least 75% of the total usage of the instrument. Major users can be individual researchers, or a group of

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1/ Institutions include health professional schools, or other academic institutions (includes all other components of the institution except the health professional schools), hospitals, state and local health agencies and non-profit research organizations.

investigators within the same department or from several departments at the applicant institution. NIH extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument can be made available to other users upon the advice of the advisory committee. These users need not be NIH awardees but priority should be given to NIH-supported scientists engaged in biomedical research.

A progress report shall be required for three years. The report will cover the period August 1 through July 31 and be submitted within 30 days following the reporting period. The report must describe the use of the instrument, listing all users, and indicate the value of the instrumentation to the research of the major users and to the institution as a whole.

V. ADMINISTRATIVE ARRANGEMENTS

Each applicant institution must propose a Principal Investigator who can assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility should also be utilized. It is expected that in most cases, the BRS Program Director and extant BRS advisory apparatus, augmented with members having technical and scientific expertise regarding the instrumentation requested, can serve this function. However, there may be circumstances where other existing or proposed arrangements are more appropriate for the applicant institution.

In any event, the Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation of all reports required by the NIH, for relocation of the instrument within the grantee institution if the major user group is significantly altered and for continued support for the maximum utilization and maintenance of the instrument in the post award period.

A plan should be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument should be described.

VI. REVIEW PROCEDURES AND CRITERIA

Applications are reviewed by specially convened initial review groups of the Division of Research Grants for scientific and technical merit and by the BRS Subcommittee of the General Research Support Advisory Committee and the National Advisory Research Resources Council of the Division of Research Resources for program considerations. Funding decisions are the responsibility of the Division of Research Resources.

Criteria for review of applications include the following:

1. The extent to which an award would contribute to research progress (for example, enhance ongoing or proposed research or open new research areas) by providing an instrument that is unavailable or to which availability is highly limited.

2. The benefit of the proposed instrument to the overall research community it will serve.

3. The availability and commitment of the appropriate technical expertise within the major user group and the institution for use of the instrumentation.

4. The adequacy of the organizational plan for administration of the grant including sharing arrangements for use of the instrument.

5. The institution's commitment for continued support of the utilization and maintenance of the instrument.

VII. METHOD OF APPLYING

A. Application Format

Applications are to be submitted on the standard PHS research grant application form (PHS 398, Rev. 5/80) available from most institutional business offices or the Division of Research Grants, NIH. Instructions supplied with these forms would be followed except for the following:

1. Face page of the application

   Item 2. Write in "DRR-BRS SHARED INSTRUMENTATION GRANT"

   Item 6. Write in August 1, 1982-July 31, 1983.

2. Application page 2. List the Principal Investigator and all major users.

3. Application page 4. A detailed breakdown of the direct costs requested will be shown on the budget page. Provide a complete description of the instrument including manufacturer, model number and cost including tax and import duties, if applicable.

4. Application page 5. Budget Estimates for All Years. Not applicable; do not submit.

5. Biographical Sketch. In addition to the personnel listed on page 2, include a biographical sketch of the person(s) who will be in charge of maintenance and operation of the instrument and a brief statement of the qualifications of the individual(s). Biographical sketches should not exceed 2 pages.

Section 2 of application. Provide information relative to the points identified under criteria for review including:

1. A description of similar instruments existing at the institution or at nearby institutions and a justification why new or updated equipment is needed.

2. A description, by major users, of the research projects for which the instrumentation is required. The descriptions need not be of the detail of a regular research grant application (should not exceed 3 pages) but should point out the benefit of the proposed instrument to the research objectives of each major user. An estimate of the percentage use for each project should be given.

3. A description of the organizational plan for administration of the grant.

4. A specific plan and a statement of institutional commitment to operate and maintain the instrument for its useful life at the same utilization level after termination of the 3-year reporting period to DRR.

B. Application Procedure

Applications must be received by October 15, 1981. Applications received after this date will not be accepted for review in this competition. The original and six copies should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

Inquiries and one copy of the application should be addressed to:

Biomedical Research Support Program
Division of Research Resources
National Institutes of Health
Building 31, Room 5B23
Bethesda, Maryland 20205

ANNOUNCEMENT

RESEARCH IN THE THALASSEMIAS

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE OF ARTHRITIS, DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Grant applications are being sought by the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute (NHLBI) and the Hematology Program, National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK) for studies related to the thalassemias. We welcome grant applications for basic and clinical research aimed at increasing our understanding of thalassemia major and providing the basis for improved methods for the clinical management of this disease.

Thalassemia major (Cooley's anemia) is a severe, inherited blood disorder characterized by a quantitative defect in the synthesis of the beta chains of hemoglobin. The result is marked anemia, a lifelong dependence on blood transfusion, and death usually before the third decade of life. Repeated transfusion therapy, the accepted treatment for this disorder, results in alleviation of the anemia and the excessive erythropoiesis, but it increases the accumulation of iron. As a result, iron is deposited in parenchymal tissues, and failure of the heart, endocrine glands, and liver ensues. These events culminate eventually in death. In areas of the world where the abnormal gene frequency is high, such as parts of Greece and Italy, the disease is a major drain on medical resources.

At present, patients are being maintained on a multiple transfusion or "supertransfusion" regimen and are being transfused with younger red cells. In addition, the iron chelating agent, deferoxamine, is administered subcutaneously over a period of eight to twelve hours daily. This regimen seems to be effective in correcting the anemia and preventing additional iron accumulation, but reversal of organ damage from previous iron buildup remains to be shown.

Significant gaps in our knowledge remain and we welcome investigator-initiated grant applications on, but not limited to, the following areas:

- o Evaluation of multiple transfusion of "supertransfusion" regimens in combination with chelation therapy and their effects on patient growth, as well as endocrine, cardiac, and hepatic function;

This program is described in the Catalog of Federal Domestic Assistance number 13.839, Blood Diseases and Resources, and 13.849, Kidney Disease, Urology, and Hematology 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 A-95 Clearinghouse or Health Systems Agency Review.

- o evaluation of removal of older cells from the patient and transfusions of young red cells;
- o reduction of iron burden by more effective chelating agents, especially those that can be administered orally;
- o development of noninvasive techniques to measure iron deposition in tissues;
- o determination of the efficacy of bone marrow transplantation as a cure for thalassemia;
- o evaluation of, and research into, methods for the prevention, education, and control of thalassemia;
- o basic research related to the molecular biology of the globin genes and hemoglobin synthesis, the identification of the DNA sequence controlling the switch from fetal to adult hemoglobin, and factors that can bring about this switch;
- o recombinant DNA techniques to demonstrate that human globin genes can be expressed in animals; and
- o iron metabolism as it relates to the accumulation of iron resulting from repeated transfusion therapy.

Applicants should use the regular research grant application (PHS 398). If the institution's business office or central application control office does not have these, an individual copy may be requested by writing to the Division of Research Grants, NIH. The original and six copies of the application should be mailed to:

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

All applications will be reviewed through the Division of Research Grants Study Section mechanism and by the appropriate national advisory council. Applications recommended for approval will compete for available funds with all other approved applications assigned to the NHLBI or the NIADDK. There are three receipt dates each year for new applications: March 1, July 1, and November 1. Competing renewal applications submitted in response to this announcement have receipt dates one month sooner (February 1, June 1, and October 1).

Applicants are encouraged to contact one of the staff members listed below prior to submitting and application.

Inquiries should be directed to:

Red Blood Cell Program Administrator
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 5C10
7550 Wisconsin Avenue
Bethesda, Maryland 20205
Telephone: (301) 496-5911

or

Hematology Program Director
National Institute of Arthritis, Diabetes
and Kidney Diseases
National Institutes of Health
Westwood Building, Room 621
Bethesda, Maryland 20205
Telephone: (301) 496-7458

NOTICE

NEW WORLD PRIMATE AVAILABILITY

As part of a major project in primate conservation and breeding, the Pan American Health Organization is providing services to South American countries in planning and operating wild primate management and primate breeding programs. These services are, in part, supported by the National Institutes of Health in recognition of the need for international cooperation in conserving primates in their natural habitats as well as in research utilization. Programs have been initiated by Peru to protect endangered species such as Lagothrix flauvicauda (yellow-tailed woolly monkey), Cacajao rubicundus (red-faced uakari), and Callimico goeldii (Goeldi's marmoset). The Government of Peru has also established a program at Iquitos to breed monkeys and from which primate surveys and population monitoring are conducted. Another program is being developed in Colombia which will breed Aotus trivirgatus (owl monkey), and extend previous nonhuman primate census work. As a consequence of their efforts, several species of primates are available to NIH grantees and contractors from Peru. These include:

Saimiri Sciureus	(gothic and roman arch squirrel monkeys) - colony produced and wild caught
Cebuella pygmaea	(pygmy marmoset) - colony produced and wild caught
Saguinus fuscicollis	(saddle-back tamarin) - wild caught
Saguinus labiatus	(white lipped tamarin) - currently wild caught; colony produced animals will become available
Saguinus mystax	(moustached tamarin) - currently wild caught; colony produced animals will become available

Services can also be made available to scientists for conducting field studies relating to nonhuman primates with the assistance of program staff at Iquitos.

In order to assist Peruvian authorities in developing programs appropriate to meet future needs, users of New World primates are requested to inform the Interagency Primate Steering Committee (IPSC) of their projected requirements. Requests for animals and information concerning costs, and services that are available should be directed to:

Dr. Orland A. Soave
Executive Director, IPSC
National Institutes of Health
Building 31, Room 4B-30
Bethesda, Maryland 20205
Telephone: (301)496-5424

ANNOUNCEMENT

CLINICAL INVESTIGATOR AWARD

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Application Receipt Date: October 1, 1981

PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of Clinical Investigator Awards. These awards are intended to:

- o provide the opportunity for promising young physicians with demonstrated aptitude in research to develop fully into independent investigators under the supervision of appropriate mentors;
- o develop basic research interest and skills in the fields of immunology, allergy and immunologic diseases, bacteriology, virology, mycology, parasitology, and epidemiology;
- o increase the pool of physician investigators in the above disciplines who will apply their training to clinical problems in allergic, immunologic, and infectious diseases.

It is not the purpose of this award to provide for advanced clinical training but rather to enable individuals trained as clinicians to obtain the requisite research experience essential to successful academic careers.

The award, made to an institution, will enable recipients to undertake up to 3 years of special study and supervised experience with a mentor competent to provide research guidance, and to provide the recipient research experience and basic laboratory training. For those seeking an epidemiologic research experience, the recipient is expected to take basic training in population-based studies. The knowledge and skills obtained during the interval of this award should be such as to permit the recipient to undertake independent sophisticated studies in microbiology, immunology, or epidemiology.

This program is described in the Catalog of Federal Domestic Assistance numbers 13.855, Immunology, Allergic and Immunologic Diseases, and 13.856, Microbiology and Infectious Diseases. Grants will be awarded 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 A-95 Clearinghouse or Health Systems Agency Review.

BACKGROUND

Despite major research advances, allergic, immunologic and infectious diseases remain high among the nation's great public health problems. Patients with infectious diseases account for 20-30% of all visits to physicians' offices while patients with allergies make at least 43 million visits each year at an estimated cost for care and medications totaling over one billion dollars. Asthma is the major cause of disability among children, and infectious diseases account for 65% of all visits to physicians for children under 16 years old. While many infections cause only mild illnesses in otherwise healthy individuals and are responsible for only temporary absence from work or school, it is emphasized that they can be serious, even fatal, particularly in certain groups of individuals such as the elderly and those with underlying chronic disease. For example, infections are now the leading cause of death in patients with cancer; the cytotoxic drugs administered in the hope of killing cancer cells also damage the bone marrow and other components of the immune system. Apart from mortality, infections are an important cause of morbidity in individuals who are at risk because of other underlying conditions or simply because of advancing age. Furthermore, even medical advances exact their price. Infections associated with the use of indwelling catheters in nursing homes and in hospitals account for more than 30% of all nosocomial infections. The new heart valve or new hip that has been inserted by skilled surgeons may become infected by bacterial resistant to antibiotics. The technically successful renal transplant may fail because of activation of a cytomegalovirus infection. Nationwide, the costs of such infections are enormous both in terms of ill health and death and in terms of expenditures for hospital care and antibiotics.

The NIAID's Immunologic, Allergic and Immunologic Diseases Program focuses upon examination of the immune system as it functions in health and disease. Owing to major innovative discoveries and advances, several areas specifically appear to hold promise for important future discoveries. Thus, regulation of the immune system, effectors and mediators of immunity, genetic control of immune cell responses, clones, hybridoma technology, tailoring of genes by recombinant DNA are but some of the exciting areas in allergy and immunology where important basic discoveries during the next decade are anticipated. These findings are expected to have important benefits in understanding and treating asthma, immunodeficiency disease, lupus erythematosus, autoimmune diseases, and transplant rejections as well as other infectious and immunologic problems.

The Microbiology and Infectious Disease Program of this Institute focuses upon the etiology, diagnosis, and treatment of infectious diseases, and supports research with the broad aim of improving health by controlling diseases caused by infectious or parasitic agents. Projects range from studies of microbial physiology and antigenic structure to collaborative trials of experimental drugs and vaccines. Also supported are studies on the mechanisms of resistance to antibiotics as well as epidemiologic observations in hospitalized patients or community populations. Recent technical advances and new knowledge in these areas can be expected to have important applications to problems of sexually transmitted diseases, hospital-associated infections, respiratory viral infections, viral hepatitis, chronic and opportunistic mycotic infections, and parasitic diseases.

Despite these exciting investigative opportunities, fewer physicians than ever before are entering into clinical and academic research careers. The projected deficit of clinical investigators in the next decade jeopardizes the necessary translation of basic research advances and knowledge into useful diagnostic techniques, therapeutic approaches, and prevention methods. The area of allergic and immunologic diseases, for example, is faced with a serious shortage of manpower. A recent NIAID survey has demonstrated that only one-half of the nation's medical schools have full-time academic faculty in their allergy and/or clinical immunology sections. Recognizing this problem, the NIAID Clinical Investigator Award Program has been designed to encourage recently trained physicians to develop their clinical and basic research interests and research capabilities in various areas of allergic, infectious, and immunologic diseases. To facilitate the transition from a clinical training status to that of a productive research investigator, the Clinical Investigator Award will provide early support for clinicians with potential for developing into independent researchers.

PROVISIONS OF THE AWARD

The Clinical Investigator Award is made on an annual basis. A maximum total of 3 years of support may be recommended. The award is non-renewable and non-transferable. Support is based on a full-time, 12- month, staff appointment. The awardee will be provided salary not to exceed $30,000 annually from NIAID funds for the 3-year period. The actual salary must be consistent with the established salary structure of the institution for persons of equivalent qualifications, experience and rank. The institution may supplement the awarded salary consistent with the institution's salary scale. No supplementation may be provided from Federal funds unless explicitly authorized by the program from which such funds are to be derived. In no case may other NIH funds be used as a means of additional salary support. In addition to the base salary, the institution's share of contributions to finance such fringe benefits as are available to all other staff members of comparable rank at the institution, under established and consistently applied institutional policies, may be paid from award funds to the extent that they are consistently treated by the institution as direct rather than indirect costs.

Up to a total of $10,000 annually will be provided for supplies, equipment, domestic travel, etc., which are necessary for pursuit of the awardee's research program.

Funds for the reimbursement of indirect costs will be provided at a rate of up to, but not to exceed, 8% of the total direct award costs of each award, exclusive of tuition, fees, and expenditures for equipment. The grant will be made annually to the awardee's parent institution for each of 3 budget periods.

Awardee's Salary: Up to a maximum of $30,000 for salary support. In addition, fringe benefits will be provided. Institutional supplementation is permitted.

Research Support: Up to a maximum of $10,000 per year for:

- Equipment: Specialized research equipment essential to the proposed program. The available facilities should include most of the necessary equipment.

- Supplies: Consumable supplies essential to the proposed program.

- Travel: Domestic travel essential to the proposed program.

- Tuition for Training Courses: If essential to the awardee's individual research development program.

- Other: Publication costs, patient costs, etc., necessary for the research program.

The applicant may not be the recipient of a federally-supported research grant, contract or New Investigator Research Award (R23) at the time of application for this award. Awardees must agree to inform the National Institute of Allergy and Infectious Diseases on request for a period of 5 years subsequent to completion of the award about academic status, publications and research grants or contracts received.

ELIGIBILITY

The Clinical Investigator Award is designed to provide supervised research experience for the physician. Candidates must have at least 3 years of total professional postdoctoral clinical and research experience by the projected start of the award. It is expected that candidates will have a minimum of 2 years of clinical experience and sufficient participation in pre- and postdoctoral research training to have demonstrated an aptitude for clinical research. In exceptional circumstances, individuals with less than 3 years of such experience may apply, but must justify those special circumstances. The award is designed to provide intensive guided research experience for clinicians. Therefore, holders of the Ph.D. or comparable research degrees, either with or without an accompanying health professional degree, are not eligible. Individuals holding the academic position of associate professor or professor at the time of the award are not eligible for the Clinical Investigator Award.

Candidates should have broad clinical training, should demonstrate individual competence in clinical activities, and should show research potential in the chosen area of interest. Candidates must provide evidence of a serious intent for an academic and research career related to the chosen area of interest.

Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.

The grantee institution must be a domestic university, medical school, or comparable institution with strong, well-established research and training programs, adequate numbers of highly trained faculty in clinical and basic science departments, and commitment and capability to provide guidance to clinically-oriented individuals in the development of independent research careers.

Candidates must be nominated by an institution on the basis of qualifications, interests, accomplishments, motivation, and potential for a research career. Evidence of the commitment of the institution to the candidate's research development must be provided.

Candidates must plan with a mentor (who should be a recognized and accomplished investigator in the field at the parent institution) a developmental and research program in which the awardee will receive research experience in preparation for a future career of independent research. The candidate's proposed research and development plans for the 3-year period of the award must be described. The candidate must be prepared to commit full-time effort to the objectives of this award.

Although it is required that recipients spend a minimum of 75% of effort in research, the NIAID and its Advisory Council will give special consideration to applicants proposing to spend a larger percentage in research.

APPLICATION

Applications must be submitted on Form PHS 398 (Rev. 10/79). For purposes of identification and processing, the words NIAID CLINICAL INVESTIGATOR AWARD should be typed in item 2 of the face page of the application and a brief covering letter should be attached indicating that the submission is in response to this NIAID announcement.

The proposed project should be presented using the format described in the "instructions" in the application kit. The chairperson of the department and the applicant's mentor sponsoring the research should submit a signed statement, as part of the application, detailing the commitments made to the project. A curriculum vitae of the principal mentor should be included. The original and 6 copies of the application should be delivered to:

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

Upon receipt of each application at NIH, a postcard acknowledging receipt will be mailed to the investigator. The applicant must request letters from 3 present or former supervisors or preceptors attesting to his/her potential for conducting research. These letters should be mailed to the Program and Project Review Branch, Extramural Activities Program NIAID, Bethesda, Maryland 20205. These letters need not comment on the merit of the specific project. The aplicant is responsible for making the necessary arrangements to ensure that the reference letters are mailed by the referees directly to the NIAID Extramural Activities Program. NIAID staff is unable to respond to individual inquiries concerning the receipt of these reference letters.

Applications for the first competition for this award are due October 1, 1981. They will undergo initial scientific review by the appropriate Institute chartered

committee in March, 1982 and will be considered at the May, 1982 meeting of the National Advisory Allergy and Infectious Diseases Council. The earliest start date for awards will be July 1, 1982. Applicants will be informed of the results of the review shortly after final consideration by the Advisory Council.

Subsequent competition for award will occur on a regularly scheduled basis as follows:

Receipt Date	Initial Review Meeting	Advisory Council Meeting	Earliest Start Date
February 1	June	October	December 1
June 1	October	January	April 1
October 1	March	May	July 1

REVIEW CRITERIA

Applications for Clinical Investigator Awards will undergo initial merit review by the chartered committees of the NIAID Extramural Activities Program. Secondary review will be by the National Advisory Allergy and Infectious Diseases Council. Criteria for review include:

- o The overall merit of the candidate's 3-year plan for research and the development of research skills;
- o The candidate's potential for a career in independent research;
- o The candidate's training in research and clinical experience in the specified area of interest;
- o The candidate's commitment to a research career;
- o The institution's commitment to providing facilities and opportunities necessary to the individual's research developments;
- o Presence and close interaction of highly-trained faculty in clinical and basic science departments relative to the area of study;
- o The ability and plans of the mentor(s) who will provide the candidate with the guidance necessary for career development in clinical investigation.

NIAID STAFF CONTACTS

Additional information regarding the policies governing the awards and other inquiries should be directed to the staff of the NIAID Program to which the aplication would be assigned.

For applications concerning allergic and immunologic diseases, contact:

Robert A. Goldstein, M.D., Ph.D.
Chief, Allergy and Clinical Immunology Branch
Immunology, Allergic and Immunologic
Diseases Program
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Westwood Building, Room 755
Bethesda, Maryland 20205

Telephone: (301) 496-7104

For applications concerning infectious diseases, contact:

Robert Edelman, M.D.
Chief, Clinical Studies Branch
Microbiology and Infectious Diseases Program
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Building 31, Room 7A49
Bethesda, Maryland 20205

Telephone: (301) 496-5893