

# NIH Guide for Grants and Contracts

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U.S. DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

## IN THIS ISSUE:

### Notice

Nominations for Small Business  
Review Groups..... Page 1

### Notice

Letters of Intent ..... Page 3

### Notice

Information Relative to New  
Cancer Control Science Program ..... Page 3  
National Cancer Institute  
Index - CANCER

### Notice

New World Primate Availability ..... Page 4  
Index - NON-HUMAN PRIMATES

### Request for Research Grant Applications: RFA

NIH-NIADDK-DEMD-83D-1  
Immunopathogenetic Mechanisms Involved in the  
Development of Insulin-Dependent Diabetes  
Mellitus (IDDM) ..... Page 5

National Institute of Arthritis, Diabetes,  
and Digestive and Kidney Diseases  
National Institute of Allergy and Infectious Diseases  
National Institute of Child Health and Human Development  
Index - ARTHRITIS, METABOLISM AND  
DIGESTIVE DISEASES  
ALLERGY AND INFECTIOUS DISEASES  
CHILD HEALTH AND HUMAN DEVELOPMENT

(Continued)

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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 you 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.

Clinical Investigator Award.....Page 11  
National Heart, Lung, and  
Blood Institute  
Index - HEART, LUNG, AND BLOOD

Announcement  
Research on Benign Prostatic Hyperplasia .....Page 18  
National Institute of Arthritis, Diabetes,  
and Digestive and Kidney Diseases  
Index - ARTHRITIS, METABOLISM, AND  
DIGESTIVE DISEASES

Announcement  
Notice of Availability of Request for  
Training Grant Applications: RFA  
RFA-NIH-NLM-EP-83-1 - Health Computer  
Sciences Research Training .....Page 21  
National Library of Medicine  
Index - LIBRARY OF MEDICINE

Notice  
Program Project Research Grant  
Application (P01) Special Directives .....Page 23  
National Institute on Aging  
Index - AGING

Notice  
Public Meeting on Laboratory  
Animal Care and Use .....Page 30  
Index - ANIMALS

NOTICE

REQUEST FOR NOMINATIONS OF INDIVIDUALS FROM SMALL BUSINESS  
ORGANIZATIONS TO SERVE AS MEMBERS OF  
NIH SCIENTIFIC REVIEW GROUPS  
FOR THE SMALL BUSINESS INNOVATION RESEARCH (SBIR) PROGRAM

The National Institutes of Health (NIH) invites nominations of individuals representing small business organizations for membership on its scientific peer review groups. These groups provide the technical and scientific merit review of Small Business Innovation Research grant applications. Scientists serving on these groups advise the NIH on the selection of the most meritorious projects to implement biomedical research programs of the highest quality. Although a number of scientists from commercial organizations now serve on these advisory bodies, NIH has a special interest in adding greater representation from the small business scientific sector than now exists.

All nominations will be carefully considered; NIH reserves the right to make final selections.

Responsibilities

Each review group is composed of primarily non-Federal scientists selected for their competence in the particular scientific area for which that group has review responsibilities. Such responsibilities generally involve several days of intensive review of research proposals prior to a meeting of the review group. Specific applications are assigned in advance of the meeting to each member who prepares written detailed critiques prior to the meeting and leads discussion at the meeting.

Criteria for Membership

The primary requirement for serving on a scientific review group is demonstrated competence as an independent investigator in a research and development specialty in a laboratory or clinical setting. Assessment of such competence is based on the quality of research accomplished, proven ability to develop a product or process with commercial applications, and/or other significant scientific activities, accomplishments, and honors. Usually a doctoral degree or its equivalent is required. Service also requires mature judgment, balanced perspective, objectivity, ability to work effectively in a group context, commitment to complete work assignments, and assurance that the confidentiality of applications will be protected.

How to Respond to Request

Any person may nominate one or more highly qualified candidates for consideration. Self-nominations are acceptable. Nominations should be made promptly for immediate consideration, and at any time thereafter for future attention. Each nomination should be clearly identified as representing the small business sector.

For each nomination:

1. Provide full name of nominee, title, complete mailing address (including organizational affiliation), and telephone number.
2. In not more than two or three lines, provide in key words information concerning the nominee's scientific areas of experience, interest, and expertise.
3. Name, address, telephone number, and signature of nominator.
4. An updated and comprehensive curriculum vitae of the nominee.

The nominator may be contacted for more detailed information. Nominees should be informed prior to being nominated. They will be sent a packet requesting relevant information upon receipt of nomination.

Send information to:

NIH Consultant File Project  
Suite 212  
6400 Goldsboro Road  
Bethesda, Maryland 20817

NOTICE

LETTERS OF INTENT

The use of letters of intent for certain types of applications for grants or cooperative agreements can be beneficial to both the awarding component and the applicant investigator/institution. Early interaction between prospective applicants and program staff can be very helpful in preparing complex or highly targeted applications and can often prevent delays resulting from the need to revise unresponsive or otherwise unsatisfactory applications. The letters also provide NIH with an indication of the number and types of applications to be submitted and the institutions that may be involved, facilitating planning for the review process. In general, letters of intent are most appropriately used for resource, center, and program project applications, and for single RFA solicitations. Applicants are urged to read the appropriate announcements carefully and follow suggestions concerning consultation with NIH staff.

Prospective applicants are reminded that letters of intent are not binding, nor can they ensure favorable review and funding decisions. Letters of intent cannot be used as a preliminary application nor required as a pre-condition for applying for any NIH award. As a general rule, the suggested content of the letter of intent will be limited to a brief description of the thrust of the envisioned research activity and the identity and basic qualifications of the key investigators. If specific eligibility requirements are spelled out in the announcement, prospective applicants may be asked to address these points in a letter of intent.

NOTICE

CANCER CONTROL SCIENCE PROGRAM

NATIONAL CANCER INSTITUTE

The National Cancer Institute announces that until new guidelines for the "Cancer Control Science Program" are written and approved, no new or revised applications will be accepted. The "Cancer Control Science Program" was announced in the March 26, 1982 edition of the NIH Guide for Grants and Contracts, Vol. 11, No. 4, pages 28-34. When the new guidelines are available, they will be published, together with information on the receipt dates.

NOTICE**NEW WORLD PRIMATE AVAILABILITY**

As part of a major project in primate conservation and breeding, the Pan American Health Organization is providing services to South American countries in planning and operating wild primate management and primate breeding programs. These services are in part supported by the National Institutes of Health (NIH), in recognition of the need for international cooperation in conserving primates in their natural habitats as well as in research utilization. The Government of Peru has established a program at Iquitos to breed monkeys and from which primate surveys and population monitoring are conducted. As a consequence of these efforts, several species of primates are available to NIH grantees and contractors from Peru. These include:

<u>Saimiri sciureus</u>	(gothic and roman arch squirrel monkeys) - colony produced and wild caught
<u>Cebuella pygmaea</u>	(pygmy marmoset) - colony produced and wild caught
<u>Aotus trivirgatus</u>	(owl monkeys, Karyotype I) - colony produced and wild caught
<u>Saguinus fuscicollis</u>	(saddle-back tamarin) - wild caught
<u>Saguinus mystax</u>	(moustached tamarin) - currently wild caught; colony produced animals will become available

Services can also be made available to scientists for conducting field studies relating to nonhuman primates with the assistance of program staff at Iquitos. Access to the colonies maintained in Iquitos and to the laboratories maintained there can be provided as well as technical support for certain types of investigative work.

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

Dr. Thomas L. Wolfle  
 Executive Director, IPSC  
 National Institutes of Health  
 Building 12A - Room 4003  
 Bethesda, Maryland 20205

Telephone: (301) 496-5424

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIADDK-DEMD-83D-1

IMMUNOPATHOGENETIC MECHANISMS INVOLVED IN THE DEVELOPMENT OF  
INSULIN-DEPENDENT DIABETES MELLITUS (IDDM).

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES AND DIGESTIVE  
AND KIDNEY DISEASES

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Application Receipt Date: July 15, 1983

I. PURPOSE

The National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases (NIADDK), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Child Health and Human Development (NICHD), invite investigator-initiated research grant applications to define the immunopathogenetic mechanisms associated with the etiology and pathogenesis of Insulin Dependent Diabetes Mellitus (IDDM).

II. DISCIPLINES AND EXPERTISE

The interdisciplinary nature of this study will require some combination of expertise in the areas of the immunology, genetics, etiology, pathophysiology and epidemiology of diabetes mellitus and its complications.

III. BACKGROUND

Diabetes mellitus and its complications are major public health problems in the United States today. The NIH sponsors broad based programs of basic and clinical research into the cause, cure and prevention of diabetes and its complications. In this regard, recent evidence for an altered immune response in the development of IDDM has prompted this solicitation in an effort to stimulate additional research in this area. Recent advances in immunology including identification of the various types of lymphocytes involved in the immune response, identification of the genetic basis for generation of unlimited numbers of antibodies, better understanding of the

This program is described in the Catalog of Federal Domestic Assistance No. 13.847, Diabetes, Endocrinology, and Metabolism. 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.

complement system and the mechanisms of effective function of immunoglobulins, and new techniques and tools including the development of specialized radioimmunoassays, monoclonal antibodies, identification of HLA and tumor antigens associated with various diseases, etc., have contributed substantially to new concepts of the etiology and pathogenesis of IDDM. The exact role of the alteration in the immune response associated with the development of IDDM is not known but evidence such as lymphocyte infiltration in the pancreas, the presence of islet-cell-directed autoantibodies, association of specific histocompatibility markers with the disease, and the presence of certain viral infections around the time of onset of the disease continues to implicate an association between the immune response and the development of IDDM. These and related observations suggest that some environmental insult may trigger onset of the disease in individuals with a vulnerable immune system.

The NIADDK, NIAID, and NIDR sponsored a workshop in November 1980 which reviewed existing data and made recommendations for future initiatives which have been incorporated in the proposed scope of this solicitation.

#### IV. OBJECTIVES

This solicitation is prompted by a perceived need for additional new research to elucidate the immunopathogenetic mechanisms important in the development of IDDM and new basic information from population studies which relate these various factors to the incidence and prevalence of the disease and the development of its complications.

#### V. SCOPE

The primary objective of this solicitation is to encourage basic and clinical research on the involvement of the immune response in the etiology and pathogenesis of IDDM and its complications. However, the objective is not to encourage submission of applications proposing clinical trials to evaluate the potential therapeutic applicability of immunosuppressive agents in the prevention/treatment of IDDM.

Some examples of research topics which would be considered responsive to this solicitation include the following:

##### A. Etiology and Pathogenesis

1. Studies of the susceptibility gene(s), gene products, and their relationship to the immune system;
2. Studies of the role of viruses in the etiology and pathogenesis of diabetes including prospective collaborative viral studies of apparently unaffected siblings of subjects with IDDM and prevention of viral effects with a vaccine;
3. Studies of the role of autoimmune factors in the development of chronic complications (e.g., in the eye, kidney, heart, etc.);
4. Studies of the sub-sets of lymphocytes and their relationship to the development of IDDM.



B. Epidemiology

1. The acquisition of more standardized data on IDDM, including information on incidence, familial occurrences, pedigree studies, prevalence, and complications;
2. Studies of HLA genotypes and their association with diabetes;
3. Studies of the epidemiology of infectious diseases in diabetics to ascertain to what extent diabetics are more prone than non-diabetics to viral, bacterial, and mycotic infections, and what immune deficits or other factors are responsible for the predisposition of IDDM patients to these disorders;
4. Prospective collaborative studies of unaffected siblings of subjects with IDDM to ascertain their relative risk according to: HLA type; presence or absence of circulating autoantibodies; and titers of anti-viral antibodies.

C. Diagnostic Approaches

1. Study of anti-viral antibodies as a measure or predictor of diabetes;
2. Development of microcytotoxicity assays or other immunoassays to detect immune activity directed against the beta cell;
3. Standardization of testing for islet cell antibodies (ICA), and their subgroups such as islet cell surface antibodies (ICSA), and assessment of their pathogenesis.

D. Other

1. Development of animal models for use in studies of pathogenic factors in spontaneous, chemical or surgically induced diabetes;
2. Research in animal models on pancreatic tissue/beta cell transplantation and prevention of immune rejection.

These areas of interest are not listed in any order or priority. They are only examples of areas of research; other areas may occur to an applicant which are related to the scope described above.

VI. MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid. The regulations (Code of Federal Regulations, Title 42, Part 52 and as applicable to the state and local governments, Title 45, Part 74) and policies which govern the research grant programs of the National Institutes of Health (NIH) will prevail. Although this solicitation is included in the sponsoring Institute's funding plans for Fiscal Year 1984, support is contingent upon receipt of appropriated funds for this purpose. The sponsoring Institutes plan to designate a total of \$1,000,000 for the support of applications submitted in response to this solicitation; however, the specific amount to be funded will depend upon the overall merit and scope of the applications received. It is anticipated that approximately eight to twelve grants

will be awarded under this solicitation. Since a variety of approaches would represent valid responses to this solicitation, it is anticipated that there will be a range of costs among individual grants awarded. With respect to post-award administration, the current policies and requirements that govern the regular research grant programs of the NIH will prevail.

## VII. REVIEW PROCEDURES AND CRITERIA

### A. Assignment of Applications

Upon receipt, applications will be reviewed by staff for their responsiveness to the objectives of this RFA. If an application is considered unresponsive, the applicant will be contacted and given an opportunity to withdraw the application or to have it considered for the regular grant program of the NIH. If an application submitted in response to this RFA is identical to a research grant application already submitted to the NIH for review, the applicant will be asked to withdraw the pending application before the new one is accepted. Simultaneous submission of identical applications will not be allowed.

Applications will be received by the NIH, Division of Research Grants (DRG), referred to an appropriate Initial Review Group (IRG) for scientific merit review, and assigned to individual Institutes (see list above) for possible funding. Referral decisions will be governed by normal programmatic considerations as specified in the Referral Guidelines of the NIH, DRG.

### B. Review Procedures

Applications in response to this solicitation will be reviewed on a nationwide basis, and in accord with the usual NIH peer review procedures. Applications will first be reviewed for scientific and technical merit by an IRG composed primarily of non-federal scientific consultants, and then by the National Advisory Council of the appropriate Institute(s). The review criteria customarily employed by the NIH for regular research grant applications will prevail.

### C. Review Criteria

The factors to be considered in the evaluation of scientific merit of each application will be similar to those used in the review of traditional research project grant applications, including the novelty, originality, and feasibility of the approach; the training, experience, and research competence of the investigator(s); the adequacy of the experimental design; the suitability of the facilities; and the appropriateness of the requested budget to the work proposed.

## VIII. METHOD OF APPLYING

### A. Letter of Intent

Prospective applicants are encouraged to submit a one-page letter of intent that includes a brief synopsis of the proposed research and identification of any other participating institutions. Such letters are requested for the purpose of obtaining an indication of the number and scope of applications to

be received. A letter of intent is not binding, and it will not enter into the review of any application subsequently submitted. This letter should be received no later than June 15, 1983, and sent to:

Valerie P. Setlow, Ph.D.  
Assistant Diabetes Research Program Director  
National Institute of Arthritis, Diabetes,  
and Digestive and Kidney Diseases  
Westwood Building - Room 605  
5333 Westbard Avenue  
Bethesda, Maryland 20205

B. Format for Applications

Applications should be submitted on form PHS 398, which is available from an applicant institution's Office of Sponsored Research or from the NIH, DRG. Use the conventional format for research project grant applications and ensure that the points identified in this RFA in the section on "Review Procedures and Criteria" are fulfilled. To identify the application as a response to this RFA, check "yes" on item two of page one of the application and enter the title "Immunopathogenetic Mechanisms Involved in the Development of IDDM" and the RFA number NIH-NIADDK-DEMD-83D-1.

As in the case with regular research project grant applications, applicants are requested to furnish their own estimates of the time required to achieve the objectives of the proposed research project. However, except under very unusual circumstances, applications submitted in response to this solicitation should not request support for more than a three year period. At the end of the initial award period, renewal applications may be submitted for further competitive review through the regular research grant program of the NIH.

C. Application Procedure

The original and six copies of the application should be sent or delivered to:

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

D. Timetable

A letter of intent should be submitted no later than June 15, 1983.

Applications must be received by July 15, 1983. Any applications not received by this date will be considered ineligible for this special solicitation.

<u>APPLICATION RECEIPT</u>	<u>INITIAL REVIEW</u>	<u>COUNCIL REVIEW</u>	<u>EARLIEST START DATE</u>
July 15, 1983	Oct./Nov.	Jan./Feb.	April 1

### E. Inquiries

For further information, investigators are encouraged to contact one or more of the following individuals:

Valerie P. Setlow, Ph.D.  
Assistant Diabetes Research Program Director  
National Institutes of Arthritis, Diabetes  
and Digestive and Kidney Diseases  
Westwood Building - Room 605  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-7888

Robert A. Goldstein, M.D., Ph.D.  
Chief, Allergy and Clinical Immunology Branch  
National Institute of Allergy and  
Infectious Diseases  
Westwood Building - Room 755  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-7104

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

Telephone: (301) 496-5893

Gilman Grave, M.D.  
Chief, Nutrition and Endocrinology Section  
Clinical Nutrition and Early Development Branch  
National Institute of Child Health and  
Human Development  
Landow Building - Room C709  
7910 Woodmont Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-5575

CLINICAL INVESTIGATOR AWARD

**NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Date: September 15, 1983

**I. PURPOSE**

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of Clinical Investigator Awards. The clinical investigator award program is intended to:

- o encourage newly trained clinicians to develop clinical and basic research interests and skills in the areas of cardiovascular, pulmonary, or blood diseases and the blood banking sciences;
- o increase the pool of physician investigators in the areas of cardiovascular, pulmonary, or blood diseases and the blood banking sciences.

These awards provide the opportunity for clinically trained physicians with a commitment to research to develop into independent biomedical research investigators.

The award will enable candidates to undertake up to five years of special study and supervised experience tailored to individual needs with a sponsor (or sponsors) competent to provide research guidance. This award is intended to cover the transition between postdoctoral experience and a career in independent investigation. The clinical investigator award differs from the National Institute of Health (NIH) Research Career Development Award (RCDA) in that it seeks to develop research ability in individuals with a clinical background early in the candidate's career rather than to promote the further development of research skills of individuals already demonstrating significant research achievement.

**II. BACKGROUND**

Despite a recent decline in the death rate from coronary heart disease, cardiovascular disease continues to be the number one cause of death in the United States. Arteriosclerosis and hypertension account for almost one million deaths annually. An estimated 40 million Americans have diseases of the heart and blood vessels, resulting in a large burden of acute and chronic illness and disability. Heart and blood vessel diseases cost the economy more than \$50 billion per year in

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This program is described in the Catalog of Federal Domestic Assistance Nos. 13.837, 13.838, and 13.839. 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.

vessels, resulting in a large burden of acute and chronic illness and disability. Heart and blood vessel diseases cost the economy more than \$50 billion per year in wages, lost productivity, and expenses for medical care.

Diseases of the lung constitute a major national health problem. An estimated 10 million Americans, both young and old, are currently affected by these diseases with an annual estimated cost to the nation of over \$29 billion. About one in every five persons has some chronic respiratory problem. In the newborn, the most common cause of death is neonatal respiratory distress syndrome. Neonatal RDS is implicated in the development of adult respiratory diseases as well. Fibrotic and immunologic lung diseases are major causes of lung problems in the young adult and may cause chronic obstructive pulmonary diseases. Of the adult respiratory diseases, emphysema and chronic bronchitis are the major causes of death.

Asthma, emphysema and chronic bronchitis represent particularly pressing health problems, since the death rate and prevalence of these conditions have increased at an alarming rate over the past 15 years. As a disabling disease, emphysema is a leading cause of worker retirement on Social Security disability payments.

Diseases of the blood underlie, or are critical contributors to, many disorders that affect mankind. As a consequence, they are major causes of death and disability in the United States. Until recently, no valid estimate of their adverse economic impact could be realistically made because disorders of the blood affect not only the blood itself but also the organs and tissues through which it flows. Recent research findings have revealed the widespread involvement of thrombosis in the pathology of numerous disorders; more aggressive therapy for cancer has resulted in increased susceptibility of patients to bleeding disorders; and many blood disorders either cause or accompany various types of diseases and injuries or result from them. A significant segment of the population has hemolytic disorders and anemias.

Recent studies have also provided data with which reliable estimates can be made about the quantities of blood collected, processed, and transfused and about the numbers and types of patients who receive transfusions. Discoveries of the biological properties of blood constituents during the past decade have greatly expanded the scope of health benefits derived from human blood donations through the use of components in increasingly specialized and effective therapy.

The clinical investigator award program is designed to encourage recently trained physicians to develop their clinical and basic research interests and research capabilities in heart, lung, or blood disease\* areas. To help support the transition from clinical training status to that of a productive research investigator, the clinical investigator award will provide early support for clinicians with potential for developing into independent researchers.

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\* The term "blood diseases" covers research into many aspects of bone marrow function and disorders of the red cell, megakaryocyte, platelet, and coagulation systems. Research on disorders of white cells, including the leukemias and other blood malignancies, and basic immunology related to the lymphoid system are the responsibility of other Institutes of the NIH and therefore cannot be supported through this mechanism.

### III. IMPLEMENTATION

Beginning in Fiscal 1980, under the authorizations in the Public Health Service Act, Section 301(c) and Section 413(a), the NHLBI has funded clinical investigator awards. Each grant has a duration of five years and is non-renewable. Funding beyond the first year of the grant is contingent on satisfactory progress during the preceding year.

The status of the clinical investigator award program will be reviewed four years from the date of the first awards to determine whether the program should be continued. In addition, to assess the effectiveness of the program in fulfilling its objectives, the Institute intends, after completion of each grant, to follow the progress of the recipient for a period of five years to determine: (1) the investigator's professional affiliation(s), (2) his/her record of subsequent grant or contract support, and (3) his/her record of scientific publications. It is anticipated that the experience and results achieved by the awardee from this special grant program, in the majority of cases, will provide the basis for successful competition in the regular research support programs of the Institute.

The receipt date for applications will be September 15, 1983. The applications will be evaluated by an initial review group and by the National Heart, Lung, and Blood Advisory Council. The earliest start date for successful applicants will be July 1, 1984.

### IV. PROVISIONS OF THE AWARD

The clinical investigator awardee will be supported for a period of five years. All funds must be used to support the original awardee. Support is based on a full-time, twelve-month appointment. The awardee will be provided salary support of up to \$30,000, plus fringe benefits. The actual salary must be consistent with the established salary structure of the institution for persons of equivalent qualifications, experience, and rank.

Up to a total of \$10,000 annually may be provided for supplies, equipment, travel, etc., which are necessary for pursuit of the awardee's research program. An appropriate sponsor must assume responsibility and provide guidance for the development of the candidate's research program.

Institutions may apply for awards on behalf of named individuals meeting the criteria for this award. Evidence of the commitment of the institution and sponsors to the candidate's research and career development is to be included in the application.

The grant will be made annually to the awardee's parent institution for each of the five annual budget periods. Costs allowed may include:

#### 1. Awardee's Salary

Up to a maximum of \$30,000 for full-time support; in addition, fringe benefits will be provided. Institutional supplementation is permitted.

## 2. Research Support

Up to a maximum of \$10,000 per year.

- a. Equipment: specialized research equipment essential to the proposed program. The available facilities should include most of the necessary equipment;
- b. Supplies: consumable supplies essential to the proposed program;
- c. Travel: domestic travel essential to the proposed program;
- d. Tuition for training courses: if essential to the awardee's individual research development program; and
- e. Other: publication costs, patient costs, technical help, etc., necessary for the research program.

## 3. Indirect Costs

Funds will be provided for the reimbursement of actual indirect costs at a rate up to, but not exceeding, 8 percent of the total direct costs of each award, exclusive of tuition, fees, and expenditures for equipment.

## V. ELIGIBILITY

- A. The award is designed to provide intensive, supervised research experience for clinicians. Thus, candidates are restricted to those holding health-professional degrees in the clinical sciences (M.D., D.O., or equivalent). Candidates ordinarily will have completed their clinical experience by the time the award can be made. Ordinarily a candidate in the following categories will not qualify:
  1. with more than six years of postdoctoral experience at the time of award;
  2. with previous independent NIH research support or its equivalent;
  3. with less than three years total postdoctoral clinical experience at the time of the award.

In exceptional circumstances, individuals in one or more of the above categories may qualify for the award. However, the applicant must provide sufficient justification for such an exception.

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

- B. Applicants for a Clinical Investigator Award may not submit a concurrent application for an NIH Research Career Development Award, Academic Award, or for a New Investigator Research Award. A Clinical Investigator Awardee may subsequently apply for a research project grant.



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

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

- D. Candidates must have one or more sponsors or advisors who are recognized as accomplished investigators in the research proposed at the applicant's institution. The sponsor must provide: 1) his/her concept of a development and research plan for the awardee; 2) his/her curriculum vitae (updated) with complete bibliography and research support; and 3) a letter indicating his/her evaluation of the proposed awardee and his/her willingness to provide guidance and support.
- E. Candidates must provide a description of the proposed research and career development plan for the five-year period of the award. The candidate must be prepared to commit full-time effort to the objectives of this award. It is required that a minimum of 75 percent effort be devoted to the research program. The balance of effort can be devoted to other clinical and teaching pursuits only if they are consonant with the program goals, i.e., the awardee's development into an independent biomedical research investigator.
- F. Awardees and their sponsors will be required to submit a special, detailed progress report at the end of the third year of support. This report is to contain specific information concerning progress and accomplishments and, in particular, an appropriately detailed research plan and protocol.
- G. Candidate must agree to inform the NHLBI annually for a period of five years subsequent to completion of the award about academic status, publications, and research grants or contracts received.
- H. Candidates for an award must be citizens or non-citizen nationals of the United States or its possessions and territories or must have been lawfully admitted to the United States for permanent residence at the time of application.

## VI. APPLICATION

Applications must be submitted on form PHS 398 which is available at the grantee institution. The original and 21 copies of the application should be clearly labeled "NHLBI CLINICAL INVESTIGATOR AWARD PROGRAM."

The chairperson of the department sponsoring the candidate should submit, as part of the application, a signed statement, detailing the department's commitment to the candidate during the term of the award.

The original and six complete copies of grant applications should be mailed to the following:

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

Fifteen additional copies should be mailed at the same time to the Executive Secretary, Research Manpower Review Committee. Upon receipt of each application at NIH, a postal card acknowledging receipt will be mailed to the applicant.

The applicant should ask three present or former supervisors or preceptors to send a letter to:

Executive Secretary  
Research Manpower Review Committee  
Review Branch  
Division of Extramural Affairs  
National Heart, Lung, and Blood Institute  
Westwood Building - Room 550  
5333 Westbard Avenue  
Bethesda, Maryland 20205

The applicant should attest to his/her potential for conducting independent research. The applicant is responsible for making necessary arrangements to ensure that the reference letters are mailed by the supervisors/preceptors directly to the Review Branch for receipt by September 15, 1983.

Applications for this award are due September 15, 1983. The earliest start date for awards is July 1, 1984.

## VII. REVIEW CRITERIA

Applications for clinical investigator awards will undergo initial merit review in the Review Branch, Division of Extramural Affairs, NHLBI. Secondary review will be by the National Heart, Lung, and Blood Advisory Council. Criteria for review include:

1. The candidate's potential for a career in independent research;
2. The candidate's commitment to a research career;
3. The eligibility of the candidate as defined in the program announcement;
4. The overall merit of the candidate's five-year plan for research and the development of research skills;
5. The quality of the candidate's clinical training and experience;
6. The institution's ability to provide quality facilities, resources, and opportunities necessary to the candidate's research development;

7. Presence of highly trained faculty in clinical and basic science departments relative to the area of study; and
8. The ability and plans of the sponsor (or sponsors) who will provide the candidate with the guidance necessary for career development in research.

#### VIII. NHLBI STAFF CONTACTS

Inquiries about the program should be directed to:

Research Training and Development Officer  
Division of Blood Diseases and Resources  
National Heart, Lung, and Blood Institute  
Federal Building - Room 514A  
Bethesda, Maryland 20205

Telephone: (301) 496-1817

Research Training and Development Officer  
Division of Heart and Vascular Diseases  
National Heart, Lung, and Blood Institute  
Federal Building - Room 3A-08  
Bethesda, Maryland 20205

Telephone: (301) 496-1724

Research Training and Development Officer  
Division of Lung Diseases  
National Heart, Lung, and Blood Institute  
Westwood Building - Room 6A-05  
Bethesda, Maryland 20205

Telephone: (301) 496-7668

Letters of reference, inquiries regarding review procedures, and 15 copies of the application should be directed to:

Dr. Carol Lentendre, Executive Secretary  
Research Manpower Review Committee  
National Heart, Lung, and Blood Institute  
Westwood Building - Room 550  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-7361

## ANNOUNCEMENT

### RESEARCH ON BENIGN PROSTATIC HYPERPLASIA

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

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) announces a continuing interest in basic and clinical research on Benign Prostatic Hyperplasia (BPH).

#### I. BACKGROUND

BPH is a condition characterized by excessive growth at the center of the prostate gland which reduces urine flow by direct obstruction and by altering the function of the outlet mechanism. Microscopic evidence of BPH has been seen as early as age 20, and may become symptomatic in about 45% of men by the age of 45. Estimates of the incidence of BPH vary between 80-100% in men over the age of 65. Morbidity and interference with daily functioning is appreciable. The disorder has been reported to occur more frequently, and about 10 years earlier in the black male. BPH may or may not be progressive, but has been noted to reoccur in 3-10 years following surgery in some patients. It is estimated that there is a 10% probability that a man of 40 will require prostatic surgery for BPH if he lives to be 80 years of age. The medical costs of BPH have been estimated to exceed one billion dollars per year.

#### II. OBJECTIVES AND SCOPE OF RESEARCH

The goals of research on BPH are to increase knowledge about the etiology of the stromal and epithelial proliferation, underlying mechanisms governing the distribution of the enlargement and the progression of the disease to determine if preventive measures and/or adequate medical alternatives to surgical treatment may be developed.

The research topics noted below are only examples and should not be construed as limiting scientific proposals to those areas of research. Some of the areas for continuing and for new research are listed below. Innovative research is needed and the list is by no means all-inclusive. Specific hormonal and biochemical events have been associated with abnormal growth of prostatic tissue both in the canine model of BPH and in man, and such studies are of continuing interest. Less well

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This program is described in the Catalog of Federal Domestic Assistance No. 13.849, Kidney Disease, Urology, and Hematology Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

explored has been the area of possible prostatic-growth factors in normal and/or abnormal prostate tissues, and how such factors might relate to the known hormonal-biochemical environment in BPH. Studies concerning agonists and antagonists to prostatic growth, pituitary contributions to prostatic growth or epithelial-stromal cell interactions are of importance. Studies of the physical factors influencing the position and distribution of the growing masses, especially in relation to the vesical neck mechanism are relevant, as are those concerning neuromuscular responses. In addition, basic controlled studies are needed on urodynamic parameters to detect early obstruction and monitor response to therapy. The NIADDK is interested in all innovative research concerning the onset, progression and treatment of BPH.

### III. MECHANISMS OF SUPPORT

Applications may be submitted for any of the conventional National Institutes of Health (NIH) grant support mechanisms. Appropriate application kits and information on applying for a research grant may be obtained from the institution's grant office, or by writing or calling:

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

Telephone: (301) 496-7441

When applying to the Division of Research Grants (DRG) the applicant should make specific note in item 2, Part 1 of the application, "Prepared in Response to the NIADDK Program Announcement: Research on Benign Prostatic Hyperplasia." A covering letter stating that the application is in response to this announcement also should be enclosed with the application. The original application and six copies should be mailed to:

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

A copy of the application with covering letter should be mailed to the NIADDK at the same time the proposal is submitted to the DRG. Applications will be reviewed for scientific merit by an appropriate initial review group in the DRG, NIADDK, depending on the support mechanism being sought. Review will be conducted in compliance with NIH policy and procedures involving peer review. Awards will be made on a competitive basis.

IV. INQUIRIES AND CORRESPONDENCE

Requests for information, letters of intent and copies of applications should be directed to:

Charles H. Rodgers, Ph.D.  
Urology Program Director  
National Institute of Arthritis, Diabetes,  
and Digestive and Kidney Diseases  
Westwood Building - Room 621  
5333 Westbard Avenue  
Bethesda, Maryland 20205

Telephone: (301) 496-7574

ANNOUNCEMENT

NOTICE OF AVAILABILITY OF REQUEST FOR

TRAINING GRANT APPLICATIONS: RFA

RFA-NIH-NLM-EP-83-1

HEALTH COMPUTER SCIENCES RESEARCH TRAINING

NATIONAL LIBRARY OF MEDICINE

Application Receipt Date: August 1, 1983

PURPOSE AND OBJECTIVES

The National Library of Medicine (NLM) has prepared a Request for Application (RFA) for training grant proposals in a single competition for postdoctoral research training in the health computer and information sciences. Such training will help meet a growing need for qualified talented investigators, well equipped to address fundamental issues in the management of health knowledge. These investigators will contribute to the growth of science by their studies of the role of knowledge in professional life, by analyses of social structures for managing this knowledge, and by advancing the frontiers of the computer sciences for organizing, retrieving, and utilizing health knowledge. It is also intended to foster the health computer sciences and health information sciences as a growing discipline with an appropriate place in academic medicine. It is expected that trainees will become able cross-disciplinary translators, taking the computer sciences to all of medicine.

It is expected that the core of training will emphasize the synthesis, organization, and effective utilization of knowledge. The curricula should be multidisciplinary--involving medicine, the cognitive sciences, information science, and computer science. It is intended to support programs at training sites which offer an excellent setting for didactic instruction, involvement in major, on-going health computer science studies, and opportunities for work in advanced information science research. It is expected that the training programs will therefore demonstrate an ability to recruit persons with high potential for academic research careers. The trainees should be recognized as potential scientific leaders, able to build new departments and strengthen existing ones. Trainees should leave the programs well versed in advanced mathematics, biostatistics, and methods of computational inference. Although candidates for training should be clearly destined for health research careers in this field, their doctorates may have been earned in any appropriate field of endeavor, such as medicine, dentistry, nursing,

This program is described in the Catalog of Federal Domestic Assistance, Medical Library Assistance No. 13.879. Grants will be awarded under the authority of the Public Health Service Act, Section 393 (42 USC 280b-4) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency review.

computer science, or any of the biological sciences. The objective is to sponsor the kind of training that can attract highly talented candidates from the most eminent universities and professional schools. Training sites should be academic medical centers, although consortium training arrangements with other graduate schools and institutions are encouraged. These grants will enable established investigators of national stature to attract the most promising junior scientists and future collaborators.

#### MECHANISM OF SUPPORT

Depending on the obligations required for the termination of currently active training programs, NLM plans to make available up to \$600,000 for new grants in this program in FY 1984. In addition, actual award of grants pursuant to this RFA is necessarily contingent upon receipt of appropriated funds for this purpose. However, it is expected that four to six training grants will be awarded in FY 1984 or possibly in early FY 1985. The specific number will also depend on the merit and scope of applications received, as well as the availability of funds.

These awards are authorized by the Medical Library Assistance Act and are not part of the National Research Service Awards Program of the PHS. However, the policies and requirements of the NLM program are similar to PHS NRSA's. Annual stipend levels for trainees are determined by the number of years of relevant postdoctoral experience at the time of appointment. Research experience, including industrial, teaching, internship, residency, etc., may be considered relevant experience. Interested applicants may refer to NRSA guidelines for allowable stipend levels, related trainee expenses, and institutional support costs.

#### STAFF CONTACT

Inquiries about the program and requests for copies of the RFA may be directed to program officials at:

Biomedical Information Support Branch  
Extramural Programs  
National Library of Medicine  
Bethesda, Maryland 20209

Telephone: 301 - 492-4221



NOTICE

PROGRAM PROJECT RESEARCH GRANT

APPLICATION (P01) SPECIAL DIRECTIVES

**NATIONAL INSTITUTE ON AGING**

The National Institute on Aging (NIA) announces special instructions for investigators submitting applications for Program Project Research Grants (P01s) which are likely to be assigned to NIA for support. These directives will apply to all new and competing program project applications submitted for the NIH-DRG application receipt date, June 1, 1983, and thereafter. This announcement supersedes the previous announcement issued in the NIH Guide for Grants and Contracts, Vol. 10, No. 11, October 9, 1981.

Program project grants are regarded by the National Institute on Aging (NIA) as a means for encouraging multidisciplinary or multifaceted approaches to the investigation of complex biomedical, behavioral and social problems of aging. A program project grant should be one in which such collaborative and cooperative research efforts accelerate the acquisition of knowledge more effectively than does a simple aggregate of research projects. There should be benefits in intellectual and scientific development, cost-effectiveness, and interdisciplinary innovation both to the investigators and to the NIA and which are not possible through other support mechanisms.

I. DEFINITION

A program project grant is a mechanism for the support of a broadly based research effort that has a well-defined, central research objective. The hallmark of a successful program project is an integrated research program where the interrelationship of individual scientifically meritorious projects will result in a greater contribution to the goals of the overall program than if each project were pursued individually. Responsibility for the goals, organization, administration and conduct of a program project lies with a principal investigator, who is usually an established investigator in the field. Each individual research component within the program project is under the leadership of a researcher with independent standing. Often, a program project will also include provisions for facilities such as administrative, clinical, laboratory, equipment, and/or animal cores, which are shared by more than one project within the program project as a whole.

II. DISTINGUISHING FEATURES OF A PROGRAM PROJECT

- A. It is expected that a substantial commitment of time and of institutional resources will be made by the applicants.
- B. The principal investigator must possess recognized scientific and administrative competence, a commitment to aging research, and must be prepared to exercise leadership in the maintenance of the quality of all proposed research.
- C. There must be a unified, well-defined goal or problem area of research to which each project relates and contributes, thereby producing a research environment that promotes interactions.

- D. There should be a clear rationale for and advantage from any proposed "cores" with a clearly defined outline of their relationship to each project.
- E. A mechanism for formalized interactions at regular intervals should be proposed, and provisions for collecting, pooling, analyzing and relating data from each project should be detailed.
- F. Each individual research project must, as assessed by peer review, both stand on its own scientific merit and complement other projects wherever feasible. Thus, a project regarded as highly meritorious in isolation might be recommended for deletion from the program if it is seen as being totally independent from the program as a whole. Conversely, a project recommended for approval with a low degree of enthusiasm nevertheless may be retained if it provides a service or is otherwise important to the program as a whole.
- G. The proposed research must meet a programmatic need in a priority area of interest. In keeping with the above, program projects ordinarily should be in the priority areas listed below, or as amended in future announcements. The Institute recognizes, however, that interdisciplinary research approaches relevant to the Institute's mission can and do arise outside areas defined by published announcements. In all cases the first action on the part of an investigator should be to communicate with an appropriate program official. Consultation in the development of a program project application is available from the following offices, depending on the subject matter of the proposed research:

Associate Director for Biomedical Research  
and Clinical Medicine  
National Institute on Aging  
Building 31 - Room 5C-11  
Bethesda, Maryland 20205

Telephone: (301) 496-4996

Associate Director for Behavioral Sciences  
Research  
National Institute on Aging  
Building 31 - Room 5C-05  
Bethesda, Maryland 20205

Telephone: (301) 496-3136

### III. PRIORITY AREAS IN BIOMEDICAL RESEARCH AND CLINICAL MEDICINE

#### A. General Programmatic Areas

1. Nutrition in relation to health of the aged and aging processes
2. Pharmacology
3. Gerontological and geriatric dermatology
4. Differentiated cells in culture for the study of age-related functional alterations
5. Senile dementia of the Alzheimer's type

6. Geriatric research, e.g., urinary incontinence, infectious diseases, epidemiological studies
7. Animal models of aging
8. Immunology
9. Exercise physiology as it affects age-related adaptation

- B. Teaching Nursing Home (TNH). See Program Announcement in NIH Guide to Grants and Contracts, Vol. 10, No. 12, November 6, 1981, for a descriptive overview of the research scope and content of TNH applications.

#### IV. PRIORITY AREAS IN BEHAVIORAL SCIENCES RESEARCH

- A. Studies in the maintenance and promotion of health and effective functioning in the middle and later years (e.g., specification of the psychosocial processes, interacting with biomedical processes, that can extend the productive middle years of life by preventing, postponing, or reversing current disabilities of old age. This includes such topics as work and retirement, health institutions, coping and social support, health behaviors and attitudes, family and household). See NIH Guide for Grants and Contracts, Vol. 10, No. 10, September 4, 1981.
- B. Cohort-longitudinal studies which serve as the data base for interdisciplinary research and potentially for secondary data analyses.

#### V. POLICY STATEMENT

The following policies shall apply to program project applications:

- o The resolution of issues regarding compliance with overall policy and procedures for program projects will be the responsibility of the NIA Associate Director for Planning and Extramural Affairs.
- o The total direct costs requested should not exceed \$500,000 for the first year, and the total for a five-year period should not exceed \$3,000,000. Budget increments for subsequent years may include some necessary cost-of-living increases.
- o The principal investigator must be in charge of at least one individual component research project or core other than the administrative core.
- o To be eligible for award as a program project, an approved application must contain a minimum of three research subprojects, including that of the principal investigator, in addition to any core projects.
- o Program projects submitted as proposals for TNH have additional requirements for interinstitutional collaborations and a limit of core expenses to \$125,000 per year. Prospective applicants for this award should consult the NIA TNH Announcement in the NIH Guide for Grants and Contracts, Vol. 10, No. 12, November 6, 1981. Copies may be obtained from the Associate Director for Biomedical Research and Clinical Medicine at the address above.

- o Initial applications may be submitted for up to a five-year period and can be renewed for a subsequent five-year period. The maximum total project period award is ten years. This limit shall be effective starting with the June 1, 1983, deadline.

## VI. APPLICATION PROCEDURES

All applicants are encouraged to communicate with NIA at least two months prior to preparation of a formal application through a "letter of intent" submitted by the prospective principal investigator. This letter of intent will assist NIA staff to determine whether the applications falls within the mission and research interests of the Institute and meets the criteria for a program project. It will also provide an opportunity for the applicant to consult with NIA staff.

The letter of intent should provide, in no more than three single-spaced, typewritten pages, the following information:

1. A statement highlighting the central theme and objectives of the proposed program project and discussing the rationale for use of the program project mechanism;
2. A brief description of each subproject including the name of the project director and a statement of how each specific subproject will contribute to the overall goal of the program project;
3. Brief biographical data for th principal investigator and key staff.

If the prospective applicant anticipates that the budget will exceed the cost limits cited above, this should be addressed in the letter of intent.

Letters of intent should be mailed to the Associate Director for Biomedical Research and Clinical Medicine Program or the Associate Director for Behavioral Sciences Research Program, NIA, depending on the primary emphasis of the proposed program project application.

At the same time, a copy of the letter of intent should be sent to the Scientific Review Office, Office of Planning and Extramural Affairs, NIA. (See next page for complete address.)

In response to the letter of intent, potential applicants will be contacted promptly by an Institute health scientist administrator who will be available for further consultation.

Applications should be prepared on form PHS 398 (Revised 5/82), which is available at most institutional business or research offices, or from the Division of Research Grants, NIH. On Page one, item two, type "PROGRAM PROJECT" on the application. "Teaching Nursing Home" should also be noted in this space, if appropriate. NIH-DRG receipt and review dates for a program project application are:

<u>Application Receipt Dates</u>	<u>Initial Review</u>	<u>Council Review</u>	<u>Earliest Beginning Dates</u>
February 1	June	September October	December 1
June 1	October November	January February	April 1
October 1	February March	May	July 1

The page limitations stated in PHS 398 kit instructions should be applied to the individual project descriptions, not to the entire program project application as a whole. Complete information, including budget, should be provided for each component project. In addition, overall program budgets (including core facilities where applicable) should be provided with the overview section of the proposal. The total program project application may not exceed 300 pages in length. Appendix materials should be kept to a minimum, and in no case should they exceed the length of the project that they support. Applications exceeding these limits may be returned to the applicant without review. NIA program staff should be consulted prior to submission if questions exist about the preparation of an application.

Several weeks prior to mailing, it is to the applicant's advantage to notify NIA program officials that a completed, formal application will be submitted.

Applications should be mailed to:

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

At the time the formal application is mailed to DRG, the applicant also should inform the Chief, Scientific Review Office, NIA, in writing, that his/her program project application has been submitted to DRG. The address is:

Scientific Review Office  
Office of Planning and Extramural Affairs  
National Institute on Aging  
Building 31 - Room 5C-06  
Bethesda, Maryland 20205

It would be desirable to include two copies of the application itself with the letter of notification.

## VII. REVIEW PROCEDURES AND CRITERIA

### A. Introduction

A grant application assigned as a program project to the NIA will be reviewed by an NIA Initial Review Committee (IRC) managed by the Scientific Review

Office, Office of Planning and Extramural Affairs. In addition to providing scientific merit review, the Committee ensures that all NIA program projects are evaluated in a uniform, consistent fashion.

The steps in the review process may include a project site visit to evaluate the overall merit of the application. However, all applications should be complete in themselves and should be prepared as if a site visit were not to be made. If a site visit is conducted, the project site visit team generally includes regular members of the IRC as well as other ad hoc consultants who have expertise in each area of the proposed program. Except in circumstances when the site visit team is a Special Review Committee, the report of the team is brought before and acted upon by the IRC. The final recommendation for all program project applications assigned to NIA is made by the National Advisory Council on Aging.

#### B. Review Criteria

The program project grant application should include a justification for the appropriateness of that support mechanism. Review criteria include evaluation of the following, not necessarily in order of importance.

- o The scientific merit of the program as a whole, as well as that of each individual project. Each project should be supportable on its own merit.
- o The significance of the overall program goals and the development of a well-defined central research focus of clear importance and relevance to the goals and mission of the NIA.
- o The cohesiveness and multidisciplinary or multifaceted scope of the program and the coordination and interrelationships among the individual projects and core(s). Also, the relationship of the core(s) to the central focus of the overall program.
- o The justification for and usefulness of the core facilities to the various research projects. Each core unit must provide essential facilities or services for two or more approved individual projects.
- o The leadership, scientific ability, and administrative competence of the principal investigator and his or her commitment and ability to devote substantial time and effort to the program.
- o The qualifications, experience, and commitment of the investigators responsible for the individual research projects or core(s) and their contribution to the program, including their ability to devote adequate time and effort to the program.
- o Accomplishments of the program to date (for renewal and supplemental grant applications).
- o The academic and physical environment in which the research will be conducted, including the availability of space, equipment, research subjects, and the potential for interaction with active scientists from other departments and/or institutions.

- o A sound administrative and organizational structure that facilitates attainment of the objective(s) of the program.
- o Arrangements for internal quality control of ongoing research, allocation of funds, day-to-day management, internal communications and cooperation among the investigators involved in the program, contractual agreements, and replacement of the principal investigator, if required, on an interim or permanent basis.
- o The institutional strength, stability, and commitment to research and to the program, including fiscal responsibility and management capability to assist the principal investigator and staff in following PHS policy.
- o The appropriateness of the period of support and budget requested in relation to the proposed program.
- o The ethical and hazardous aspects of the projects.

#### C. Review Committee Recommendation

The IRC will consider all of the above factors, and will vote a priority score for projects and budgets recommended for approval. In this regard, it is important to note that the judgment of the principal investigator in including marginal projects in an application will be an important consideration in arriving at an overall recommendation. It is to the applicant's advantage, therefore, to limit submission of projects to only those with the highest individual as well as collective merit.

#### D. Review by Council

The last step in this process is a final review action by the National Advisory Council on Aging. Factors considered in the review include:

- o The results of the initial review for scientific and technical merit;
- o The significance of the research program to the fields of gerontology and geriatrics;
- o National needs and program balance;
- o Policy and budgetary considerations; and
- o Program relevance to the goals and mission of the Institute.

NOTICEPUBLIC MEETING ON LABORATORY ANIMAL CARE AND USE

The National Research Council's Institute of Laboratory Animal Resources (ILAR) will hold an open meeting on May 17, 1983, beginning at 9:00 a.m., to receive statements from the public relevant to its preparation of a sixth edition of the Guide for the Care and Use of Laboratory Animals. The meeting will be held in the auditorium of the National Academy of Sciences, which is located in the 2100 block of "C" Street, N.W., Washington, D.C.

The revision of the "Guide" is being carried out under contract to the Academy from the National Institutes of Health by a 14-member Committee on Care and Use of Laboratory Animals, chaired by Dr. Steven P. Pakes of the University of Texas Health Sciences Center, Dallas, Texas.

Oral presentations must be scheduled by the ILAR office and will be limited to five minutes each in order to accommodate as many speakers as possible, while allowing the committee ample time for questions. Each oral presentation should be accompanied by a written statement, which may be of any length. Twenty (20) copies of the written statement should be provided to the Committee at the meeting. To request scheduling write to:

Dr. Earl W. Grogan  
ILAR, National Research Council  
2101 Constitution Avenue, N.W.  
Washington, D.C. 20418

Requests must be received on or before April 29, 1983. Written statements from those who do not speak at or who do not attend the public meeting will be accepted any time at the above address. All statements will be made available to the Committee.

Two additional regional public meetings are planned, one in the mid-west, and one on the west coast. Public announcements will be made for these meetings when the locations and schedules are selected.

Parking for meeting participants is not available at the Academy building.