

NIH Guide for Grants and Contracts

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U.S. DEPARTMENT OF HEALTH
AND HUMAN SERVICES

IN THIS ISSUE:

Notice to Small Business

Small Business Innovation Research Program
Change of Receipt Date..... Page 1

Erratum

Highlights of Revised PHS Grants Policy
Statement by NIH Grantees..... Page 1
Index - PHS GRANTS POLICY STATEMENT

Notice

Receipt Date of Clinical Cancer Education
Program Grants Page 2
National Cancer Institute
Index - CANCER

Site Visits to Animal Care Facilities Page 3

National Institutes of Health
Index - ANIMALS

Notice

Period for Individual NRSA Fellowship
Activation Reduced Page 5
National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration
Health Resources and Services Administration
Index - NATIONAL SERVICE RESEARCH AWARDS

Notice

Availability of Congenic Mouse Strains..... Page 6
National Cancer Institute
Index - CANCER

(Continued)

The NIH 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.

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.

Index - Page 2

Notice of Availability - RFA

Cooperation Agreements for Orphan Drugs
and Medical Devices Research Page 7
✓ Food and Drug Administration
Index - FOOD AND DRUG ADMINISTRATION

Announcement

RFA: Exploratory Grants for Digestive
Diseases Core Centers Page 8
✓ National Institute of Arthritis, Diabetes, and
Digestive and Kidney Diseases
Index - NIADDK

Request for Research Grant Applications: RFA

NIH-NIAID-83-2
Program Projects in Mechanisms of
Immunologic Diseases..... Page 14
✓ National Institute of Allergy and
Infectious Diseases
Index - ALLERGY AND INFECTIOUS DISEASES

Announcement

State Service System Research Grants on
the Chronically Mentally Ill..... Page 19
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration
✓ National Institute of Mental Health
Index - SPECIAL RESEARCH AWARDS

Announcement

New Investigator Research Award
in Prevention Page 25
Public Health Service
✓ Alcohol, Drug Abuse, and Mental Health Administration
National Institute on Drug Abuse
National Institute of Mental Health
Index - NEW INVESTIGATOR RESEARCH AWARD

NOTICE TO SMALL BUSINESS

SMALL BUSINESS INNOVATION RESEARCH PROGRAM (SBIR)

As a result of many discussions with representatives of research oriented small businesses, the Public Health Service (PHS) has determined that potential applicants would benefit from additional time to prepare grant applications for the Small Business Innovation Research (SBIR) program. Therefore, the PHS announces that the first receipt date for SBIR applications has been changed from March 15, 1983 to May 1, 1983.

ERRATUM

HIGHLIGHTS OF REVISED PHS GRANTS POLICY STATEMENT FOR NIH GRANTEES

A Notice in the January 29, 1983, NIH Guide for Grants and Contracts (Vol. 12, No. 1) printed on page 4, had a sentence omitted from paragraph 2 under HIGHLIGHTS. The correct paragraph 2 should read as follows:

"2. Page 6 - Supplemental Applications for Administrative Increases to Meet Institution-Wide Increased Costs - The following long-standing NIH practice remains in force: Where the project is located in an organizational component that receives an NIH Biomedical Research Support Grant, no supplemental funds will be provided by NIH for administrative increases which take effect during a current budget period (such as institution-wide salary and/or fringe benefit increases). A request for funds to cover such increases may be included in the next application for non-competing continuation support."

NOTICE**NATIONAL CANCER INSTITUTE**

The National Cancer Institute will resume accepting new and competing renewal applications for the clinical cancer education program grants (R25). Next receipt date will be June 1, 1983. For copies of the new guidelines contact:

Dr. Olga G. Joly
Program Director, CCEP, DRCCA
National Cancer Institute
Blair Building - Room 722
8300 Colesville Road
Silver Spring, Maryland 20910

Telephone: (301) 427-8855

SITE VISITS TO ANIMAL CARE FACILITIES

NATIONAL INSTITUTES OF HEALTH

The National Institutes of Health (NIH) is embarking on a series of site visits to randomly selected awardee institutions to assess the adequacy of the current process for promoting proper care and use of animals in the biomedical research which NIH funds.

In particular, the visits are intended to determine whether or not the facilities, systems, and practices for the care and use of laboratory animals are consonant with the statements of assurance now on file with the NIH.

The information gathered will be valuable for addressing three overriding questions: Is the present assurance system adequate? Even if adequate, how can it be improved? If inadequate, what other approaches should be explored?

I. BACKGROUND

As a part of its overall mission to fund high-quality biomedical research and research training, the NIH has an obligation to promote the appropriate care and use of laboratory animals. Since 1971, the NIH has required awardee institutions which conduct experiments with laboratory animals to submit written statements of assurance committing themselves to follow the principles set forth in the NIH Guide for the Care and Use of Laboratory Animals as well as all federal, state and local statutes relating to laboratory animals. In addition, many institutions have sought and received accreditation by the American Association for Accreditation of Laboratory Animal Care (AAALAC).

As a matter of policy, the NIH negotiates these assurance statements carefully but has made no systematic effort to assess compliance unless concerns are raised by: (a) peer reviewers and/or staff during the normal processes of evaluating applications, proposals, and progress reports, (b) individuals or groups who submit evaluable allegations, and/or (c) authorized inspection, such as performed by the United States Department of Agriculture under the Animal Welfare Act of 1966 (as amended). In recent years, critics of NIH policies have questioned the adequacy of the assurance process both in concept and in relation to a few specific instances of actual or apparent failure by awardees to ensure appropriate practices. Because of the need to maintain public confidence in science and in the officials who administer Federal funds, the NIH has decided to examine its assurance system.

II. APPROACH

The effort is being conducted under the leadership of the Office of Extramural Research and Training (OERT). NIH staff and advisors have developed a protocol for conducting the site visits. The first group of institutions will be visited during the period March through September 1983. Visits will be made to a stratified, random sample of ten institutions which operate under approved assurances but which do not have accreditation from the AAALAC. The institutions will be selected according to the following plan: (a) one institution will be chosen from each of the ten Department of Health and Human Services geographic regions, and (b) three or four institutions will be taken from each of three categories of total annual NIH support of more than \$10 million, \$5-10 million, and less than \$5 million

Each site visit team will be composed of several members (usually 3-5), comprising NIH employees and non-federal consultants. A member of the NIH staff will notify the appropriate institutional representative(s) about one month before the scheduled visit.

Additional information concerning this notice may be obtained from:

Dr. Louis R. Sibal
Office of Extramural Research and Training
National Institutes of Health
Shannon Building - Room 314
Bethesda, Maryland 20205

Telephone: (301) 496-4716

NOTICE

PERIOD FOR INDIVIDUAL NRSA FELLOWSHIP ACTIVATION REDUCED

A recent policy decision by the Public Health Service (PHS) has reduced the maximum period of time for activation of Fellowship awards from twelve months to six months. The activation period is that period of time from the initial award of an individual NRSA fellowship, to the actual initiation of the fellowship experience. Previously, fellows have been permitted up to a maximum of twelve months following award to begin their fellowship. Effective for new fellowship awards issued in the Government's fiscal year 1983 (October 1, 1982 - September 30, 1983), the maximum activation period is six months. Extensions of the activation period may be granted for good reason. Recipients of NRSA fellowship awards are encouraged to keep the awarding units of the National Institutes of Health (NIH), Alcohol, Drug Abuse and Mental Health Administration (ADAMHA), and the Health Resources and Services Administration (HRSA) Division of Nursing, well-informed of their activation plans.

This notice revises and updates information published in the PHS Grants Policy Statement dated December 1, 1982 and NIH Guide for Grants and Contracts, Vol. 11, No. 7, June 18, 1982 Special Edition, "National Research Service Awards Guidelines for Individual Awards - Institutional Grants." Questions on this issue may be addressed to staff of the awarding unit as identified on the Notice of Fellowship Award.

NOTICEAVAILABILITY OF CONGENIC MOUSE STRAINS**NATIONAL CANCER INSTITUTE**

This announcement is being issued to inform investigators of the availability of strains of congenic mice representing discriminative alleles of genes of special interest in viral leukemogenesis.

The Biological Carcinogenesis Branch, Division of Cancer Cause and Prevention, supports a congenic mouse production facility at Sloan-Kettering Institute for Cancer Research under NCI contract N01-CP7-1003. At present there are 14 strains of congenic mice in various stages of development and 2 Gix-gp70 mutant strains. The gene substitutions involved include Akvp, Fv-1, Gv-1, Gv-2, H-2, Pca-1 and T1a. In several cases, reciprocal substitutions of alleles have been effected between inbred strains that differ categorically in one or more characteristics pertaining to leukemia or leukemia virus providing a quartet of inbred strains, two standard and two congenic with switched alleles, for each gene system.

There is a charge for the animals and the shipping costs are the responsibility of the recipient. For further information please contact:

Dr. Edward A. Boyse
Sloan-Kettering Institute for Cancer Research
1275 York Avenue
New York, New York 10021

Telephone: (212) 794-7500

NOTICE OF AVAILABILITY - RFA

COOPERATIVE AGREEMENTS FOR ORPHAN DRUGS AND

MEDICAL DEVICES RESEARCH

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration will soon announce in the Federal Register the availability of funds for Fiscal Year 1983, for the award of cooperative agreements to support clinical trials on the safety and effectiveness of orphan drugs and medical devices.

Approximately 20 to 80 awards will be made in the range of \$20,000 to \$100,000 each. Applications must be submitted on form PHS 398, Public Health Service Research Grant Application.

A Request for Application (RFA) is to be published in the Federal Register in February announcing the details.

For further information, contact:

Office of Orphan Products Development
Parklawn Building - Room 12-11
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4903

ANNOUNCEMENT

RFA: EXPLORATORY GRANTS FOR DIGESTIVE DISEASES CORE CENTERS

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

Application Receipt Date: May 16, 1983

The National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK) invites applications for Exploratory Grants for Digestive Diseases Core Centers to be initiated in Fiscal Year 1983.

The objective of the Exploratory Grant is to provide partial support for the planning phase of a Digestive Diseases Core Center. The planning phase may consist of, but is not limited to:

- a. departmental and interdepartmental planning to integrate a broad spectrum of digestive disease related activities;
- b. planning the establishment of specialized resources and facilities;
- c. feasibility surveys to identify appropriate patient populations, identify special problems and opportunities, etc.;
- d. use of consultants to solidify plans for Center activities and core resources.

The Core Center must include clinically relevant research focused on the cause, diagnosis, early detection, prevention, control and treatment of digestive diseases and related physiological, pathophysiological, congenital or metabolic disorders resulting from such diseases. This represents a change from the original program in Digestive Diseases and Nutrition Centers announced in 1973, which were Specialized Centers of Research in specified areas (obesity, peptic ulcer and hepatitis and cirrhosis).

NIADDK expects to award no more than eight Exploratory Grants for Digestive Diseases Core Centers in FY 83 on a competitive basis. Direct costs cannot exceed \$25,000 each. The anticipated awards are contingent upon the availability of appropriated funds. It is anticipated that successful applicants would be prepared to apply for a Digestive Diseases Core Center in FY 84 or FY 85. The general description of a Core Center, the format of the application for the Exploratory Grant, and the review criteria for such applications are presented on the following pages. The special receipt date for submission is May 16, 1983, with earliest funding September 26, 1983.

This program is described in the Catalog of Federal Domestic Assistance No. 13.848, Digestive Diseases and Nutrition. 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 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

I. Objective

The objective of the Exploratory Grant is to provide partial funding for the cost of planning and developing a high quality Digestive Diseases Center. Successful Exploratory Grant applications will be funded in amounts not to exceed \$25,000 direct cost for a 12-month period. Under certain circumstances a no-cost extension of up to another 12 months can be requested. The anticipated Core Center awards are contingent upon authorization and appropriation of funds.

It is important to note that the award of an Exploratory Grant does not imply a commitment by the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases to future funding of any Digestive Diseases Center planned with the support of such an Exploratory Grant. Center applications are reviewed on the basis of their own merit. A future announcement will be made for applications for Digestive Diseases Core Center grants, at which time any applicant may apply, and be funded whether or not they previously had an Exploratory Grant.

II. Background and Rationale

The Centers component of the Digestive Diseases Program of the NIADDK is being expanded at the recommendation of the National Digestive Diseases Advisory Board. The Digestive Diseases Centers will be charged to develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of Digestive Diseases and related physiological, pathophysiological, congenital or metabolic disorders resulting from such diseases.

The type of Center to be planned initially will be a Core Center. The Core Center grant is a mechanism designed to enhance and extend the effectiveness of a group of related projects and investigators that are already funded through other mechanisms such as Research Project Grants or Research Program Projects. In this respect the Core Center mechanism builds upon an established base of research excellence. The Core Center grant may provide funds for: (1) core resources such as tissue culture, immunoassay or biostatistics units which must be utilized by at least two or more Center participants, (2) pilot/feasibility projects to encourage new investigators or investigators from other fields to pursue new and innovative ideas to a point where they can compete for independent support and (3) program enrichment to provide for small conferences or symposia, special consultants and temporary salary support for a "new" investigator. This temporary salary support can be requested for one individual at a time for a period of up to 24 months in specified areas of research complementary to ongoing activities of the group. "New" refers to recently trained investigators. The Core Center does not provide funds for ongoing major research projects of established investigators. A Core Center application must include clinically relevant research in which the focus can be a disease (pancreatitis, functional bowel disease, inflammatory bowel disease, chronic hepatitis), an organ (liver, esophagus, large bowel), a process (absorption, secretion, motility), or an appropriate combination thereof which may also include areas of relevant technology.

Guidelines are available from the NIADDK that describe the Core Center and the application process. These guidelines should be requested before applying for an Exploratory Grant.

In the future, after a strong research and training base of the Core Center becomes well developed, and the Center administrative structure can support additional

functions, it is the intention of the Digestive Diseases Program to allow further expansion of Center activities. This expansion will provide an opportunity for the Core Center to convert, on a competitive basis, to a Comprehensive Center and to support new activities in the area of education and information for physicians and paramedical personnel, for patients and their families and for the general public. It may also consider model programs for cost effective and preventive patient care. The NIH will make a further announcement when such Comprehensive Centers may be submitted for review.

III. Criteria for Eligibility

Institutions that are planning to apply for a Digestive Diseases Core Center for the first time are eligible to apply for an Exploratory Grant. An institution that already has a Digestive Diseases Center and plans to submit a renewal application for the same type of center is not eligible to apply for an Exploratory Grant.

IV. Application Procedures and Guidelines

- A. For the proper development of an application for an Exploratory Grant for a Digestive Diseases Core Center, the institutional representatives should contact:

Dr. Kirt Vener
Esophageal, Gastric and
Colonic Diseases
NIADDK
Bethesda, Maryland 20205

Telephone: (301) 496-7821

Dr. G.G. Roussos
Intestinal and Pancreatic
Diseases
NIADDK
Bethesda, Maryland 20205

Telephone: (301) 496-7121

Dr. Sarah C. Kalser
Liver Biliary Diseases
NIADDK
Bethesda, Maryland 20205

Telephone: (301) 496-7858

Such contacts should be made during the early planning stages of grant application.

- B. The application should include the following:

1. Title

The title of the grant application should be "Exploratory Grant for a Digestive Diseases Core Center."

2. Format of Application

Applications must be submitted on form PHS-398 which is available at most institution business offices or from the Division of Research

Grants, NIH. The application should contain information on the following points:

- a. Goals and objectives of the planning effort.
- b. Relevance of the Core center being planned to the Digestive Diseases Program.
- c. Institutional organization to implement the goals of the planning effort.
- d. Listing of the programs (sponsored research) to be included in terms of the utilization and expansion of ongoing activities and inauguration of new projects.
- e. Interrelationship with other institutions, if any, and with the scientific and medical communities.
- f. Description of the effect that establishment of a Core Center directed towards research in digestive diseases will have on the internal structure or organization of the institution.

3. Grant Amount and Project Period

A maximum of \$25,000 direct cost for 12 months is allowable. If necessary, an extension of the initial budget period will be allowed, if adequately justified.

4. Allowable Costs

- a. Salaries for staff.
- b. Travel required to carry out the planning effort.
- c. Supplies.
- d. Other related costs.
- e. Payment of consultant and technical assistance needed for feasibility surveys, identification of special problems and opportunities for expansion of scientific staff and activities, cost estimates, evaluation of existing space, conceptual design, etc., but not for the development of detailed architectural plans and specifications.
- f. Indirect costs.
- g. ALTERATION AND RENOVATION ARE NOT ALLOWED.

V. Review Criteria

Applications for Exploratory Grants for Digestive Diseases Core Centers will be evaluated in national competition by the NIH grant peer review process. Applications will be reviewed initially by a special review committee convened by

the NIADDK, and subsequently by the National Arthritis, Diabetes, and Digestive and Kidney Diseases Advisory Council. During this process, applications will be evaluated on the basis of the following review criteria:

1. Clarity and appropriateness of the applicant's planning effort, including goals, definition and scope.
2. Applicability of the proposal to the Digestive Diseases Center Program.
3. Composition and competence of the planning Group.
4. Adequacy of applicant's consideration of the following factors:
 - a. Patient load and referral patterns.
 - b. Staff recruitment.
 - c. Needs and utilization of space, including space for recruitment of appropriate personnel.
 - d. Financial resources.
 - e. Scope of projects
5. Applicant's commitment to digestive diseases programs:
 - a. Background of the applicant organization's commitment to digestive diseases programs (program contact, personnel, facilities, financial obligations and commitments).
 - b. Current priority of the program within the organization in commitment of personnel, facilities and funds.
6. Planning director:
 - a. Background, training and experience.
 - b. Leadership, scientific and administrative capabilities, and potential for development.
 - c. Commitment to the digestive diseases program, burden of other duties, etc.
 - d. Authority in relation to recruitment, staff appointments and promotions, space, fiscal and administrative, review and direction of the planning effort.
7. Research competency and multidisciplinary interests of staff in place or to be recruited.

8. Administration, organization and management capabilities of the applicant organization (letters of agreement from associated institutions).
9. Intellectual environment of applicant organization:
 - a. Ability to recruit required talent.
 - b. Success in developing similar programs.
 - c. Continuity of leadership

VI. Reporting Requirements

As with research grants, terminal progress reports must be submitted to the NIADDK in accordance with the current PHS Grants Policy Statement. Terminal project reports are due no later than 90 days following the end of the project period. In addition, consultation with NIADDK program staff is encouraged throughout the course of the grant period.

VII. Submission of Applications

A special deadline of May 16, 1983, has been established for the receipt of applications in order that applications which are recommended for approval may be eligible for funding during the present fiscal year (FY 83). Final review will be in September with earliest funding September 26, 1983. The original and six copies of each application should be mailed to the Division of Research Grants. An address label is included in the form PHS 398 kit. One additional copy should be mailed to:

Associate Director
Extramural Activities
National Institute of Arthritis, Diabetes
and Digestive and Kidney Diseases
Bethesda, Maryland 20205

VIII. Staff Contacts

For further information, prospective applicants are encouraged to contact the staff members listed under IV.A.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA**NIH-NIAID-83-2****PROGRAM PROJECTS IN MECHANISMS OF IMMUNOLOGIC DISEASES****NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

Application Receipt Date: October 15, 1983

I. BACKGROUND INFORMATION

The Allergy and Clinical Immunology Branch of the Immunology, Allergic and Immunologic Diseases Program of NIAID is concerned with asthma, allergic, and immunologic diseases and with relevant mechanisms of hypersensitivity and inflammation. This request for applications (RFA) is intended to encourage the development of proposals from collaborative basic science and clinical investigative groups, and to coordinate the submission of new and renewal program project applications providing equitable opportunity for both to compete for funds currently available for existing programmatic activities concerned with the study of mechanisms of immunologic diseases. As such, this program is intended to complement the Branch's Asthma and Allergic Disease Center program as well as the Centers for Interdisciplinary Research in Immunologic Diseases program.

Immunologic diseases together with asthma, allergic diseases, and hypersensitivity and inflammatory disorders constitute major areas of endeavor of the Allergy and Clinical Immunology Branch. The programmatic activity on immunologic diseases is designed to further investigate underlying mechanisms of disease and to enhance basic knowledge relevant to the etiology, prevention, and management of immunologic disorders. Studies are effected from either one of two disciplinary approaches: clinical immunology or immunopathology. Clinical immunology studies are directed toward acquired and inherited diseases associated with dysfunctions of the immune system. Immunopathology studies include specific areas of genetics, cytology, biochemistry, physiology, and pharmacology of the immune system and its disorders.

The research to be supported by this announcement is concerned with and seeks to define the etiologic factors, pathogenic mechanisms, development of critical diagnostic measures and approaches to effective prevention, control, and treatment of immunologic abnormalities.

This program is described in the Catalog of Federal Domestic Assistance No. 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.

II. RESEARCH GOALS AND SCOPE

- A. Program project grants are awarded to an institution on 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 basic resources shared by individuals in a program where the sharing facilitates the total research effort. Each project supported under a program project grant is expected to contribute to and be directly related to the common theme of the program; the projects under the direction of a principal investigator should demonstrate an essential element of unity and interdependence. This program does not provide support for nonresearch components, such as a clinical referral service, programs in continuing medical education, or programs for demonstration projects and technology transfer.
- B. It is planned that awards will be made during fiscal year 1984, to support at least one program project grant depending on the availability of funds. It is anticipated that projects will be initiated September 1, 1984.
- C. Proposals should emphasize new ideas and new initiatives and should be concerned with the clinical relevance of new knowledge to the immune system and its disorders deriving from studies in related disciplines.
- D. Protocols focused on the study of immune mechanisms in disease should be designed to favor integration and coordination of intra-institutional research projects concerned with immunologic disorders and those in basic biomedical sciences. Programs should include clinical investigative components drawing upon immunologically relevant endeavors in medicine, pediatrics, surgery, pathology, and their subspecialties.
- E. While proposals should be based on clinical investigation as the major requirement, the value and place of experimental studies are recognized. Inclusion of basic research components utilizing samples of human source materials in in vitro procedures and those involving laboratory animals serving as feasible models for required in-depth studies are acceptable. Such work, however, should clearly demonstrate relevance to human diseases.
- F. Patient oriented studies and those involving in vitro laboratory procedures and the use of experimental animal models should have an immunologic base or draw upon immunologically relevant areas in the disciplines of biochemistry, pharmacology, microbiology, virology, genetics, or pathology.
- G. The proposals should consist of a number of demonstrably integrated projects utilizing multifaceted experimental approaches and investigative probes bearing upon either a well defined immunologic disease or upon immune mechanisms common to multiple human disorders.
- H. The proposal should clearly explain how the projected multidisciplinary integrated program can be expected to accomplish the stated goal more efficiently and effectively than a series of independent individual grant supported studies.

- I. Designation of a program 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 devoting a significant amount of his/her time to the project. Each project or subproject in the program should have a designated principal investigator also with a demonstrable record of accomplishment in clinical immunology, immunopathology, or one of the basic science disciplines or clinical specialties relevant to the particular subject of investigation.
- J. Thematic approaches involving combined clinical and basic immunologic approaches to the study of autoimmune disorders, congenital and acquired immunodeficiency disorders of children, Acquired Immunodeficiency Disease Syndrome (AIDS), and other related areas are encouraged.

III. MECHANISM OF SUPPORT

Support of a program project in Mechanisms of Immunologic Diseases 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 preceeding years, and availability of funds. It is recommended that budgetary requests be limited to an approximate total direct cost of \$250,000 to \$300,000 per annum.

The receipt date for applications will be October 15, 1983. They will undergo initial review in March by the Allergy and Immunology Research Committee and subsequent review by the National Advisory Allergy and Infectious Disease Council in May 1984. September 1, 1984, will be the earliest starting date for successful applicants.

Grant funds may be utilized to support the research activities of scientific and professional personnel, administration, consultation services, central support services, equipment, supplies, travel, and publication 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 proposed program.

IV. LETTER OF INTENT

Prospective applicants are encouraged to submit to the Chief, Allergy and Clinical Immunology Branch, NIAID a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. The Institute requests such letters for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding, it will not enter into the review of any application subsequently submitted, and is not a necessary requirement for application.

Inquiries should be directed to:

Robert A. Goldstein, M.D., Ph.D.
Chief, Allergy and Clinical
Immunology Branch, IAIDP
National Institute of Allergy
and Infectious Diseases
National Institutes of Health
Westwood Building - Room 755
Bethesda, Maryland 20205
Telephone: (301) 496-7104

V. REVIEW PROCEDURES AND CRITERIA

These are outlined in the NIAID Information Brochure on Program Projects (METHOD OF APPLYING below).

VI. CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR OF LATE SUBMISSION

If a letter of intent is submitted, 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 October 15, 1983, will not be accepted for review and will be returned to the applicant.

VII. METHOD OF APPLYING

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

Dr. Nirmal Das
Executive Secretary
Allergy, Immunology and Transplantation
Research Committee
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 706
Bethesda, Maryland 20205

Telephone: (301) 496-7966

The Information Brochure contains special instructions for preparing program project grant applications, review procedures and criteria, and other important information.

Use the standard research grant application form PHS 398 (Rev. 5/82). For purposes of identification and processing, the words PROGRAM PROJECT ON MECHANISMS OF IMMUNOLOGIC DISEASES 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. In addition to following the accompanying format instructions for the development of the application, include expanded material listed below:

- A. A brief description of the intended project;
- B. A description of available laboratory facilities;
- C. Ongoing basic and clinical research relating to immunologic diseases, identifying existing projects and sources of support;
- D. Past research by members of the proposed investigative group in basic and clinical immunology;
- E. A description of all clinic facilities available for use by the proposed project;
- F. Specific information on the institution's present patient load and projections for patient involvement in clinical investigations;
- G. The academic positions and major research interests of the program director and his professional staff who will be involved in the work of the program projects;
- H. Collaborative possibilities 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.

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

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

Forward the complete application to:

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

Please forward a copy (not the original) of the cover letter and the application face page to Dr. Robert A. Goldstein in order to alert NIAID to the submission of the proposal, and to:

Chief, Program and Project Review Branch
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building - Room 703
Bethesda, Maryland 20205

ANNOUNCEMENT

STATE SERVICE SYSTEM RESEARCH GRANTS ON THE
CHRONICALLY MENTALLY ILL

**PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH**

Application Receipt Date: April 1, 1983

I. BACKGROUND

In 1977, the National Institute of Mental Health (NIMH) initiated the Community Support Program (CSP), a demonstration program to stimulate and assist States and communities in improving services for adults with long-term seriously disabling mental health problems, i.e., the adult chronically mentally ill population.

National goals for the program are:

- o to promote development within States and communities of comprehensive community support systems to meet the needs of, increase opportunities for, and improve the quality of life for adults with disabling long-term mental illnesses,
- o to promote more effective use of resources to meet the needs of the population of concern,
- o to reduce burden on families and communities of coping with major mental disorder and resulting disability,
- o to advance the understanding of how most effectively to plan, organize, deliver, monitor, finance, and evaluate treatment, rehabilitation, and support services to chronically mentally ill individuals.

Since the inception of the program, 39 States and the District of Columbia have received NIMH CSP grants to address these goals. Additional States have participated in national and/or regional CSP conferences and other technical assistance initiatives.

In fiscal year 1983, up to \$700,000 is available for State service systems research on the chronically mentally ill. Grants will be made for a maximum period of one year. This grant announcement defines activities that can be supported with these funds.

This program is described in the Catalog of Federal Domestic Assistance No. 13.242, Grants for Mental Health Service System Research. Awards will be made under the authority of the Public Health Service Act, 42 U.S.C. 242a and 42 C.F.R., Part 52. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

II. PURPOSE AND OBJECTIVES

The fiscal year 1983 research program recognizes that opportunities and services for chronically mentally ill individuals are shaped, to a large extent, by policy and program decisions at Federal and State levels. Such decisions have to do with legislation, regulations, financing, fiscal incentives and disincentives, organization and staffing of service systems, eligibility for certain levels of care, benefits or service packages, interagency collaboration, and similar factors.

Often these critical decisions are made with limited research knowledge of the costs, consequences, benefits, or other potential effects of alternative approaches.

Research to be supported under this announcement is intended to improve Federal, State, and local planning, policymaking and program management relative to services provided to chronically mentally ill individuals in State mental health and related service delivery systems.

All research projects supported under this announcement must develop generalizable knowledge. Priority will be given to multi-State collaborative projects or to State-specific projects with potential for generalizing to other States.

III. RESEARCH TOPICS

Areas in which research will be supported are:

- o Studies on the structure, operation, client outcome, and other effects of State mental health service delivery systems for the chronically mentally ill, including research that compares systems in different States or different locales within States; examines the relation and integration of State mental health, health, and other human services for the chronically mentally ill population; and investigates the impact of such service systems on other components of the broader State mental health service delivery system.
- o Studies that assess State mental health and related service delivery systems for particular subgroups of chronically mentally ill clients, such as severely disturbed children and youth, the young adult chronic patient, the homeless chronically mentally ill, and chronically mentally ill individuals in nursing homes and correction settings, or different locales within States and research that assesses innovative service configurations developed by States for serving these subpopulations.
- o Studies that examine State service funding and cost issues pertinent to the chronically mentally ill population, including research that compares systems in different States; investigates different funding models and benefit configurations; examines efficiency and cost-effectiveness of services; and investigates resource channeling and coordination for particular subgroups of the chronically mentally ill population.
- o Studies on service management and mix in State mental health service delivery systems for the chronically mentally ill, including research that compares systems in different States or different locales within States;

addresses the interaction between service management and continuity of care; and examines the appropriate mix of mental health, health, and other human services for various age, minority, diagnostic, and disability groups within this target population.

IV. ELIGIBILITY

- A. State mental health agencies or other appropriate units of State government. (Priority will be given to proposals in which States demonstrate their research capacity and/or research collaboration with university departments and research units.)
- B. Regional interstate organizations with experience in mental health service system research and with documented, established links with State mental health agencies.
- C. Other public or private, for-profit or nonprofit organizations, such as universities, corporations, etc., in a position to develop collaborative research projects involving single or multiple States (such applicants must provide documented evidence of: established linkages with State mental health and human services agencies responsible for addressing the issue; and willingness of the collaborating State government(s) or other agencies to participate in the projects.)

V. APPLICATION CHARACTERISTICS

Potential applicants are urged to seek pre-application consultation (see page 5). Detailed instructions are included in the application kit. Depending on the specific nature of the project and participating organizations, applications should:

1. Define the issue and discuss its relevance to the overall goal of improving State mental health service delivery systems for chronically mentally ill individuals.
2. Review and document relevant prior and ongoing research.
3. Document the qualifications of the applicant organization and, where appropriate, the collaborating organizations to undertake research on this particular issue.
4. Provide a detailed research plan that includes:
 - a. specific goals and objectives of the project,
 - b. availability of data relevant to the objectives and the plan for use of currently available data, where appropriate,
 - c. research design and, where appropriate, the process for gathering and analyzing data,
 - d. plans for reporting project results in a usable form which will encourage intended user group(s) to consider project results in the decision-making process,

- e. role(s) of all collaborating organizations, with documentation of their willingness to participate and to assume the intended role(s). (Letters indicating willingness to participate should be included as appendices to the application.)
- f. specific management plan for carrying out the collaborative activities in multi-setting or multi-State projects,
- g. description of facilities and personnel available, including resumes of key personnel that reflect pertinent research experience, with a clear delineation of specific duties and responsibilities of each,
- h. timetable for the accomplishment of the main steps in the project in a one-year period,
- i. budget justification.

VI. GENERAL INFORMATION

A. Application

- 1. Application kits (State applicants use PHS-5161-1; nongovernment applicants use PHS-398 rev. 5/82) may be obtained by contacting:

Grants Operation Section
Parklawn Building - Room 7C-05
5600 Fishers Lane
Rockville, Maryland 20857

- B. The original and six copies (two if form PHS-5161-1 is used) of the application should be submitted to:

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

C. State Consultation

- 1. NIMH staff are available for consultation concerning proposal development in advance of or during the process of preparing an application. Potential applicants should contact NIMH as early as possible for information and guidance in initiating the application process. Inquiries regarding relevance of the proposed project to community Support Program goals should be directed to:

Judith Turner, Chief or
Jacqueline Rosenberg
Research and Evaluation Coordinator
Community Support and Rehabilitation Branch
Division of Mental Health Service Programs
Parklawn Building - Room 11C-22
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4113

2. Inquiries regarding the technical aspects of proposal submission, research design, and methodology should be directed to:

Ronald W. Manderscheid, Ph.D., Acting Chief
Survey and Reports Branch
Division of Biometry and Epidemiology
Parklawn Building - Room 18C-05
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-3343

3. Review and Award

Applications will be reviewed in accord with the usual Public Health Service peer review procedures. They will first be reviewed for technical merit by a review group composed primarily of non-Federal consultants (Initial Review Group) and then by the National Advisory Mental Health Council. Only those applications recommended for approval by the Council will be considered for funding.

Applicants should not expect that site visits will be made.

D. Review Criteria

1. Clarity and specificity of project objectives.
2. Quality of project design and methodology as evidenced by a detailed research plan which includes:
 - a. description of the proposed research,
 - b. specific aims and rationale for the study,
 - c. hypothesis to be tested, if any,
 - d. kinds of data expected to be obtained and the means by which the data will be collected, analyzed, and interpreted,
 - e. discussion of the limitations of the procedures proposed, if appropriate, in light of the pitfalls that might be encountered, anticipated, and dealt with,
 - f. timetable for the accomplishment of the main steps in the project in a one-year period.
3. Significance of the issue(s) and potential of the project for improving State mental health service delivery systems for chronically mentally ill individuals; generalizability of the findings.
4. Appropriateness of the collaborative arrangements to the nature of the problem.

5. Evidence of cooperation and commitment from significant persons and organizations whose support is essential to successful implementation of the project.
6. Potential of the project to foster effective links between university-based researchers and State mental health authorities.
7. Quality of the plan for disseminating results of the project to appropriate audiences in a manner that will facilitate the use of the information.

E. Receipt and Review Schedule

<u>Receipt of Application</u>	<u>Initial Review</u>	<u>National Advisory Mental Health Council</u>	<u>Earliest Award Date</u>
Apr. 1, 1983	May/June 1983	Aug./Sept. 1983	Sept. 1983

F. Award Criteria

1. Quality of the proposed project as determined during the review process.
2. Relationship of the project to the goals and objectives of the NIMH Community Support Program, and likelihood that, if funded, the project will contribute significantly to improving policy-making and/or program management of State mental health service delivery systems for chronically mentally ill individuals.
3. Generalizability of project results to multiple localities or States. (In instances of two projects of similar quality addressing the same issue, priority for funding will be given to a multi-State collaborative project.)

G. Terms and Conditions of Support

1. Support may be requested for one year.
2. Applicants must certify that all applicable Federal regulations will be adhered to. Awards will be administered in accordance with the PHS Grants Policy Statement (rev. 12/1/82).*

* Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-500-000 (Rev.) December 1, 1982, available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

ANNOUNCEMENT

NEW INVESTIGATOR RESEARCH AWARD (NIRA) IN PREVENTION

PUBLIC HEALTH SERVICE
ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM
NATIONAL INSTITUTE ON DRUG ABUSE
NATIONAL INSTITUTE OF MENTAL HEALTH

January 1983

I. INTRODUCTION

Under the authority of Section 301 of the Public Health Service Act, Section 501 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, as amended, Section 503 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act, as amended, Federal Regulations at 42 CFR Part 52, the three Institutes of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are seeking applications for New Investigator Research Awards (NIRAs) in Prevention. It is anticipated that approximately six awards will be made in Fiscal Year 1983. Applications must be received by April 1, 1983, to be considered for funding in Fiscal Year 1983.

II. PURPOSE

The NIRA in Prevention is an award to an institution on behalf of a specific individual and is designed to encourage new investigators (or investigators who have established careers in closely related fields and who wish to specialize in prevention research) in the biomedical and behavioral disciplines to develop their research interests and capabilities in prevention research methodology and preventive intervention research in alcohol, drug abuse, and mental health (ADM) fields. The long-range goal of this program is to expand the scientific and clinical knowledge base of prevention theory and thereby produce demonstrable reductions in the incidence of ADM disorders and dysfunctions. To assist in the transition either from training status to that of established investigator or from a related field, this program provides research grant funds for relatively inexperienced investigators (or investigators refocusing their careers) with meritorious research ideas.

III. AREAS OF INTEREST

Prevention research is defined for this Announcement as research focused on, or directly related to, reducing the incidence of: ADM disorders; the high-risk precursors of the disorders; the adverse consequences of high-risk precursors or early manifestations of the disorders themselves. It includes research on (1) primary preventive and health promotion interventions, (2) nonclinical secondary preventive interventions, (3) general population screening methods for early identification, and (4) the role of contributing and inhibiting factors as a basis for development or refinement of preventive intervention strategies.

Applications are particularly encouraged in areas which include but are not limited to:

1. The design, implementation, and evaluation of models of early preventive interventions targeted to individuals/populations at risk for ADM disorders and behavior dysfunctions or who display early signs or precursors thereof. (Interventions should aim to reduce demonstrably both the incidence of a specific disorder or dysfunction and the need/demand for treatment.)
2. Assessment of the differential applicability of preventive interventions for different populations and age groups and the duration of their effects for different demographic, cultural, ethnic, and age segments of the population.
3. Refinement of techniques for differentiating within epidemiologically identified at-risk populations those individuals who are vulnerable for specific ADM disorders and assessment of their receptivity to early preventive intervention.
4. Assessment of the relationship between stressful life events and individual vulnerability and resistance to specific ADM disorders and behavior dysfunctions with the intent of applying these research findings directly to the development of preventive interventions.
5. Development and/or refinement of prevention research and evaluation methods such as instrumentation and measurement techniques, cost-benefit analysis, and community-impact analysis.

IV. ELIGIBILITY

A. Applicant Institutions

All domestic, nonprofit and for-profit organizations and institutions, qualified entities of State and local governments, and eligible Federal institutions may apply.

B. Principal Investigator

This award is restricted to new investigators pursuing a career in prevention research and investigators in closely related fields who are refocusing their careers on prevention research.

For purposes of this announcement, new investigators are defined as those who hold a doctoral degree or its equivalent or have completed formal professional and research training (e.g., someone with an MPH degree and formal research training), have no more than five years of research experience after completion of formal training at the time the award is made, and have not previously been a principal investigator on any PHS-supported research project grant.

Investigators refocusing their careers on prevention research are defined as established investigators with at least five years experience, who have not previously been principal investigators on a National Institute on Alcohol

Abuse and Alcoholism (NIAAA), National Institute on Drug Abuse (NIDA), or National Institute of Mental Health (NIMH) supported research project grant in prevention and who have research training and experience in closely related fields.

C. Concurrent Applications

Submission of an application under this announcement precludes concurrent application for an ADAMHA Research Scientist Development or Research Scientist Award, National Research Service Award, or another NIRA or similar award.

An applicant may apply concurrently for a separate research project grant, provided the time and effort devoted to the research project grant will not conflict or interfere with the time or other commitments of the NIRA.

V. REVIEW CRITERIA

Applications will undergo peer review for scientific and technical merit by Initial Review Groups (IRGs) consisting primarily of non-Federal technical and scientific experts. Particular attention will be given to the following:

1. Adequacy of the principal investigator's research and research-training background as a guide to future development into a creative, independent investigator in the field of ADM-related prevention research.
2. Quality of the individual's past education, scientific training, and potential for a prevention-related research career or letters of reference if research originality and potential are not reflected in past experience.
3. Evaluation of the research proposal for scientific merit, including (a) originality, (b) feasibility, (c) adequacy of the design, (d) plans for analysis and evaluation of data, and (e) overall evidence of the investigator's ability to develop a sound research plan.
4. Adequacy of resources and environment for the successful completion of the proposed research.

VI. SPECIAL TERMS OF THE AWARD

Except as otherwise stated in this announcement, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement.*

* Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 82-50-000 GPO-017-020-0090-1 (rev.) December 1, 1982, available for \$5.00 from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

salary, title, and staff privileges are determined by the grantee institution in accordance with its established policies for other individuals of the same rank, faculty, or employment status without regard to source of support.

2. Principal investigators must make a significant commitment of time or effort to the research project proposed; while this must be at least 50 percent of full-time activities, a larger commitment is encouraged.

B. Duration

Direct costs may be requested for up to three years of support. Continuation of research support beyond this award may be sought as a regular research grant.

C. Direct Costs

1. The total direct costs requested must not exceed \$112,500 for the three-year period; no more than \$37,500 may be requested in any one year.
2. An institution may request up to \$25,000 plus applicable fringe benefits to support that portion of the principal investigator's salary and benefits which reflects the percentage of time devoted to the NIRA project. The base annual salary from which this amount is derived must be consonant with the policies of the grantee institution governing full-time salary for other individuals of similar rank.
3. Technical support, supplies, publication costs, and limited equipment, as well as necessary travel, may be requested within the direct-cost budget. Requested funds may not be used to supplement a project supported by other funds.

D. Indirect Cost

Indirect costs are allowable in accordance with DHHS policies for research grants.

E. Follow-up Information

To assist in the evaluation of this program, the principal investigators may be requested to provide ADAMHA staff with information about their scientific accomplishments and changes in professional status or institutional affiliation for a period of six years subsequent to termination of the award.

VII. APPLICATION

- A. The regular research grant application form PHS 398 (rev. 5/82) must be used in applying for these awards. State and local agencies should use form PHS 5161. Application kits are available in university grants offices or from the following:

Grants Operations Section
Parklawn Building - Room 7C-05
5600 Fishers Lane
Rockville, Maryland 20857

General instructions for applicants are included in the kit.

- B. Further information on program requirements and application procedures can be obtained from:

Dr. Ernestine Vandervee
Chief, Psychosocial Research Branch
National Institute on Alcohol Abuse
and Alcoholism
Parklawn Building - Room 14C-17
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4223

Dr. Robert Battjes
Acting Chief, Prevention Research Branch
National Institute on Drug Abuse
Parklawn Building - Room 10A-20
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-1514

Dr. Morton Silverman
Chief, Prevention Research Branch
Parklawn Building - Room 11C-06
5600 Fishers Lane
Rockville, Maryland 20857

Telephone: (301) 443-4283

- C. New Investigator Research Award in Prevention should be typed on line 2 of the face page of the application form.
- D. The signed original and six (6) copies of the completed application should be sent to:

Division of Research Grants
National Institutes of Health
5333 Westbard Building
Bethesda, Maryland 20205

- E. New investigators should request present or former supervisors to submit letters attesting to their potential for conducting independent research. These should be submitted directly to the Executive Secretary of the review group handling the application. Applicants will be advised of name and address of the Executive Secretary after the application is received.

VIII. RECEIPT AND REVIEW SCHEDULE

<u>Receipt of Application</u>	<u>Initial Review</u>	<u>Advisory Council Review</u>	<u>Earliest Award Date</u>
March 1*	June	September/ October	December **
July 1	October/ November	January/ February	April
November 1	February/ March	May	July

IX. AWARD CRITERIA

Applications recommended for approval by the relevant Institute's National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the proposal as determined by peer review, program balance, relevant to national need as reflected by each of the ADAMHA Institutes' prevention research priorities, and the availability of funds.

* April 1, 1983, for first review cycle
 ** September 1983 for first review cycle