NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 17, No. 23
July 15, 1988

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NOTICES

DATED ANNOUNCEMENTS (RFPs AND RFAs)

NOTICES

Presolicitation: EPIDEMIOLOGIC STUDIES OF HIV-ASSOCIATED MALIGNANCIES

RFA: 88-CA-16

P.T. 34; K.W. 0785055, 0715120, 0411005

National Cancer Institute

Anticipated RFA Availability Date: September 6, 1988
Anticipated Application Receipt Date: December 19, 1988

INTRODUCTION

The purpose of this announcement is to alert the scientific community to the proposed reissuance of an RFA for epidemiologic studies to establish the incidence rates, natural history, and etiology of malignancies in individuals at risk for human immunodeficiency virus (HIV) infection.

RESEARCH GOALS AND SCOPE

The objective of the proposed RFA is to encourage epidemiologic research into the etiology of HIV-associated malignancies. Questions of interest include: whether any epidemiologic risk factor patterns or laboratory analyses suggest a mechanism of carcinogenesis in contrast to other clinical outcomes of HIV infection; the relationship between the severity and expression of immune alteration in HIV-infected individuals and development and progression of cancer; the effect of host factors such as histocompatibility antigen polymorphisms on susceptibility to HIV-related malignancies; the effect of HIV antigenic variation, and coinfection with related retroviruses or unrelated viruses, on the development of specific malignancies; international variation in incidence of HIV-related malignancies; the relationship of acquired immunodeficiency syndrome (AIDS) prophylaxis and treatments, and related immune alterations, to tumor development and progression; the latency period between exposure to initiating agent(s) and development of premalignant conditions or malignancy; and the effects of drug and environmental exposures.

Investigations considered responsive to the proposed RFA include, but are not limited to:

- Epidemiologic studies, in the diverse groups at risk for HIV infection, comparing individuals who develop malignancies to those with other outcomes of HIV infection;
- Epidemiologic studies comparing individuals with HIV-associated tumors to those with nonepidemic tumors of the same pathologic type, including those occurring in other immunosuppressed states;
- Epidemiologic studies of malignancies occurring in individuals receiving treatment for AIDS with particular attention to treatment-related immune alterations.

MECHANISM OF SUPPORT

The mechanism of support for this RFA will be the traditional National Institutes of Health (NIH) research project grant. Approximately $1,500,000 will be set aside in FY89 to fund applications which are submitted in response to this RFA. Non-profit and for-profit institutions are eligible to apply. Foreign as well as domestic institutions are eligible.

The reissued Request for Applications will be available on or about September 6, 1988. Receipt date for applications will probably be December 19, 1988. Awards are planned for June, 1989.

INQUIRIES

A copy of the previous RFA describing the research goals and scope, and a copy of the reissued RFA when available, can be obtained by sending two self-addressed mailing labels to:

G. Iris Obrams, M.D., Ph.D.
Extramural Programs Branch
Epidemiology and Biostatistics Program
Division of Cancer Etiology
National Cancer Institute
Executive Plaza North, Room 535
Bethesda, Maryland 20892
Telephone: (301) 496-9600

DATED ANNOUNCEMENTS (RFPs AND RFAs)

IMMUNOTOXICOLOGICAL EVALUATION OF AIDS THERAPEUTICS

RFP AVAILABILE: NIH-ES-88-14

P.T. 34; K.W. 0715120, 0740020, 1007009

National Institute of Environmental Health Sciences

The purpose of this project is to perform immunotoxicity and myelotoxicity studies on potential AIDS therapeutics. The contractor shall employ an Immune Testing Panel provided by the National Toxicology Program to examine the immuno/myelotoxicity of one selected AIDS therapeutic in normal mice and in mice infected with a murine retrovirus per year. The Government estimates that a level of effort of approximately 0.5 professional person years, 0.5 senior technical person years and 0.5 technical person years per contract year will be required. All responsible sources may submit a proposal which shall be considered by the agency. The expected release date of the Request for proposals is July 18, 1988, with proposals due for receipt 45 days thereafter.

Requests should reference RFP NIH-ES-88-14 and should be forwarded to:

National Institute of Environmental Health Sciences
Contracts Management Office, OAM
ATTN: Ms. Elizabeth B. Ford
79 T.W. Alexander Drive, 4401 Building
P.O. Box 12874
Research Triangle Park, North Carolina 27709

DEVELOPMENT OF DOSAGE FORMS AND DELIVERY SYSTEMS FOR NEW ANTITUMOR AGENTS

RFP AVAILABLE: NCI-CM-97576-68

P.T. 34; K.W. 0740020, 0710130, 0710080

National Cancer Institute

The Developmental Therapeutics Program, Division of Cancer Treatment, National Cancer Institute, is seeking contractors to: 1) carry out innovative studies leading to more effective approaches for the intravenous delivery of compounds that possess limited solubility and/or stability; and 2) develop parenteral dosage forms of potential antitumor agents that exhibit inadequate solubility and/or stability in vehicles commonly used for intravenous administration. Compounds to be studied are selected by the NCI. Resolution of these problems requires approaches more complex than simple solvent approaches or pH adjustment. These projects will also require considerable pharmaceutical analysis including the development and application of a stability indicating assay. The following analytical instrumentation should be available: ultraviolet, infrared, and proton magnet resonance spectroscopy; high pressure liquid chromatograph with variable wavelength ultraviolet detection, optical rotation apparatus and thermal analysis equipment.

The goal of the contract effort is to develop a pharmaceutical dosage form suitable for intravenous administration. The Government will provide certain target solubility and stability goals. The Contractor will prepare a pilot batch (30-100 units) of the finished dosage form as a product of the non-clinical research effort.

The Principal Investigator should have a Ph.D. degree in Pharmaceutical, Physical or Medicinal Chemistry, Physical Pharmacy, or Pharmaceutics and have at least three years of experience in the development of injectable formulations.

The Government anticipates multiple contract awards. Offerors must propose at the two and three staff-year levels. The Principal Investigator should devote

475 direct labor hours annually at both levels of effort. Contracts will be awarded on an incrementally funded basis for a three-year period beginning on or about 6/30/89.

RFP NO. NCI-CM-97576-68 will be issued, upon written request, on or about July 20, 1988, and proposals will be due October 5, 1988. RFP requests should be addressed to:

Karlene W. Ruddy
Contract Specialist
Treatment Contracts Section, RCB
National Cancer Institute, NIH
Blair Building, Room 228
Bethesda, Maryland 20892
Telephone: (301) 427-8737

DEVELOPMENT AND PRODUCTION OF PHARMACEUTICAL DOSAGE FORMS

RFP AVAILABLE: NCI-CM-97577-27

P.T. 34; K.W. 0740020, 0710130

National Cancer Institute

The Pharmaceutical Resources Branch (PRB), Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI), is seeking organizations with the capability to provide pharmaceutical services in the following areas: development of freeze dried and liquid small volume parenterals; development of tablet and capsule solid oral dosage forms; and production of sterile freeze dried dosage forms, small forms, volume parenterals, tablets and capsules. Batch sizes of injectables will be in the 4000-6000 vial range and batches of tablets and capsules will likely range from 10,000 to 50,000 units. The Government will select and provide the antitumor agents for dosage form development and production. The dosage forms will be used in preclinical toxicology evaluation, in pharmacology studies and in clinical trials.

As a minimum requirement, the Contractor and sub-contractor must be registered with FDA as a pharmaceutical manufacturing facility for both sterile products and solid oral dosage forms at time of best and final offer. Annual work load estimates for development are: injectable - 3000 technical staff hours; and oral dosage forms - 1000 technical staff hours per year. Annual workload estimates for production are: 10 injectable batches; and 6 tablet/capsules production runs. The oral dosage form aspects may be subcontracted in part or in total to a manufacturing concern that meets FDA's Current Good Manufacturing Practice (CGMP) requirements and is acceptable to NCI. Shelf life monitoring of production batches will not be required.

Data obtained from this contract will: 1) be used to support IND applications submitted by the National Cancer Institute to the U. S. Food and Drug Administration; 2) be provided to other NCI contractor's engaged in large-scale dosage form manufacture and analytical evaluation of these dosage forms; and 3) be provided to physicians, pharmacists, nurses and other medical personnel handling these products in a clinical setting.

The Contractor selected for this work must prepare all products in accord with FDA's Current Good Manufacturing Practice regulations and the National Cancer Institute's product specifications. The contractor will be responsible for the quality control testing of all formulation components including the active ingredients, excipients, container closure system, as well as the finished products prepared under the contract.

All products will be labelled and packaged according to the Government's specifications. Label preparation may be subcontracted, but labelling must be performed at the manufacturing site. It is anticipated that an incrementally funded contract will be awarded for a period of three years beginning on or about June 15, 1989.

RFP No. NCI-CM-97577-27 will be issued, upon written request, on or about July 15, 1988, and proposals will be due approximately ten weeks thereafter.

Requests for this RFP must be addressed to:

Johnny Jordan
Contract Specialist
Treatment Contracts Section, RCB
National Cancer Institute, NIH
Blair Building, Room 228
Bethesda, Maryland 20892
Telephone: (301) 427-8737

NATIONAL RESEARCH SERVICE AWARD-INSTITUTIONAL GRANTS

RFA AVAILABLE: 88-DE-7

P.T. 44; K.W. 0720005, 0502009

National Institute of Dental Research

Application Receipt Date: December 1, 1988

AUTHORITY AND PURPOSE

Under authority of Section 487 of the Public Health Service (PHS) Act as amended (42 USC 288), the National Institute of Dental Research (NIDR) will award National Research Service Award (NRSA) institutional grants to eligible institutions to develop or enhance research training opportunties for individuals selected by them who wish to prepare themselves for careers in biomedical and behavioral oral health research. With this Request for Applications (RFA), the NIDR is announcing significant changes in both the structure and the administration of its NRSA institutional program. These changes have been endorsed by the National Advisory Dental Research Council and by the Dental Research Programs Advisory Committee. This RFA contains a description of the new policies and procedures and lists areas in which research training proposals are especially encouraged.

LEVELS OF TRAINING

Applications will be accepted for predoctoral and postdoctoral training to meet national priorities in oral health research. The NIDR is requesting that applicants for institutional grants propose training programs in which the training is part of a research degree program. Priority will be given to proposals that offer dentists the opportunity of obtaining a Ph.D. degree. However, in certain cases, proposals offering training as part of a masters degree program will be acceptable.

APPLICANT ELIGIBILITY REQUIREMENTS

Domestic nonprofit private or public institutions may apply for grants to support research training programs. The applicant institution must have the staff and facilities required for the proposed program. The training program director at the institution will be responsible for the selection and appointment of trainees and for the overall direction of the program. Clinical departments or programs should have a significant relationship with basic scientists that will assure trainees with clinical backgrounds the opportunity to acquire the necessary foundation for future investigative work.

GENERAL PROVISIONS

NRSAs may not be used to support studies leading to the D.D.S. or other similar professional degrees, or to support residencies. Since dentists usually have had little or no prior research training, their training program must have, as a minimum, two years of basic research training.

TRAINEE ELIGIBILITY REQUIREMENTS

The individual to be trained must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence. Postdoctoral individuals must have a D.D.S., D.M.D., or equivalent dental degree from an accredited domestic or foreign institution. Individuals with a research doctoral degree (Ph.D. or equivalent) are expected to apply for the individual postdoctoral fellowship award (F32). As a rule, they should not be appointed to the traditional institutional training grant (T32).

PROGRAM STRUCTURE

The NIDR does not set any upper limits to the number of postdoctoral or predoctoral trainee positions an applicant may request. However, training programs with fewer than five positions for postdoctoral trainees over the five year period will not be funded. The program should be structured in such

a way that acceptance of new postdoctoral trainees be limited to the first three years of the five year award, i.e., as a minimum, two trainees the first year, another two the second year, and one the third year. A similar pattern is to be proposed by applicants requesting more than five positions. Ultimately, the number of positions awarded will be decided by the review process, program needs, and availability of funds. The NIDR will not fund more than one training grant from the same institution unless distinctly different training programs are proposed.

PERIOD OF SUPPORT

Institutional grants may be made for competitive segments of 5 years and are renewable. No individual trainee may receive more than 5 years of total NRSA support at the predoctoral level and 3 years of aggregate NRSA support at the postdoctoral level, including any combination of support from institutional training grants and individual fellowship awards, except under certain circumstances. Any exception to this policy requires a waiver from the NIH. Dentists requiring additional time to complete training as a participant in a Ph.D. program may anticipate favorable consideration of a waiver request, contingent upon certification of the recipient's good academic standing.

REVIEW PROCESS

Applications will be evaluated for merit by an NIDR initial review group (IRG). Site visits may be involved. The IRG, following their assessment of the quality of training grant applications and assignment of priority scores indicative of merit, will comment on each applicant's plans for attracting individuals from underrepresented minority groups into the research training program. Applications are then reviewed by the National Advisory Dental Research Council. Funding decisions will be made based on the review groups' recommendations, the need for research personnel in specified program areas, and the availablility of funds.

REVIEW SCHEDULE

The NIDR will initiate, with this RFA, a new policy establishing a single annual NRSA training grant receipt date and review cycle for all new and competitive renewal applications. The schedule for this first cycle is indicated below. It is designed to allow Program Directors time to recruit candidates during the fall of 1989 for appointments to begin the following summer.

Application Receipt Date	Initial Review Meeting	Council Meeting	Earliest Award Date
December 1, 1988	February/ March 1989	May/June 1989 or July 1989	August 1989

ADDITIONAL INFORMATION

The NIDR supports training in biomedical and behavioral oral health research. This year we are particularly interested in applications proposing training in molecular and cellular biology as related to studies of mechanisms underlying development, function, disease, and repair of oral tissues. In addition, the NIDR wishes to encourage applications for training in nutrition, epidemiology, and in neurobiological/neuroanatomical aspects of oral motor function and orofacial pain.

The NIDR intends to issue an RFA for this program annually to indicate the particular areas of emphasis for which it wishes to receive applications. It is anticipated that the future application receipt date will be September 10th of each year. The remainder of the review and award schedule will be approximately as indicated above.

The establishment of the new format will require some realignment of existing programs. For that reason, NIDR will contact all currently supported program directors with information about their status in the near future. However, program directors whose training grants are scheduled to terminate on June 30, 1990, should be aware that they may have to meet the December 1, 1988, receipt date deadline if they wish to submit a competing renewal application.

Complete details on the mechanism of the award, application procedure and review criteria may be obtained from:

Thomas M. Valega, Ph.D.
Special Assistant for Manpower Development and Training
National Institute of Dental Research
National Institutes of Health
Westwood Building, Room 510
Bethesda, Maryland 20892
Telephone: (301) 496-6324

PREVENTION CLINICAL TRIALS UTILIZING INTERMEDIATE ENDPOINTS AND THEIR MODULATION BY CHEMOPREVENTIVE AGENTS

RFA AVAILABLE: 88-CA-15

P.T. 34; K.W. 0745055, 0755015, 0710095, 0740020, 0715035

National Cancer Institute

Application Receipt Date: October 13, 1988

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to support clinical trials which are directed toward examining the role of various chemopreventive agents and/or diet in the prevention of cancer. This is a follow-up to earlier RFAs which had requested grants, and then later, cooperative agreement proposals in this area.

The major objective of this solicitation is to encourage cancer chemoprevention clinical trials which utilize biochemical and/or biological markers to identify populations at risk and/or to provide intermediate endpoints that may predict later reduction in cancer incidence rates.

These studies may be developed in phases, including a pilot phase, which could later proceed to a full scale intervention. The main emphasis should be on small, efficient studies aimed at improving future research designs of chemoprevention trials, providing biologic understanding of what is happening in the trials, or providing better, more quantitative and more efficient endpoints for these trials. After successful completion of the pilot phase; (i.e. demonstrated modulation of marker endpoints by the intervention), subsequent studies can include Phase III clinical trials involving the designated agent, the utilization of the monitoring test system and a cancer incidence or mortality endpoint.

Investigators may apply at this time for the pilot phase, or submit an application for both phases. However, if the application is for the pilot phase only, the proposed study must describe its relevance to a clinical application and utilize a chemopreventive agent, marker test system, and study population which could later be the subject of a full scale, double-blind, randomized, risk-reduction clinical trial.

Applicants funded under this RFA will be supported through the cooperative agreement mechanism. An assistance relationship will exist between NCI and the awardees to accomplish the purpose of the activity. The recipients will have primary responsibility for the development and performance of the activity. However, there will be government involvement with regard to: (1) assistance securing an Investigational New Drug (IND) approval from the Food and Drug Administration (FDA); (2) monitoring of safety and toxicity; (3) coordination and assistance in obtaining the chemopreventive agent; (4) quality assurance with regard to the clinical chemistry aspects of the study. Awards will not be made until all arrangements for obtaining the IND, agent, and its delivery are completed. Final awards will also consider not only the cost of the clinical trial but also the cost of the agent and its formulation if necessary.

Approximately $1 million in total costs per year for 3 years will be committed to specifically fund applications which are submitted in response to this RFA. It is anticipated that 3 to 5 awards will be made annually. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit.

This RFA solicitation represents a single competition, with a specified deadline of October 13, 1988, for receipt of applications. All applications received in response to the RFA will be reviewed by the same National Cancer Institute Initial Review Group (IRG).

To ensure their review, applications should be received by October 13, 1988. Applications received after that date will not be considered under this RFA.

Inquiries may be directed to:

Marjorie Perloff, M.D.
Chemoprevention Branch
Blair Building, Room 616
National Cancer Institute
Bethesda, Maryland 20892-4200
Telephone: (301) 427-8680

CARDIAC TRANSPLANT ATHEROSCLEROSIS

RFA AVAILABLE: 88-HL-18-H

P.T. 34; K.W. 0715040, 0745040, 0745055, 0745065, 0715125, 0415000

National Heart, Lung, and Blood Institute

Application Receipt Date: December 5, 1988

The Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute invites grant applications to be considered in a single competition for five years' support of basic research on cardiac transplant atherosclerosis. The emphasis of this program is on elucidating the etiology and natural history of this form of atherosclerosis which affects the arteries and arterioles of the transplanted heart. The ultimate goals are to develop knowledge which will lead to effective prevention and/or treatment.

BACKGROUND

Cardiac transplantation is now an accepted procedure for the treatment of some forms of end-stage heart disease. The number of cardiac transplant procedures has increased dramatically in the last five years. One year survival post-transplantation is now 80-90 percent with combination immunosuppressive therapy. Improved immunosuppressive therapy has reduced the risks from rejection and infection so that another complication, namely accelerated transplant atherosclerosis (ATxA), is emerging as the most significant threat to long-term survival of cardiac transplant patients. The etiology of this disease is unknown at this time. A popular theory is that it is a manifestation or result of chronic rejection. Another school of thought is that the disease is a side effect of some immunosuppressant drugs. Other factors may be involved such as hyperlipidemia or viral infections. The effectiveness of drug intervention with antiplatelet therapy is unresolved at this time.

OBJECTIVES AND SCOPE

The overall goal is to develop knowledge which will contribute to understanding the etiology, treatment and prevention of cardiac transplant atherosclerosis. The research solicited in this RFA concerns the causes and natural history of the disease as well as possible interventions in the disease process. Either animal models or human patients may be studied. However applications should not include clinical trials.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional, individual research grant. All current policies and requirements that govern the research grant programs of the National Institutes of Health will apply to grants awarded under this RFA. Awards will be made to foreign institutions only for research of very unusual merit, need, and promise, and in accordance with Public Health Service policy governing such awards.

Although the financial plans for fiscal year 1989 include $2,000,000 for the total costs of this program, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that approximately six to eight grants will be awarded under this program. The specific number to be funded will, however, depend on the merit and scope of the applications received and on the availability of funds.

REVIEW PROCEDURES

All applications submitted in response to this RFA will be evaluated for scientific and technical merit by an initial review group, which will be convened for this purpose, by the Division of Extramural Affairs, NHLBI.

METHOD OF APPLYING

Potential applicants should write or phone the individual listed below for the full RFA document, which includes instructions for the submission of applications:

Judith G. Massicot, Ph.D.
Cardiac Diseases Branch
Federal Building, Room 3C06
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-1081

PROGRAMS OF EXCELLENCE IN MOLECULAR BIOLOGY

RFA AVAILABLE: 88-HL-20

P.T. 34; K.W. 1002008, 0710030, 1002058, 0710060, 0785070, 0715165, 0715165

National Heart, Lung, and Blood Institute

Application Receipt Date: February 10, 1989

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) inviting grant applications to develop Programs of Excellence in Molecular Biology. Each Program of Excellence will support a multidisciplinary team of independent research investigators, and will have two major objectives: (1) to foster utilization of molecular biology approaches in important research areas within the mission of the National Heart, Lung, and Blood Institute where the use of these technologies has yet to be fully employed; and (2) to provide opportunities for investigators who have the potential for independent research careers to become skilled in the experimental strategies and techniques of molecular biology and their application to research relevant to the mission of the Institute.

A Program of Excellence will be multidisciplinary in nature, and should be designed to share ideas, data, and facilities. The total scientific effort must be directed toward a central, unifying theme. In keeping with the tradition of investigator-initiated research, the NHLBI expects the applicants to define their own theme and to develop the approaches that would be used to accomplish the objectives of the proposed research program.

Each applicant has considerable flexibility in devising a plan to accomplish the broad objectives of this RFA on the basis of the imagination and talents of the investigators, the resources and commitment of their respective institutions, and the unique features of this RFA. However, in order to evaluate the proposed plans effectively, each application should include an assessment of the applicant Institution's current research activities and how these will serve as a basis for development of a program of research using molecular biology approaches, a description of the proposed new program goals to achieve the integration of molecular biology into areas related to the mission of the NHLBI by the end of a seven year period, a description of the scientific and administrative plans to attain these goals, and a summary of anticipated research opportunities and directions that will be made possible by a Program of Excellence.

Although the financial plans for fiscal year 1989 include $5 to $10 million in total costs for this announcement, award of grants pursuant to this RFA is contingent upon availability of funds for this purpose. It is anticipated that 3-5 grants will be awarded under the program established by this announcement. The specific number to be funded will, however, depend on the merit and scope of the applications received and the availability of funds.

PROGRAM FEATURES

To provide a suitable structure for achieving the objectives of the RFA, a Program of Excellence in Molecular Biology will have the following elements:

- SEVEN YEAR AWARD: This extended period will enable a Program of Excellence to be innovative, to pursue new developments in rapidly advancing areas, to embark on the application of molecular biology to more complex experimental systems, and to develop new experimental models.

- RECRUIT ESSENTIAL SCIENTIFIC EXPERTISE: In order to provide the most effective combination of scientific disciplines, applicants

may request funds to recruit faculty to augment or strengthen the skills and capabilities of existing faculty.

- INSTITUTIONAL ENVIRONMENT AND RESOURCES: Applicants may request funds for incidental alteration and renovation of facilities consistent with Public Health Service policy, as well as the purchase of equipment needed to conduct research using the technologies of molecular biology.

- EXPERIMENTAL DESIGN AND METHODS: In an effort to provide broader degrees of research freedom, and to encourage innovative approaches, the application requires only a brief description of the preferred and alternative experimental approaches, strategies and proposed research directions. The application will not require specific details for individual experiments and protocols. In addition, the application will use a simplified budgetary format.

- SUPPORT FOR NEW INVESTIGATORS: To provide for the development of new research workers with skills required to conduct research utilizing the technologies of molecular biology, applications may include a request to support young investigators or investigators new to the discipline of molecular biology.

APPLICATION

In 1987, the NHLBI initiated a two-phase strategy to establish a network of Programs of Excellence in Molecular Biology to stimulate the application of molecular biological strategies in conjunction with other pioneering and conventional technologies. The Institute will complete the establishment of this program through this announcement. A similar announcement was released approximately one year earlier. This two-stage process was designed to provide institutions with additional time to augment scientific expertise and/or to solidify interactions among the various scientific disciplines. New applications and amended applications will be accepted.

Applications should be submitted on the revised (9/86) form PHS 398 according to the instructions provided with the form and according to Supplemental Guidelines prepared by the NHLBI. Because of the unique features and goals of the Programs of Excellence, applicants will require these Supplemental Guidelines to prepare an acceptable application.

TIMETABLE

Letter of Intent	October 4, 1988
Application Receipt Date	February 10, 1989
First Stage of Technical Review	May 1989
Second Stage of Technical Review	July 1989
Advisory Council Review	September 14-15, 1989
Award Date	September 30, 1989

INQUIRIES

To obtain copies of the detailed RFA and the detailed Supplemental Guidelines (which must be followed if an acceptable application is to be submitted) contact:

Stephen C. Mockrin, Ph.D.
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building - Room 4C10
7550 Wisconsin Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-1857

HYPERGLYCEMIA AND CARDIOVASCULAR DISEASE RISK FACTORS: Field Centers, Coordinating Center and Support Laboratories

RFA AVAILABLE: 88-HL-11-P

P.T. 34; K.W. 0715040, 0411005, 0715075, 1004008

National Heart, Lung, and Blood Institute

Application Receipt Date: December 1, 1988

The Clinical and Genetic Epidemiology Branch of the Division of Epidemiology and Clinical Applications, National Heart, Lung and Blood Institute (NHLBI),

announces the availability of a Request for Applications (RFA) on the above subject. Copies of the RFA will be available June 2, 1988, from staff of the NHLBI.

This program will support epidemiologic investigators and supporting staff to collaboratively plan and execute a study to assess the relationships between glucose and insulin concentrations and other risk factors for cardiovascular disease (CVD). A major aim of the study is to employ a common protocol to assess the associations of increasing concentrations of glucose and changing levels of insulin and insulin resistance with levels of other CVD risk factors, using a population derived stratified sample so there are adequate numbers to assess variations in individual CVD risk factors over a range of glucose tolerance from normal through overt diabetes. This survey will provide insight into the reasons for the changing risk of CVD at increasing glucose levels and may help to explain the apparent difference in the contribution of hyperglycemia to the risk of CVD in men and women.

In view of the size of this study and the anticipation that some needs will not be identified until the protocol is developed, central functions of the collaborative activity: a Coordinating Center, a Central Laboratory and an Electrocardiogram Reading Center, will be performed by or under the direction of one or more of the examination centers. Each Field Center applicant is invited to apply to serve as one or more of these support units for the study. A separate application should be submitted for each support unit. Applicants should discuss the special functions of any proposed support activity, including methodology and quality control assessment, and provide an estimated time for the work to be completed.

It is anticipated that two or three awards will be made under this RFA for a total of approximately 3.5 million dollars (including direct and indirect costs for field centers and all central functions) over a three-year period.

Interested institutions may request copies of the RFA.

Requests for copies of the RFA should be addressed to:

Peter J. Savage, M.D.
Clinical and Genetic Epidemiology Branch
Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building, Room 300
7550 Wisconsin Ave.
Bethesda, Maryland 20897
Telephone: (301) 496-4333

DEVELOPMENT OF SEROLOGICAL TESTS FOR INVASIVE UREAPLASMA UREALYTICUM INFECTIONS

RFA AVAILABLE: 88-AI-12

P.T. 34; K.W. 0715125, 0715220, 0755010, 0760045

National Institute of Allergy and Infectious Diseases

Extension of Due Date and Award RFA # 88-AI-12, for the Development of Serological Tests for Invasive Ureaplasma Urealyticum Infections, appeared in the NIH Guide for Grants and Contracts, page 4, Vol. 17, No. 18, May 20, 1988, with an originally announced due date of July 15, 1988, and an award date of April 1, 1989.

The National Institute of Allergy and Infectious Diseases announces the extension of the due date for these applications to September 15, 1988. The award date will be extended to July 1, 1989.

All of the known applicants have been contacted by NIAID staff about this revised due date. Investigators who had not previously contacted NIAID about this RFA and submitted their application on July 15, have the option to submit supplemental material or a revised application up to September 15, 1988. In such instances, the revised application or supplemental material must be mailed directly to:

Dr. Robert Edelman
Chief, Clinical and Epidemiological Studies Branch
National Institute of Allergy and Infections Diseases
Program
Building 31, Room 7A52
Bethesda, Maryland 20892
Telephone: (301) 496-5893

The full, revised RFA (general description and Guidelines) and consultation may be obtained from Dr. Edelman.

*U.S.GOVERNMENT PRINTING OFFICE:1988-201-770;80003