

# NIH GUIDE

# for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Vol. 10, No. 12, November 6, 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.

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NOTICE

AMENDMENTS TO THE NATIONAL RESEARCH SERVICE AWARD ACT

The Omnibus Reconciliation Act of 1981 (P.L. 97-35), which was signed by President Reagan on August 13, 1981, contains several provisions of interest to program directors and individuals who will be, are being, or have been, supported under the National Research Service Award (NRSA) Act. In implementing these provisions NIH, ADAMHA, and HRA/DN call attention to the following:

1. An increased emphasis has been placed on the research training of physicians. The Secretary is instructed, in taking account of the Nation's overall need for biomedical research personnel, to give special consideration to physicians who agree to undertake a minimum of two years of biomedical research.
2. Prebaccalaureate candidate holders of Minority Access to Research Careers (MARC) support under the NRSA are relieved of further payback obligation for research training obtained under a MARC award.
3. That portion of the law which speaks to a payback obligation has been amended to require it only for awards made in excess of 12 months. This amendment has been interpreted to eliminate 12 months of NRSA support from computation of the payback obligation for:
  - a. All recipients of NRSA awards made on or after August 13, 1981.
  - b. All recipients of NRSA awards in research training on August 13, 1981.
  - c. All recipients of NRSA awards prior to August 13, 1981 who have not yet begun fulfillment of the payback obligation.
  - d. All recipients of NRSA awards prior to August 13, 1981 who are in the process of fulfilling the payback obligation.

These provisions do not apply to individuals in delinquent payback status prior to August 13, 1981.

4. Alternate service in a health-related activity in lieu of engaging in biomedical research and/or teaching has been eliminated as an optional form of fulfilling the payback obligation for individuals entering the NRSA program on or after August 13, 1981.

For additional information:

ADAMHA

The Deputy Associate Administrator for  
Extramural Programs, ADAMHA  
Parklawn Building, Room 13301  
5600 Fishers Lane  
Rockville, Maryland 20857  
(301) 443-4266

HRA/DN

Acting Chief, Nursing Research Branch  
3700 East West Highway  
Center Building, Room 350  
Hyattsville, Maryland 20782  
(301) 436-6204

NIH

Research Training and Research  
Resources Officer, NIH  
Building 1, Room 115  
Bethesda, Maryland 20205  
(301) 496-9743

NRSA Payback and Project Clearance Officer  
Building 1, Room 314  
Bethesda, Maryland 20205  
(301) 496-1963

Director, MARC Program  
Westwood Building, Room 9A18  
5333 Westbard Avenue  
Bethesda, Maryland 20205  
(301) 496-7941

NOTICE

PROPOSED CONTRACT SEMINARS

The National Institutes of Health, Division of Contracts and Grants, is considering the possibility of conducting a series of special topic contract seminars. Whether these seminars are undertaken will depend on the response generated by this notice. These seminars will focus on matters of interest expressed by NIH contractors and other interested parties. Examples of possible topics are: "competitive range" selection procedures, cost analysis of offerors' proposals; Cost Accounting Standard No. 414, "Facilities Capital Cost of Money"; P.L. 95-507, "Amendments to the Small Business Investment Act of 1958"; NIH contract financial reporting requirements, etc. The objective is to develop a dialogue between NIH and contractor organizations leading to a better understanding of the contracting process. Presentations may be of the lecture or workshop type, but regardless of format, substantial time will be allotted for discussion.

The date, location and agenda for each seminar will be announced in this publication approximately 30 days in advance to permit prospective participants to register as attendees on a space available basis. No registration fees are anticipated. Travel and associated costs are to be borne by the participants.

At this time, we request NIH contractors and other interested parties to submit their ideas for these seminars including suggested topics, format, length, participants, etc. Only research and development contract related topics will be considered. Ideas should be submitted to:

Mr. Carl Fretts, Director  
Division of Contracts and Grants  
National Institutes of Health  
Building 31, Room 1B03  
9000 Rockville Pike  
Bethesda, Maryland 20205

Any questions may be directed to either Mr. Fretts or to Mr. Curtis Tate, Deputy Director of DCG. Both may be reached by telephone at (301) 496-4422. Please submit your ideas within forty-five days of the date of this NIH Guide for Grants and Contracts.

**NOTICE****UNITED STATES V. HEBER, ET AL. — Conversion of Grant-Related Income**

Grantee institutions should be aware of the reasoning leading to the court's decision in the above-captioned case. Although the facts are not spelled out in the decision, it appears the defendants were employed by the University of Wisconsin in connection with a grant from the then Office of Education, HEW. While doing so they converted to their own use program income earned under the grant. As the result they were indicted for criminal conversion.

In refusing to dismiss the indictments, the court held in effect that (1) the defendants could be prosecuted even though they were not technically the grantee, but simply worked under the grant, (2) the program income at issue constituted funds of the United States for purposes of the criminal statute under which they were being prosecuted, and (3) in order to prosecute the defendants successfully the Government must merely prove knowing and intentional conversion of the funds, but need not show that the defendants knew the funds belonged to the United States.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA 82-1

INTERNATIONAL COLLABORATION IN INFECTIOUS DISEASES RESEARCH

**NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES  
MICROBIOLOGY AND INFECTIOUS DISEASES**

The National Institute of Allergy and Infectious Diseases plans to continue its current effort in international health by encouraging and strengthening scientific linkages between U.S. and foreign investigators to develop research centers of excellence in geographic areas with major health problems in infectious diseases. Two interrelated programs, Part A, International Program Project Grants, and Part B, International Exploratory/Developmental Research Grants, have been designed to provide flexibility and to insure maximum opportunity for participation.

Part A

International Program Project Grants

The Microbiology and Infectious Diseases Program (MIDP) of the National Institute of Allergy and Infectious Diseases (NIAID) invites the submission of Program Project Grant applications to establish a program in International Collaboration in Infectious Diseases Research (ICIDR) that will link U.S. institutions to research units at overseas sites. Authority for establishing this international program is provided by Public Law 86-610, the International Health Research Act of 1960. The program focuses on infectious diseases and the immunology of these diseases.

Solicitation

Solicitation by RFA is used by the Institute to open the areas of international biomedical research for which it is responsible to national competition. It is anticipated that institutions and/or their constituent departments will develop integrated, multidisciplinary research projects designed to utilize fully the expertise of their staff and, if appropriate, staff from other universities to develop strong collaborative efforts in partnership with local scientists in selected foreign countries. In developing this team effort, the talents of recognized investigators in bacteriology, virology, parasitology, medical entomology, epidemiology and such related scientific disciplines as biochemistry, immunology, genetics, pharmacology, biophysics, molecular biology, and zoology should be combined as appropriate. Applications approved for funding, originally submitted in response to this RFA, will be supported through the grant mechanism with special provisions to accommodate the off-site component. Insofar as possible, every effort will be made to achieve a geographic distribution of ICIDR grants so there will be research opportunities on the broadest possible spectrum of tropical disease.

A special research program for individual investigators to work with a foreign affiliate will be covered under this announcement as described under Part B.



### Program Objective

The program objective is a collaborative effort in biomedical research of recognized relevance to the health of people in tropical countries. It is anticipated that this combined research effort will foster improved health in the host country. It is intended that there be active collaboration between sponsoring U.S. staff and scientists of the foreign affiliate. It is also desired that the effort give particular emphasis to the development of self-direction and self-sufficiency of the collaborating off-site laboratory for biomedical research.

### Diseases of Interest

The Institute is interested in research on tropical diseases involving medical entomology, protozoology, helminthology, malacology, mycology, virology, and bacteriology. Special attention will be given to the six diseases of the WHO Special Program for Research and Training in Tropical Diseases: malaria, schistosomiasis, filariasis, trypanosomiasis, leishmaniasis and leprosy. While these diseases constitute major world health problems, it is not the intent of the program to exclude other diseases equally important to a particular geographic location. The Institute has a broad interest in the epidemiology, etiology, diagnosis, treatment, control, and prevention of all infectious diseases.

### Definition of Program Project Grant

By definition, a program project grant is a mechanism for the support of a broadly based multidisciplinary research program that has a well-defined central research focus or objective. The responsibility for leadership of the overall program resides with the program director who must possess demonstrated scientific and administrative competence. The program project grant consists of a number of interrelated projects that contribute to the program objective. Each of these scientifically meritorious projects usually is under the leadership of a principal investigator.

### Site of Research

The major portion of the research, 70-80%, must be conducted in a foreign country, and it must be relevant to one or more important health problems of that country. In addition, the foreign research component must be sponsored by a United States based institution. The U.S. institution is responsible for developing a mutually acceptable affiliation(s) with an established university, research institute, federal or state health department, hospital, etc., in the host country. The awarding of a grant will be contingent upon having an off-site component as a base of operations and one or more indigenous specified collaborators as co-investigators. The grant application will not be reviewed unless proof of an acceptable foreign affiliation accompanies the grant proposal.

In addition, it will be necessary to establish a working agreement with the Government of the foreign host country to expedite deputation of personnel, equipment and supplies from the U.S. to the off-site base; such an agreement must be a part of the application at the time of submission. An agreement may be developed directly between the U.S. sponsors and representatives of the foreign government, or it may be more convenient for the U.S. side to arrange such an agreement through organizations such as the Pan American Health Organization or other WHO regional office. The investigators should be aware of other U.S. or WHO sponsored research so as to avoid duplication of effort or to take advantage of biomedically related programs already established.

### Off-site Facilities

Regarding off-site facilities, the grant can provide support for certain common resources. Such resources (e.g., laboratory or clinical facilities) should be utilized by two or more projects within the program when such sharing facilitates the total research effort. Since this program is covered by Public Law 86-610, existing facilities may be renovated, but new structures may not be constructed.

Proposed research programs must be acceptable to the resident (foreign) scientists and to the advisory group(s) of their particular institution. Also, it is expected that a core of scientists from the U.S. base would spend six months to two years or longer at the host institution collaborating with the resident scientists in working toward solution(s) of local health problem(s). Senior scientists with major institutional responsibilities in the U.S. would be expected to spend shorter periods of time, e.g., one or two months several times a year, working abroad with their associates as necessitated by the status of a particular project. Also, it is permissible to travel and support foreign professionals and selected technical staff for short visits to the U.S. institution to obtain additional training.

From past experience it has been observed that the most successful international programs thoroughly integrate the resident scientists into a truly collaborative research program. It is anticipated that publications resulting from such a collaborative research effort will be co-authored by the foreign scientist(s) and that the data will be made readily available to the Government of the host country.

### Guest Scientists

To increase the cross-fertilization of scientific ideas, it may be desirable to include one position in the overall personnel projection for a guest scientist from another institution in the U.S. to spend 6-12 months of a sabbatical at an off-site unit with an interest in applying his/her concepts to the research area. The individual nominated must have the joint approval of the NIAID, the U.S. based university, and the foreign institution as well.

### Administration

Support for the administrative activities of the American base is permitted, but the bulk of the funds will be expended for off-site research. Indirect costs will be based on the percentage effort expended by the grantee personnel. This administrative support must provide the necessary requirements of the off-site unit. Less than first-class travel on U.S. flag carriers must be used for international travel. Travel, salaries, and benefits, will be subject to university rules and regulations, as well as housing of off-site based American families.

Plans should be made for an orderly rotation of principal investigators which would not be disruptive to the ongoing research program. For those persons planning a prolonged residence at the off-site base, opportunities should be made for periodic return visits both to the parent or related domestic institutions and to scientific meetings, both domestic and international. Consequently, the investigator off-site should have the opportunity to maintain and enhance his knowledge, to discuss periodically his particular area of research with his colleagues, and not become isolated from the mainstream of scientific progress.

### Grant Support

The grant provides support for performing research at an off-site location where a disease(s) of local health importance is (are) endemic and/or epidemic. With increased knowledge of the field site, it is anticipated that the collaborative research unit might try new and improved approaches to the treatment, prevention, and control of diseases under study. The grant supports the conduct of biomedical research which can only be done outside of the U.S.

Approved grants will be funded for five (5) year periods. Long-term support is considered a necessary ingredient for the development of university careers in science which will fully utilize the international medical experience of the individual scientist and fully develop effective linkages between U.S. and foreign investigators. However, continued support will be based on the satisfactory performance of the grantee as judged by program progress described in annual reports and by periodic site visits.

### Grant Review

Applicants should use Form PHS 398 in conjunction with a brochure prepared by NIAID for the preparation of a program project grant. The reviews will be by the Microbiology and Infectious Diseases Advisory Committee (MIDAC), with ad hoc consultants as necessary. The review process will be completed by the National Advisory Allergy and Infectious Diseases Council.

## Part B

### International Exploratory/Developmental Research Grant

The NIAID wishes to encourage additional linkages between U.S. and foreign investigators with common research interests in infectious diseases and immunology through International Exploratory/Developmental Research Grant. Considered under this arrangement will be receipt of individual research proposals from a U.S. investigator involving collaboration with a foreign affiliate at an off-site base. Authority for establishing this international research grant program is provided by Public Law 86-610, the International Health Research Act of 1960.

Current grantees are ineligible to submit competing continuation applications for additional support for their current Exploratory/Developmental grants.

### Definition of International Exploratory/Developmental Research Grant

By definition, an International Exploratory/Developmental Research Grant is a mechanism used to encourage the development of biomedical research activities between a U.S. investigator and an off-site affiliate. The purpose of this collaboration is to identify and investigate common areas of interest in infectious diseases and the immunology of these diseases. Approved grants may be funded up to 5 years, although the length of support will depend upon the nature and complexity of the collaborative project. Part B grants are not renewable. It is not the intent of this type of grant to provide long-term support, but rather to encourage the investigator to expand his scientific efforts into a program project grant (P01) or to continue his off-site effort with support from a traditional research project grant (R01) or to seek funding from another Government agency or private foundation. Another approach is to encourage the foreign collaborator to submit a regular research grant proposal.

### Program Objective

The program objective is a collaborative effort in biomedical research in countries with geographic areas where infectious diseases are still a major health problem. It is intended that there be active collaboration between the responsible U.S. investigator and scientist(s) of the foreign host institution. Also, it is desired that the effort give particular emphasis to the development of self-direction and self-sufficiency of the off-site collaborator(s).

### Diseases of Interest

The Institute is interested in research on tropical diseases involving medical entomology, protozoology, helminthology, malacology, mycology, virology, and bacteriology. Special attention will be given to the six diseases of the WHO Special Program for Research and Training in Tropical Diseases: malaria, schistosomiasis, filariasis, trypanosomiasis, leishmaniasis and leprosy. While these diseases constitute a major world health problem, it is not the intent of the program to exclude other disease categories equally important to a particular geographic location. The Institute has a broad interest in the epidemiology, etiology, diagnosis, treatment, control, and prevention of all infectious diseases.

### Program Description

Success of the grant application will depend upon project design and the commitment of the investigator(s) to work at the foreign site. The NIAID will favor research projects which will fully utilize the talents of a foreign scientist in developing an active and productive collaborative effort. If certain expertise is lacking in the host country, the U.S. scientist and his associate(s) will be expected to initiate steps to transfer these skills to their collaborator(s) so that in the future the research effort may be intensified. For example, the U.S. investigator may spend two or three months abroad several times a year participating in laboratory and/or field studies. During the early months of project development, research associates and technicians from his laboratory may work off-site to train local staff to perform appropriate technical procedures, or the foreign professional and selected local staff may spend short periods of time in the U.S. investigator's laboratory. Projects submitted primarily for collecting specimens to be used at a later date in a U.S. laboratory will not be considered. The research effort should reflect a workable and effective partnership between the U.S. and foreign investigators in attacking the host countries' disease problem(s). This will generally require the imaginative use of available resources abroad, and the thoughtful selection of those procedures which can only (at present) be done in the U.S. Accordingly, a component of the proposal should outline how the investigator intends to adapt initially to local circumstance and to improve, subsequently, the technical capacity and proficiency of the host laboratory.

### Site of Research

The major portion of the research, 70-80%, must be conducted in a foreign country, and it must be relevant to one or more important health problems of that country. In addition, the applicant must be sponsored by a United States based institution. The awarding of a grant will be contingent upon identifying an off-site collaborator(s) and proof of acceptance by the host institution of such a joint research effort. Review will not be initiated unless this documentation accompanies the grant proposal.

In addition, it will be necessary to establish a working agreement with the Government of the foreign host country to permit the U.S. investigator and his foreign counterpart to enter or to leave the country as required. Such an agreement must be a part of the application at the time of submission. An agreement may be developed directly between the U.S. sponsor and representatives of the foreign Government, or it may be more convenient for the U.S. side to arrange such an agreement through organizations such as the Pan American Health Organization or another WHO regional office. The investigator should be aware of other U.S. or WHO sponsored research so as to avoid duplication of effort or to take advantage of biomedically related programs already established.

#### Administration

The grantee institution may request support for administering the grant. Although the bulk of the funds will be expended at the foreign site, there may be instances when it will be necessary to do a limited portion of the research in the U.S. Indirect costs will be provided the grantee institution concomitant with the percentage effort expended in the United States. Less than first-class on the U.S. flag carriers must be used for international travel. Travel, salaries, fringe benefits and off-site housing will be subject to grantee rules and regulations.

#### Grant Review

Applicants should use the form PHS 398, in the preparation and submission of an international exploratory/developmental research grant. The initial review will be by the MIDAC in February-March, 1983. A second level review will be conducted by the National Advisory Allergy and Infectious Diseases Council in May, 1983. Depending on the availability of funds, the earliest award date could be July 1, 1983, but it is anticipated that most of the awards will be made December 1, 1983.

#### GRANT SUBMISSION

In response to this RFA, prospective applicants for one or both of the International Programs are requested to submit a letter(s) of intent for program information on or before April 1, 1982. Compliance with this request is not a prerequisite for submitting a grant proposal.

The regular grant application format, PHS 398, will be used to apply for both Part A and Part B. Application kits are available at most institutional business offices, or from the Division of Research Grants, NIH. However, in preparing Part A, it will be necessary to follow instructions as described in an NIAID brochure. This brochure may be obtained by writing or calling:

Dr. Earl S. Beck  
Special Assistant to the Director  
Microbiology and Infectious Diseases Program  
National Institute of Allergy and Infectious Diseases  
Westwood Building, Room 749  
Bethesda, Maryland 20205

Requests for additional information relating to this RFA may be obtained by writing to the above or by telephoning (301) 496-7065.

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The submission date for receipt of proposals is October 15, 1982. Therefore, letters of intent and receipt of applications will be due as indicated below:

Letter of Intent

April 1, 1982

Receipt of Applications

October 15, 1982

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

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

For purposes of identification and processing the words INTERNATIONAL COLLABORATION IN INFECTIOUS DISEASES RESEARCH should be typed in item 2 on the fact page of the application. A copy of the application should also be sent to Dr. Beck.

The intent is to fund projects from both Parts A and B with total cost amounting up to \$2.7 million for the first year. The number of grants awarded in either category will depend upon the quality of the approved grant proposals.

**REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA NIH-NIAID-82-2****EPIDEMIOLOGY AND NATURAL HISTORY OF GENITAL HERPES****NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Application Receipt Date: February 15, 1982

**I. BACKGROUND**

The Microbiology and Infectious Diseases Program of the NIAID encourages research on genital herpes and on the viruses that cause it in efforts to develop more effective approaches to its control, prevention or treatment. To promote research in areas where information is needed, the MIDP solicits applications for program projects on prospective studies of the epidemiology and natural history of herpes genitalis, particularly transmission, in humans or appropriate animal models.

Genital herpes is now recognized as a public health problem as well as a serious clinical problem. However, the true magnitude of the public health problem and its growth rate are unknown. Estimates of six to 20 million clinically apparent episodes of genital herpes in the U.S. each year and up to 500,000 newly presented cases each year are based on extrapolations and assumptions from unreliable data.

NIAID is concerned about the lack of reliable epidemiologic information, about incidence rate of genital herpes infections in the U.S. population, about the rates of active genital disease among various subsets of the population, and about the parameters of transmission. This information base is essential for the ultimate evaluation of any approaches to control of genital disease when they become available.

The predominant agent of genital herpes is herpes simplex virus type 2 (HSV-2), although the type 1 virus (HSV-1) that is usually associated with oral and ocular lesions can also cause genital disease. The course of the infection in animals or humans matches the complexity of the viruses themselves. After entering a break in the integument or mucous membrane, HSV-2 infects local cells, multiplies, causes cell destruction and disseminates. The virus may invade nerves and be maintained in a latent state in ganglionic cells until conditions favor its reactivation. Recurrent episodes of disease are associated with reactivation of latent infections or with reinfection by re-exposure with another virus. The mechanisms of reactivation are not understood and little is known about reinfection other than it can occur. There is evidence to suggest that expression of recurrent disease is influenced by the immune response.

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 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

anatomic sites whereas recurrent episodes are usually less severe and limited to areas of the genitalia. The effects of gender on severity and frequency rates in recurrent episodes of the disease is not well studied, but there are some data that suggest that recurrent episodes occur more frequently in men than women.

Transmission of the virus is usually associated with venereal contact, but little is known about efficacy of transmission or transmission rates from individuals with primary and reactivated manifestations of disease to cohorts. Transmission from mothers to neonates can occur during delivery and postnatally, and, there is some evidence to suggest that transmission to the neonate can occur even in the presence of neutralizing antibodies acquired transplacentally. In neonates the disease is often severe but inapparent infections probably also occur. Recently HSV-2 has been proven to be pathogenic to the eyes of human neonates, and its role in neonatal ocular infections appears to be of increasing importance.

Not all individuals who are exposed to HSV-2 develop genital disease. There is a paucity of information about the biological markers of resistance or susceptibility to infection and about those markers associated with susceptibility to clinical disease. The questions of who is susceptible and who is immune have not been answered satisfactorily.

Clinical studies have shown that the majority of individuals who develop clinically recognized genital herpes will be afflicted with recurrent episodes of the disease. Some evidence indicates that those who experience the more severe forms of the disease during the initial episode may be at greater risk of having recurrent episodes. Similarly, there appears to be a positive correlation between the magnitude of the antibody response following the initial episode and the likelihood of experiencing recurrent disease later on. The pathogenic mechanisms underlying this association remain to be elucidated.

Predisposing factors, such as menstruation, have been associated with recurrent genital disease, but data and conclusions drawn from different studies have not been consistent. Although components of the immune system may be factors in maintaining the latent state of the virus in nervous tissue, the actual mechanisms of latency of HSV-2 and of its reactivation of the infection are totally unknown. The molecular state of the virus itself during latency is unknown.

Many of the questions raised about the natural history of the human disease can only be answered by well designed epidemiologic and clinical studies. Questions regarding latency and mechanisms of reactivation may be more approachable with model systems. Naturally recurring episodes of genital lesions caused by HSV-2 have been reported in guinea pigs and more detailed study of this model may be warranted. A nonprimate animal model of naturally recurring genital herpes lesions would also be desirable for study, but no simian model has been described.

## II. RESEARCH GOALS AND SCOPE

The MIDP encourages multidisciplinary approaches to problems of genital herpes through the mechanism of the program project grant. Approaches should include clinical studies and have promise of providing significant new information about the epidemiology and natural history of human genital herpes within the U.S. population. Special emphasis should be given to studies of transmission of the disease. Studies should be prospective and longitudinal correlating clinical events with virologic and immunologic responses employing methodologies as sophisticated



as the current state of the art. The longitudinal investigations should be performed in both sexual partners, as information concerning genital HSV infection in the male is lacking relative to the female. Not only must the overt infection be studied but the silent infection as well, most particularly with regard to their roles in both vertical and horizontal transmission. To round out the program, collaborative studies between clinical and basic researchers are encouraged. Studies with appropriate model systems as subprojects are of interest if expected results of such research have substantial relevance to human genital disease.

### III. MECHANISM OF SUPPORT

The MIDP intends to support multidisciplinary research programs through the mechanism of the program project grant. Applicants are expected to organize their proposals so that subprojects may be executed semi-independently but coordinated with a clinical and/or epidemiologic core project. It is expected that experienced investigators will form the nucleus of the program but opportunities for new talent and ideas may also be provided and are encouraged.

The Institute anticipates awarding just one program project grant, contingent upon available funds. This announcement is a one-time invitation and does not obligate NIAID to make an award.

### IV. REVIEW PROCEDURES AND CRITERIA

#### A. Application Review

The deadline for receipt of applications will be February 15, 1982. They will undergo initial review by an Institute Advisory Committee and subsequently will be reviewed by the National Advisory Council for NIAID in September 1982. If an application is recommended for funding, the starting date will be immediately following the September council meeting.

#### B. Review Criteria

Applications responsive to this RFA must:

1. Demonstrate high scientific merit for: problems addressed, rationale of approaches, experimental design and methodology;
2. Hold substantial promise of providing new information about important clinical, epidemiologic, immunologic, and/or virologic problems associated with human genital herpes;
3. Have access to adequate facilities, resources and patients; and
4. Have staff with sufficient qualifications and experience in biomedical research.

## METHOD OF APPLYING

An information brochure entitled: "The Program Project Grant, National Institute of Allergy and Infectious Diseases" should be requested by prospective applicants prior to preparation of an application. This brochure may be obtained from:

Dr. William P. Allen  
Bacteriology and Virology Branch  
Westwood Building, Room, 736  
National Institutes of Health  
Bethesda, Maryland 20205

The standard research grant application form PHS 398 (Rev. 10/79) should be used. If copies are not available at the applicant institutional business office, they may be obtained from:

Office of Grants Inquiries  
Division of Research Grants  
National Institutes of Health  
Bethesda, Maryland 20205

For the purpose of identification, the RFA number, NIH-NIAID-82-2 and the words GENITAL HERPES should be typed in item 2 on the face page of the application. A brief letter specifying that the application is in response to this RFA should be submitted with the application. The application should be forwarded to:

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

The deadline for receipt of applications is February 15, 1982. Applications received after this date will not be considered for review unless prior approval for waiver of this deadline is received from appropriate NIAID staff.

## VI. INQUIRIES AND CORRESPONDENCE

It is recommended that NIAID staff be contacted, either by letter of intent or by phone, when development of a program project proposal is being considered. Inquiries should be directed to:

William P. Allen, Ph.D.  
Virology Program Officer  
BVB, MIDP, NIAID  
Westwood Building, Room 736  
National Institutes of Health  
Bethesda, Maryland 20205  
Telephone: (301) 496-7453

Please forward a copy (not the original) of the cover letter and face page of the application to the NIAID program officer shown above.

**REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA****NIH-NIAID-82-3****PROGRAM PROJECTS IN LYMPHOCYTE BIOLOGY****NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Application receipt date: February 15, 1982

**BACKGROUND INFORMATION**

The Immunobiology and Immunochemistry Branch of the Immunology, Allergic and Immunologic Diseases Program of the NIAID supports fundamental studies on the structure and function of the immune system to gain an understanding of immune response mechanisms at their basic cellular and molecular levels as they function in health and disease. Program Projects in Lymphocyte Biology represent an award mechanism which the Branch has employed to meet this objective. Each program project utilizes an integrated multidisciplinary approach for basic biologic studies of immunologically-functional lymphocyte populations. Five such program projects are now supported although support for two is scheduled to conclude in 1983. This request for applications (RFA) is intended to encourage the development of proposals from collaborating investigators and to coordinate the submission and review of new and competing renewal program project applications, providing an equitable opportunity for both to compete for funds currently available to the Program in this area of research.

**RESEARCH GOALS AND SCOPE**

The ultimate goal of these program projects is the attainment of a complete knowledge of the life history of immunocompetent cells and of the genetic and phenotypic factors that determine their fate and function in vivo and in vitro. The ultimate practical application would be the use of selected cloned lymphocytic cells and their products for the clinical care or reconstitution of immunodeficient individuals, to alleviate allergic states, to provide resistance to life-threatening infections and to correct aberrant or defective immunoregulatory mechanisms.

The scope of these program projects includes studies of every facet of the immune response, ranging from the initial step of antigen recognition to the final elaboration of immunologically distinctive products of specific lymphocytes. Research currently supported by this mechanism was designed to greatly expand knowledge of the morphologic and functional heterogeneity of lymphocyte populations and to develop the capability for identification and selection of lymphocyte subpopulations with specific immune reactivity or antigenic composition, for hybridization of such populations and for selective production of specific, biologically-active, lymphocyte products.

This program is described in the Catalog of Federal Domestic Assistance number 13.855, Immunology, Allergic and Immunologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

Proposals submitted in response to this RFA should consist of a number of integrated component projects utilizing multifaceted experimental approaches and the technical expertise of cell biologists, cellular immunologists, immunochemists, microbiologists, and geneticists. However, the proposal should clearly explain how the planned multidisciplinary approach can be expected to accomplish the stated goal more efficiently and effectively than a series of independent individual grant-supported studies.

Proposals should emphasize new ideas and new initiatives and should be concerned with the acquisition of new knowledge relevant to the immune system and its structure and function. Although proposals are expected to be based primarily on experimental laboratory investigations, the value and place of clinical studies are recognized. Inclusion of patient oriented studies or laboratory procedures utilizing human source materials is acceptable, provided such studies have an immunologic base or draw upon immunologically relevant technology.

Designation of an individual to serve as the program project director should be based upon accomplishment, experience as a senior scientist, and ability to assume both leadership of the investigative group and responsibility for scientific, professional, and administrative functions, and commitment of a significant amount of time to the project. Each component project in the proposal should have a designated principal investigator, also with a demonstrable record of accomplishment in one of the basic science disciplines or clinical specialties relevant to the particular subject of investigation.

#### MECHANISM OF SUPPORT

Program project grants are awarded to an institution in behalf of a program director for the support of a broadly based, multidisciplinary, long-term research program which has a specific major objective or basic theme. A program project generally involves the organized efforts of groups of investigators, members of which conduct research projects related to the overall program objective. The grant can provide support for the projects and for certain core resources shared by individuals in a program where the sharing facilitates the total research effort. Each component project supported under a program project grant is expected to contribute to and be directly related to a common theme; the projects should demonstrate an essential element of unity and interdependence. This program does not provide support for nonresearch components, such as a clinical referral service or a clinical laboratory service function.

Grant funds may be utilized to support the research activities of scientific and professional personnel, administration, consultation service, central support services, equipment, supplies, travel, and publications costs. Support for research-related costs of patient involvement and medical care may be authorized. Since the Program cannot provide funds for new construction, adequate physical facilities must be available for the primary needs of the project. However, moderate alterations or renovations to enhance clinical or laboratory facilities may be allowed if they are necessary to meet objectives of the proposal.

Support of a program project in Lymphocyte Biology will be limited to a maximum of five years. If a competing renewal application is planned, it should be submitted only in response to an RFA. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years.

## REVIEW PROCEDURES AND CRITERIA

The receipt date for applications will be February 15, 1982. They will undergo initial review in June by the Transplantation Biology and Immunology Subcommittee and subsequent review by the National Advisory Allergy and Infectious Disease Council in September 1982. It is planned that awards will be made during fiscal year 1983 to support at least two program project grants depending on the availability of funds. January 1, 1983 will be the earliest starting date for successful applicants.

Prospective program directors are strongly advised to submit a "letter of intent" for preliminary screening by NIAID staff. Letters of intent should cover the following points:

1. A brief description of the intended project.
2. A description of available laboratory and clinical facilities.
3. Ongoing relevant research studies, identifying existing projects and sources of support.
4. Past research by members of the proposed investigative group relevant to the proposal.
5. The academic positions and major research interests of the program director and his professional staff who will be involved in the proposed studies.
6. Collaborative arrangements with other area laboratories and investigators and delineation of the roles and manner of anticipated participation and interaction of the principal investigators, consultants, and collaborators.

Letters of intent are due no later than December 15, 1981, and upon receipt will be screened by NIAID staff to determine the eligibility and suitability of the project proposals for this announcement.

Inquiries should be directed to:

Bernard W. Janicki, Ph.D.  
Chief, Immunobiology and Immunochemistry  
Branch, IAIDP  
National Institute of Allergy and Infectious  
Diseases  
Westwood Building, Room 757  
National Institutes of Health  
Bethesda, Maryland 20205  
Telephone: (301) 496-7551

## CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR OF LATE SUBMISSION

Based on the letter of intent, potential applicants will be promptly advised whether or not their proposal is found to be within the research goals and scope of the program as defined in this RFA. Applicants will then have an opportunity to correct deficiencies or

weaknesses and to restructure their submissions accordingly. Formal applications that are not responsive to the RFA or are not received by February 15, 1982, will not be accepted for review and will be returned to the applicant.

#### **METHOD OF APPLYING**

Before preparing an application, the prospective applicant should request from NIAID staff a copy of the NIAID Information Brochure on Program Projects which contains details on the requirements for multidisciplinary grant applications.

Use the standard research grant application Form PHS 398 (Rev. 5/80). In addition to following accompanying format instructions for the development of the application, include expanded material listed above for the letter of intent. For purposes of identification and processing, the words PROGRAM PROJECT IN LYMPHOCYTE BIOLOGY should be typed in item 2 on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement.

Application kits may be obtained from the institution's application control office. If not available there, they may be obtained from:

Office of Grants Inquires  
Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 448  
Bethesda, Maryland 20205

Forward the original application and six (6) copies to:

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

In order to alert NIAID to the submission of the proposal, please forward a copy (not the original) of the cover letter and the application face page to the Chief, Program and Project Review Branch, NIAID, Westwood Building, Room 703, National Institutes of Health, Bethesda, Maryland 20205.

## ANNOUNCEMENT

NONHUMAN PRIMATES AVAILABLE

## DIVISION OF RESEARCH RESOURCES

The National Institutes of Health has established supply sources of nonhuman primates for the National Institutes of Health (NIH) and Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) supported projects. Production colonies of Rhesus (Macaca mulatta) and Cynomolgus (Macaca fascicularis) monkeys have been established. Priority is given to investigators with NIH or ADAMHA supported projects.

Investigators in nonprofit institutions who wish to obtain primates for use in biomedical and behavioral projects are invited to submit requests. The requests should be in letter form and indicate the source of support, and if NIH or ADAMHA, include the title, number and principal investigator of the grant or contract. The request should also include the specifications for the animals required, including number, age, sex or other special characteristics. The entire request need not exceed one typewritten page. All inquiries should be addressed to:

Dr. Carl E. Miller  
Building 31, Room 5B59  
Division of Research Resources  
National Institutes of Health  
Bethesda, Maryland 20205  
(301) 496-5175

The price indicated for each animal includes shipping costs. The funds will be paid directly to the contractor supplying the animals to partially offset the cost of the NIH-supported breeding program.

Animals currently available are as follows:

1. Normal colony produced Rhesus monkeys - Macaca mulatta

73	male	2-4 kg	\$ 750
16	male	4-10 kg	850-950
5	male	12-18 lbs	950
1	male	20 lbs	950
1	male	24 lbs	950
17	males	born 1967-77	950
3	Old obese		
	males	12,14,20 kg	500
	Reproductive culls as available		850
100	Adult female breeders		1170
16	Female cull breeders as available		850

Prices include delivery in Continental United States.

2. Normal colony produced Cynomologus monkeys - Macaca fascicularis

21	males	born 1980	\$ 350
52	males	born 1979	350
11	males	born 1978	400
1	male	born 1977	400

Prices include delivery in Continental United States.



**CENTER FOR POPULATION RESEARCH****REPRODUCTIVE SCIENCES PROGRAM****REPRODUCTIVE DISORDERS IN WOMEN****NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT**

Application Receipt Dates: March 1, July, and November 1

**I. BACKGROUND INFORMATION**

The Reproductive Sciences Branch (RSB) of the Center for Population Research at the National Institute of Child Health and Human Development (CPR/NICHHD) is encouraging research grant applications for investigations of reproductive disorders in women. This is the first announcement in this research area. A Program Announcement is used when CPR wishes to stimulate investigator interest in a particular research area that is important to its mission. Applications submitted in response to this announcement will be supported through the customary NIH research project grant mechanism.

The RSB supports research on all biomedical aspects of reproduction in humans and relevant experimental animals including the causes and treatment of human reproductive disorders. This announcement is designed to stimulate research on disorders affecting the genito-urinary, gonadal and reproductive endocrine systems of women other than conditions directly related to reproduction itself, malignancies, and venereal diseases. Examples of areas which might be considered by interested investigators are described below. These areas are not listed in any priority order and are only intended to indicate examples of studies which can be considered responsive to this announcement. It should be emphasized that this statement of interest is neither a Request for Applications (RFA-grants) nor a Request for Proposals (RFP-contracts), but rather represents an announcement of the CPR's intent to stimulate investigator-initiated research in a particular area of its Reproductive Sciences Program.

**II. RESEARCH GOALS AND SCOPE**

Recent survey data indicate that the frequency of physician visits for reproductive system disorders and diseases is greater than that for either cancer, heart disease or hypertension. Such frequencies may actually be understated due to limitations in the detection, understanding and treatment of those conditions. The research areas for which applications are sought are:

The antecedents, course and consequences of diseases and disorders

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This program is described in the Catalog of Federal Assistance number 13.864, Population Research. Awards will be made under the authority of the Public Health Service Act, Title II, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Par 52 and 45 CFR Part 75. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

affecting the tissues and organs of the female reproductive system, including the ovaries, fallopian tubes, uterus, cervix, and vagina. Such studies may investigate anatomical, physiological and/or psychological factors affecting female reproductive health and involve a variety of gynecological conditions such as dysmenorrhea, menstrual disorders (other than menopausal), endometriosis, polycystic ovarian disease, and non-venereal infections. Malignancies, venereal diseases, and conditions directly related to reproduction itself, such as pregnancy, would not be considered responsive to this announcement.

Applications which include investigations of new or improved methods for the diagnosis or therapy of reproductive disorders in women would also be considered responsive to this announcement. Areas of high interest would concern, but not be limited to, morphological, biochemical or immunological methods which would establish criteria for normal and abnormal values of diagnostic potential in assessing ovarian, fallopian or uterine function and/or studies on the development of new or improved methods for detecting subclinical states of reproductive disorders which may develop new approaches to the therapy of menstrual disorders.

### III. MECHANISM OF SUPPORT

Applications in response to this announcement will compete for funding in accord with the traditional research project grant mechanism of NIH and extant policies guiding the research grant program of the NICHD.

### IV. REVIEW PROCEDURES AND CRITERIA

#### A. Assignment of Applications

Applications will be received by the Division of Research Grants, NIH; referred to an appropriate study section for technical merit review; and assigned to an Institute for possible funding. Assignments will be made by DRG in accord with the NIH Handbook of Referral.

#### B. Review Procedures

Technical merit review of applications received in response to this Program Announcement will be conducted on a nationwide competitive basis in accord with established NIH peer review procedures. Proposals will be initially evaluated for scientific and technical merit by a DRG, NIH initial review group (IRG) composed of mostly non-federal scientific consultants. Following the IRG review, applications will be further reviewed for program relevance by the National Advisory Child Health and Human Development Council at its regularly scheduled meetings. The customary NIH review criteria for regular research grant applications will prevail.

### V. METHOD OF APPLYING

Applications should be submitted on form PHS 398 (revised 5/80), the application form for the traditional research grant. This form is available in most institutional business offices or from the Division of Research Grants, NIH. The conventional presentation for research grant applications should be used.

Applications should be identified by checking the "yes" box in Item Number 2 on the face page of the application and typing the words "IN RESPONSE TO PROGRAM ANNOUNCEMENT: REPRODUCTIVE DISORDERS IN WOMEN."

The original and six copies of the application must be received at DRG on the usual receipt dates specified by NIH. Receipt date deadlines for new proposals are July 1, November 1, and March 1. Applications should be sent or delivered to:

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

## VI. INQUIRIES

Inquiries may be directed to:

Dr. Michael E. McClure  
Reproductive Sciences Branch  
Center for Population Research  
National Institute of Child Health  
and Human Development  
Landow Building, Room 7C33  
National Institutes of Health  
Bethesda, Maryland 20205

Telephone: (301) 496-6515

## ANNOUNCEMENT

### SMALL GRANT AWARD FOR PILOT PROJECTS

#### NATIONAL INSTITUTE ON AGING

First application receipt date: February 1, 1982

The National Institute on Aging (NIA) is initiating a Small Grant Award for selected categories of research (noted below) beginning with the February 1, 1982 application receipt date. This announcement solicits applications for Small Grants pilot projects. The National Eye Institute (NEI) announced a similar small grant award for all NEI program areas in the July 31, 1981 issue of the Guide.

#### Research Scope

Categories of research are limited to the areas outlined:

##### Biomedical and Clinical Research:

- I. Nutrition and health of the aged adult. The areas of special interest are:
  - a. age-related changes which affect nutrient requirements or nutrient status, including change in nutrient ingestion, absorption and utilization;
  - b. nutrition-disease interaction in the elderly; and,
  - c. effect of long-term drug use on nutritional status.
- II. Pharmacology and Aging:
  - a. clinical and basic studies aimed at understanding the pharmacodynamics and pharmacokinetics of drugs on the central and peripheral nervous systems and the cardiovascular system;
  - b. clinical investigations of drug - drug interactions are also encouraged.
- III. Senile Dementia of the Alzheimer Type:
  - a. studies to elucidate the etiology or pathogenesis of Alzheimer's Disease, improved diagnosis and effective therapeutic interventions are of particular interest to NIA.

Awards will be made under the authority of the Public Health Service Act, Section 301 (P.L. 78-410, as amended; 41 USC 241) and administered under HHS grant policies and Federal Regulations 41 CFR Part 52 and 42 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review. The Catalog of Federal Domestic Assistance number is 13.866, Aging Research.

## APPLICATION AND REVIEW PROCEDURES

Applications should be submitted on Form PHS 398, available at most institutional business offices or from the Division of Research Grants, NIH. Specific supplementary instructions required for use by applicants to the NIA Small Grant Program MUST be obtained from the NIA Staff Contacts Listed below. An accelerated review will be scheduled as follows:

<u>Receipt Date</u> <u>Annually</u>	<u>Institute Committee</u> <u>Review</u>	<u>Council</u> <u>Review</u>	<u>Earliest Date</u> <u>for Funding</u>
October 1	Nov./Dec.	Jan./Feb.	February
February 1	March	May/June	June
June 1	July	Sept./Oct.	October

(First receipt date, for NIA, is February 1, 1982)

Approved applications will either be funded or withdrawn immediately after review by the National Advisory Council on Aging (NACA).

## REVIEW CRITERIA

Applications will be evaluated with respect to the following criteria: the significance and scientific merit of the proposed project, and its characterization as an innovative and/or pilot project which provides a basis for more extended research; the methodology; the investigator's background and training for carrying out the project; adequacy of the available and requested facilities, and the adequacy of justifications presented for budget requests.

## STAFF CONTACT

For further information and instructions, prospective applicants are urged to contact:

Associate Director  
Biomedical Research and Clinical Medicine  
National Institute on Aging  
Building 31, Room 5C11  
National Institutes of Health  
Bethesda, Maryland 20205  
(301) 496-5996

Associate Director  
Social and Behavioral Research  
National Institute on Aging  
Building 31, Room 5C05  
National Institutes of Health  
Bethesda, Maryland 20205  
(301) 496-3136

Behavioral Sciences Research:

- IV. Health and effective functioning in the middle and later years.
- a. linkages between particular psychosocial variables and the development of disease and disability;
  - b. psychosocial factors in restoration of functioning or reversal of common forms of disability in old age (e.g., in chronic ill health, cognitive and motor performance);
  - c. psychosocial interventions in maintenance of functioning and productivity at work or in the household.

PURPOSE OF AWARD

This is a one-year, non-renewable award intended to provide support for pilot projects, testing of new techniques, or feasibility studies of innovative and high-risk research which would provide a basis for more extended research.

ELIGIBLE APPLICANTS

This program is intended primarily for:

1. Clinicians with limited research experience.
2. Recently trained or less experienced investigators.
3. Investigators whose research career was interrupted and is intended to be resumed.
4. Investigators changing field of research.
5. Investigators at institutions with substantial enrollments of minority students, or located in a largely non-research environment.
6. Established investigators needing prompt support for a pilot project to maintain research momentum and productivity.

The award may not be used to supplement support for an ongoing project nor to provide interim support for projects under review by the Public Health Service.

TERMS OF THE AWARD

The award will provide a maximum of \$15,000 (direct costs) for technical assistance, supplies, small equipment, and travel required by the project.

For information regarding review of applications, contact:

Associate Director  
Office of Planning and Extramural Affairs  
Attention: Scientific Review Office  
National Institute on Aging  
Building 31, Room 5C12  
National Institutes of Health  
Bethesda, Maryland 20205  
(301) 496-9666

## ANNOUNCEMENT

### SMALL GRANT PROGRAM

#### NATIONAL INSTITUTE OF DENTAL RESEARCH

First application receipt date: February 1, 1982

#### PURPOSE

The new National Institute of Dental Research (NIDR) Small Grants Program is intended to provide limited support for meritorious dental research projects in all program areas which include, but are not limited to, the following purposes:

- To conduct research which determines the feasibility of a research project. This may be described as the conduct of pilot studies or venture research.
- To develop and test new techniques and procedures for solving a particular research problem.
- To carry out a small clinical research project.
- To analyze existing data.

#### ELIGIBILITY

Investigators from any scientific discipline and at any stage of their career may apply for a Small Grant. These awards are appropriate for new investigators, those changing areas of research or resuming research careers. Participation in this program by minority and women investigators and those located at institutions not traditionally associated with oral health research is encouraged.

#### TERMS AND CONDITIONS OF THE AWARD

The proposed project may be related to, but the aims must be distinctly different from those of, pending grant applications or funded research projects. The request may not be used to supplement projects currently supported by Federal or non-Federal funds or to provide interim support for projects under review by the Public Health Service.

- Applicants may request up to \$15,000 (direct costs) over a period not to exceed two years. This grant is not renewable; however, grantees under this program are encouraged to apply for regular Research Project Grant to maintain continuity in their studies.

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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. Research programs of the NIDR are described in the Catalog of Federal Domestic Assistance, Numbers 13.840, 13.841, 13.842, 13.843, 13.844, 13.845, and 13.878.



## APPLICATION PROCEDURE

Applications are to be submitted for February 1, June 1 and October 1 deadlines on form PHS 398. Forms are available at most institutional business offices or from the Office of Grants Inquiries, DRG, NIH, Bethesda, Md. 20205. Specific supplementary instructions required for use by applicants to the NIDR Small Grant Program should be obtained from the NIDR Grants Management Office, Room 518, Westwood Building, Bethesda, Md. 20205. (301) 496-7437.

## ALLOWABLE EXPENSES

Support may be requested for the following categories:

- Supplies
- Travel to attend a domestic meeting or to visit another laboratory for the purpose of gathering more information or to learn a new technique or procedure relevant to the application.
- Small items of equipment. The purchase of large pieces of equipment will be discouraged.
- Salary for technical personnel. Salary of the principal investigator will be allowed only with strong justification.

## REVIEW AND AWARD

A special NIDR review committee will determine the overall quality and scientific merit of each Small Grant application. Applications will be evaluated with respect to the following criteria: the significance and scientific merit of the proposed project, its characterization as an innovative and/or pilot project which provides a basis for more extended research. Additional consideration will be given to the investigator's potential for carrying out the project, the time commitment of the investigator, the adequacy of the facilities and the adequacy of the justifications presented for budget requests.

The application will be recommended for approval and assigned a priority score or recommended for disapproval. All applications will be forwarded to the National Advisory Dental Research Council (NADRC) for final review and recommendation on an accelerated schedule as follows:

<u>Receipt Date</u> <u>Annually</u>	<u>Institute Committee</u> <u>Review</u>	<u>Council</u> <u>Review</u>	<u>Earliest Possible</u> <u>Beginning Date</u>
February 1	March	May-June	July
June 1	July	Oct.-Nov.	December
October 1	November	Jan.-Feb.	March

Awards for applications judged to have high scientific merit will be made as soon after the final review as possible.

For additional information, contact the office of:

Associate Director for Extramural Programs  
National Institute of Dental Research  
Westwood Building, Room 503  
Bethesda, Maryland 20205  
Phone: (301) 496-7723

**REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA-NIH-NIDR-NCP-82-1****CHARACTERIZATION OF BACTERIOCINS AND THEIR ROLE IN****PLAQUE FORMATION AND DENTAL CARIES****NATIONAL INSTITUTE OF DENTAL RESEARCH**

Application Receipt Date: February 15, 1982

The National Caries Program (NCP) of the National Institute of Dental Research (NIDR) is a special initiative research and development effort to devise methods to eliminate dental caries as a major health problem by preventing the disease. One of the principal strategies of this Program is to combat the responsible microbial agent or agents. This includes efforts to study microbial interactions among populations in the mouth and more specifically to examine microbial inhibitory factors or bacteriocins which may regulate the ecologic balance.

The oral cavity contains distinct microhabitats populated by different microorganisms. The existence of dental plaque is a prerequisite for induction of caries. Dental plaque forms on tooth surface by the accumulation of various bacteria and their products, together with salivary and food components. Intermicrobial antagonisms may occur, causing one species or strain of bacteria to interfere with the colonization and growth of other organisms and modify plaque formation and caries production. Factors such as hydrogen peroxide, free fatty acids and other organic acids, hydrogen sulfide, deconjugated bile salts, bacteriophages and bacteriocins have been implicated in these antagonisms among oral streptococci.

The role of bacteriocins as major factors in the successful establishment and stability of the oral microflora has been the subject of several recent studies. Because of their ubiquity, bacteriocins have the potential to influence and regulate the development of plaque. Bacteriocins may confer a protective effect by controlling the colonization of the oral cavity by deleterious microorganisms. Likewise, bacteriocin production by pathogenic bacteria may be detrimental to nearby innocuous flora. Additional studies are required to determine the physicochemical characteristics, binding properties, and the mechanism of action of bacteriocins and to define their significance in the etiology of caries.

**BACKGROUND INFORMATION**

Studies with mixed cultures of Gram-positive bacteria isolated from dental plaque have shown that one organism can interfere with the growth and metabolism of other organisms. This inhibitory activity is attributable in part to a heterogeneous class of

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This program is described in the Catalog of Federal Domestic Assistance, Caries Research, 13.840. 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 requirements of OMB circular A-95 or Health Systems Agency review.

potent antimicrobial agents called bacteriocins. Bacteriocins are high molecular weight antibiotics acting on strains of the same or closely related species of bacteria. For example, streptococci may produce bacteriocins which demonstrate antimicrobial activity against a limited range of other Gram-positive organisms, but not against Gram-negative organisms. In contrast, most conventional antibiotics are small molecules, which are active against a broad spectrum of microorganisms. In general, bacteriocins are more potent than are antibiotics; only a few molecules per cell are needed to kill sensitive strains. Their physicochemical properties indicate a protein moiety, often complexed with lipids and/or carbohydrates. This proteinaceous nature of bacteriocins further differentiates them from most antibiotics. Bacteriocins demonstrate different sensitivities to heat, organic solvents and proteolytic and lipolytic enzymes. The bacteriocins of Gram-positive bacteria differ from those of Gram-negative bacteria in both their mode of action and activity spectra. Gram-positive bacteria generally possess a broader host-range pattern. Cells sensitive to bacteriocins are rapidly killed but not lysed. Initially, the bacteriocins bind to cell surface receptors producing membrane conformational changes which result in: 1) a modification of intra-cellular macromolecular synthesis; 2) inhibition of active transport due to altered permeability; and 3) a decrease in the levels of intra-cellular ATP and energy production.

The types and quantities of bacteriocins synthesized and released by bacteria are markedly affected by nutritional conditions and may also be regulated by plasmids.

Recent data demonstrate that bacteriocins are produced in vivo and can provide a definite ecological advantage in the establishment and proliferation of a particular bacterial species in the oral cavity. Bacteriocin producing strains can invade and compete successfully with pre-existing microbial communities in addition to preventing the establishment of sensitive strains. Furthermore, purified bacteriocins added to the diet, can reduce the induction of caries in rats infected with Streptococcus mutans.

Both in vivo and in vitro studies clearly establish a role for bacteriocins in regulating the oral microflora. Bacteriocin produced by S. mutans shows inhibitory activity against several gram-positive plaque microorganisms. This phenomenon may be important in the establishment and maintenance of S. mutans in situ. The ability of non-pathogenic oral bacteria to synthesize bacteriocins active against S. mutans may also represent a significant mechanism in the control of some strains of S. mutans in the oral cavity and subsequently, of dental caries.

Individual research grant applications are invited for research on this topic. Initially, there will be a single competition with an application receipt date of February 15, 1982; this RFA may be re-issued at a later date.

#### RESEARCH GOALS AND SCOPE

The purpose of this RFA is to solicit proposals that could contribute to the understanding of bacteriocin activity in the oral cavity relative to the induction of caries and determine the ecological significance of this activity. It leaves the choice of research objectives, identification of specific aims, development of appropriate protocols and

methodologies, and the procedures for analysis and interpretation of data to the investigators' initiative. However, once an award is made under this program, any substantial modification of the research originally proposed must be mutually agreed upon by the investigator and the NCP.

Possible topics for study include:

- o Identification of bacteriocin producing and susceptible microorganisms.
- o Isolation, purification, and characterization of bacteriocins produced by oral and/or non-oral microorganisms. This would include studying the mechanism of action of bacteriocins against susceptible bacteria.
- o Isolation and purification of bacteriocin receptors; immunological and chemical characterization of these receptors.
- o Examination of the natural and artificial mechanisms by which the production and action of bacteriocins can be controlled.
- o Epidemiological studies to determine the physiological significance of bacteriocins and their relationship to caries activity.

The above topics are merely examples of the areas of research the NCP is interested in pursuing. Support will not be limited to these subjects.

#### MECHANISM OF SUPPORT

The support for this program will be the traditional grant-in-aid. It is anticipated that two or three awards will be made, if a sufficient number of high quality applications is received. Although funds have been allocated for this program in the NCP financial plans for fiscal years 1983 through 1985, award of grants resulting from this RFA is contingent upon receipt of appropriated funds for this purpose. Requests should be restricted to three years of support. Starting dates as early as December 1, 1982 may be requested. Funding beyond the first year of the grant will be contingent upon satisfactory progress during the preceding year. All policies and requirements which govern the research grant programs of the PHS, including cost sharing, will apply to grants made as a result of responses to this invitation.

#### METHOD AND CRITERIA FOR REVIEW

Applications in response to this invitation will be reviewed in competition with each other. The initial review of the applications for scientific and technical merit will be by a special study section of the Division of Research Grants (DRG); secondary review will be by the National Advisory Dental Research Council in October 1982. Applicants will be informed of the outcome of the review shortly thereafter. The earliest possible beginning date will be December 1, 1982.

Questions concerning this RFA and other grant-related activities of the NCP should be addressed to:

John D. Townsley, Ph.D.  
Chief - Telephone: (301) 496-7884

or

David L. Klein, Ph.D.  
Health Scientist Administrator  
Telephone: (301) 496-7135

Caries Research Grants and Contracts Branch  
National Caries Program  
National Institute of Dental Research  
Room 522, Westwood Building  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Applications must be responsive to the objectives of this RFA. Applications judged nonresponsive by the DRG and NIDR will be processed as regular grant applications, as will applications received after February 15, 1982. The DRG will not accept an application in response to this announcement that is the same as one concurrently being considered by any other NIH awarding unit. The factors to be considered in evaluating each application will be: (a) the importance of the research problem and the information sought; (b) the adequacy of the experimental design; (c) the feasibility and promise of the methods proposed; (d) the novelty or originality of the application; (e) the training, experience and research competence of potential of the investigator(s); (f) the suitability of the facilities, including the availability of any special resources required; and (g) the appropriateness of the requested budget relative to the work proposed.

Applications should be prepared on Form PHS 398, the application form for the traditional research grant, which can be obtained from the DRG, NIH, or from the institution's application control office. The first (face) page of the application and the outside of the mailing package should be labeled "RESPONSE TO RFA NIH-NIDR-NCP-82-1 - BACTERIOCINS AND CARIES." The conventional presentation in format and detail for regular research grant applications should be followed and the points identified under the "Review Criteria" must be fulfilled.

The receipt date, for an original and six copies of the completed application is on or before February 15, 1982. Applications should be sent to:

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

## ANNOUNCEMENT

### TEACHING NURSING HOME AWARD

#### National Institute on Aging

#### I. BACKGROUND

The NIA Teaching Nursing Home (TNH) award program will support research by academic medical centers and nursing homes on geriatric health problems in nursing homes and other clinical settings. A major goal of the program is to encourage research on health problems which are particularly prominent in nursing homes and among geriatric outpatients, rather than in acute care hospitals. Similarly, the program seeks to develop research on current and new therapies and health maintenance strategies in nursing homes and geriatric outpatient settings, as well as in the acute care hospital.

The following are examples of subjects for research to be supported by the TNH award:

- . dementia
- . sleep apnea in the elderly
- . incontinence
- . musculoskeletal disorders producing functional disability in the geriatric population
- . nosocomial infections in geriatric care settings
- . fall injuries in the elderly
- . diagnostic assessment of the geriatric patient
- . the effect of morbidity and mortality of psychological, behavioral and organizational interventions designed to increase patient independent functioning within nursing homes and other settings
- . preventive, rehabilitative, and prosthetic approaches to chronic disabling conditions of the elderly

In addition to direct support for research, the TNH award will provide support for a "center core" staff to facilitate the development of new research through administrative and technical support services. Further details on the goals of the TNH program are found in Guidelines for Prospective Applicants: NIA Teaching Nursing Home Award.

This announcement provides general information concerning the NIA Teaching Nursing Home Award. Details, including the required format and content for responses to this announcement, are contained in Guidelines for Prospective Applicants: NIA Teaching Nursing Home Award, available from NIA staff listed at the end of this announcement. Prospective applicants must obtain that publication prior to preparing an application.

## II. Award Structure

Funding will be provided by a specialized center grant (P50) award. The award will support: (a) research projects by members of participating institutions, and (b) research and administrative activities by the TNH center core staff. The maximum initial duration of the award will be five years. Awards may be extended to a maximum total duration of eight years by competing renewal applications. First-year direct costs for center core activities (category (b) above), excluding alteration and renovation expenses, may be requested up to \$300,000, with appropriate annual incremental increases in future years. Additional expenditures for approved alteration and renovation up to \$75,000, or 25 per cent of total direct costs for the project period, whichever is less, are also reimbursable. It is expected the Institute will initiate support for only a very small number of TNH centers in fiscal year 1982. However, support for any TNH awards is contingent on availability of NIA funding for the program. The TNH award will support the following range of activities:

### A. Research Projects by Members of Participating Institutions

The TNH award will support research projects developed by members of participating components (e.g., staff of teaching hospital, medical school, nursing school, and nursing home). Each of these projects should be structured for administrative and budgeting purposes as a specific project with the responsible individuals identified. Proposed activities must be approved and coordinated by the center core staff.

### B. Center Core Activities, Personnel, and Facilities

The TNH award will provide funding to the center core to:

- 1) Expand necessary inter-institutional and inter-individual liaisons to permit desired research activities.
- 2) Develop a system of "internal" review and program development of ongoing and proposed TNH activities (including the development of alternative NIA, NIH and other sources of funding) by representatives of participating components.
- 3) Conduct day-to-day administrative functions (such as patient appointments and referrals, record keeping, and financial management) connected with TNH activities. The TNH center will provide administrative support for only those activities connected with TNH research. The center will supplement, and not replace, existing nursing home administrative activities.
- 4) Develop an organized system of liaison with sources of referral, consultation, and support (independent practitioners, clinics, social services, etc., as well as the nursing home and teaching hospital) to establish an adequate population base for clinical geriatric research involving subjects in outpatient, chronic, and acute care settings, and to facilitate the referral of subjects to interested investigators.



- 5) Establish a clinical research and/or evaluation unit. This unit may be used for the evaluation of prospective nursing home admissions to one or several nursing homes in the area served by the medical center, and/or the evaluation of clinical problems of patients within the nursing home and other geriatric patients. Specific research protocols involving these populations could be conducted in this unit. The TNH program would provide financial support for only those research and clinical evaluation activities extending beyond routine indicated medical evaluation and care, and would support activities associated with analysis and management of the data arising from such a unit.

Items (1) through (5) above are considered essential center core activities, though the requirement for item (5) may be waived if the applicant can demonstrate substantial access to an existing clinical research unit for TNH projects. Other optional activities for which the NIA may provide support include:

- 6) Establishment of a data and statistics unit.
- 7) Initiation of center core research projects. In many cases, particularly in the early years of the program, it may be desirable for the center core to initiate research projects directly, including pilot projects to generate needed preliminary data for future independent projects.
- 8) Information dissemination regarding center programs and results to lay, professional, and local communities.

### III. Eligibility

In order to provide an appropriate environment to achieve the goals of the TNH program, certain attributes are considered essential. As a minimum requirement, to be considered for a TNH award, prospective applicants must document the participation of the following essential components (any one of which may serve as the grantee institution, subject to NIH policy as detailed in Appendix I of the Guidelines to Prospective Applicants) in their proposed program: 1) one or more nursing homes; 2) a school of medicine; 3) a teaching hospital, 4) a school or department of nursing. Components to be affiliated with the nursing home need not represent a single academic medical center. Other institutions whose participation in a TNH program may be desirable, though not obligatory, include:

- . School of Pharmacy
- . School of Public Health
- . School of Dentistry
- . Schools of Allied Health Professions
- . School of Social Work
- . Graduate departments in the biological, behavioral, and social sciences

In addition to the participation of the four essential components listed above, these components must satisfy certain prerequisites at the time of submission of letters of intent (see below):

- . A nursing home patient population of at least 60.
- . Inclusion of at least one certified SNF (skilled nursing facility) SNF and one certified ICF (intermediate care facility) in the project. This requirement may be met either by one nursing home with simultaneous ICF/SNF certification or by separate ICF and SNF facilities.
- . geographic proximity between the nursing home and other components of the project.
- . Evidence of significant integration of nursing home and academic staff and activities. At least one senior staff member connected with the proposed project must hold joint appointment at the medical and/or nursing school and nursing home.
- . A strong clinical capability in geriatrics within the teaching hospital and/or nursing home.
- . Substantial experience in clinical research on health problems of the geriatric population.

Though the foregoing represents the minimal institutional resource base required for application, the degree to which this resource base extends beyond this minimum will be considered in the review process. The criteria by which the institutional resource base will be evaluated are outlined in the Guidelines for Prospective Applicants: NIA Teaching Nursing Home Award.

These eligibility requirements are subject to change. Prospective applicants should consult the latest edition of the Guidelines for Prospective Applicants regarding the current status of these requirements.

IV. Application and Review Procedures

Prospective applicants are encouraged to communicate with NIA staff very early in their planning process, and should send a letter of intent to NIA staff listed at the end of this announcement before submitting a formal application. The schedule for initial funding is as follows:

<u>Review Cycle</u>	<u>Letter of Intent</u>	<u>Formal Application</u>	<u>Initial Funding</u>
I	February 1, 1982	March 1, 1982	September 1982
II	June 1, 1982	October 1, 1982	July 1983

Subsequent review cycles will be conducted on a once-a-year basis using the same schedule as cycle II.

The letter of intent should document the applicant's capability to satisfy the eligibility requirements described above, and should outline the proposed center core activities and research projects by members of participating institutions.

Details on the information and format required for the letter of intent are specified in the Guidelines for Prospective Applicants: NIA Teaching Nursing Home Award.

After receiving letters of intent, NIA program staff will study the proposed project and consult with prospective applicants regarding its responsiveness to the TNH program as outlined in this announcement and the Guidelines for Prospective Applicants. Applicants should submit a formal application only if notified that the proposed project is responsive. Applications received without a prior letter of intent will be returned to the applicant.

#### Formal application procedure

The required format and content for formal applications is detailed in the Guidelines for Prospective Applicants. An original and six copies of formal applications should be submitted according to the deadline schedule listed above to:

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

At the time of submission, three copies should also be sent to NIA staff at the address listed at the end of this announcement.

#### Review procedures and criteria

Applications for each review cycle will be evaluated through peer review by an NIA committee including consultants in geriatrics, long term care, nursing, and social, biomedical and behavioral research, as appropriate to the individual proposal. The center core and each research project will be reviewed separately as a basis for funding priority decisions concerning each component of the proposed program.

Center core administrative components will be evaluated on their ability to facilitate research through liaison and central service activities such as described in section II. Center core research projects and research projects by members of participating institutions will be reviewed on the basis of scientific merit. The suitability for TNH projects of the resource base provided by the participating institutions described in section III will also be considered. Review procedures and criteria are detailed more fully in Guidelines for Prospective Applicants.

V. Inquiries and Correspondence

Requests for information, including the Guidelines for Prospective Applicants: NIA Teaching Nursing Home Award and letters of intent, should be directed to:

Evan Hadley, M.D.  
Biomedical Research and Clinical  
Medicine Program  
National Institutes on Aging  
National Institutes of Health  
Building 31, Room 5C-21  
Bethesda, Maryland 20205  
(301) 496-1033

This program is described in the Catalog of Federal Domestic Assistance Number 13.866, Aging 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 Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

## ANNOUNCEMENT

### RESEARCH GRANT SUPPORT IN NUTRITION

### ENVIRONMENTAL AND HOST FACTORS AFFECTING NUTRITIONAL REQUIREMENTS

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND  
DIGESTIVE AND KIDNEY DISEASES

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

#### I. PROGRAM OBJECTIVES

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK)\*, in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), administers the U.S. Malnutrition Panel Program of the U.S.-Japan Cooperative Medical Science Program. The Malnutrition Panel Program is concerned with developing solutions to nutritional problems of importance to Asian people through basic, applied, and clinical research. Such research has been supported principally by grants from NIADDK and from the National Institute of Child Health and Human Development (NICHD).

#### II. RESEARCH SCOPE

The Malnutrition Panel has recommended that priority attention be given to Environmental and Host Factors Affecting Nutritional Requirements. This Program Announcement amplifies this objective but does not replace other portions of the previous Announcement in NIH Guide for Grants and Contracts, Vol. 7, No. 15, October 16, 1978, pages 35-37.

Studies are needed to quantitate the dietary requirements for the essential nutrients (singly and interaction) known to be limiting in populations living under various ecological conditions as these may be affected by age, state of human development (from fetal life to adulthood), sex, and occupation. Special interest is

\* Change of Institute name; formerly National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD).

Nutrition research programs of the NIADDK, NICHD, and NIAID are described under Federal Catalog of Domestic Assistance numbers 13.848, 13.865, and 13.856, respectively. 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.

expressed in research directed toward determining whether populations living under conditions of chronic environmental and physiological stress can physiologically adapt to lower levels of intake without undue impairment of health and performance. Dietary components of special interest include energy, protein, essential amino acids, iron, zinc, vitamin A, and vitamin B<sub>12</sub>.

Examples of research areas of interest include, but are not limited to, the following:

- (a) Effect of chronic infection, diarrheal disease, and/or parasitism (topical enteropathy) on digestion and absorption of specific nutrients or diet components;
- (b) Effect of nutritional and non-nutritional dietary components on the bioavailability (absorption and utilization) of limiting essential nutrients;
- (c) Studies designed to determine the functional significance of nutrients considered to be potentially limiting under a variety of dietary and ecological conditions. Examples of functional outcome measures include physical activity, work performance, psychological development, cognitive performance, social competence, reproduction, and lactation.
- (d) Assessment of the influence of functional performance on dietary needs. Studies are especially needed to assess the effect of physical activity and work on the dietary requirements for energy and specific nutrients.
- (e) Basic studies designed to elucidate the factors involved in the apparent physiological adaptation to low levels of nutrient intake over extended periods, and to examine the mechanisms involved and the degree to which specific functions are affected.

### III. ELIGIBILITY

Investigators working in: nonprofit organizations and institutions; universities, whether public or private; authorized Federal agencies; and research institutions in foreign countries having the expertise and experience necessary to conduct the proposed research.

The National Institutes of Health (NIH) and the U.S.-Japan Malnutrition Panel wish to stimulate collaborative research between U.S. investigators and investigators in Asia or in other countries with nutritional problems similar to those in Asian countries. Either foreign or U.S. investigators who desire to develop such programs but are unaware of individuals or institutions interested in collaboration may contact the individuals listed under VIII.

### IV. FORMAT FOR APPLICATIONS

Applications are to be submitted on Form PHS 398 which is available in the business or grants and contract office at most academic and research institutions

or from the Division of Research Grants, NIH. Research grant applications prepared in response to this announcement should be labeled across the top of the front page, "For U.S.-Japan Malnutrition Panel."

All applications are to be submitted to:

Application Receipt Office  
Division of Research Grants  
National Institutes of Health  
Bethesda, Maryland 20205

V. DEADLINE FOR APPLICATIONS

Applications will be accepted by the usual receipt dates for new proposals: March 1, July 1, November 1.

VI. ASSIGNMENT AND REVIEW OF APPLICATIONS

Applications will be received by the Division of Research Grants, NIH; referred to an appropriate study section for review; and assigned to an institute for possible funding. Assignments to institute will be made by the DRG according to the NIH Handbook of Referral.

VII. FUNDING

Funding of scientifically meritorious applications will be contingent upon the availability of funds.

VIII. FOR ADDITIONAL INFORMATION CONTACT:

Gerald F. Combs, Ph.D.  
Project Officer, U.S. Malnutrition Panel  
U.S.-Japan Cooperative Medical Science Program and  
Director, Nutrition Program  
National Institute of Arthritis, Diabetes,  
and Digestive and Kidney Diseases  
Room 606, Westwood Building  
Bethesda, Maryland 20205  
(301) 496-7823

Thorsten A. Fjellstedt, Ph.D.  
Health Sciences Administrator  
National Institute of Child Health  
and Human Development  
Room 7C17, Landow Building  
7910 Woodmont Avenue  
Bethesda, Maryland 20205  
(301) 496-5575

Robert Edelman, M.D.  
Chief, Clinical Studies Branch  
National Institute of Allergy  
and Infectious Diseases  
Room 7A49, Building 31  
Bethesda, Maryland 20205  
(301) 496-5893



## ANNOUNCEMENT

### CLINICAL OTOLARYNGOLOGIC RESEARCH CENTERS

#### NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

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

#### I. INTRODUCTION

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), through the Communicative Disorders Program (CDP), invites clinical research grant applications as part of the Institute's program to stimulate and support innovative clinically-related otolaryngologic research studies directed to improve the prevention, treatment and remediation of disorders of communication.

The Center grants will support research in areas where gaps in knowledge are inadequately addressed by ongoing research, or where efforts are needed to stimulate or intensify endeavors in promising research areas. The primary objective of the NINCDS/CDP clinical otolaryngologic clinical research centers program is to provide support for a cohesive program of research in otolaryngology and related aspects of communicative disorders.

#### II. BACKGROUND

A major goal of the NINCDS/CDP Clinical Research Center Program is to prevent and/or ameliorate communicative disorders. The degree of impairment to hearing, language and speech varies in relation to the type and cause of the impairment. Effective communication of spoken and written language forms is dependent upon normal function and interaction of all the senses. Interference with certain portions of the communication process by developmental anomalies, diseases, physical injury, surgical extirpation, degeneration or functional abnormalities may modify hearing capabilities, or production and perception of language and/or competence in speech. The individual disorders of human communication must be studied to provide a better understanding of underlying normal processes. Systematic development and evaluation of effective methods of prevention, intervention, and amelioration of otolaryngologic communicative disorders are encouraged.

The emphasis on prevention is of major interest to the NINCDS/CDP; prevention strategies may be primary, secondary or tertiary. Primary prevention involves research in the prebiologic or prepathologic phase of the natural history of the

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This program is described in the Catalog of Federal Domestic Assistance Number 13.851, Communicative 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.

disease or disorder. Secondary prevention is intervention research in the preclinical phase of the natural history of the disease or disorder. With tertiary prevention, intervention research (diagnosis/treatment/rehabilitation) phase of the natural history of the disease or disorder. The CDP recognizes that a Center's proposal may embody all three levels, or a combination of the prevention strategies.

III. SCOPE

Clinical Otolaryngologic Research Centers are designed to provide support for innovative clinically-related otolaryngologic research protocols with goals of improving the prevention, treatment and remediation of communicative disorders. A clinical population and collaborative research team are essential to meet the objectives of the announcement.

IV. ELIGIBILITY

Non-profit organizations or institutions are eligible to apply. It should be noted that NINCDS will not support more than one (1) Center in a given department or specialty unit. Applicants are urged to contact Dr. Ernest J. Moore at (301) 496-5061 prior to submission of the formal application.

V. METHOD OF APPLYING AND APPLICATION REQUIREMENTS

A. Guidelines

Detailed guidelines are in the PHS-398 (Revised 5/80) application kit. Your institution's business office or grants and contracts office has the PHS-398 kits, or single copies may be requested by writing to:

Office of Grants Inquiries  
Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 449  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Please type CLINICAL OTOLARYNGOLOGIC RESEARCH CENTERS in block letters in the upper left-hand corner of the face page of the application. Please include with the application a brief letter indicating that the application is in response to this Program Announcement. Please send a copy of the letter to:

Ernest J. Moore, Ph.D.  
Program Administrator  
Clinical Otolaryngologic Research Centers  
Communicative Disorders Program  
National Institute of Neurological  
and Communicative Disorders and Stroke  
Federal Building, Room 1C-11  
Bethesda, Maryland 20205

B. The Application

The applicant should prepare a complete application on research grant application form PHS-398 (Revised 5/80). The NINCDS recommends that the application be developed in close cooperation with the Program Administrator, Communicative Disorders Program, Clinical Otolaryngologic Research Centers, who will provide guidance in relation to administrative problems.

VI. TIMETABLE FOR RECEIPT AND REVIEW OF APPLICATIONS

A. Receipt Date

The original and six (6) copies of the application are due in the Division of Research Grants on or before February 1, June 1 or October 1. Applications must be sent to:

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

A copy of the application should be sent to the Program Administrator, Communicative Disorders Program.

B. Review Schedule

Applicants should note that there is an approximate 10-month time period from receipt of an application to activation of an award.

VII. REVIEW PROCEDURES AND CRITERIA

A. Review Procedures

Applications will be reviewed for scientific and technical merit by an NIH-NINCDS peer review group and for program relevance by the National Advisory Neurological and Communicative Disorders and Stroke Council.

B. Review Criteria

1. The relevance of the application to the goals and scope of the announcement.
2. The scientific merit of the proposed clinical research protocols.
3. The technical merit and justification of the research protocol or protocols.

4. The expertise, qualifications and commitment of the proposed personnel and their ability to devote adequate time and effort to the proposed research.
5. The appropriateness of the resources (clinical population) and the environment.
6. The appropriateness of the budget for the proposed research.

#### VIII. FUNDING

Although this program is included and provided for in the financial plans for FY 1982, all awards are contingent upon ultimate allocation of appropriated funds. The initial award will be made for a period of three (3) years.

#### IX. STAFF CONTACT

For further information, potential applicants may write or call:

Ernest J. Moore, Ph.D.  
Program Administrator  
Clinical Otolaryngologic Research Center  
Communicative Disorders Program  
National Institute of Neurological  
Communicative Disorders and Stroke  
Federal Building, Room 1C-11  
Bethesda, Maryland 20205