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and
Contracts**

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The NIH Guide announces scientific
initiatives and provides policy and
administrative information to individ-
uals and organizations who need to
be kept informed of opportunities,
requirements, and changes in extra-
mural programs administered by the
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NOTICES

GRANTS ASSOCIATES PROGRAM

P.T. 44; K.W. 0901026, 0710030

Public Health Service

Scientists interested in an administrative career with Federal programs supporting research and training in health-related fields may wish to consider the Grants Associates Program of the U. S. Public Health Service. The program is governed by the Grants Associates Board and is administered by the Office of Extramural Research, Office of the Director, National Institutes of Health (NIH).

The program prepares each Grants Associate for a responsible position in health science administration in the Public Health Service. For a 12-month period, the Grants Associate participates in an individually structured training experience including on-the-job training assignments, courses and seminars. The program provides opportunities for participation in the development and administration of policies in Federal support of health related research, and in the fundamentals of effective management. The program also attempts to develop a sensitivity to the consequences of program decisions on other Federal health programs, research institutions, and national health needs.

Admission to this program as a full-time permanent Federal employee, is highly competitive for the few positions available. Motivation for a career in science administration, good interpersonal skills, and evidence of executive potential are important. If you are a U.S. citizen and hold a doctorate or equivalent in a discipline related to the biomedical or behavioral sciences, have significant independent research experience beyond the doctorate and are attracted to health science administration as a profession, you should inquire about the Grants Associates Program. Administrative experience is not required.

Grants Associates may be appointed either in the U.S. Civil Service at grade levels General Schedule (GS) 12 (\$33,218), GS-13 (\$39,501), or GS-14 (\$46,679) or in the Commissioned Corps of the U.S. Public Health Service at ranks beginning with senior grade (O3 Lieutenant, base salary of \$20,390 dependent on prior military experience.)

The NIH does not discriminate in employment on grounds of race, color, sex, national origin, age, or handicap. For further information, write to:

Director
Health Scientist Administrator
Development Programs
Office of Extramural Research
Office of the Director, NIH
Building 31, Room 1B-62
Bethesda, Maryland 20892

DIRECTORY OF INTERNATIONAL OPPORTUNITIES IN BIOMEDICAL AND BEHAVIORAL SCIENCES

P.T. 16, 22; K.W. 0720005

Fogarty International Center

The Fogarty International Center (FIC), National Institutes of Health (NIH), announces the availability of a limited number of booklets entitled Directory of International Opportunities in Biomedical and Behavioral Sciences. This is an updated version of the Directory that was published in January 1984. This publication is available to individuals who are seeking information about fellowship support in biomedical and behavioral sciences.

To receive a copy of this booklet, please send a self-addressed label with your request to the following address:

International Research and Awards Branch
Building 38A, Room 613
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20892

DATED ANNOUNCEMENTS (RFPs AND RFAs)

LONG TERM MORTALITY STUDY OF MEN WHO HAVE UNDERGONE VASECTOMY

RFP AVAILABLE: NICHD-CE-88-9

P.T. 34; K.W. 0705075, 0411005, 0785210, 0785055

National Institute of Child Health and Human Development

The Contraceptive Evaluation Branch, Center for Population Research, National Institute of Child Health and Human Development, is seeking organizations capable of conducting a retrospective cohort study of the relationship between vasectomy and altered patterns of mortality. The objective is to address the mortality risks associated with vasectomy at fifteen or more years following the procedure. The project will require the identification of a cohort of men who were vasectomized at least fifteen (15) years ago, and identification of a suitable comparison cohort, of sufficient sizes to detect differences in overall mortality and mortality due to causes such as heart disease, cancer, and immunologic disorders. In addition, the successful offeror will be required to determine vital status and cause of death and conduct appropriate survival analysis to determine whether vasectomized men are at any increased risk of mortality. It is estimated that a single contract award will be made for a two-year performance period and will require epidemiological and statistical expertise.

This announcement is not a request for proposals (RFP). RFP-NICHD-CE-88-9 will be issued on or about April 4, 1988. Proposals will be due 60 days thereafter. Copies of the RFP may be obtained by sending a written request to the following address. Please enclose a self-addressed label.

Paul J. Duska, Contracting Officer
Contracts Management Section, OGC
National Institute of Child Health and Human Development
Executive Plaza North, Room 610
6130 Executive Boulevard
Rockville, Maryland 20892

CORONARY ARTERY RISK DEVELOPMENT IN YOUNG ADULTS (CARDIA) -
ECHOCARDIOGRAPHY READING CENTER

RFP AVAILABLE: NHLBI-HC-88-06

P.T. 34; K.W. 0715035, 0411005, 0706030

National Heart, Lung, and Blood Institute

The Epidemiology and Biometry Research Program, DECA, NHLBI, seeks an echocardiography reading center for a project in which four field centers will continue to examine and follow a total of 5000 men and women who were aged 18 to 30 years at the baseline examination in a longitudinal study of the evolution of coronary heart disease risk factors in young adults (CARDIA). The echocardiography reading center will develop a protocol for collection of echocardiography data on the 4000 participants expected to return for Exam 3 at the four field centers and perform precise measures of cardiac structure and function from the echocardiogram data collected.

The echocardiography reading center is the only competitive RFP anticipated for the CARDIA study.

RFP NHLBI-HC-88-06 for the Echocardiography Reading Center will be available on or about April 15, 1988, with proposals due about June 15, 1988. One award is anticipated. Your written request should include three mailing labels, self-addressed, and must cite RFP No. NHLBI-HC-88-06.

Requests for copies of the RFP should be sent to:

Betty Nordan
Contracting Officer for Epidemiology and
Biometry Research Program,
ECA Contracts Section
National Heart, Lung, and Blood Institute
Federal Bldg, Room 3C16
Bethesda, Maryland 20892

RESEARCH ON ALCOHOL-RELATED BEHAVIOR THAT INCREASES THE RISK OF AIDS AND/OR RESEARCH ON PREVENTION STRATEGIES TO REDUCE THAT RISK

RFA AVAILABLE: 88-AA-02

P.T. 34; K.W. 0404003, 0715020, 0715120

National Institute on Alcohol Abuse and Alcoholism

Application Receipt Date: May 25, 1988

INTRODUCTION

At the National Institute on Alcohol Abuse and Alcoholism (NIAAA) most of the research on AIDS has addressed biomedical aspects of this illness. More attention needs to be given to the effect of alcohol on behavior that increases the risk of HIV infection for the individual and his or her contacts. To stimulate such research, the Prevention Research Branch of NIAAA invites grant applications that focus on alcohol-related behaviors that may heighten the risk of HIV infection and/or that focus on prevention strategies to reduce or modify such behaviors.

RESEARCH ALTERNATIVES

The RFA offers two research options:

- 1) Investigators may focus entirely on the underlying nature and dynamics of alcohol-related behaviors that might increase the risk of AIDS, addressing the interaction of psychological and social variables; or
- 2) Investigators may move directly to intervention research, testing the effectiveness of strategies to prevent alcohol-related behaviors that can result in AIDS.

Topics relevant to this initiative might include: risk taking behaviors among specific target groups; the effect of alcohol use on judgement, decision making, perception of risk with respect to AIDS, and moral commitments to others; the impact of alcohol as a disinhibitor for indiscriminate sex or intravenous drug use; the consequences of alcohol consumption on the role of women or men as possible gatekeepers for protective or unsafe sex practices; and the function of alcohol environments (e.g., the singles or gay bar) as facilitators or disincentives for AIDS-related risk taking behavior. In topic areas such as these, it would be possible to explore underlying behavioral dynamics or appropriate prevention strategies.

Among populations at high risk for AIDS (e.g., homosexuals, bisexuals, prostitutes, intravenous drug users, and their sexual partners) disentangling the independent and interactive effects of alcohol on AIDS-related behaviors may call for special and creative research skills. Within such vulnerable populations, NIAAA is particularly interested in research which targets Blacks and Hispanics, who are presently overrepresented among AIDS patients.

This RFA encourages the submission of applications using multifaceted or singular research methodologies indigenous to any discipline that can contribute to this area of prevention research.

ELIGIBILITY

Applications may be submitted by public and private non-profit or for-profit organizations such as universities, colleges, hospitals, laboratories, research institutes and organizations, units of state and local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

APPLICATION PROCEDURES AND FUNDING

The single application receipt date is May 25, 1988. It is estimated that \$500,000 to \$1,000,000 will be available to make approximately three to six awards for the first year of study, including direct and indirect costs. Awards may be made late in FY 1988 or early in FY 1989. Applicants should use the Public Health Service research grant application form PHS 398 (Revised, 9/86) which is usually available at institutional offices of sponsored research at most major universities and colleges.

Support will be provided for a period of up to 5 years (renewable for subsequent periods) subject to continued availability of funds and research progress achieved. Any expenses associated with treatment, rehabilitation, or prevention services must be clearly justified in terms of research needs.

INQUIRIES

The complete RFA including application procedures, review criteria, and terms of support can be obtained from:

Donald F. Godwin
Prevention Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
5600 Fishers Lane, Room 16C-03
Rockville, Maryland 20857
Telephone: (301) 443-1677

STUDIES FOR DEVELOPING PROCEDURES TO EVALUATE THE SAFETY OF BOUND DRUG RESIDUES

RFA AVAILABLE: RFA-FDA-CVM-88-2

P.T. 34; K.W. 1007009, 0740025

Food and Drug Administration

Application Receipt Date: May 31, 1988

Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM) is announcing the availability of approximately \$300,000 for Fiscal Year 1988 for cooperative agreements to support studies for developing procedures to evaluate the safety of drug residues that are bound to tissues of food producing animals. This notice, which amends a prior RFA that published in the NIH Guide for Grants and Contracts on December 4, 1987, extends the application receipt date from January 19, 1988, to May 31, 1988.

BACKGROUND

The purpose of these agreements will be to provide financial assistance to support research on new models, procedures, or combinations of models and procedures that can contribute to a general approach to evaluating the safety of bound drug residues. Compounds that are known to form covalent bonds, by various mechanisms, to tissue components should be selected as model compounds for the proposed studies. Techniques dealing with the identification or isolation of sufficient quantities of bound residues for toxicological testing and in vitro approaches to the toxicological evaluation of bound residues will also be considered for support under this program. The agency is most interested in complete strategies that will have broad application to the bound residue problems encountered with several classes of animal drugs but will give consideration to proposals addressing significant segments of the problem. FDA anticipates making up to three awards. Support for this program may be for a period of up to three years.

MECHANISM

Support will be in the form of cooperative agreement awards which will be subject to all policies and requirements that govern the research cooperative agreement programs of the Public Health Service.

REVIEW PROCEDURES

All applications responding to this request for applications will be reviewed and evaluated for scientific and technical merit by experts in the scientific field. The applications will also be subject to a second level of review to evaluate them in light of the aims of the Food and Drug Administration.

Questions concerning the programmatic aspects of the RFA should be addressed to:

Dr. David B. Batson
Center for Veterinary Medicine (HFV-500)
Food and Drug Administration
5600 Fishers Lane, Room 8-89
Rockville, Maryland 20857
Telephone: (301) 443-6510

Request for copies of the RFA and application kits are available from:

Robert L. Robins
Grants Management Officer
State Contracts and Assistance Agreements Branch
Food and Drug Administration
5600 Fishers Lane (HFA-520)
Parklawn Building, Rm. 320
Rockville, Maryland 20857
Telephone: (301) 443-6170

Applications must be submitted to the Food and Drug Administration using Form 398 (Rev. 9/86). The outside of the mailing package and the top of the application face page should be labeled "Response to RFA-FDA-CVM-88-2 Food and Drug Administration(FDA), Center for Veterinary Medicine."

PHARMACOKINETICS OF AGENTS FOR BLADDER CANCER INTRAVESICAL THERAPY

RFA AVAILABLE: 88-CA-04

P.T. 34; K.W. 0710100, 0740020, 0705075, 0715035

National Cancer Institute

Application Receipt Date: July 11, 1988

The Organ Systems Program through the National Cancer Institute (NCI), Division of Cancer Prevention and Control, invites grant applications from organizations which are capable of participating in a network of research laboratories charged with carrying out studies on the pharmacokinetics and pharmacodynamics of drugs used in the intravesical treatment of urinary bladder cancer. This request for applications (RFA) will be used to: (1) initiate inter-organizational studies of the actions of intravesical drugs in clinically derived bladder cancer cell specimens; (2) identify and carry out laboratory-based studies of the actions of these drugs in bladder cancer cells in animals or in tissue culture and; (3) coordinate resources among the successful applicant organizations for the collection and use of exfoliated bladder cancer cells and of surgical specimens from patients.

OBJECTIVE AND SCOPE

The NCI proposes to encourage the development of a network of laboratories for carrying out pharmacokinetic studies of drugs used in intravesical bladder cancer therapy. Organizations which qualify would have the expertise and facilities to conduct studies of exfoliated cells and tissue specimens from patients, and studies involving animal or in vitro model systems. The network would have responsibility for planning studies which would make use of collective patient resources, and would have advisory responsibility for pilot or lead-in research carried out in the laboratories of individual members of the network. NCI assistance in organizing a pharmacokinetics network is aimed at encouraging scientists in research laboratories and cancer clinics to collaborate and to address the needs of this rapidly advancing field of intravesical drug therapy. The major goal for the network would be to determine the optimum use of intravesical drug therapy to increase survival, maintain a functioning bladder, and prevent the need for recurrent cystoscopy.

BACKGROUND

At the time of diagnosis, about 70 percent of patients have superficial bladder cancer, and the remainder have more advanced disease. The risk for metastasis for patients after treatment of superficial bladder cancer is less than 10 percent, but the risk for appearance of new tumors following treatment is about 50 percent. New occurrences often are multiple and tend to occur more frequently with time. There is 10 to 20 percent risk for progression of grade, stage or both at the time of each recurrence. Such tumors may arise from progressive neoplastic growth in regions of epithelial hyperplasias, atypia or carcinoma in situ. They might also result from implantation of tumor cells on urothelial surfaces that are traumatized during local resection or fulguration.

Approximately 70 percent of bladder cancer patients at diagnosis can be treated with intravesical drugs. Lesions which are treatable include low-grade and high-grade papillary neoplasms and flat carcinoma in situ.

Bladder cancers are highly appropriate targets for localized drug therapy. Intravesical drugs have been used with varying degrees of success to treat existing bladder cancer lesions and to prevent or delay recurrence. Approaches using pharmacokinetic information to optimize intravesical drug treatments for bladder cancer are rudimentary; however, knowledge of

pharmacokinetics has become important for the effective use of several classes of cancer drugs which are used systemically.

The pharmacokinetics of antitumor agents have application in tailoring therapy to specific forms of cancer and means of drug delivery, but this approach has yet to become a significant clinical tool for bladder cancer intravesical drug therapy. Study of the pharmacokinetics of bladder cancer drugs in the laboratory coupled with the analysis of clinically derived materials from significant populations of patients represents an area of research where major effort is needed. Several drugs are known to be effective in the intravesical treatment of superficial bladder cancer, but there is a need for more precise experimental information to determine major advantages of one drug over another, with subsequent confirmation using clinical materials.

ELIGIBILITY

It is the intent of this RFA to initiate network studies by combining expertise among organizations which already are contributing significantly to the pharmacokinetics of cancer drugs. An organization which can establish a liaison between a pharmacokinetics laboratory and a clinical facility currently involved in bladder cancer research is encouraged to respond to this RFA. At the time of submission, a core of qualified investigators, patient populations and facilities should exist in the applicant organization and its proposed affiliates.

The staff of an applicant organization and its affiliates should have demonstrated proficiency and achievement in pharmacokinetics in cancer research, and in research involving the clinical application of intravesical therapy. The principal investigator should be responsible for the day-to-day operation of a currently successful and fully funded pharmacokinetics laboratory. The responsibilities and authority of the principal investigator should be described fully in the application. Descriptions of key personnel should include each individual's qualifications, scientific contributions, level and type of effort, and relevant publications. Mechanisms available for multi-disciplinary input into the proposed pharmacokinetics laboratory should be described. Expertise should be available in the areas of bladder oncology, pathology, cell biology and biostatistics.

APPLICATION SUBMISSION AND REVIEW

For scientific merit review, each applicant will be required to propose an area of collaborative research for the Network, which would involve study of combined patient populations and use of exfoliated cells or tissue specimens from bladder cancer patients. Also, each applicant will be responsible for elaborating research to be carried out in the applicant organization, which would involve animal models, cell culture models, or the use of clinical materials from patients at that institution. The latter research should be designed with the aim of advancing the collaborative capabilities of the Pharmacokinetics Network.

A potential applicant organization is encouraged, but is not required, to submit a letter of intent and is encouraged to consult with NCI staff by telephone before submitting. The letter of intent is requested by May 6, 1988. It will not enter into the review of an application submitted in response to this RFA.

Applications responsive to this RFA will be reviewed for scientific merit by an appropriate peer review group composed primarily of non-Federal experts and set up by the Division of Extramural Activities, National Cancer Institute. Reviewers will consider each application in terms of its projected research plans, and of the proposed means for implementing collaborative activities. Applicants will be reviewed in competition with each other on a nationwide basis. This RFA solicitation is a single competition and has one specific deadline for receipt of applications.

MECHANISM OF SUPPORT

The support mechanism for this program will be the NIH investigator-initiated research grant (R01). Awards will be made to non-profit and profit organizations. An applicant organization may apply for a period of support of up to three years. Funds, if awarded, would support research done individually by the applicant organization and research done collaboratively within the network of participating organizations. The awards would also support travel, planning, communications and data management connected with a collaborative effort.

Contingent upon the continued availability of funds and dependent upon the receipt of a sufficient number of applications of high scientific merit, it is

anticipated that five awards will be made at an annual overall total cost of approximately \$600,000. Before the end of the three-year period of funding, the Pharmacokinetics Network for Bladder Cancer will be evaluated by the NCI and a means for possible continued or expanded support determined.

Requests for copies of the RFA in its expanded form should be addressed to:

William E. Straile, Ph.D.
Cancer Centers Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building, Room 727
Bethesda, Maryland 20892-4200
Telephone: (301) 427-8818

PROSPECTIVE RANDOMIZED STUDIES CORRELATING CURRENT TREATMENT PROCEDURES WITH PAIN REDUCTION IN PANCREATIC CANCER PATIENTS

RFA AVAILABLE: 88-CA-03

P.T. 34; K.W. 0705025, 0715035, 0415000, 0715150

National Cancer Institute

Application Receipt Date: July 11, 1988

The Organ Systems Program, through the National Cancer Institute (NCI), Division of Cancer Prevention and Control, invites research grant applications from organizations capable and interested in participating in a Network of collaborating research groups charged with carrying out studies in the reduction of pain in pancreatic cancer patients. The NCI proposes to encourage up to five existing pain research groups to assemble the expertise and patients needed to evaluate pancreatic cancer pain.

OBJECTIVE AND SCOPE

This Request for Applications (RFA) will be utilized to initiate prospective, randomized studies, which will be implemented through a collaboration among the successful applicant organizations.

The main goal of this RFA is to determine which of the currently used, single or combined, procedures for treating pancreatic cancer patients are correlated with measurable and significant pain relief. Pain and weight loss are common symptoms associated with pancreatic cancer. Pain is a considerable problem in 90 to 100 percent of patients with this disease and is often continuous and severe. The majority of pancreatic cancer patients suffer pain from the onset of their diagnosed illness.

For scientific merit review, each applicant will be required to propose one research project for Network study, and this should involve describing how the research might be adapted to the collaborative research mode and to the use of combined patient populations. Also, each applicant will be responsible for elaborating a second study, either in the same area of pain research or in a dissimilar area, to be carried out totally within the applicant organization. The latter study should be designed with the aim of advancing an aspect of pain research which subsequently might be addressed collaboratively by the Network.

BACKGROUND

Since there are no treatments for pancreatic cancer which increase survival significantly (5-year survival is 2 percent), and there is no known way to prevent the disease, a special research emphasis to identify the best current methods to reduce pain and thus improve the quality of life deserves high priority.

The NCI recognizes that research on pain in pancreatic cancer is difficult to conduct. The relatively low incidence of the disease combined with a brief survival results in few study subjects becoming available at an institution at any specific time. Furthermore, the complexity of the disease course elevates the numbers of patients which would be required for testing hypotheses adequately. An inter-organizational networking effort might overcome these difficulties and make possible the accrual of sufficient patients to answer definitive questions. Organizations with established pain research facilities are encouraged to take the leadership in response to this RFA. Such organizations before applying are required to have the capacity for establishing liaison with investigators involved in clinical research in

cancer, including specific expertise in the treatment of pancreatic cancer. The applicant organization or its affiliate should be involved in treating pancreatic cancer patients. At the time of submission, the required qualified investigators, technical expertise, patient populations, and facilities should exist in the applicant organization and its proposed affiliates.

APPLICATION SUBMISSION AND REVIEW

A potential applicant organization is encouraged, but is not required, to submit a letter of intent, and is encouraged to consult with NCI staff before submitting. Letters of intent are requested by May 6, 1988. The letter of intent will not enter into the review of an application submitted in response to this RFA.

Applications responsive to this RFA will be reviewed for scientific merit by an appropriate peer review group composed primarily of non-Federal experts and set up by the Division of Extramural Activities, National Cancer Institute. Reviewers will consider each application in terms of its projected research plans, and of the proposed means for implementing collaborative network activities. Applications will be reviewed in competition with each other on a nationwide basis. This RFA solicitation is a single competition and has one specific deadline for receipt of applications.

MECHANISM OF SUPPORT

The support mechanism for this program will be the NIH investigator-initiated research grant (R01). Awards may be made to domestic non-profit and profit organizations. An applicant organization may apply for a period of support of up to three years. Funds, if awarded, would support research related to the activities of the collaborative Network. The awards would also support travel, planning, communications and data management connected with the network effort.

Contingent upon the availability of funds and dependent upon the receipt of a sufficient number of applications of high scientific merit, it is anticipated that five awards will be made at an annual overall total cost of approximately \$400,000. Before the end of the three-year period of funding, the Pancreatic Cancer Pain Network will be evaluated by the NCI and a means for possible continued or expanded support determined.

INQUIRIES

Requests for copies of the RFA in its expanded form should be addressed to:

William E. Straile, Ph.D.
Cancer Centers Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building, Room 727
Bethesda, Maryland 20892-4200
Telephone: (301) 427-8818

NATIONAL COOPERATIVE VACCINE DEVELOPMENT GROUPS FOR THE ACQUIRED IMMUNODEFICIENCY SYNDROME

COOPERATIVE AGREEMENT RFA AVAILABLE: NIH-NIAID-88-AI-06

P.T. 34; K.W. 0740075, 0715120, 1002008, 0710070, 1002045

National Institute of Allergy and Infectious Diseases

RFA Availability Date: Immediately
Letter of Intent Receipt Date: May 15, 1988
Application Receipt Date: July 15, 1988

The National Institute of Allergy and Infectious Diseases (NIAID) announces the availability of an RFA for the funding of National Cooperative Vaccine Development Groups for the Acquired Immunodeficiency Syndrome (NCVDG). The RFA (available on request) invites applications aimed at the development of effective vaccines for the prevention of AIDS. Scientific approaches to the development of effective AIDS vaccines appropriate to the RFA may range from research on whole virus vaccines, through the production of preparations with recombinant DNA techniques and synthetic approaches, to the use of viral vectors to deliver antigenic materials. Applications directed towards vaccine development for AIDS associated opportunistic infections are not invited. Otherwise, scientific approaches to the development of effective vaccines appropriate to the RFA are broad and limited only by the creativity and

ability of the applying group to exploit leads from basic studies in virology, molecular biology, and immunology.

Each NCVDG will be assembled by the Principal Investigator to form a multidisciplinary consortium representing the various skills needed to successfully design and evaluate vaccine entities and strategies for the prevention of AIDS. Inasmuch as it is unlikely that all of the outstanding talents required to exploit fundamental leads from various scientific disciplines will be found in a single institution, each Group is envisioned as being multi-institutional as well. Thus each NCVDG will be assembled by the Principal Investigator and may consist of a number of Research Projects representing the scientific disciplines required to attain the Group's goal and objectives. The various Research Projects, including that of the Principal Investigator, may be mobilized from academic or research institutions, and industry. It is expected that the rationale for design of potential vaccines, the synthesis or production of specific candidates, and the models for evaluation will originate within the Group and be based on leads from their own and others' fundamental research.

Awards will be made as Cooperative Agreements. Assistance via a Cooperative Agreement differs from the research grant in that the Government component (in this instance, the NIAID) awarding the Cooperative Agreement anticipates substantial involvement during performance. The nature of NIAID staff participation is described in the full RFA. However, the applying Group must define its objectives in accord with its own interests and perceptions of approaches to vaccines for AIDS prevention. NIAID has set aside \$10 million in total costs for the initial year's funding; it is anticipated that 8 to 10 awards will be made. The earliest starting date for the initial annual period will be February 1989.

REVIEW METHOD AND PEER REVIEW CRITERIA

Applications that are incomplete for review or nonresponsive to this RFA will be screened out by NIH staff upon receipt and returned to the applicants without further consideration. Those applications that are complete and responsive may be subjected to a triage by a peer review group to determine their scientific merit relative to the other applications received in response to this RFA. The NIH will withdraw from competition those applications judged to be noncompetitive and notify the applicant and institutional business official. Those applications judged to be competitive will be further reviewed for scientific and technical merit by a Review Committee convened by the Extramural Activities Program, NIAID. The second level of review will be provided by the National Advisory Allergy and Infectious Diseases Council.

The proposed applicant institution will be responsible for the Group's application. Awards will be made to the applicant institution on behalf of the group as a whole and not to individual Research Projects within the Group. The applicant institution will provide a Central Operations Office for the Group. The applicant institution will be responsible for the performance of the entire Group and will be accountable for the funds awarded. The participation of the Government through the NIAID extramural staff is aimed at facilitating a concerted effort by the Group. The interaction of academic and non-profit research institutions with commercial organizations and Government is expected to favor efficient development of AIDS vaccines and will facilitate their subsequent refinement and evaluation in clinical trials.

For further information and to obtain a copy of the complete RFA, contact:

Dr. Wayne C. Koff
NIH, NIAID, AIDS Program
6003 Executive Blvd., Rm. 234 P
Rockville, Maryland 20892
Telephone: (301) 496-8200

MENTAL RETARDATION RESEARCH CENTERS

RFA AVAILABLE: HD-88-10

P.T. 04; K.W. 0715130, 0710030

National Institute of Child Health and Human Development

Application Receipt Date: July 14, 1988

Letter of Intent Receipt Date: April 8, 1988

The National Institute of Child Health and Human Development (NICHD), through the Mental Retardation and Developmental Disabilities Branch (MRDD), Center for Research for Mothers and Children (CRMC), invites research center core grant applications (P30) to develop new knowledge in the field of prevention, treatment, and amelioration of mental retardation and developmental disabilities. Three centers may be supported in response to this announcement.

The primary objective of the NICHD Mental Retardation Research Centers (MRRCs) is to provide support and facilities for a cohesive, interdisciplinary program of research and research training in mental retardation and related aspects of human development.

NICHD has supported MRRCs through the provision of core grants (P30) which facilitate program coordination and support central research core units. Funds for the research projects using these core units come from independent sources including Federal, State and private organizations. This announcement seeks applications from existing MRRCs and from other comparable institutions that meet the qualifications for a program of mental retardation research.

BACKGROUND

A major goal of the MRDD Branch's research program is to prevent and/or ameliorate mental retardation. The degree of impairment associated with mental retardation varies in relation to the cause. Moderate and more severe mental retardation often results from problems that produce profound alterations in brain development and/or function. Diminished intellectual and adaptive capacity can often be traced to defective genes, teratogenic agents, infections, nutritional deficits, accidents, diseases and other disorders causing brain damage. A larger proportion of cases of mental retardation is related to environmental conditions and disorders of unknown etiology. These complex problems require integrated, multidisciplinary approaches involving biomedical and behavioral sciences in a variety of settings.

The purpose of a Mental Retardation Research Center is to provide a research environment in which interdisciplinary collaboration among investigators who are working in areas of relevance to the prevention and amelioration of mental retardation is facilitated. Such research will cover a broad spectrum of scientific approaches ranging from laboratory research on fundamental processes of abnormal development to clinical and educational research in which persons with mental retardation are studied.

It is thought that major solutions to the problems of mental retardation will be found as a result of multidisciplinary collaboration involving a variety of approaches in the Mental Retardation Research Centers. As a result of the administrative and scientific organization within a MRRC and across the network of MRRCs, opportunities for breakthroughs will be enhanced.

RESEARCH SCOPE

MRRC Core Grants are intended to bring together in a center a variety of disciplines to work on the common problems of mental retardation. Consequently, applications for Mental Retardation Center Core Grants (P30) should include investigators studying a range of topics in basic and clinical or applied research. Applicants are encouraged to include both biomedical and behavioral components from among the following topics:

- o Developmental neurobiological studies relevant to MRDD.
- o Inborn errors of metabolism relevant to MRDD.
- o Genetic/cytogenetic disorders associated with MRDD.
- o Molecular biology; development of animal models.
- o Toxicology and physical environmental factors in the etiology, treatment and prevention of MRDD.
- o Intellectual, behavioral, physical and the intergenerational effects of malnutrition.
- o Developmental pharmacology and psychopharmacology.
- o Infectious diseases in the etiology, prevention and treatment of MRDD.
- o Diagnosis.
- o Perinatal problems associated with MRDD.
- o Psychobiological processes in MRDD.
- o Psychological processes in MRDD.
- o Early intervention for infants born at risk.
- o Behavioral analysis of MRDD individuals.
- o Family and community studies.
- o Language and communication of MRDD populations.
- o Learning disabilities, dyslexia, and attention deficit disorder.

- o Behavior in residential and educational settings.
- o Socioecological processes.
- o Epidemiology of MRDD.

ELIGIBILITY

Any of the following organizations are eligible to apply: Non-profit organizations and institutions; State and local governments and their agencies; and authorized Federal institutions. As stated in the NICHD Centers Guidelines, the NICHD will not support more than one NICHD center (P30, P50) in a given department or specialty unit.

MECHANISM, SCOPE AND SCALE OF SUPPORT

Mental Retardation Research Center grants will be supported through the customary grant-in-aid mechanism. Review of applications and management of grants will be subject to applicable policies for NIH research center grants.

Awards will be made for a period of five years. To be eligible for award as an MRRC, the Center must provide core support for a minimum of 10 projects funded from non-university sources.

The total direct costs requested for the first year may not exceed \$500,000 for new grants and not more than 104 percent of the level recommended for the previous budget period of a competing renewal grant. Budgets of applications for new and renewal support will be stringently reviewed within these guidelines. Applications with budget request exceeding these guidelines will be administratively withdrawn by NICHD and returned to the applicant.

ESTIMATED NUMBER OF AWARDS

This is the second of a series of annual announcements. Plans are to make three awards in fiscal year 1989.

WHERE COMPLETE RFA MAY BE OBTAINED

A complete Request for Applications entitled "Mental Retardation Research Centers" and guidelines concerning "NICHD Research Centers Programs-Center Core Grants (P30) may be obtained from:

Mental Retardation and Developmental Disabilities Branch
 Center for Research for Mothers and Children, NICHD
 Executive Plaza North, Rm. 631
 6130 Executive Boulevard
 Bethesda, Maryland 20892
 Telephone: (301) 496-1383

This program is described in the Catalog of Federal Domestic Assistance No. 13.865 Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

THE OCULAR COMPLICATIONS OF AIDS

RFA AVAILABLE: 88-EY-01

P.T. 34; K.W. 0715100, 0715120, 0785055, 0755015

National Eye Institute

Application Receipt Date: June 8, 1988

The National Eye Institute invites applications for assistance awards to support Study Chairman activities, Coordinating Centers, and Fundus Photograph Reading Centers for clinical trials and/or other epidemiology research projects on the ocular complications of AIDS. These awards will be cooperative agreements in which substantial involvement with the funded investigators by NEI staff is anticipated during performance of the projects.

BACKGROUND INFORMATION

Ophthalmic disorders are commonly associated with the acquired immunodeficiency syndrome (AIDS), and blindness is among its many tragic complications. Two of these ophthalmic clinical manifestations occur in patients with AIDS with sufficient frequency that further study is warranted

through clinical trials and other epidemiological studies. Cotton wool spots and retinal hemorrhages may not alter visual acuity. However, the presence of these retinal lesions may be related to other systemic alterations associated with HIV infection and may have prognostic significance. Cotton wool spots are the most common ophthalmic manifestation of AIDS, occurring in at least 65% of patients. In AIDS patients, cotton wool spots are caused by ischemia that results from damage to the capillaries of the retina. The cause of the capillary damage, which probably occurs in all AIDS patients, has not yet been determined.

Cytomegalovirus retinitis is an opportunistic infection of the retina which occurs predominantly in immunosuppressed individuals and is a direct viral infection of the retina characterized by white infiltrates and hemorrhages. This ocular complication of AIDS leads to necrosis and atrophy of the retina and is the major cause of visual loss and blindness in patients with AIDS. Although it appears to occur in the more severely immunocompromised patients with AIDS, little is known about other risk factors that influence the development or prognosis of this ocular disease.

In several small, uncontrolled treatment trials some antiviral drugs appear to favorably alter the clinical course of cytomegalovirus retinitis. However, when the therapy is discontinued, the cytomegalovirus retinitis has been observed to recur in virtually all patients. In view of the high potential of visual loss and blindness in patients with cytomegalovirus retinitis, therapeutic clinical trials to clearly demonstrate the benefits and risks of alternative treatment strategies are needed.

RESEARCH GOALS AND SCOPE

The goal of this RFA is to begin to assist groups of collaborating investigators in their attempts to develop specific, detailed protocols for multicenter clinical trials and/or other epidemiological studies. This will be done by providing immediate support for Study Chairman, Coordinating Center, and Fundus Photograph Reading Center functions that will be needed for these efforts. The NEI is not requesting the submission of individual participating clinic applications at this time. It may do so subsequently when detailed protocols are developed.

Funded investigators will be expected to provide a focus and capability for stimulating the investigator-initiated development of uniform study protocols by consensus among interested investigators and for conducting the specific treatment clinical trials and other epidemiological studies that are developed. This will involve the preparation of detailed manuals of operation for each study, estimation of sample size requirements, preparation of data questionnaires, development of quality assurance programs, development of fundus photograph classification and grading systems, and the development of data management and analysis systems.

Investigators applying for Study Chairman awards should have expertise in the design and conduct of ophthalmic clinical studies.

Investigators applying for coordinating center awards should have expertise in ophthalmic clinical studies and in biostatistics, epidemiology, and data management/computing. Investigators should provide, at a minimum, general designs for possible clinical trials and/or other epidemiological studies. Detailed Manuals of Operation are not required; if available, they should be submitted with the application. Active collaboration with ophthalmologists, internists, and other professionals involved in the treatment of patients with AIDS is expected and encouraged. Recruitment potential for proposed studies should be documented. Applicants should also document the interest, capabilities, and commitment of all potential participating clinics identified; letters from potential participating clinic investigators should be provided as part of this documentation.

Investigators applying for Fundus Photograph Reading Center awards should have expertise in studies of retinal disease and in the development and use of fundus photograph classification/grading systems. Investigators should provide, at a minimum, a general description of the type of system that they would use to classify and assess changes in the development of cytomegalovirus retinopathy and/or non-infectious retinopathies.

MECHANISM OF SUPPORT

Awards will be made as cooperative agreements. These awards reflect an assistance relationship in which substantial involvement with the funded investigators by NEI staff is anticipated during performance of the project. Cooperative agreements resulting from this RFA will be subject to the same administrative requirements pertaining to all assistance awards of the U.S.

Public Health Service. The terms and conditions of NEI staff involvement are included in the complete RFA.

It is anticipated that up to two Study Chairman awards, two Coordinating Center, and two Fundus Photograph Reading Center awards will be made as a result of this one-time competition. Awards will be made for project periods of five years. Up to \$3 million will be available for this program in Fiscal Year 1988, but the specific amount and the number of awards will depend on the merit and scope of the applications received.

Timetable:	Application receipt date	June 8, 1988
	Scientific merit review	July 1988
	National Advisory Eye Council review	September 15-16, 1988
	Anticipated award date	September 26, 1988

REVIEW PROCEDURES

All applications responding to this RFA will be reviewed for scientific and technical merit by an initial review group which will be convened by the Review and Special Projects Officer, NEI, solely to review these applications. Second level review will be by the National Advisory Eye Council. If an application is judged unresponsive to the specific objectives of this RFA, the applicant will be contacted and the application will be returned.

INQUIRIES

Investigators are strongly encouraged to contact the NEI program director:

Dr. Richard L. Mowery
Chief, Collaborative Clinical Vision Research Branch
National Eye Institute
Building 31, Room 6A24
Bethesda, Maryland 20892
Telephone: (301) 496-6583

He will provide a copy of the complete RFA providing background information, research goals and scope, the nature of NEI staff participation, review procedures and criteria, and method of applying.

SENIOR FELLOWSHIPS: ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

P.T. 22; K.W. 0720005, 0715010, 0715185

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) wishes to re-emphasize its continuing support of Senior Fellowships (F33) to facilitate research training for experienced scientists who wish to make major changes in the direction of their research careers and to acquire new research capabilities.

NIAMS encourages applications from investigators in all areas of interest to the Institute. Following are several broad, but not complete, categories of NIAMS research interests:

1. Structure, function and physiology of connective tissue, joints, muscle, bone, and skin
2. Metabolism of muscle, bone, and skin
3. Development and genetic diseases of connective tissue, muscle, bone, and skin
4. Exercise physiology of the musculoskeletal system and gait analysis
5. Rheumatic and connective tissue diseases and disorders
6. Bone diseases and disorders
7. Muscle diseases
8. Musculoskeletal disorders
9. Skin diseases and disorders
10. Epidemiologic research related to connective tissue, joints, muscle, bone, and skin

Research training may be in any scientific discipline relevant to proposed future research, such as molecular biology, biochemistry, biophysics, molecular genetics, cell biology or immunology.

MECHANISM

Senior research training is provided as a National Research Service Award (NRSA), subject to provisions of authorization legislation. Support is generally for one year, at a maximal annual rate of \$30,000. Sponsoring institutions may request up to \$3,000 per year to defray allowable expenses of the awardee.

APPLICATION PROCEDURE

January 10, May 10, and September 10 are the annual receipt dates for individual NRSA applications. Application materials and guidelines are available from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20892

For further information, please contact:

Dr. Richard Lymn
National Institute of Arthritis and
Musculoskeletal and Skin Diseases
Westwood Building Room 403
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7495

ONGOING PROGRAM ANNOUNCEMENTS

CUTANEOUS MANIFESTATIONS OF HIV INFECTION AND AIDS

P.T. 34; K.W. 0715120, 0715185

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The Skin Diseases Program supports research on the structure, function, and diseases of the skin. This Program Announcement is to encourage submission of research grant applications in the area of cutaneous manifestations of HIV infection and diseases, including AIDS, that are caused by HIV infection. Research grant applications may be basic, clinical or epidemiologic. Research mechanisms to support these investigations include regular research grants (R01), Clinical Investigator Awards (K08), First Independent Research and Transition (FIRST) Awards (R29), and Individual National Research Awards (F32).

The vast majority of patients with AIDS manifest cutaneous disease at some time during their illness. Patients with HIV infection not meeting the criteria for the diagnosis of AIDS also frequently manifest cutaneous disease. In addition, there has been recently described an exanthem that is associated with initial HIV infection in man; it precedes by weeks to months seroconversion to HIV positivity. The skin diseases seen in HIV infection include diseases of less than clear-cut pathogenesis including psoriasis and seborrheic dermatitis, among others; infectious diseases such as candidiasis and viral and bacterial infections; and malignancies, particularly Kaposi's sarcoma.

This Program Announcement is designed to encourage grant applications to investigate basic, clinical and epidemiologic aspects of these diverse cutaneous manifestations of HIV infection. Projects may be oriented specifically towards the cutaneous manifestations of HIV infection. They may also be oriented towards utilizing the high incidence of skin disease in the HIV-infected and AIDS populations to investigate the pathogenesis of the idiopathic skin disease. Thus, we would hope to obtain new information relevant to idiopathic skin diseases as well as new information relevant to the understanding of the coexistence of AIDS and skin disease.

An exanthem as the initial manifestations of HIV infection has been reported. This phenomenon needs to be more specifically defined, both as regards to the manifestations of the exanthem and its frequency and the time course between the exanthem and seroconversion to HIV positivity. If established as a specific and relatively high frequency manifestation of initial HIV infection, this phenomenon may prove to be extremely valuable for the identification very early in the course of infection of HIV-infected individuals. It would provide a cohort of individuals appropriate for the testing of therapeutic modalities.

ELIGIBILITY

Non-profit organizations and institutions, governments and their agencies, for-profit organizations, and individuals are eligible to apply.

DEADLINE

Commencing May 2, 1988, applications will be accepted in accordance with newly announced receipt dates for unsolicited AIDS R01 and R29 applications, May 1, September 1, and January 2. Principal Investigators who do not wish to have their R01 or R29 applications subjected to expedited review may submit applications to meet the receipt dates for new applications listed in the application kit 398 (Rev. 9/86). Applicants for the K08 or F32 awards should submit applications to meet the receipt dates listed in the instructions for those mechanisms.

REVIEW PROCEDURES AND CRITERIA

Applications should be submitted on Form PHS-398 or 416-1 which are available in the institution's collaborative research or business office. Additional application kits may be obtained from the Office of Grants Inquiries, Division of Research Grants (DRG), NIH. The phrase "Prepared in Response to Research Grants Announcement on "Cutaneous Manifestations of HIV Infection and AIDS" should be typed on line 2 of the first page of the application form 398 or item 3 of the form 416-1. The original and 32 copies of an R01 or R29 application submitted for expedited review, or the original and 6 copies for normal receipt dates of R01, R29 or K08 applications, or the original and 2 copies of a fellowship application should be sent to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, Maryland 20892**

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research grant applications, and, when requested, in accord with the expedited NIH peer review procedures for AIDS related research.

Applications will first be reviewed for technical merit by initial review groups and then by the National Advisory Council. The review criteria customarily employed by the NIH for regular research grant applications will prevail.

Applicants from institutions which have a General Clinical Research Center (GCRC) funded by the NIH Division of Research Resources may wish to identify the Center as a resource for conducting the proposed research. In such a case, a letter of agreement from the Program Director of the GCRC should be included with the application material.

All PHS and NIH grant policies governing regular research project grants apply to applications received in response to this program announcement.

For further information contact:

Dr. Alan N. Moshell
Director, Skin Diseases Program
National Institute of Arthritis and
Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, Maryland 20892
Telephone: (301) 496-7326

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, Maryland 20816