

NIH GUIDE

for GRANTS and CONTRACTS

JAN 08 REC'D

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

Vol. 9, No. 1, January 3, 1980

IN THIS ISSUE:

SPECIAL NOTICE

OUTBREAK OF ECTROMELIA (MOUSE POX)

Page 1

REPRINTING OF STATEMENT OF APPOINTMENT
OF TRAINEE FORMS (PHS 2271, REV. 8/78)

Page 3

Index: DRG

NHLBI POLICY AND GUIDELINES FOR INVESTIGATOR-
INITIATED COLLABORATIVE CLINICAL TRIALS

Page 5

Index: NHLBI

STUDIES OF DIABETES MELLITUS AND RELATED PROBLEMS
NEI, NHLBI, NIAID, NIAMDD, NICHD, NIDR, NIEHS,
NINCDS, NIA

Page 7

Application receipt dates: March 1, July 1,
and November 1.

Index: Trans-NIH

THE EPIDEMIOLOGY OF DIABETES
NEI, NHLBI, NIAMDD, NICHD, NIDR,
NINCDS, NIA

Page 19

Application receipt dates: See page 23

Index: Trans-NIH

PULMONARY ACADEMIC AWARD, NHLBI

Application receipt date: April 1, 1980

Page 27

Index: NHLBI

(over)

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 B3B10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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

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

IN THIS ISSUE: (continued)

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA
NIH-NHLBI-DLD-80G-B, NHLBI

Page 29

SPECIALIZED CENTERS OF RESEARCH

in

Chronic Obstructive Lung Diseases

Pediatric Pulmonary Diseases

Fibrotic and Immunologic Interstitial Lung Diseases

Pulmonary Vascular Diseases

Application receipt date, September 15, 1980.

Index: NHLBI

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA
NIH-NHLBI-DLD-80G-C, NHLBI

Page 37

NUTRITIONAL STATUS AND NONRESPIRATORY LUNG INFECTION

Application receipt date, March 14, 1980.

Index: NHLBI

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA
NIH-NHLBI-DHVD-80G-D, NHLBI

Page 43

SPECIALIZED CENTERS FOR RESEARCH ON ARTERIOSCLEROSIS

Application receipt date, September 2, 1980.

Index: NHLBI

SMOKING, CANCER AND HEALTH PROGRAM
NATIONAL CANCER INSTITUTE

Page 53

Application receipt dates: investigator initiated grants - March 1, July 1, and November; renewal grants - February 1, June 1, and October 1.

Index: NCI

DIET, NUTRITION, AND CANCER PROGRAM ANNOUNCEMENT
OF RESEARCH INTERESTS IN ALCOHOL AND CANCER
NATIONAL CANCER INSTITUTE

Page 59

Application receipt dates: March 1, 1980, July 1, 1980, and November 1, 1980

PREVENTIVE ONCOLOGY ACADEMIC AWARD
NATIONAL CANCER INSTITUTE

Page 63

Application receipt date, March 1, 1980.

Index: NCI

NEW INVESTIGATOR RESEARCH AWARD (NIRA)

Application receipt dates: November 1, March 1, and July 1.

Page 67

Index: Trans-NIH

PROGRAM INFORMATION

NIH awarding units may use the NIRA to emphasize areas of investigation that are perceived to need special emphasis. Therefore, any proposal that does not fall within one of the listed areas will be returned. It is suggested that potential applicants contact one of the individuals listed below prior to submitting an application.

NIA: Research programs on aging support studies on the biological processes of aging at the cellular, tissue, body system and whole organism level; clinical research on the medical problems and diseases of the aged; and the social, cultural, economic and psychological factors affecting both the aging process and the status of older people in society.

Dr. Don Gibson
National Institute on Aging
Building 31, Room 5C06
(301) 496-5398

NIAID: Research with clinical relevance in virology, immunology, mycology and tropical diseases.

Dr. William I. Gay
National Institute for Allergy
and Infectious Diseases
Westwood Building, Room 703
(301) 496-7291

NIAMDD: Research in the following program areas: diabetes, endocrinology, metabolism, digestive diseases, liver diseases, pancreatic diseases, nutrition, hematology, renal physiology, renal pathophysiology, urology and chronic renal diseases.

Dr. George Brooks
National Institute of Arthritis,
Metabolism, and Digestive Diseases
Westwood Building, Room 655
(301) 496-7277

NCI: Research in cancer etiology, prevention, detection, diagnosis, treatment, restorative care and cancer biology.

Dr. Thomas J. King
National Cancer Institute
Building 31, Room 10A03
(301) 496-5147

NICHD: Research relating to: Mothers and children (including pregnancy and infancy, developmental biology and nutrition, mental retardation, child and adolescent development); and Population (including reproduction, fertility-infertility, fertility control, social and behavioral aspects of reproduction, population change), with special interest in the social and behavioral aspects of population research.

Dr. Betty Pickett
National Institute of Child Health
and Human Development
Building 31, Room 2A04
(301) 496-1848

NIDR: Research in cariology, mineralization, craniofacial anomalies, nutrition, dental pain control, periodontal diseases, restorative materials, salivary secretions, soft tissue diseases and selected behavioral studies.

Dr. George Hausch
National Institute of Dental Research
Westwood Building, Room 509
(301) 496-7748

NIEHS: Research in the general areas of epidemiology, identification of environmental hazards, development of test methods for risk assessment, pollutant pharmacokinetics in both the body and the external environment, and molecular and cellular mechanisms of damage. Special emphasis areas include physical factors, and, in particular, ionizing and non-ionizing irradiation; the effects of environmental agents on the endocrine system, digestion and nutrition; the synergistic and additive effects of smoking; the effects of environmental agents upon the immune system; and the development of rapid, reliable and inexpensive tests for toxicity.

Dr. Edward Gardner
National Institute of Environmental
Health Sciences*
Research Triangle Park, NC 27709
(919) 672-4019

NEI: Research related to vision and disorders of the visual system: retinal, choroidal and corneal diseases, cataract, glaucoma, sensory and motor disorders and rehabilitation.

Dr. Ronald Geller
National Eye Institute
Building 31, Room 6A04
(301) 496-4903

NIGMS: Research in anesthesiology, trauma and burns.

Dr. Elizabeth O'Hern
National Institute of General
Medical Sciences
Westwood Building, Room 952
(301) 496-7001

NHLBI: Research in areas related to heart, vascular, lung and blood diseases and blood resources.

Dr. Jerome Green
National Heart, Lung, and Blood
Institute
Westwood Building, Room 7A17
(301) 496-7416

NLM: Research in information science for representation of medical knowledge and its application to the health care system. Studies using computer based systems for information retrieval and application to actual problems confronting the health professional. Research in new methods of classifying, indexing and abstracting information for the organization of biomedical knowledge. Greater research in user needs and behavior and the properties of the user/system interface.

Dr. Roger Dahlen
National Library of Medicine
Federal Building, Room 902
(301) 496-4221

NINCDS: Research in basic and clinical neurosciences and in basic and clinical communicative sciences.

Dr. John Dalton
National Institute of Neurological and
Communicative Disorders and Stroke
Federal Building, Room 1016A
(301) 496-9248

DRR: Research in the following technological areas: computer science applications in medicine, biomedical engineering, nuclear magnetic resonance, electron spin resonance, electron microscopy or biomedical kinetics. Research in laboratory animal sciences related to etiology, pathogenesis and control of laboratory animal diseases and environmental requirements of laboratory animals. Studies directed toward finding animal models of human disease.

Dr. James O'Donnell
Division of Research Resources
Building 31, Room 5B03
(301) 496-6023

*Except as noted for NIEHS all Institutes are located in Bethesda, MD 20205



OUTBREAK OF ECTROMELIA (MOUSE POX)

*
* Ectromelia (mouse pox) has recently been identified *
* in a colony of mice housed at the NIH campus in *
* Bethesda. Subsequent investigations revealed that *
* the disease is present in at least one contract *
* laboratory that has exchanged mice or their tissues *
* with the affected NIH laboratory. Mice obtained *
* directly from NIH veterinary resources colonies are *
* not infected. While ectromelia does not represent a *
* hazard to man, it is a widely feared disease in *
* laboratory mice. In susceptible colonies, it can *
* spread rapidly and be highly fatal. *
*
* Attempts are being made to alert those institutions *
* by direct contact that are known to have received *
* suspect animals or materials. In addition, NIH has *
* identified principal investigators believed to be *
* utilizing mice in their studies and has alerted *
* them directly. *
*
* The experience at NIH suggests that research institu- *
* tions should not assume that their mouse colonies are *
* free of ectromelia without definite proof. *
*
* Individuals desiring additional information about *
* ectromelia should contact: *
*
* Albert E. New, DVM *
* Director, Laboratory of Animal Science, *
* OD, NCI, NIH *
* 9000 Rockville Pike *
* Bethesda, Maryland 20205 *
*
* Telephone: (301) 496-1866 *
*

REPRINTING OF STATEMENT OF APPOINTMENT

OF TRAINEE FORMS (PHS 2271, REV. 8/78)

DIVISION OF RESEARCH GRANTS

NOTICE

The first printing of the 8/78 revision of the Statement of Appointment of Trainee Form (PHS 2271) has an alignment problem involving the DRG Statistical Copy. The second printing of the 8/78 revision is now available and should be used for all trainee appointments. Program Directors should request copies from their PHS awarding components. Central offices should request copies from the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205.

The first printing, which can be identified by (1) the instructions stapled to the form, and (2) the copy distribution identification on the bottom of such pages in black letters, should be destroyed. The instructions on the second printing are an integral part of the form and the copy identification lettering is in red.

NHLBI POLICY AND GUIDELINES FOR INVESTIGATOR-INITIATED

COLLABORATIVE CLINICAL TRIALS

The existence and availability of a "National Heart, Lung, and Blood Institute Policy and Guidelines for Investigator-Initiated Collaborative Clinical Trials" is announced.

This document is not a solicitation or a program announcement seeking collaborative clinical trials. It is a document which summarizes the policies and guidelines of NHLBI to aid potential applicants. Copies are available from:

Executive Secretary
Clinical Trials Review Committee
Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Room 548, Westwood Building
National Institutes of Health
Bethesda, Maryland 20205

ANNOUNCEMENT

STUDIES OF DIABETES MELLITUS AND RELATED PROBLEMS

NATIONAL EYE INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE OF ALLERGY AND
INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM
AND DIGESTIVE DISEASES
NATIONAL INSTITUTE OF CHILD HEALTH AND
HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF DENTAL RESEARCH
NATIONAL INSTITUTE OF ENVIRONMENTAL
HEALTH SCIENCES
NATIONAL INSTITUTE OF NEUROLOGICAL AND
COMMUNICATIVE DISORDERS AND STROKE
NATIONAL INSTITUTE ON AGING

The above-named Institutes of the National Institutes of Health invite applications for research grants in the general area of diabetes mellitus and related problems. Investigators working in other areas of research are particularly encouraged to develop diabetes-related projects either independently or, where appropriate, in collaboration with individuals currently engaged in diabetes research.

I. PROGRAM SPECIFICATIONS

A. Program Objectives

Diabetes mellitus and its complications are major public health problems in the United States today. In recognition of this, the National Commission on Diabetes recommended an expanded national research effort in basic and clinical research into the cause, cure and prevention of diabetes mellitus and related endocrinologic and metabolic disorders.

B. Research Scope

The emphasis of this solicitation is upon research in both diabetes and diabetes-related activities. Activities identified

as being related to diabetes generally fall into one of the following categories:

1. projects directly concerned with diabetes;
2. projects directly concerned with diabetes-related endocrine, metabolic, or vascular disorders;
3. projects directly concerned with the prevention, etiology, natural history, or treatment of disorders caused by diabetes, within specific organ systems; and
4. projects which are not directly concerned with diabetes but which could reasonably be expected to contribute new knowledge relative to the prevention, diagnosis, or cure of diabetes or a diabetes-associated disorder.

Some areas of current research interest are listed below. They are not listed in any order of priority. Moreover, these are examples only; other areas of research may occur to the applicant which are related to diabetes and which would be appropriate to the scope described above:

1. AGING - Research on the effects of age on the etiology, epidemiology, and pathogenesis of non-insulin-dependent diabetes. Studies that examine the interrelationship of the physiological change with age and diabetes on the mechanism of hormone release and action; the effects on body composition, nutrition, and physical activity; standards for diagnosis; and the special problems of complications and treatment of diabetes in the geriatric population are also appropriate.
2. ANIMAL MODELS - Studies which develop or utilize spontaneous or induced animal models of insulin-dependent or noninsulin dependent diabetes (including the role of obesity and insulin resistance in the latter type), and which are directed toward elucidating the etiopathology of these disorders or their complications.
3. DENTAL COMPLICATIONS - Studies on the dental complications of the chronic diabetic syndrome, especially on the increased susceptibility of diabetics to periodontal disease. Such studies may focus on alterations in white cell functions (chemotaxis and phagocytosis), in the oral flora, in the immune response, or in collagen metabolism. Studies on the incidence of cleft palate in offspring of diabetic mothers, and research to develop artificial sugar substitutes for dietary control of tooth decay and diabetes are also appropriate.
4. DIAGNOSIS - Research into the development of new or improved techniques for establishing the diagnosis of diabetes and of the specific complications of diabetes, including the development of satisfactory

and reliable genetic, enzymatic, biochemical, or other markers of the various types of diabetes. Studies to replicate and further refine the association of the chlorpropamide-alcohol flush reaction with noninsulin-dependent diabetes. Studies to investigate the validity of the new "Classification and Diagnosis of Diabetes Mellitus" (see Diabetes, December 1979).

5. ENVIRONMENTAL FACTORS - Acute and chronic toxicological effects of environmental chemicals on the pancreas with reference to acinar cell cytotoxicity; islet cell cytotoxicity; effects leading to duct obstruction; and cancer induction. Studies on the basic mechanisms of toxic injury to pancreatic cells using animal models. Development of more sensitive and specific methods to detect "subclinical" degrees of acute acinar cell injury and focal duct obstruction. Studies concerning population groups who may be at risk from exposures to known pancreatotoxic agents and prospective studies to detect glycosuria or abnormal glucose tolerance in human populations considered to be at risk for exposure to any toxic agents suspected of affecting islet cells.
6. EPIDEMIOLOGY - Epidemiologic studies of the various types of diabetes (insulin-dependent, noninsulin-dependent, gestational, secondary to other conditions, etc.) or of impaired glucose tolerance in discrete populations that can be well-characterized as to their glucose tolerance and those factors which may be associated with the development of diabetes, such as demographic, nutritional, environmental, genetic, prenatal, immunologic, infections, or other etiologic factors. Such population groups might include discordant twins, sibs of diabetics, communities, migrant groups, specific racial or ethnic groups, or case/control studies. Other studies are epidemiologic approaches to the natural history of the various types of differences between population groups in the frequency of development and extent of the complications of diabetes, including cardiovascular, renal, neurologic, ocular, dental, and pregnancy complications; analysis of secular trends and geographic clustering of diabetes as an underlying and contributing cause of death.
7. ETIOLOGY, NATURAL HISTORY, PATHOGENESIS - Studies of the nature, etiology, and pathogenesis of the several types of diabetes mellitus and their "complications". Such studies may be approached from any discipline appropriate to basic research, clinical investigation, or epidemiologic studies.

8. GENETIC FACTORS - Research into the role of genetic factors in diabetes mellitus, including identification of genetic markers which characterize individuals who have predisposing genes for diabetes or for specific complications of diabetes, and definition of the mechanisms by which the genes associated with these loci express themselves. Such studies could consider the unique genetic characters of insulin-dependent and noninsulin-dependent diabetes.
9. GLUCOSE HOMEOSTASIS - Studies of factors that influence glucose tolerance and related hormone secretion and action, including age, body weight, nutrition, and physical activity, to name but a few. Clinical, metabolic, nutritional, and epidemiologic studies all offer appropriate approaches.
10. HORMONE SYNTHESIS AND SECRETION - Basic and clinical studies of normal and abnormal mechanisms of biosynthesis and secretion of insulin, glucagon, and other hormones as they relate to diabetes mellitus including studies in applicable areas of biochemistry, cell and molecular biology, genetics, immunogenetics, cellular immunology and virology; investigations of membrane structure, function and biogenesis; studies on the biosynthesis of peptide hormones and of the processing mechanisms and enzymes involved in the conversion of their precursor forms; research to examine all levels and processes involved in insulin production including beta cell differentiation, replication and regeneration, as well as the steps involved in the readout of the genes for insulin via transcription and translation, and the effects of agents such as glucose, other nutrients, hormones and growth factors on all of these processes.
11. IMMUNOLOGY, VIRUSES - Assessment of the role of viruses in the etiology of insulin-dependent diabetes, including investigation of their mechanism(s) of action and the host-parasite relationship determining their diabetogenic action, including further work on animal models of viral etiology. Assessment of the role of the immune response in the etiology of both insulin-dependent and non-insulin dependent diabetes mellitus is appropriate. Studies of immunologic aspects in pathogenesis or complications of treatment such as autoimmune processes, Ir gene control of anti-insulin antibodies, mechanisms of insulin resistance, tolerance, and allergic reactivity are also appropriate.

12. INFANTS OF DIABETIC MOTHERS - Developmental studies of intermediary metabolism and the control of hormonal synthesis, release and interaction in infants of insulin-dependent, non-insulin dependent, or gestational diabetics and nondiabetic women.
13. MECHANISM OF HORMONE ACTION - Basic and clinical studies of the mechanism of hormone action as it relates to diabetes including studies of insulin, insulin co-factors, insulin receptors, and glucagon. Other hormones such as somatostatin, somatomedin, growth hormones and factors, and catecholamines may be included, but only as they relate to diabetes as defined above. Investigation of the integrated reaction of these hormones and the regulation of metabolic processes is appropriate. Studies involving production of defined or single component insulin by such means as biochemical fractionation or recombinant DNA are also appropriate.
14. METABOLIC REGULATION - Studies of normal and abnormal metabolic regulation as they relate to diabetes mellitus and its complications.
15. NEUROLOGICAL COMPLICATIONS - Studies including physiological, biochemical, morphologic, and morphometric analysis of nerves from diabetics. Information of the type and distribution of lesions in the various forms of human diabetic neuropathy is needed and expected to offer insight into possible metabolic, vascular, or immunologic injuries. Data on vascular permeability, endoneurial pressure, axoplasmic flow and myelin composition may be obtained in experimental animals (genetic, surgical, alloxan, and streptozotocin diabetes) and correlated with physiologic and biochemical findings. Morphologic, biochemical, and physiological investigations of the structure and functions of peripheral nerves in organ cultures subjected to conditions similar to those occurring in diabetics are also appropriate. These may be expected to help define the roles of insulin, glucose, sorbitol, and myoinositol on myelination, Schwann and nerve cell metabolism.
16. NUTRITION, OBESITY - Research into the relationship between nutrition and diabetes, including the relationship between noninsulin-dependent diabetes, exercise, obesity, and insulin resistance. Such studies may focus on nutrition in early life as well as in the adult. Studies of feeding patterns in infancy and childhood are sought as well as research on the development of appetite, tastes, and dietary habits as antecedents to the development of obesity, insulin resistance, and diabetes mellitus. In addition, research into the central and peripheral regulation of appetite and feeding behavior within the context of diabetes, obesity, and insulin resistance is also appropriate.

17. OCULAR COMPLICATIONS - The eye is a particularly appropriate model for studying the pathology and manifestations of micro-angiopathy which are frequently associated with diabetes; e.g., diabetic retinopathy. Characterizing the blood-retinal barriers, determining the etiology of neovascularization and developing non-invasive techniques for measuring blood flow are highly relevant areas of research, as are clinical trials employing new treatment modalities for diabetic retinopathy. Research related to the role of metabolic agents in the etiology and management of diabetic cataract is also appropriate.
18. PREGNANCY AND DIABETES - Research into the effects of pregnancy and parity on glucose tolerance and the development of gestational diabetes and studies on all types of diabetes in pregnancy, including functional definition of optimal diabetic control throughout pregnancy are appropriate. Studies of the pathophysiologic mechanisms which contribute to abnormalities of the infants of diabetic mothers such as congenital malformations, stillbirths, neonatal deaths, and perinatal complications are also appropriate, as are studies on the role of prenatal and perinatal factors in the development of insulin-dependent diabetes in the offspring.
19. PSYCHO-SOCIAL ASPECTS - Studies of the emotional and psycho-social factors associated with diabetes and its complications which may influence the course of the disease, and identification of approaches aimed at modifying the impact of these factors on the diabetic patient, the family unit, and the community.
20. RENAL COMPLICATIONS - Research relating to diabetic nephropathy, including the impact of diabetic control on the rate of development of diabetic kidney lesions; the role of altered renal physiology, hormonal and effector systems in the development of diabetic nephropathy; effects of early intervention with antihypertensive treatment on the progression of renal failure in diabetes; further studies of basement membrane biochemistry; the natural history of nephropathy in non-insulin dependent diabetes; development and evaluation of animal models of diabetic nephropathy; and studies of end stage diabetic nephropathy in man.
21. TRANSPLANTATION, ARTIFICIAL DEVICES - Research approaches to transplantation of the pancreas or pancreatic islets (including special requirements and techniques for tissue matching, development, and monitoring of islet antibody) and development of "closed-loop" devices which both monitor plasma glucose and administer insulin appropriately.

22. TREATMENT - Clinical studies utilizing various modalities to treat diabetes mellitus and its complications including surgical and medical management of the sequelae of diabetes; studies of the complications of diabetes resulting from treatment, such as the exaggerated immune responsiveness to insulin and infections in immuno-compromised or otherwise normal diabetes and the effects of ocular surgery on visual function and the development of neo-vascular glaucoma are also appropriate.
23. VASCULAR COMPLICATIONS - Studies of the nature, epidemiology, etiology, pathogenesis or complications of atherosclerosis as they may relate to or be affected by diabetes or glucose intolerance in men and/or women. Studies of normal and abnormal cardiac phenomena as affected by or induced by diabetes or glucose intolerance in humans or in models of the diabetic state in experimental animals. Studies of macro- and microvascular disease in diabetes that may contribute to a better understanding of the epidemiology, etiology, and pathogenesis of peripheral vascular disease, gangrene of the lower limb and cerebrovascular disease among diabetics. Studies of the interactions in some individuals of carbohydrate intolerance, hypertriglyceridemia, adiposity, hypertension, and vascular disease. Studies utilizing spontaneous or induced models of diabetes in animals directed toward elucidating micro- or macrovascular circulatory disease or its complications. Studies relating to the rheology and coagulation of platelets in the diabetic state. Studies relevant to diabetes and infant respiratory distress syndrome are also appropriate.

C. 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 will prevail. The award of grants pursuant to this Program Announcement is contingent upon receipt of appropriated funds for this purpose.

II. METHOD AND CRITERIA OF REVIEW

A. Assignment of Applications

Applications will be received by the NIH Division of Research Grants, referred to an appropriate Study Section 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 Division of Research Grants.

B. Review Procedures

Applications in response to this solicitation will be reviewed on a nation-wide basis in competition with other research grant applications, and in accord with the usual National Institutes of Health peer review procedures. Applications will first be reviewed for scientific and technical merit by a review group composed mostly of non-federal scientific consultants (Study Section), and then by the National Advisory Council of the appropriate Institute(s). The review criteria customarily employed by the National Institutes of Health for regular research grant applications will prevail.

C. Deadline

Applications will be accepted in accordance with the usual NIH receipt dates for new applications as follows:

<u>APPLICATION RECEIPT</u>	<u>INITIAL REVIEW</u>	<u>COUNCIL REVIEW</u>	<u>EARLIEST START DATE</u>
March 1	June	Sept./Oct.	Dec. 1
July 1	Oct./Nov.	Jan./Feb.*	April 1*
Nov. 1	Feb./March*	May*	July 1

*of the year following application receipt.

III. METHOD OF APPLYING

Applications should be submitted on form PHS 398, which is available in the business or grants and contracts office at most academic and research institutions. The phrase "PREPARED IN RESPONSE TO NIH DIABETES PROGRAM ANNOUNCEMENT" should be typed across the top of the first page of the application.

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

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

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

National Eye Institute

Chief, Retinal and Choroidal Disorders Branch
NEI
Room 6A52, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-5983

National Heart, Lung and Blood Institute

Associate Director
Etiology of Arteriosclerosis, Hypertension
and Lipid Metabolism Program
Division of Heart and Vascular Diseases
NHLBI
Room 412C, Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-1613

National Institute of Allergy and Infectious Diseases

Chief, Epidemiology Biometry Branch
NIAID
Room 739, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7067

National Institute of Arthritis, Metabolism and Digestive Diseases

Diabetes Research Program Director
NIAMDD-DEMD
Room 605, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7731

Chief, Diabetes Programs Branch
NIAMDD-DEMD
Room 626, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7348

National Institute of Child Health and Human Development

Chief
Developmental Biology and Nutrition
Branch
NICHD
Room 7C17, Landow Building
Bethesda, Maryland 20205

Telephone: (301) 496-5575

National Institute of Dental Research

Special Assistant for Program Coordination
NIDR Extramural Programs
Room 509B, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7748

National Institute of Environmental Health Sciences

Associate Director for Extramural Program, NIEHS
Room 4B31, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-3511

National Institute of Neurological and Communicative Disorders and Stroke

Health Scientist Administrator
for Peripheral Neuropathies
Neurological Disorders Program
NINCDS Extramural Programs
Room 710, Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-1431

National Institute on Aging

Chief
Molecular and Biochemical Gerontology Program
Extramural and Collaborative Research Program
NIA
Room 5C23, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-9350

THE EPIDEMIOLOGY OF DIABETES

ANNOUNCEMENT

NATIONAL EYE INSTITUTE
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE
NATIONAL INSTITUTE OF ALLERGY AND
INFECTIOUS DISEASES
NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM,
AND DIGESTIVE DISEASES
NATIONAL INSTITUTE OF CHILD HEALTH AND
HUMAN DEVELOPMENT
NATIONAL INSTITUTE OF DENTAL RESEARCH
NATIONAL INSTITUTE OF NEUROLOGICAL AND
COMMUNICATIVE DISORDERS AND STROKE
NATIONAL INSTITUTE ON AGING

Research Grants
Individual National Research Service Awards
Special Emphasis Research Career Awards
Research Career Development Awards
New Investigator Research Awards
Academic Investigator Awards
Clinical Investigator Awards

Diabetes mellitus is a major public health problem in the United States today. Approximately 5 million Americans are known to have the disease, and it is estimated that an equal number are undiagnosed or will develop diabetes. It is the fifth leading cause of death by disease, accounting for 35,000 deaths each year and is a contributory factor in at least another 90,000 deaths annually. Diabetes is a major risk factor for the development of cardiovascular disease and a prime cause of end stage renal failure. Blindness is 25 times more common in the diabetic than in the nondiabetic population. About 0.5 million women in their child-bearing years are diabetic, and perinatal losses in their pregnancies are five times higher than in normal pregnancies; congenital abnormalities are three times the expected rate. Diabetes is a leading cause of visits to physicians, hospitalizations, and disability in the United States.

Despite the enormity of the public health impact of diabetes and considerable research on diabetes, our ability to prevent or control the disease is unsatisfactory. The etiologies of the various types of diabetes remain unknown, although genetic, immunologic, virologic, and nutritional hypotheses have been invoked. In addition, reliable quantitative data on the extent and nature of each type of diabetes in discrete populations, and the factors which contribute to the development of complications in various subgroups, is lacking.

In order to fully address these and related issues in diabetes, epidemiologic research is needed to complement the ongoing clinical and basic research sponsored by the NIH. In recognition of this, the above-named Institutes invite applications for research grants and individual

National Research Service Awards in the epidemiology of diabetes and its complications. In addition, certain Institutes solicit applications for Special Emphasis Research Career Awards, New Investigator Research Awards, and Academic Investigator Awards. The award of grants pursuant to this program announcement is contingent upon receipt of appropriated funds for this purpose.

RESEARCH GRANTS

Many needs and opportunities for epidemiologic research exist in diabetes. Among these are studies on the etiology of the various types of diabetes (insulin-dependent, noninsulin-dependent, gestational, drug-induced, secondary to other conditions, etc.) or of impaired glucose tolerance in discrete population groups that can be well-characterized as to their glucose tolerance and factors which may be associated with the development of diabetes, such as demographic, nutritional, environmental, prenatal, immunologic, infectious, or other etiologic factors. Such population groups might include discordant twins, sibs of diabetics, communities, migrant groups, specific racial or ethnic groups, or case/control studies. Other studies include: epidemiologic approaches to the natural history of the various types of diabetes; assessment of risk factors for each type; the causes of differences between populations and groups in the frequency of development and extent of the complications of diabetes, including cardiovascular, renal, neurologic, ocular, dental, and pregnancy complications; epidemiologic assessment of the relationship between obesity and noninsulin-dependent diabetes; assessment of changes of glucose tolerance with aging; the relationship of gestational diabetes to subsequent overt diabetes; the relationship of diabetes to the loss of teeth through periodontal disease; secular trends and geographic clustering of diabetes as an underlying and a contributing cause of death by age, race, and sex; evaluation of the socioeconomic costs of diabetes and its complications; and the problems of patient compliance in this chronic disease. These are only a few of the areas where epidemiologic investigations are needed; they are not meant to be restrictive and are cited for illustrative purposes only. Research that utilizes or builds on existing population-based or clinic-based data sets, where diabetes or glucose tolerance can be well-defined, is particularly encouraged. Such data sets would include those associated with studies on diabetes or other diseases, the second Health and Nutrition Examination Survey of the National Center for Health Statistics (which contains glucose tolerance data on over 7,000 individuals), and the Health Interview Surveys of NCHS.

INDIVIDUAL NATIONAL RESEARCH SERVICE AWARDS (postdoctoral fellowships)

These awards are made to individuals, for the support of full-time research training, who have completed the requirements for the M.D., Ph.D., D.D.S., or equivalent degree by the time of the award. Applicants must be citizens or noncitizen nationals of the U.S. or have been admitted to the U.S. for permanent residence. They must have arranged for an appointment at a U.S. or foreign nonprofit private or public

institution and have been accepted by a sponsor who will supervise their training and research experience. Individuals trained in epidemiology are particularly encouraged to consider further research training at an institution which has a well-established clinical program in diabetes and/or its complications. Conversely, individuals trained in diabetes-related clinical areas are encouraged to apply for postdoctoral fellowship support to obtain research experience in epidemiologic methods which can be applied to diabetes and its complications.

SPECIAL EMPHASIS RESEARCH CAREER AWARD

These awards, which provide both salary support and funds for the conduct of research, are specifically designed to provide qualified clinicians with the opportunity to develop research skills in either the cardiovascular, metabolic, and endocrinologic aspects of diabetes or the obstetrical, perinatal, and pediatric aspects of diabetes. For the first three years, the recipient is expected to develop capabilities in fundamental, applied, or clinical research. This training should include exposure to multiple disciplines, which may include epidemiology. During the fourth and fifth years, the recipient is expected to initiate and implement a research program of his/her own design, which may be epidemiologic in nature. These awards are funded jointly by NIAMDD with either the NHLBI or the NICHD and applications that include epidemiologic components in the training and research phases of the award are welcomed.

Candidates for the SERCA Award must (1) hold an M.D. or equivalent professional degree (e.g. D.D.S., D.O., D.V.M., etc.); (2) have a minimum of three years post-M.D. experience, including one year of clinical training in the subspecialties of either cardiovascular disease/endocrinology/metabolism or obstetrics/pediatrics, or two years post-M.D./Ph.D. experience or equivalent. M.D./Ph.D. applicants should possess significant experience in metabolic, endocrine, or related areas, cardiovascular or pediatric physiology, obstetrics, biochemistry, pharmacology, or other relevant areas of interest, such as epidemiology; (3) be citizens or noncitizen nationals of the United States or its possessions or territories or must have been lawfully admitted to the U.S. for permanent residence at the time of application; (4) meet certain other eligibility requirements specified in the SERCA Program Guidelines.

RESEARCH CAREER DEVELOPMENT AWARD

This award is a special 5-year salary grant of up to \$30,000 per year to support individuals who have demonstrated outstanding potential for contributing as independent investigators to health-related research. The awards are designed for persons whose research potential is apparent but who need additional experience in a productive scientific environment conducive to the development of a career in independent research. The award is not intended for the untried investigator (see New Investigator Research Award, below) nor for those who are well established as independent investigators. Individuals who receive salaries from an RCDA are expected to devote essentially full time to research and research-related activities.

NEW INVESTIGATOR RESEARCH AWARD

This award provides three years of research grant support for studies on diabetes and related areas for the initial independent research efforts of new investigators. The applicant must have been awarded a M.D., Ph.D., or equivalent degree by the time of the award; present evidence of at least two years of prior research experience; not have been named as the principal investigator or other primary recipient of a federally-supported research grant or contract (except a pre- or postdoctoral fellowship or traineeship); meet certain U.S. citizenship or residence requirements.

NEI ACADEMIC INVESTIGATOR AWARD

This award is designed to facilitate the development of academic faculty in clinical or laboratory sciences related to diseases of the eye and the visual system. To be eligible, applicants must: (1) be citizens or non-citizen nationals of the U.S., or have been admitted for permanent residence, (2) have the M.D., Ph.D., O.D., DVM, or equivalent degree in addition to three to seven years of post-doctoral research training, (3) be nominated by the institution in which the candidate holds an academic appointment. Applications receive initial merit review by the Vision Research Program Committee. Awards are made on an annual basis and are renewable for a period up to two years.

CLINICAL INVESTIGATOR AWARD

This program, offered solely by the NIAMDD, is directed toward clinically trained individuals with demonstrated aptitude in research and provides them with the opportunity to develop into independent biomedical investigators. Contrasted with the Research Career Development Award, this program specifically seeks to develop research ability in individuals with clinical background and training. It is anticipated that this award provide research support in the transition between fellowship or trainee experience and a career in independent investigation.

METHOD OF APPLYING

Application kits and appropriate guidelines are generally available in the business or grants and contracts office at most academic and research institutions. They can also be obtained from the Division of Research Grants, NIH, Room 448, Westwood Building, Bethesda, Maryland 20205, or the appropriate Institute.

Applications will be accepted in accordance with the following receipt dates:

Research Grants and New Investigator Research Awards:

March 1
July 1
November 1

Individual National Research Service Awards and Research Career Development Awards:

February 1
June 1
October 1

Special Emphasis Research Career Awards:

June 1

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

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

METHOD AND CRITERIA FOR REVIEW

A. Assignment of Applications

Applications received by the NIH Division of Research Grants will be referred to an appropriate scientific review group. They will be assigned to individual Institutes as governed by normal programmatic considerations specified in the NIH Referral Guidelines.

B. Review Procedures

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with each other, and in accord with the usual National Institutes of Health peer review procedures. They will first be reviewed for scientific and technical merit by a review group composed mostly of non-Federal scientific consultants (e.g., study section), and then by the appropriate Institute's National Advisory Council. The review criteria customarily employed by the National Institutes of Health for the specific type of application will prevail.

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

National Eye Institute

Program Director, Retinal-Vascular Disorders Program
NEI Extramural and Collaborative Programs
Room 6A52, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-5983

National Heart, Lung, and Blood Institute

Associate Director, Etiology of Arteriosclerosis
and Hypertension Program
Division of Heart and Vascular Diseases, NHLBI
Room 516, Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-1613

or

Associate Director for Epidemiology and Biometry
Division of Heart and Vascular Diseases, NHLBI
Room 2C08, Federal Building
Bethesda, Maryland 20205

Telephone: (303) 496-2327

National Institute of Allergy and Infectious Diseases

Chief, Epidemiology and Biometry Branch, NIAID
Room 739, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7067

National Institute of Dental Research

Special Assistant for Program Coordination
NIDR Extramural Programs
Room 507, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7748

National Institute of Arthritis, Metabolism, and Digestive Diseases

Chief, Diabetes Programs Branch
Diabetes, Endocrinology and Metabolic Diseases, NIAMDD
Room 626, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7348

or

Program Director
National Diabetes Data Group, NIAMDD
Room 607, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7595

National Institute of Child Health and Human Development

Chief, Section on Nutrition and Endocrinology
Center for Research for Mothers and Children, NICHD
Room C717, Landow Building
Bethesda, Maryland 20205

Telephone: (301) 496-5575

National Institute on Aging

Associate Director for Extramural and
Collaborative Research Programs, NIA
Room 5C21, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-5534

or

Associate Director for Epidemiology,
Demography, and Biometry, NIA
Room 5C12, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-1178

National Institute of Neurological and Communicative Disorders
and Stroke

Chief, Section on Neuroepidemiology
Office of the Director, Intramural Research Program, NINCDS
Room 7C10, Federal Building
Bethesda, Maryland 20205

Telephone: (301) 496-1714

PULMONARY ACADEMIC AWARD

ANNOUNCEMENT

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application due date: April 1, 1980

The Division of Lung Diseases, National Heart, Lung, and Blood Institute invites national competition for Pulmonary Academic Awards, which have the dual purpose of improving the quality of pulmonary curricula and of fostering research and careers in the respiratory field. Each school of medicine or osteopathy in the United States or its possessions and territories is eligible for such an award. (Awards will be limited to one for each eligible school, for a project period up to five years.) The number of new awards made each year depends on the availability of funds.

The Division has initiated the Pulmonary Academic Award Program to provide a stimulus for development of a pulmonary curriculum in those schools that do not have one and to strengthen and improve the pulmonary curriculum in those schools that do. Awards provide support to individual faculty members for their educational development, and for implementation of the pulmonary curriculum.

Applications must be received no later than April 1, 1980 for review at the September (1980) meeting of the National Heart, Lung, and Blood Advisory Council. Awards will be made with a beginning date of June 1, 1981.

For information about preparing applications, contact:

Barbara Marzetta Liu
Prevention, Education, and
Manpower Branch
Division of Lung Diseases
National Heart, Lung, and
Blood Institute
Room 6A05, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

NIH-NHLBI-DLD-80G-B

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TITLE: *SPECIALIZED CENTERS OF RESEARCH*

in

Chronic Obstructive Lung Diseases

Pediatric Pulmonary Diseases

Fibrotic and Immunologic Interstitial Lung Diseases

Pulmonary Vascular Diseases

Application receipt date, September 15, 1980

I. BACKGROUND INFORMATION

The Division of Lung Diseases of the National Heart, Lung, and Blood Institute invites new or competitive renewal applications for grants to support Specialized Centers of Research (SCOR) for basic and clinical investigations addressed to only one of the following four pulmonary disease categories:

- *Chronic Obstructive Lung Diseases*
- *Pediatric Pulmonary Diseases*
- *Fibrotic and Immunologic Interstitial Lung Diseases*
- *Pulmonary Vascular Diseases*

The SCOR program complements other programs supported by the Division. It fosters a concerted research effort that involves basic disciplines but has major emphasis on clinical problems relative to the prevention, diagnosis and treatment of diseases within the purview of the Division of Lung Diseases. Special features of the SCOR grant are these:

- It provides the opportunity for investigators with mutual or complementary interests to engage in interdisciplinary research. However, it must focus on problems of pulmonary diseases identified in this announcement.
- While clinical aspects of disease must be the primary emphasis, the center program must include fundamental studies. The basic research must be clearly related to the disease focus, and must contribute, directly or indirectly, to elucidation of mechanisms underlying the disease process, or to better diagnosis, management or prevention of disease. The SCOR grant may include projects designed to accelerate the transfer of knowledge gained from research to its use in community medicine.

This program is described in the Catalog of Federal Domestic Assistance, number 13.838. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended: 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74.

- Each center must have a well-delineated organizational structure and administrative mechanism to ensure a productive research effort that will further the stated goals of the grant.
- Inherent in the SCOR program is a special relationship between the center's director, the sponsoring institution, and the Division of Lung Diseases. The Division will provide advice and guidance, and oversee the center to the extent needed to meet the goals of the Division's National Program as well as the goals of the SCOR grant. To these ends, the Division will provide, as part of the grant, funds specifically allocated for SCOR coordination. This makes it possible for investigators in different centers to meet and discuss problems of mutual interest and to engage in workshops addressed to specific facets of the SCOR program.
- The Division's SCOR program and each SCOR grant undergo periodic evaluation. Also, reports of progress are prepared for the information of the Pulmonary Diseases Advisory Committee and the National Heart, Lung, and Blood Advisory Council.

Because of the size and complexity of a SCOR, prospective applicants are urged to take advantage of the opportunity to consult with the staff of the Division of Lung Diseases early in the preparation of the application. (See Section V).

II. RESEARCH GOALS AND SCOPE

To be acceptable for the SCOR competition, applications must be addressed to only one of the disease categories identified below. For the guidance of applicants, some topics of particular interest to the Division's program are identified, but other topics may be included if they are relevant to the goals of a particular center. Proposals may include longitudinal studies or epidemiologic surveys if they are based on populations already under study. The SCOR grant will not provide funds for selection of new populations, but will support appropriate expansion of populations already being examined.

Chronic Obstructive Lung Diseases

The Division's mandate in this program area includes chronic bronchitis and emphysema, and the pulmonary impairment in asthma, but not its allergic or immunologic aspects.

Of particular interest are basic mechanisms involved in the structural and functional derangements associated with onset and progression of chronic bronchitis and emphysema; improved management of these diseases through identification of presymptomatic stages, critical assessment of current therapeutic measures, and development of more effective regimens; and prevention, through understanding of host and environmental risk factors, their interactions, and roles in etiology and pathogenesis.

With regard to asthma, there is special interest in mechanisms involved in bronchoconstriction and the development of more effective measures to ameliorate or prevent the bronchoconstrictor response.

Pediatric Pulmonary Diseases

Major emphasis in this program is on the neonatal respiratory distress syndrome and bronchopulmonary dysplasia, the pulmonary aspects of cystic fibrosis, and the relationship of bronchiolitis in childhood to pulmonary damage that may lead to chronic pulmonary disorders in the adult.

Topics of particular interest with regard to these neonatal respiratory disorders are derangements in the normal processes of development of respiratory and non-respiratory lung functions that result in such disorders, and studies that will improve their detection, management, and prevention.

Topics relevant to the Division's programs in cystic fibrosis are identification of the basic defect underlying the pulmonary disease, early pathogenetic changes in the lung, and improved management through critical assessment of current modes of therapy and development of new regimens.

The emphasis of the Division's program on bronchiolitis relates to the pathophysiologic features of this disease and its potential contribution to subsequent chronic lung disease in the adult. Other areas of interest include methods of early detection applicable to children.

Fibrotic and Immunologic Interstitial Lung Diseases

The Division's mandate in this program area includes fibrotic and granulomatous lung diseases of unknown etiology and those that result from exposure to inhaled agents that may be found in the ambient air, including the home and occupational environments.

Topics of special interest are the immunologic and other basic mechanisms involved in the onset and progression of these lung diseases and in the development of preventive and therapeutic measures.

Pulmonary Vascular Diseases

Pulmonary edema and pulmonary hypertension are the major concerns of this program area. Topics of particular interest are the fundamental mechanisms involved in these disorders, development of noninvasive techniques for their early detection, and more effective therapeutic interventions.

Additional topics of interest include studies of mechanisms of lung injury leading to pulmonary vascular diseases, sites of injury, and processes involved in progression and repair.

III. MECHANISM OF SUPPORT

The support mechanism will be the grant-in-aid. Thus, all policies and requirements which govern the grant programs of the PHS will prevail, including the requirement for cost sharing. However, it will differ from other research grants in its degree of goal orientation and in the degree of direct participation by the National Heart, Lung, and Blood Institute. While it is expected that the investigators of the individual SCOR's will plan, direct, and execute their own research program, any substantive modifications in that program must be mutually agreed upon by the National Heart, Lung, and Blood Institute. Ongoing evaluation will include periodic visits to the SCOR Institutions and review of formal progress reports.

Applicants are requested to furnish their own estimates of the time required to achieve specific objectives of the proposed work, a schedule for completion of the work, or an outline of the phases or segments into which the proposed program can be logically divided. Awards will be for a maximum five year period; a December 1, 1981 start date should be requested.

Although this solicitation will be included and provided for in the fiscal plans for Fiscal Year 1982, support of grants pursuant to this request for applications is contingent upon receipt of appropriate funds for this purpose. The current program involves nineteen grants which have a total annual funding base of approximately twelve million dollars (including indirect costs). At this time, it is not possible to predict whether future funding will be at the current level or at a lower or higher level. This will be influenced by the amount of funds available to the Division, by the overall merit of proposals, and by their relevance to the program goals. A variety of approaches would be responsive to this announcement; accordingly, it is anticipated that there will be a range of costs among individual grants awarded.

IV. REVIEW PROCEDURES AND CRITERIA

The merit review of these applications will be conducted by the National Heart, Lung, and Blood Institute. Primary review will be conducted by a review group of consultants with appropriate scientific expertise. Secondary review will be by the National Heart, Lung, and Blood Institute Advisory Council. Applicants will be informed of the results of the competition as soon as possible after the May 1981 meeting of the Council.

The initial scientific and technical merit evaluation will emphasize the review of each component project and core unit and review of the program as an integrated research effort focused on the specific clinical goals.

Review of Projects and Core Units

The review criteria include:

- o the scientific merit of each research project and the relation of the project to the overall goals of the center;

- the technical merit and justification of each core unit;
- the accomplishments and progress to date, particularly for renewal applications;
- the qualifications, experience, and commitment of the investigators responsible for the research projects or core units and their ability to devote adequate time and effort to the program; and
- the appropriateness of the budget for the proposed projects and core units.

Review of the Center as an Integrated Effort

The review criteria include:

- the significance and the importance of the research to the programmatic goals of the SCOR announcement;
- the multidisciplinary scope of the center and the coordination and interrelation of the research projects and core units;
- the leadership and scientific stature of the program director and his or her commitment and ability to devote adequate time and effort to the program;
- the participation of an effective number of responsible experienced investigators;
- the academic and physical environment in which the research would be conducted, including the availability of space, equipment, patients, and the potential for interaction with scientists from other departments and other institutions;
- the internal arrangement for quality control of on-going research, the allocation of funds, day-to-day management, communication and cooperation between the investigators involved in the program, and contractual agreements;
- the presence of an administrative and organizational structure that would facilitate attainment of the proposed objective of the program;
- the institutional commitment to the requirements of the program; and
- the appropriateness of the budget to the proposed program.

The last step in the review process is conducted by the National Heart, Lung, and Blood Advisory Council.

Review of the Proposed Center by the National Heart, Lung, and Blood
Advisory Council

Factors considered in this review include:

- the results of the initial review for scientific and technical merit;
- the significance of the research program to the pulmonary disease categories in this announcement;
- national needs and program balance; and
- policy and budgetary considerations.

V. METHOD OF APPLYING

SPECIFIC GUIDELINES FOR PREPARATION OF AN APPLICATION FOR A SPECIALIZED CENTER OF RESEARCH ARE AVAILABLE UPON REQUEST. PROSPECTIVE APPLICANTS ARE URGED TO WRITE FOR THESE GUIDELINES EARLY IN THE PLANNING STAGE.

To the extent possible, the Division of Lung Diseases is prepared to discuss plans for developing SCOR proposal with prospective applicants. However, to provide effective guidance, the Division must receive a draft that is complete with regard to all substantive sections. These include description of SCOR goals, detailed presentations of projects and cores, description of organization and administrative plans, detailed budgets for each project and core and biographical data for all participating investigators.

Inquiries about preparation of applications should be addressed to:

Claude Lenfant, M.D.
Director
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Room 6A16, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7208

To provide an estimate of the number of applications, for purposes of planning the review, prospective applicants should submit a brief letter of intent (not to exceed two pages) no later than July 1, 1980 describing the proposed goals of the SCOR, types of projects to be included, names of responsible investigators with academic titles, and an estimate of the level of funding (direct costs) required. Letters of intent are not binding.

Letters of intent should be sent to:

Charles Turbyfill, Ph.D.
Chief, Centers and Special Projects Review Section
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Room 553A, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

Application form PHS 398 should be used. Forms may be obtained from the Institution's Application Control Office or from the Division of Research Grants, NIH.

The completed application and 24 copies should be delivered to:

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

Two additional copies should be mailed to the Division of Lung Diseases, National Institutes of Health.

Applications must be received by 5:00 p.m. EDT September 15, 1980.

A brief covering letter should accompany the application indicating that the proposal is being submitted in response to this Request for Applications NHLBI-DLD-80G-B.

Consequences of Lack of Responsiveness to the RFA or Late Submission

Applications submitted in response to this request will be reviewed by NHLBI staff to determine responsiveness to the criteria for a Specialized Center for Research. Those applications that are judged not responsive, or are not received by September 15, 1980, will not be accepted for review and will be returned to the applicant.

Timetable

Letters of intent should be submitted no later than July 1, 1980.

The original and 24 copies of the completed application should be submitted to the Division of Research Grants, NIH, no later than September 15, 1980. Two additional copies should be submitted to the Division of Lung Diseases.

The final review of applications by the National Heart, Lung, and Blood Institute Advisory Council will be completed by May 1981.

Notice to applicants on the outcome of the review will be in June 1981.

Initiation of awards will not be before December 1, 1981.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

ANNOUNCEMENT

NIH-NHLBI-DLD-80G-C

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TITLE: *NUTRITIONAL STATUS AND NONRESPIRATORY LUNG INFECTION*

Application receipt date, March 14, 1980

I. BACKGROUND

A systematic approach to the study of nutritional effects on the lung is an essential step toward determining the role of nutrition in the etiology, pathogenesis and management of pulmonary disease. The effects of nutrition have not been studied as extensively in the lung as in other organs such as liver, muscle, brain and bone.

Animal studies indicate that ultrastructural characteristics, mechanical properties, and metabolic activities of the lung may be altered by starvation or markedly reduced food consumption. For instance, the changes in lung mechanical properties which have been observed following food deprivation are believed to be due to alterations in both surface forces and tissue elastic forces. Studies have been reported which suggest that lung surfactant metabolism is altered following food deprivation, but the mechanisms involved are not understood. Moreover, little information is available on the turnover or metabolism of lung connective tissue components following food deprivation. Diets deficient in essential fatty acids and vitamin A seem to lead to biochemical changes in lung tissue, but little is known about the processes involved in these changes. Our understanding of the influence of nutrition on lung function during stress is also rather limited. This is unfortunate as inadequate nutrition could have adverse effects on lung function in situations where it is already compromised, for example, during exposure to oxidants.

More information is needed about how nutritional status alters lung defense functions. It is known that acute starvation may depress the rate of bacterial clearance by alveolar macrophages in rats, but the nature of underlying mechanisms remains to be determined. Moreover, the extent to which ciliary activity and mucociliary transport are altered by changes in nutritional state is not known. Whether dietary antioxidants such as vitamin E protect the lung against oxidant injury is another question that needs to be investigated further.

This program is described in the Catalog of Federal Domestic Assistance number 13.838. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; USC 241) and administered under PHS grant policies and Federal Regulations Part 52 and 45 CFR Part 74.

II. GOALS AND SCOPE

The specific goal of this program is to encourage research in animals to elucidate the mechanisms by which nonrespiratory functions of normal mature lungs are influenced by nutritional status. Other lung functions, i.e. lung mechanics, may be studied if the intent is to correlate them with nonrespiratory functions, but major emphasis must be on the latter. Multidisciplinary approaches involving expertise in biochemical nutrition and in lung nonrespiratory functions are encouraged. Nutritional states to be studied may include calorie or protein undernutrition, essential fatty acid deficiency, and supplementation to documented nutritional deficiencies. The studies must be designed to test a specific hypothesis and the choice of a particular nutritional aspect for study must be based on a clear rationale. Studies which are not designed to test a specific hypothesis, or which are merely designed to test a random selection of diets or nutritional deficiencies will not be considered responsive to this announcement. Isolated lung cells or tissues may be studied to the extent needed to investigate a particular nutritional state in the intact animal, but studies aimed at elucidating nutritional requirements for lung cells or tissue cultures are not acceptable.

Nonrespiratory lung functions such as protein synthesis and degradation, including collagen and elastin, lipid metabolism, DNA and RNA content, alteration in enzymes participating in lung defense and energy metabolism exemplify areas of research that will be supported under this announcement. Studies which attempt to correlate observed changes with morphologic alterations are encouraged. Studies on lung defense mechanisms such as ciliary activity, phagocytosis and bacterial clearance by alveolar macrophages are also acceptable. Immunologic defense functions of the lung may be included, but proposals with main emphasis on specific immune responses will not be acceptable. Studies on developing lung will not be supported under this announcement; neither will epidemiological studies, clinical trials, and other clinical studies.

The research topics presented below are intended to provide examples of research areas that would meet the goals of this program. Investigators are encouraged to consider other relevant topics and approaches that would lead to an understanding of how nonrespiratory functions of mature lung are influenced by nutritional status, and the mechanisms underlying such influences.

A. Lung Connective Tissue Metabolism

While it has been reported that caloric deprivation influences lung pressure-volume characteristics by altering both surface forces and tissue elasticity, the cause of these changes is not understood. Information on the effects of nutrition on lung connective tissue is, in particular, very limited. It is not known, for example, if the changes in lung elasticity and morphology observed during food deprivation are related to substrate deficiencies, enzymatic changes, altered turnover rates of elastin or collagen or changes in the ratios of different collagen types.

It also is not known if the changes are totally or partially reversible. Studies suggest that ascorbic acid deficiency results in the under-hydroxylation of collagen and reduces collagen secretion. However, the exact role of ascorbic acid in lung connective tissue biosynthesis is not known.

B. Lung Defense Functions

Animal studies have demonstrated that impairment of alveolar macrophage function may occur during starvation. However, the mechanism of the alteration in macrophage activity is not known. Whether or not these changes are reversed by subsequent refeeding is also not clear. It is not known if nutritional status can alter bacterial colonization of the respiratory tract. There is some evidence to suggest that an increase in the saturated fatty acid content of lung triglycerides through dietary manipulation results in increased susceptibility to oxidants. However, it is not known if increasing dietary unsaturated fatty acids can counteract the toxic effects of oxidants. While deficiency of vitamin E appears to enhance the toxic effects of oxidants, it also is not clear if vitamin E can protect against oxidant-induced lung damage.

C. Lung Lipid Metabolism

While it is known that food deprivation decreases the amount of dipalmitoyl phosphatidylcholine, a major component of lung surfactant, our understanding of how these changes occur and what their consequences are is still not complete. Systematic investigations of key substrate requirements for lung lipid synthesis in normal lung are of interest.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional NIH grant-in-aid; successful applicants will plan and execute their own research program. Upon initiation of the program, the Division of Lung Diseases will sponsor periodic workshops to encourage exchange of information between investigators who participate in this program.

Although this program is included and provided for in the financial plans for Fiscal 1980, award of grants pursuant to this request for grant applications is contingent upon ultimate receipt of appropriate funds for this purpose. It is anticipated that a limited number of proposals (more than one but not more than four to six) will be awarded under this program. A variety of approaches would represent valid responses to this announcement. Accordingly, it is anticipated that there will be a range of costs among individual grants awarded. Applicants are requested to furnish their own estimates of the time required to achieve the objectives of the proposed research project; however, the total project period of this proposal must not exceed 5 years. At the end of the project period, renewal proposals may be submitted for competitive review. A project period start date of September 30, 1980 is anticipated.

The current policies and requirements which govern the research grant programs of the National Institutes of Health will prevail, including the requirement for cost sharing.

IV. REVIEW PROCEDURES AND CRITERIA

Upon receipt, applications will be reviewed for their responsiveness to the specific objectives described in this announcement. If an application is received after the March 14, 1980 deadline or is judged unresponsive, the applicant will be contacted and given an opportunity to withdraw the application or to submit it for consideration in the traditional grant program of NIH. Initial technical merit review will be arranged by the Division of Research Grants (DRG). Secondary review will be undertaken by the National Heart, Lung, and Blood Advisory Council.

If a proposal submitted in response to this RFA is identical to one already submitted to 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.

The factors considered in the scientific merit evaluation of each application will be identical to those used in traditional NIH research grant application evaluation, including an assessment of the importance of the proposed research problem; the novelty and originality of the approach; the training, experience, and research competence or promise of the investigator(s); the adequacy of the experimental design; the suitability of the facilities; and the appropriateness of the requested budget relative to the work proposed.

V. METHOD OF APPLYING

1. Letter of Intent

Prospective applicants are asked to submit a one-page letter of intent which includes a very brief synopsis of proposed areas of research and identification of any other participating institutions. This letter should be sent no later than January 15, 1980 to:

Dr. Dorothy Berlin Gail
Division of Lung Diseases
Room 6A10, Westwood Building
National Institutes of Health
5333 Westbard Avenue
Bethesda, Maryland 20205

The Institute requests such letters only to provide 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 proposal subsequently submitted nor is it a necessary requirement for application.

2. Format for Applications

Applications should be submitted on Form PHS-398, the application form for the traditional research grant which may be obtained at Institution business or research offices. If Form 398 is not available at the institution, it may be obtained by contacting:

Division of Research Grants
Room 449, Westwood Building
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7591

The conventional presentation in format and detail for regular research grant applications should be utilized. Specific attention is directed towards the inclusion of a statement indicating the willingness of the applicant to work cooperatively with other participants in the program and with the National Heart, Lung, and Blood Institute.

3. Application Procedure

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

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

To ensure their review, applications must be received by 5:00 p.m. EST on March 14, 1980.

The face page of the application must be labeled to indicate that it is submitted in response to this program announcement:
RFA-NHLBI-DLD-80G-C "NUTRITIONAL STATUS AND NONRESPIRATORY LUNG FUNCTION."

VI. Inquiries may be directed to:

Dr. Dorothy Berlin Gail
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Room 6A03, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7171

ANNOUNCEMENT

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NHLBI-DHVD-80G-D

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

TITLE: *SPECIALIZED CENTERS OF RESEARCH ON ARTERIOSCLEROSIS*

Application receipt date, September 2, 1980

INTRODUCTION

The Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute announces a national competition to support a limited number of Specialized Center(s) of Research (SCOR) focused upon arteriosclerosis. Applications will be considered for possible renewal of the current Arteriosclerosis SCOR and for the addition of new centers to the program. The period of support will be five years extending from December 1, 1981 through November 30, 1986.

BACKGROUND

The prevalence of the disease and the magnitude of its consequences ranks arteriosclerosis as a major public health problem in the United States. Of the 1,900,000 deaths from all causes in 1977, 50% were attributable to complications of arteriosclerosis manifested clinically as coronary heart disease, and cerebrovascular and peripheral vascular disease. It is estimated that more than 40 million Americans suffer illness and disability from these cardiovascular diseases and that virtually all adult males and postmenopausal women are afflicted to some degree with arteriosclerosis. The annual economic burden of the morbidity and mortality from heart and vascular diseases has been calculated to be in excess of 50 billion dollars. The national significance and desirability of preventing and controlling arteriosclerosis is thus self evident, and the attainment of this goal is the long-range objective of the Arteriosclerosis SCOR program.

OVERVIEW

The development of means for prevention and control rests upon a thorough understanding of the etiology and pathogenesis of arteriosclerosis. Animal and human research have identified and characterized cellular, humoral, and environmental factors associated with arteriosclerosis, demonstrated relationships of these elements to the disease process, and suggested possible mechanisms for the the initiation of the disease. These studies have provided new and improved methods for diagnosis and treatment, and a rationale for prevention and control based on the reduction of risk factors

This program is described in the Catalog of Federal Domestic Assistance number 13.837. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (P.L. 78-410, as amended; 42 USC 241) and administered under Public Health Service grant policies and Federal Regulations 42 CFR, Part 52 and 45 CFR, Part 74.

for arteriosclerosis. The etiology of arteriosclerosis, however, still remains a complex and incompletely understood issue. More certain and effective applications from research to prevention and control therefore continue to be dependent upon defining the underlying causes of the disease.

In initiating the Arteriosclerosis SCOR program, the Institute sought to focus resources, facilities, manpower, and common efforts on particular problems in arteriosclerosis for the purpose of expediting the development and application of new knowledge essential to improved diagnosis, treatment, and prevention of arteriosclerosis. Through open competition in 1971 and in 1972, the Institute established 15 centers. A subsequent solicitation for renewal and new applications in 1975 resulted in the selection of the current eight Arteriosclerosis SCOR. The total funding commitment for the eight centers in fiscal year 1981 is \$9,800,000, including overhead costs.

This announcement reaffirms the interest of the Institute in continuing to employ the SCOR program to extend the "state of the art" of arteriosclerosis research and to exploit its applications. It does not, however, constitute an obligation to support the SCOR at any predetermined fiscal level. Although a limited expansion of the SCOR is anticipated by the Institute, the number of centers to be selected will be contingent upon the overall merit and relevance of the proposals to the program goals, and upon the ultimate level of funds appropriated to the Institute.

The following guidelines are to assist in the preparation and submission of a SCOR proposal.

CHARACTERISTICS OF THE ARTERIOSCLEROSIS SCOR PROGRAM

Attributes of a SCOR

A SCOR should be an identifiable organizational unit within the sponsoring institution. Each applicant organization will be expected to propose its own program based on local interests and resources. The research program should represent a coordinated and multi-disciplinary approach to problems associated with the etiology, pathogenesis, diagnosis, treatment, and/or prevention of arteriosclerosis.

The scope of a SCOR program may be broad and responsive to a wide range of the research interests cited below or it can be highly focused and limited to only several closely related issues or areas of research. The program, however, must identify and reflect a central theme(s) with clearly defined objectives. It must also demonstrate that the specific objectives of the separate program components relate to the primary goals. Evidence of program integration will be sought for in the review process. A collection of unrelated research activities will be deemed unresponsive to the announcement.

It is expected that a SCOR program will include both basic and human clinical research. However, a proposal which meets all announcement criteria and objectives but is dedicated solely to fundamental research and clinical research involving animals will be given full consideration.

A SCOR may comprise two or more institutions affiliated in a consortium arrangement. A consortium usually addresses a research problem(s) which requires a combination of complementary activities and capabilities (facilities, resources, skills) not generally available at a single institution. The need, advantages, and research opportunities of a consortium, and the coordination and interaction of the research activities within the joint program must be demonstrated. The adequacy of administrative arrangements and lines of responsibility must also be made evident. Additional information for a consortium application is given below.

The Director of the SCOR is expected to be an established investigator, capable of providing both scientific and administrative leadership. The principal staff members should also be experienced and productive investigators. The staff must be willing to join in collaborative associations within the SCOR and with other centers having similar research interests, and be willing to make a long-term commitment to the SCOR program.

An assurance of a long-term commitment of the physical resources and staff necessary for the operation and development of the SCOR is also expected from the applicant institution. Facilities must be available to meet the primary research and support needs of the SCOR at the time of application, and must require no more than moderate modification. Funds will not be available for new construction. Where appropriate, a SCOR should establish core laboratory and support facilities as centralized service units to assure the efficient utilization of resources.

The above are the general characteristics and requirements of a SCOR. The special attributes which define the particular nature of the SCOR and distinguish a SCOR grant from other research grants and multi-project grants such as the program project are discussed below. They represent expectations of inter-center and Institute-center associations consequent to the Institute's perception and administration of the SCOR as an integrated program.

Mechanism of Support

The support mechanism for the SCOR will be the research grant. A SCOR grant differs from other research grants, however, in its orientation to goals defined by the Institute and in the extent of Institute interaction with the SCOR. While it is expected that the SCOR will plan, direct, and execute its own research program, the collective programs of the SCOR will be coordinated by the Institute. The SCOR must be responsive to specific program requisites which may be identified by the Institute as particularly appropriate to the SCOR and be willing to cooperate with the Institute in developing means for addressing perceived needs within the SCOR program. The participation with the Institute in quality control programs and the standardization of techniques and methods for certain procedures is also expected.

Unless specifically stated otherwise, a SCOR grant will also be subject to all other policies and requirements which govern the grant programs of the Public Health Service, including the requirement for cost sharing.

Relationship of the Institute to the SCOR

The award of a SCOR grant will establish a special relationship between the Institute and the grantee institution. Accordingly, the Institute will designate a scientific program officer to work in conjunction with the staff of the SCOR. The program officer will advise the SCOR of the Institute's research goals and will participate in decisions affecting levels of support, rebudgeting of funds, initiation of new projects, etc. The program officer will coordinate plans for special projects and initiatives of mutual interest to the Institute and the SCOR, and will oversee program activities which relate to the SCOR collectively. Periodic visits will also be made to the SCOR to evaluate progress and to assist in administrative aspects of the SCOR program. A comprehensive evaluation of each center will be conducted at the mid-point of the SCOR grant period. This assessment of the individual program components and of the overall performance of a SCOR in attaining its objectives will generally be conducted on-site with a review panel consisting of members of an Institute Advisory Committee, special consultants, and the program officer. The panel report will be provided to the SCOR Director and the program officer will join with the Director in effecting its recommendations. The program officer will also employ consultants to the Institute for special reviews of the SCOR program when necessary.

Interactions among SCOR

The award of a SCOR grant also anticipates a commitment by the SCOR to participate in various inter-center activities. It is expected that the SCOR will be willing to exchange research information, join in collaborative research programs with other centers, undertake joint SCOR initiatives, and facilitate research at other SCOR as may be appropriate and useful. To promote these objectives, the SCOR Directors will meet at least once a year to review progress, discuss common interests and problems, and plan collaborative efforts. The Directors and scientific staff of the collective centers will also hold an annual technical meeting to share experimental findings and to consider new directions for research on arteriosclerosis. To further information exchange among the SCOR, the Institute program officer will compile the annual progress reports of the SCOR and distribute the comprehensive report to each of the centers.

The SCOR will also be encouraged to hold workshops on topics of mutual interest to the centers. The workshops may be initiated by a center or by the Institute. They will provide a means to foster communication and collaboration among the SCOR and with other scientists, and to inform the Institute of accomplishments, problems, and needs of research on arteriosclerosis. The workshops will also enable the scientific community to participate in and keep abreast of SCOR activities.

Organization and Administration of a SCOR

The organization of the SCOR should reflect the particular research interests and capabilities of the grantee institution. The SCOR Director will be responsible for the organization of the Center and for communication with the Institute on all scientific and operational aspects of the center's program. To monitor the program, the Director will establish an internal advisory committee consisting of staff members and expert consultants from other institutions. The committee will conduct an annual evaluation of the individual projects and the overall program, and will provide the Director with its assessment of the progress, weaknesses and strengths of the program. In addition, the committee may conduct the initial review of new initiatives. Although SCOR investigators will work within the workscope of the approved program, the pursuit of promising new leads and pilot studies should be encouraged. The incorporation of a new project into the SCOR program will, however, require review and approval by the Institute.

The SCOR should also be organized to enhance interactions and collaboration among the various disciplines of the investigators. To promote associations, the staff should be made aware of the activities of the entire program and the SCOR should plan a regularly scheduled series of seminars to maintain an ongoing exchange of information.

Research Goals of the SCOR

The goals for the Arteriosclerosis SCOR embrace a broad range of disciplines and areas of research, including studies on the relationship of disorders of lipid metabolism, hypertension, thrombosis, connective tissue metabolism, smoking, diabetes, and other diseases to the etiology and pathogenesis of arteriosclerosis. It is not anticipated that an individual center will be responsive to each of the specific goals and special interests cited for the SCOR. The Institute, however, holds the expectation that the collective SCOR will comprise a comprehensive and integrated program which addresses a full range of issues pertinent to arteriosclerosis.

The previous solicitations for Arteriosclerosis SCOR applications identified the areas of research outlined below as of particular importance and interest. More progress has been made in resolving issues and in attaining information in some of the areas than in others. However, questions still remain and the Institute considers each of the research areas to be relevant to this solicitation.

1. Clinical Studies of Hyperlipidemia and/or Vascular Disease
 - a. Characterization, Biochemical-Genetic-Disease Relationships
 - b. Dietary and Drug Control
 - c. Development of Diagnostic Markers and Instrumentation for Assessment of Lesions

- d. Pediatric Coronary Heart Disease Risk Factors: Their Prevalence and Development
 - e. Adult Coronary Heart Disease Risk Factor Reduction via Behavior Modification
 - f. Adult Coronary Heart Disease Risk Factor Population Studies, Trials and Interventions
 - g. Behavioral and Psychosocial Factors
2. Animal and Tissue Studies of Arteriosclerosis
- a. Experimental Arteriosclerosis (Nonhuman primates, other mammals, and non-mammalian species)
 - b. Diet and Drug Effects on Lesion Progression/Regression
 - c. Parameters of Atherogenesis in Aterial Wall and Tissues
 - d. Cell Culture and Lipid-Lipoprotein Metabolism
 - e. Relationships of Hypertension, Diabetes, and Cigarette Smoking, to Arteriosclerosis
3. Basic Laboratory Investigations
- a. Characterization of Lipoproteins, Apoproteins, and their Interactions with Lipids
 - b. Metabolism of Lipoproteins and Lipids
 - c. Vascular Thrombosis and Intravascular Coagulation, as these Effect Arteriosclerosis

The Institute expresses a special interest in extending the research efforts of the SCOR on the role of normal and abnormal coagulation and thrombotic phenomena as these pertain to the structure, function, and growth of endothelial and other vascular cells generally, and to the generation and progression of arterial lesions particularly. Relevant but not exclusive interests include: mechanisms by which platelets, platelet-derived mitogens, thromboxanes and prostaglandins, and other blood components compromise vascular integrity and function; mitigation of thrombotic effects and vascular injury by vascular tissue factors; and the identification of coagulation and thrombotic events and factors as diagnostic markers for susceptibility or resistance to arteriosclerosis.

Additional areas of interest and concern to which proposals may be addressed include the following:

- Studies on infancy, childhood, and adolescence with particular reference to nutrition, lipid metabolism, hemostasis, inheritance, diagnostic markers for risk or susceptibility, and hypertension and obesity as these relate to the risk or progression of arteriosclerosis; and pediatric studies employing non-human primate models.
- Biobehavioral studies combining psychosocial, cultural and behavioral variables with epidemiological, physiological, biochemical and clinical studies in normal human subjects, patients with arteriosclerosis and cardiovascular disease, and in animal models of arteriosclerosis. Biobehavioral studies may include: interactions of behavioral processes with genetic, nutritional, pharmacological, physiological, and biochemical factors influencing arteriosclerosis and thrombosis; influence of behavioral processes on neurogenic and endocrine mechanisms which effect arteriosclerosis; developmental aspects of behavior in children that predispose them to risk factors for arteriosclerosis (smoking, eating habits, physical activity); behavioral models in non-human primates that simulate pathophysiological mechanisms and risk factors predisposing to arteriosclerosis in humans; elucidation of the biobehavioral mechanisms associated with the "coronary prone" behavior pattern, including the development of such patterns in children; and methods for inducing and maintaining health behaviors that reduce risk for arteriosclerosis.
- Genetic studies not necessarily oriented to systemic lipid metabolism but relevant to arteriosclerosis.
- Studies of endogenous or exogenous factors that determine or alter health related behavior particularly in the asymptomatic stages of arteriosclerosis.
- Studies of susceptibility or resistance to arteriosclerosis (as distinct from risk factors that predispose to arteriosclerosis).
- Studies on the vascular or circulatory components of cerebral vascular disease, or peripheral vascular disease.

Please note that education and demonstration projects will be considered responsive to this solicitation only if they are clearly research-oriented and time-limited.

METHOD OF APPLYING

Letter of Intent

The National Heart, Lung, and Blood Institute should receive a brief letter of intent from all prospective applicants not later than the close of business on June 16, 1980. The Institute request such letters in order to have a reasonable estimate of the number of applications to be expected and to begin planning for review. A letter of intent is not binding and will not enter into the review of any proposal submitted subsequently. The letter should briefly describe the overall approach of the proposed SCOR application and should list the names of key participants.

Letters should be addressed to:

Dr. Charles L. Turbyfill
Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Room 533, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

A copy of the Letter of Intent should also be sent to:

Dr. Bernard J. Krask
Atherogenesis Branch
Division of Heart & Vascular Diseases
National Heart, Lung, and Blood Institute
Room 4C-12, Federal Building
Bethesda, Maryland 20205

Format for Applications

A copy of the instructions for the preparation of a SCOR proposal can be obtained by calling the Atherogenesis Branch (301) 496-1978.

Submission of Application

The original and twenty eight (28) copies of the complete SCOR application must be received by September 2, 1980. The application should be sent or delivered to:

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

A covering letter should accompany the application indicating that it is submitted in response to this announcement.

Two (2) copies of the complete SCOR application must also be sent to Dr. Bernard J. Krask by September 2, 1980 (see address given in section, "Letter of Intent."

CRITERIA FOR REVIEW

The applications for Arteriosclerosis SCOR will be evaluated in national competition with each other. The criteria utilized in evaluation will include:

- The scientific merit of the research objective(s) of the SCOR, their importance to arteriosclerosis research, as well as the rationale for the planned attack on the designated problem area(s).
- The scientific merit of each individual project and its relationship to the central theme(s) or goal(s) of the overall proposal.
- Inter-relationships among, and between the research projects.
- Willingness to work cooperatively with other SCOR and with the National Heart, Lung, and Blood Institute.
- The scientific and administrative leadership ability of the SCOR Director and the research competence of all professional personnel, including the Director.
- The arrangements established by the SCOR for:
 1. Internal quality control of on-going research.
 2. Allocation of funds.
 3. Day-by-day management and scientific decision making.
 4. Intra SCOR integration and information exchange (seminar program, etc.)
- The justification for requested core facilities and their relevance to the individual research projects.
- The appropriateness of the budget required to support each component of the total program.
- Institutional commitment to SCOR goals.
- The academic and physical environment in which the research will be conducted.
- Institutional arrangements to assure continuity of the program and fiscal responsibility for the management of grant funds.

TIMETABLE FOR REVIEW

Due Date for Letters of Intent: June 16, 1980

Due Date for Applications: September 2, 1980

Initial Review: The initial review will be conducted by the Division of Extramural Affairs, NHLBI, during the period September 1980 - March 1981. An ad hoc committee of expert consultants chosen by the NHLBI will evaluate each application to determine if a site visit should be conducted. Following the site visits, the committee will review all applications again and will make its recommendations.

Secondary Review: The National Heart, Lung, and Blood Advisory Council will conduct the secondary review of all applications in May 1981. Applicants will be advised of the Council decision in June 1981.

Grant Start Date: December 1, 1981.

INQUIRIES

Questions regarding the Arteriosclerosis SCOR program should be addressed to Dr. Bernard J. Krask (301) 496-1978.

The staff will strive to provide consultation regarding the preparation of the application or any other matters relevant to this solicitation. However, the inability to provide staff consultation cannot justify extension of the deadline for receipt of applications or any other special considerations.

SMOKING, CANCER AND HEALTH PROGRAM

NATIONAL CANCER INSTITUTE

ANNOUNCEMENT

The NCI's Smoking, Cancer and Health Program desires to expand its involvement with the role of smoking as a public health problem in cancer cause and prevention. The program is seeking applications for research and demonstration grants concerned with basic and applied studies in toxicology, epidemiology, prevention, behavior, attitudes, pharmacology, education, information, training, and other appropriate areas related to Smoking and Health. It is not the intent of this announcement to make or imply any delimitation related to the nature or scope of the research which might be proposed.

It should be emphasized that this statement of interest in developing new grant proposals is neither a Request for Applications (RFA-Grants) nor a Request for Proposals (RFP-Contracts), but rather an announcement of NCI's intent to stimulate investigator-initiated research in its Smoking, Cancer and Health Program. As such, the proposals are reviewed by the usual NIH peer review groups for technical merit and recommendation to the National Cancer Advisory Board. Additional needs for specific in-depth activity in any or all of the Programs may be met in the future with the issuance of RFA's and/or RFP's.

Examples of areas which might be considered by interested investigators are listed below. These studies are not listed in any priority order but are given as examples of studies which can be considered under this program announcement. Human and laboratory studies are being sought through this announcement.

1. Biomedical Aspects

- Epidemiologic studies to determine the effects of smoking low tar, low nicotine cigarettes on smoking-related cancers such as lung cancer, bladder, head and neck cancer, etc. Consideration can be given to studies which examine broad health issues in addition to cancer.
- Studies to define the patterns and risks of cigarette smoking in special populations (e.g., persons with toxic industrial exposures, with co-existent disease states, etc.); current risk patterns and/or trends.

This program is described in the Catalog of Federal Domestic Assistance numbers 13.393 and 13.398. Awards will be made under the authority of the Public Health Service Act, Section 301 (Public Law 78-410, as amended; 42 USC 241 and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. NRSA awards will be made under the authority of the Public Health Service Act, Section 472, 42 USC 291-1, and administered under PHS grants policy and Federal Regulations 42 CFR Part 66.

- Studies on health effects of passive or secondary smoking.
- Studies to develop and evaluate objective measures for the determination of smoking status.
- Studies to determine the combined effect of smoking and other environmental carcinogens (e.g., industrial exposures, nutritional factors, etc.)
- Studies on the effectiveness of materials, such as vitamins and pro-vitamins, in inhibiting or altering the deleterious health effects of cigarette smoking.

2. Psycho-social Aspects

- Studies to define the knowledge and beliefs of health professionals and the public about the health effects of smoking, the risks of low tar versus high tar cigarettes, etc.
- Communications research to develop the means to inform the public on the health hazards of smoking, and especially to develop methods to evaluate these efforts.
- Studies to define the attitude of adolescents toward low tar, low nicotine cigarettes, and the effects of that attitude on initiation or cessation behavior.
- Studies to develop innovative techniques in smoking prevention and cessation, especially for groups such as women, children, adolescents, blue collar workers, non-white populations, etc.
- Comparative studies (cross validation) of the commonly-used approaches to smoking cessation, including those of commercial, institutional, religious, and educational sponsors.
- Studies to evaluate smoking prevention and cessation programs among industrial workers, especially those exposed to occupational carcinogens which may have additive or synergistic effects with smoking.
- Studies to define the cost effectiveness and cost benefit of various approaches to smoking prevention and cessation.
- Studies of the effectiveness of social pressures and mores, legislative or administrative actions (i.e., requirements for non-smoking areas in public buildings, etc.) on the reduction of smoking.

3. Other Appropriate Research or Demonstration Grants in Smoking, Cancer and Health

Programs are available for the training of individuals as these might relate to the Smoking, Cancer and Health Program. Two programs--

Individual Postdoctoral Fellowships (F-32) and Institutional Postdoctoral Fellowships (T-32) provide full-time, long-term support to promising individuals and well-qualified institutions through the National Research Services Act (P.L. 93-348).

Additionally, the Cancer Research Career Development Award (RCDA) (K04) provides support for individuals with demonstrated research potential who require additional experience in preparation for careers in independent research.

GENERAL INFORMATION

The announcement leaves the choice of specific research objectives, identification of specific aims, development of appropriate protocols and methodology, and the procedures for analysis and interpretation of data to the investigator's initiative. However, once the award is made under the program, any substantial modification of the research originally proposed must be mutually agreed upon by the investigator and the respective NCI division.

For purposes of tracing responses to this program announcement, investigators should type in bold face characters at the top of the face page of the application: **SMOKING, CANCER AND HEALTH PROGRAM**. A copy of the face page of the application should be sent to Dr. Diane Fink, Coordinator of the Smoking, Cancer and Health Program, Building 31, Room 11A33, National Cancer Institute, Bethesda, Maryland 20205.

A number of Bureaus, institutes, and offices within the Department of Health, Education, and Welfare (DHEW) have mandates and/or interest in Smoking and Health. To provide maximum coordination among interested DHEW groups, a staff working group with representatives from the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, and the Office of Smoking and Health will meet on a regular basis to follow the progress of grants submitted in response to this announcement.

APPLICATION AND REVIEW PROCEDURES

A letter of intent may be sent to the staff person for the investigator's area of interest if desired by the investigator prior to submission of the application. Application kits may be obtained from an organization's application control office or from the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205.

The application receipt dates for grants submitted under this program announcement are the usual DRG receipt dates for investigator initiated grants; namely, new grants (Type I) March 1, July 1, and November 1; and renewal grants (Type II) February 1, June 1, and October 1. Research and demonstration grants are to be submitted on Form PHS 398.

Training applications for individual postdoctoral fellowships should be prepared on Form PHS 416-1; for institutional training on Form PHS 6025; for RCDA's, on Form PHS 2557-1.

Applications should be sent to:

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

STAFF CONTACTS

Questions related to various aspects of the NCI Smoking, Cancer and Health Program can be directed to:

Epidemiology: Dr. Donald Luecke
DCCP, National Cancer Institute
Room 8C18, Landow Building
Bethesda, Maryland 20205

Telephone: (301) 496-9600

Toxicology: Dr. Gio Gori
DCCP, National Cancer Institute
Room 3A16, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-6616

Behavioral Studies, Smoking Cessation and Demonstration Programs:

Dr. David Monsees
DCCR, National Cancer Institute
Room 720, Blair Building
Silver Spring, Maryland 20910

Telephone: (301) 427-8630

Training Programs: Dr. Barney Lepovetsky
DCRRC, National Cancer Institute
Room 10A18, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7803

Information and Education: Mr. Bernard Ellis, Jr.
OCC, National Cancer Institute
Room 4B39, Building 1
Bethesda, Maryland 20205

Telephone: (301) 496-6792

General Information:

Dr. Diane Fink
ADMACR
National Cancer Institute
Room 11A33, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-1316

DIET, NUTRITION, AND CANCER PROGRAM ANNOUNCEMENT

OF RESEARCH INTERESTS IN ALCOHOL AND CANCER

NATIONAL CANCER INSTITUTE

ANNOUNCEMENT

The Diet, Nutrition, and Cancer Program of the National Cancer Institute, with the cooperation of the National Institute of Alcohol Abuse and Alcoholism is encouraging the submission of applications for research grants in the study of alcohol and cancer.

INTRODUCTION

A Workshop on Alcohol and Cancer was held October 23 and 24, 1978, and was sponsored jointly by the Division of Cancer Control and Rehabilitation of the National Cancer Institute and the Division of Extramural Research of the National Institute of Alcohol Abuse and Alcoholism. The purposes of this conference were threefold: (1) to begin a dialogue between investigators and practitioners from both cancer research and alcohol studies; (2) to describe the state of the art including methodologies of common interest; and, (3) to develop recommendations for future areas of study and investigation. The program included reviews on the epidemiology of alcohol and cancer, rehabilitation and continuing care, and experimental approaches to the study of alcohol effects on the etiology and pathogenesis of cancer. The proceedings of the Workshop were published in Cancer Research, 39, 2815-2908, 1979.

BACKGROUND AND PROGRAM SPECIFICATIONS

The Diet, Nutrition, and Cancer Program encourages the submission of research grant applications in the broad areas of: (1) epidemiological studies in alcohol-related cancer, and (2) basic research on alcohol effects on tumor development.* However, it is not the intent of this announcement to make or imply any delimitation relative to the nature or scope of the research which might be proposed.

Epidemiological Studies in Alcohol-Related Cancer

Alcohol combined with tobacco smoking is an established risk factor for cancers of the oropharynx, esophagus, and larynx. It should be possible to clarify further the role of alcohol itself, the modifying effects of tobacco, dose-response relationships, and nutritional co-factors. Studies are also needed to delineate the steps by which alcohol consumption leads to liver cancer and to resolve the suggestion that certain beverages may predispose to other cancers, including those of the pancreas and rectum.

*This program is described in the Catalogue of Federal Domestic Assistance numbers 13.393 and 13.396. Awards will be made under the authority of the PHS 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.

Epidemiological investigations and pilot surveys should be combined with experimental work to identify hazardous fractions in alcoholic beverages and to delineate the mechanisms by which alcohol promotes carcinogenesis. Epidemiologists and biometricians may also contribute toward the development of programs aimed at primary prevention and early detection of cancers related to alcohol and tobacco.

Incorporation of research questions into data collection systems deserves serious consideration as a means of obtaining additional valuable information for etiological studies.

Alcohol and Carcinogenesis

Possible mechanisms whereby alcohol abuse and alcohol-related diseases may affect carcinogenesis and the development of cancer:

- (a) contact-related local effects on the upper gastrointestinal tract;
- (b) the presence of low levels of carcinogens in alcoholic beverages;
- (c) induction of microsomal enzymes involved in carcinogen metabolism;
- (d) various types of cellular injury produced by ethanol and its metabolites and their relationship to cancer;
- (e) the dietary and nutritional disturbances frequently associated with alcohol abuse.

Review of the scientific literature provides relatively few reports in basic research on alcohol and cancer.

Illustrative examples of research areas of need are:

- Effects of alcohol on the natural history and pathogenesis of experimentally induced tumors in animals, including the effects of alcohol on immune responses.
- Influence of alcohol on the malignant potential of chemicals, oncogenic viruses and radiation.
- Effects of alcohol on carcinogenesis in vivo and in vitro.

These examples are not intended to delimit the nature or scope of the research proposed.

METHOD AND CRITERIA OF REVIEW

Applications will be received by the NIH's Division of Research Grants and will be referred to an appropriate peer review group for initial review for scientific merit. The specific scientific area addressed will

be the basis for review group assignment with subsequent review by the National Cancer Advisory Board. The review criteria customarily employed by the Public Health Service for regular research grant applications will prevail.

APPLICATION RECEIPT DATES

Applications will be accepted in accordance with the usual receipt dates for new research grant applications. Each applicant should include a letter of transmittal referring to this program announcement. Due dates are:

March 1, 1980

July 1, 1980

November 1, 1980

Copies of letters of transmittal and inquiries should be addressed to:

Dr. Vincent Groupe'
Diet, Nutrition, and Cancer Program
National Cancer Institute
Room 11A33, Building 31
Bethesda, Maryland 20205

Telephone: (301) 496-1316

METHOD OF APPLYING

Applications should be submitted on form PHS-398, which is available in the business or grants and contracts office at most academic and research institutions or may be obtained from NIH. The words "ALCOHOL AND CANCER" should be typed across the top of the first page of the application.

Applications should be sent to:

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

PREVENTIVE ONCOLOGY ACADEMIC AWARD

NATIONAL CANCER INSTITUTE

ANNOUNCEMENT

The National Cancer Institute invites national competition for Preventive Oncology Academic Awards. Each school of medicine, school of dentistry, school of osteopathy, school of public health, or NCI-designated cancer center in the United States and its possessions or territories is eligible to compete for one Preventive Oncology Academic Award for a project period that does not exceed five years. The number of new awards made each year will depend on the availability of funds.

The Preventive Oncology Academic Award Program is to stimulate research and education for cancer prevention in schools that do not have such programs and to strengthen and improve these programs in schools that do. Awards support individual faculty members for their research and educational development and the implementation of curriculum. It is expected that each program in cancer prevention builds upon demonstrable expertise and experience in epidemiology and/or human genetics, biostatistics, clinical oncology and basic cancer research.

I. OBJECTIVES OF THE AWARD

The Preventive Oncology Academic Award is made to:

1. develop superior faculty with requisite academic skills and a major commitment to preventive oncology research and training;
2. ensure superior learning opportunities which attract outstanding students to research careers and contribute to the prevention of cancer;
3. facilitate interchange of ideas and methods among awardees and institutions; and
4. develop the grantee institution's capacity to attract local support that will continue to strengthen and improve preventive oncology research and education.

II. CRITERIA FOR THE AWARD

Competitive review for a Preventive Oncology Academic Award will assess the intentions of both the sponsoring institution and the proposed candidate.

This program is described in the Catalog of Federal Domestic Assistance number 13.393. 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.

The institution must:

- name and sponsor a candidate with competence in preventive oncology and with major career interest in research and in improving educational programs (the candidate must be a citizen, a noncitizen national of the U.S. or have been lawfully admitted to the U.S. for permanent residence);
- present plans to develop or improve the preventive oncology research and educational programs;
- identify and demonstrate availability of the resources (populations, patients, manpower, materials) necessary to implement the proposed program;
- provide the candidate with time to acquire the skills necessary for personal development and for the development of the preventive oncology program;
- provide access to facilities for rigorous preventive oncology research and high quality patient care;
- provide evidence of commitment from the administration and from the sponsoring departmental Chairman to implement the proposed program so there is coordination of preventive oncology with other relevant research and education; and
- state the mechanisms for continued institutional support of the preventive oncology program subsequent to the Award.

The candidate must:

- have appropriate academic appointment at the institution at the time the award is activated;
- have sufficient research experience and clinical background in oncology, to be effective in developing and actively implementing a quality research and education program in preventive oncology;
- specify a program for enhancing personal skills as needed;
- present a program for developing or improving preventive oncology research and education in the grantee institution and for evaluating the outcome of the effort;
- commit a substantial portion of effort to the proposed programs;
- agree to report annually on the status of the program; and
- agree to meet annually with other recipients of Preventive Oncology Academic Awards to exchange ideas, methods and program evaluations.

Preventive Oncology research and education requires an unusual complement of education and experience, deriving from several professional and disciplinary fields. A candidate may qualify for appointment without the full range of skills provided a plan for acquiring them is incorporated in the application. The candidate should have sufficient training and experience so that no more than one year of intensive supplemental preparation is needed to meet basic requirements. Basic requirements include:

- demonstrated competence in: medical science or related fields of biomedical research relevant to cancer prevention, epidemiology and/or human genetics and biostatistic research methods, and
- substantive knowledge of: carcinogenesis research; health service delivery systems; public health regulation and practice; medical education procedures and administration; and nutrition.

III. PROVISIONS OF THE AWARD

Within available funds and consonant with the objectives of the Preventive Oncology Academic Award, the Institute will provide funds annually for a project period up to five years.

The Award may provide funds for:

support for the candidate in direct proportion to the effort expended on the preventive oncology program; research assistants as justified;

travel to enable the candidate to develop essential skills and to meet with other candidates to exchange ideas, methods and program evaluations;

equipment necessary to develop the preventive oncology curriculum;

supplies necessary to achieve the program's objectives;

consultant fees for a limited number of experts in the area of preventive oncology and in education;

research allowance for limited participation in research experiences related to preventive oncology, such as the investigation of clusters, feasibility studies, and supporting services;

supplemental educational expenses which may be proposed by the candidate (Section II - Criteria for the Award); and

indirect costs as described in Instructions for Preparing Applications (up to but not to exceed eight percent of allowable direct costs).

IV. REVIEW OF APPLICATIONS

Applications for initial Preventive Oncology Academic Awards will be appraised in terms of criteria outlined for the institution and the candidate in Section II, "Criteria for the Award."

The review will include an assessment for scientific merit by an NIH Initial Review Group. When necessary, a site visit may be made to the institution. The initial review group will make recommendations for consideration by the National Cancer Advisory Board.

V. METHOD OF APPLYING

For 1980 only, applications for Preventive Oncology Academic Awards must be received by the National Institutes of Health not later than March 1 for review by the National Cancer Advisory Board in May or June. For subsequent years an annual receipt date will be May 1. The requested begin date for funding should be July 1 of the following year.

Application forms (PHS 398) may be obtained from the institution's application control office. If not otherwise available, they can be requested from:

Grant Inquiries Office
Division of Research Grants
National Institutes of Health
Room 448, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

Type the phrase "PREVENTIVE ONCOLOGY ACADEMIC AWARD" as the title for the proposal on the front page of the application. Use the special Guidelines for preparation of a Preventive Oncology Academic Award. These and limited staff consultation relating to eligibility and appropriate areas of emphasis may be obtained from:

Donald H. Luecke, M.D.
Special Programs Branch
National Cancer Institute
National Institutes of Health
Room 8C-16, Landow Building
7910 Woodmont Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-9600

NEW INVESTIGATOR RESEARCH AWARD (NIRA)

ANNOUNCEMENT

Under the authorizations in the Public Health Service Act (Title III Section 301(c) and applicable sections pertaining to individual Institutes and Bureaus of Title IV) the Bureaus, Institutes and Divisions (BIDs) of the National Institutes of Health (NIH) may, under certain circumstances, make New Investigator Research Awards (NIRAs).

I. INTRODUCTION AND EFFECTIVE DATE

This issuance collates under a single title, NIRA, elements of all new and young investigator awards* which were announced separately and at different times. Users of this document should consult, prior to submission, the individual BID officers whose names are appended to the main text for specific details related to the awarding unit's special areas of interest. Areas to be supported under this program reflect the awarding unit's judgment that there is need to stimulate research in a particular field. These policies and guidelines become effective for New Investigator Research Award applications received on or after March 1, 1980. Awards based on applications received prior to that date will be guided by the program announcement and policies in effect at the time the award was made.

II. PURPOSE

The New Investigator Research Award program is designed to encourage new investigators (including those who have interrupted early promising research careers) in basic or clinical science disciplines to develop their research interests and capabilities in biomedical and behavioral research within the program interests of the National Institutes of Health. To help bridge the transition from training status to that of established investigator, this special grant supported program provides research grant funds for relatively inexperienced investigators with meritorious research ideas. Funds for this program are being allocated from appropriations made to the participating NIH awarding units to fulfill their legislatively mandated missions.

* Formerly known as: Young Investigator Research Grants (NCI, NHLBI), Special Research Award Program (NIA), Special Dental Research Award, Young Environmental Scientist Health Research Grant Program, Special Visual Science Research Awards, NIRA in Diabetes, Special Grants for New Investigators in Anesthesiology, Special Grants for New Investigators in Trauma and Burn Research, New Investigator Research Grant in Medical Information Science, New Investigator Research Grants in Clinical Immunology and Virology, and New Investigator Awards in Tropical Medicine (recently announced.)

III. ELIGIBILITY

A. Applicant Institutions

Only domestic nonprofit organizations and institutions, qualified entities of State and local governments and their agencies and Federal institutions may apply.

B. Principal Investigator

These awards are restricted to individuals who have not previously been principal investigators on a PHS supported research project. Exceptions may be granted to individuals who are changing their field of scientific endeavor. If there are questions, applicants should consult with NIH staff concerning the choice of application best suited to their needs.

The principal investigator must ordinarily have a doctorate degree or its equivalent. The applicant should have completed his/her formal professional education. In most instances the principal investigator will have no more than five years of research experience after completion of formal training at the time the award is made. Under unusual circumstances, if clearly justified, there may be an exception to this five year limitation.

C. Concurrent Applications

The requirement for eligibility for an NIRA precludes concurrent application for a Research Career Development Award, Clinical Investigator Award, Academic, Teacher Investigator Award, or National Research Service Award. A New Investigator Research Award recipient may apply for a research project grant provided the second award does not conflict with the time or other commitments to the NIRA.

IV. REVIEW

Applications for NIRAs will undergo peer review by DRG Study Sections. Particular attention will be given to the following.

- A. The adequacy of the applicant's research and research training background as a guide to future development into a creative independent investigator will be evaluated. The quality of the individual's past education, scientific training and commitment to a health-related research career will be taken into account along with the research proposal. Letters of reference are particularly valuable where the investigator's research originality and potential for independent investigation are not reflected in his/her past research experience.

- B. The principal investigator's research proposal will be evaluated for scientific merit, originality, feasibility, adequacy of design and plans for analysis and evaluation of data. It is recognized that an investigator of limited experience is less likely to be able to submit an application in the same breadth and depth as an experienced investigator. The application must, however, give clear evidence of the investigator's ability to develop a sound research plan.

V. TERMS OF THE AWARD

A. Principal Investigator

Principal investigators are directly responsible to the grantee institution to which the awards are made. The employment status, 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.

Principal investigators must make a truly significant commitment of time or effort to the research project proposed; while in no case can this be less than 50%, for most applicants a larger commitment is encouraged. Salary support can be provided from the award up to \$25,000 plus fringe benefits according to the time or effort devoted to the project.

B. Duration

NIRA awards are made for periods up to three years and are not renewable. A continuation of research support beyond the NIRA award may be sought as a regular research grant.

C. Follow-up Information

The principal investigators, upon request, are expected to provide the NIH with information about their scientific accomplishments, changes in professional status or institutional affiliation for a period of six years subsequent to termination of the award.

D. Applicable Policy

Except as otherwise stated in this issuance, awards will be administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74, including requirements for cost sharing.

VI. APPLICATION PROCESS

- A. The regular research grant application form PHS 398 must be used in applying for these awards. Application material may be obtained from the institution's application control office or from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20205.
- B. The title of the program New Investigator Research Award should be typed on Line 2, face page of the application form PHS 398.
- C. Direct costs may be requested for up to three years of support. The total direct costs requested must not exceed \$107,500 for the three-year period; no more than \$37,500 may be requested in any one year.
 - 1. Up to \$25,000 salary plus applicable fringe benefits may be requested for the principal investigator. The amount requested should reflect the time and effort to be directed to the project and must be consonant with the policies of the grantee institution governing salary for other individuals of similar rank.
 - 2. Technical support, supplies, publication costs and limited equipment, as well as necessary travel, may be requested within the direct cost budget.
 - 3. Requested funds may not be used to supplement a project supported by other funds.
- D. Indirect costs are allowable in accordance with HEW policies for research grants.
- E. Because many new investigators may not have developed a significant bibliography of research accomplishments, principal investigators may request present or former supervisors to submit letters attesting to their potential for conducting independent research.

VII. GENERAL INFORMATION

A. Review Cycle

Receipt date for applications and review schedules are the same as for regular research grant applications.

<u>Application Receipt Date</u>	<u>Initial Review</u>	<u>Advisory Council</u>
November 1	Feb/Mar	May
March 1	June	Sept/Oct
July 1	Oct/Nov	Jan/Feb