

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific
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duals and organizations who need to
be kept informed of opportunities,
requirements, and changes in extra-
mural programs administered by the
National Institutes of Health.

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NOTICES

CONFERENCE: FOSTERING SCIENTIFIC INTEGRITY IN BIOMEDICAL RESEARCH

P.T. 42; K.W. 1014004, 1014006

National Institutes of Health

The National Institutes of Health (NIH), the Association of American Medical Colleges, and Washington University School of Medicine are co-sponsoring an interactive conference for biomedical investigators, research administrators, and university attorneys with an interest in fostering the integrity of scientists. The goals of the workshop are to discuss the scope of the problem of scientific misconduct; to identify perceived or real factors contributing to misconduct; to discuss the roles of Congress, NIH, and institutions in managing allegations of scientific misconduct; to examine how well specific institutions have dealt with allegations of fraud, plagiarism or other unacceptable scientific practices; to discuss any special ethical considerations associated with Industry/University ties; and to discuss the responsibilities of authors and collaborators in maintaining scientific integrity in research. Several break-out sessions will address focussed topics of particular concern.

This conference is approved for credit in AMA Category 1.

DATES: April 25-26, 1990

SITE: The Adams Mark Hotel, St. Louis, MO

PROGRAM AND REGISTRATION INFORMATION: Telephone: (800) 325-9862, interstate
(314) 362-6893, in Missouri

NOTICES OF AVAILABILITY (RFPs AND RFAs)

NATIONAL EPIDERMOLYSIS BULLOSA REGISTRY - CLINICAL COORDINATING CENTER

RFP AVAILABLE: RFP-NIH-NIAMS-91-1

P.T. 04; K.W. 0780030, 0785045, 0755018

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has a requirement for the continuation of a Clinical Coordinating Center for the National Epidermolysis Bullosa Registry. The National Epidermolysis Bullosa Registry (NEBR) that will consist of one (1) Clinical Coordinating Center and four (4) Clinical Sites, is aimed at searching for the basic defect, improving methods of diagnosis, and developing effective methods in treatment and prevention. The NEBR will continue to: (1) develop a roster of well-characterized patients with the different forms of Epidermolysis Bullosa (EB). Selected patients will be requested to contribute specimens and to be followed as part of diagnostic, research, and in some cases therapeutic,

protocols; (2) determine with accuracy and precision the incidence and prevalence of disease by clinical genetic type in a sufficiently broad geographic region to permit extrapolation of data to the United States as a whole; (3) increase information on genetics, particularly family patterns or sporadic occurrence of disease, including penetrance and severity; (4) assess disease distribution geographically, to search for clusters and patterns and assess the societal and economic impact of the disease; (5) develop a pool of patients of the same genetic type from a wide variety of studies on pathogenesis and genetics of EB, including support for the banking of appropriate tissue specimens; and (6) foster and support well designed and well executed clinical trials of new therapeutic interventions in carefully selected groups of patients with one or another form of EB.

The responsibilities of the Clinical Coordinating Center are primarily the coordination of the clinical and basic science aspects of the NEBR and, to a lesser degree, the handling of the raw data. Performance of the primary functions of the Clinical Coordinating Center, both at the time of the award and during the contract period, will require extensive and continuing hands-on involvement in the clinical laboratory and basic science aspects of EB. It is necessary that the Clinical Coordinating Center be located at one of the Clinical Sites. (Offerors to this solicitation must also submit proposals in response to RFP No. NIH-NIAMS-91-4, "National Epidermolysis Bullosa Registry - Clinical Sites", published in this issue of the NIH Guide for Grants and Contracts.)

This Request for Proposals, RFP No. NIH-NIAMS-91-1, will be available on or about March 22, 1991, with a closing date set for May 6, 1991. To receive a copy of the RFP, please supply this office with two (2) self-addressed mailing labels. Requests for the RFP should be sent to the following address:

Patrick M. Sullivan, Acting Chief
Contracts Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institutes of Health
Westwood Building, Room 602
5333 Westbard Avenue
Bethesda, MD 20892

This advertisement does not commit the Government to award a contract.

NATIONAL EPIDERMOLYSIS BULLOSA REGISTRY - CLINICAL SITES

RFP AVAILABLE: RFP-NIH-NIAMS-91-4

P.T. 04; K.W. 0780030, 0785045, 0755018

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) has a requirement for the continuation of Clinical Sites for the National Epidermolysis Bullosa Registry. The National Epidermolysis Bullosa Registry (NEBR), which will consist of one (1) Clinical Coordinating Center and four (4) Clinical Sites, is aimed at searching for the basic defect, improving methods of diagnosis, and developing effective methods in treatment and prevention. The NEBR will be continued to: (1) develop a roster of well characterized patients with the different forms of Epidermolysis Bullosa (EB). Selected patients will be requested to contribute specimens and to be followed as part of diagnostic, research, and in some cases therapeutic, protocols; (2) determine with accuracy and precision the incidence and prevalence of disease by clinical genetic type in a sufficiently broad geographic region to permit extrapolation of data to the United States as a whole; (3) increase information on genetics, particularly family patterns or sporadic occurrence of disease, including penetrance and severity; (4) assess disease distribution geographically, to search for clusters and patterns and assess the societal and economic impact of the disease; (5) develop a pool of patients of the same genetic type for a wide variety of studies on pathogenesis and genetics of EB, including support for the banking of appropriate tissue specimens; and (6) foster and support well-designed and well-executed clinical trials of new therapeutic interventions in carefully selected groups of patients with one or another form of EB. The Clinical Sites will be responsible for direct contact with EB patients and for their enrollment in the registry. This will include standardized history, physical examination, general laboratory examination, and those specialized studies required for EB diagnosis. Determination of the studies required for the diagnosis of EB and its subgroups will be the responsibility of the offerors. Clinical sites will be responsible for the conduct of clinical trials and for the submission of tissue specimens from appropriate patients for tissue banking. (The Clinical Coordinating Center

must be located at a Clinical Site. Please refer to RFP No. NIH-NIAMS-91-1, published in this issue of the NIH Guide for Grants and Contracts.) The institute plans to make four awards from this solicitation.

This Request for Proposals, RFP No. NIH-NIAMS-91-4, will be available on or about March 22, 1991, with a closing date set for May 6, 1991. To receive a copy of the RFP, please supply this office with two (2) self-addressed mailing labels. Since a limited number of copies will be printed, requests shall be filled on a first-come-first-served basis until the supply is exhausted. Requests for the RFP should be sent to the following address:

Patrick M. Sullivan, Acting Chief
Contracts Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institutes of Health
Westwood Building, Room 602
5333 Westbard Avenue
Bethesda, MD 20892

This advertisement does not commit the Government to award a contract.

EVENT RECORDINGS OF HIGH RISK INFANTS ON APNEA MONITORS

RFA AVAILABLE: HD-91-02

P.T. 34; K.W. 0765035, 0706020, 0403020, 1004008

National Institute of Child Health and Human Development

Application Receipt Date: June 10, 1991

The Pregnancy and Perinatology Branch (PPB) of the Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) invites applications from clinical investigators and statisticians willing to participate with NICHD under a cooperative agreement in a multi-center collaborative study regarding the usefulness of home monitors in the management of infantile apnea. Applications are sought from clinical centers intending to participate as clinical units in the study and from institutions intending to serve as a Data Coordinating and Analysis Center. An institution may apply for either function or both.

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity. This Request for Applications (RFA), "Event Recordings of High Risk Infants on Apnea Monitors," is related to the priority area of "Maternal and Infant Health." Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

BACKGROUND

Each year between 6,000 and 7,000 infants in the United States die with a diagnosis of Sudden Infant Death Syndrome (SIDS). SIDS is defined as the "sudden death of an infant or young child, which is unexpected by history, and in which a thorough postmortem examination fails to demonstrate an adequate cause of death."

In order to conduct an investigation of whether infantile apnea monitors are obtaining appropriate data to identify and describe life-threatening events, we must study a subpopulation of infants who have been diagnosed as "at risk" for sudden death. These infants, for whom home monitoring of respiration and heart rate is medically indicated, include: premature infants who have apnea at time of discharge from the hospital, infants who have experienced a severe apparent life-threatening event (ALTE), and subsequent siblings of SIDS victims.

The NICHD intends to establish a network of clinical trial sites, with central data management and data analysis, that will evaluate home apnea monitoring in high-risk infants. The specific aims of the study conducted in response to this solicitation are to obtain physiologic parameters of cardiorespiratory episodes in infants at risk for life-threatening events, improve the quality of home monitoring, and determine compliance in monitor use.

STUDY ORGANIZATION AND SCOPE

The NICHD will establish a network of approximately five clinical units and a Data Coordinating and Analysis Center that will develop and conduct a standard, common protocol, under a cooperative agreement with NICHD. The clinical units will have primary responsibility for enrollment and evaluation of study participants. One of the units will serve as a Clinical Trial Operations Center for primary central data collection and to support the sites regarding protocol implementation. The Data Coordinating and Analysis Center will have responsibility for data collection and management.

The work accomplished under the cooperative agreement is expected to follow this general outline (duration of phases are estimates only):

Phase 1 (12 months): The Steering Committee, composed of Principal Investigators and NICHD staff, will:

- o identify study objectives, considering the relevant research questions, and available resources.
- o develop the standard protocol and data forms.
- o develop a standard system for analysis of event recordings and polysomnograms.
- o develop a database management system, with primary input from the Data Coordinating and Analysis Center and consultant NICHD statisticians.
- o adopt/develop standard manuals and training programs for physicians and parents to support the appropriate use of the monitors and to optimize compliance.
- o adopt/develop standard autopsy, pathology, and death scene investigation protocols for all infant deaths within the first year of life.

The Clinical Units and Data Coordinating and Analysis Center will enroll a limited number of infants in a pilot test of the protocol and data management system.

The awardees will hire and train staff in preparation for protocol implementation and data management.

The Data Coordinating and Analysis Center will develop a quality assurance system.

Note: Phases 2 and 3 will run concurrently.

Phase 2 (44 months): The Clinical Units will evaluate and enroll patients into the protocol. Every effort will be made to enroll minority populations. The units will collect data with adequate attention to the fidelity of records and will provide information in uniform data format for analysis. The Data Coordinating and Analysis Center will implement the data coordination and quality assurance systems and provide data summaries to the Steering Committee as determined by the protocol.

Phase 3 (30 months): Based on reports of the aggregated data, and recommendations of the Data Safety and Monitoring Board (DSMB), the Steering Committee will decide to modify the protocol or determine the need to terminate the study because the data is sufficient to meet the objectives of the protocol. (The DSMB will be empowered to oversee the safety of the study.)

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT - Terms of the Agreement

The funding mechanism to be used to assist the scientific community in undertaking this system of clinical investigation will be a cooperative

agreement between the participating units and NICHD. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of NICHD staff above and beyond the levels required for traditional program management of grants. All parties will agree to accept the coordinating role of the group and the participatory and cooperative nature of the group process. Up to \$ 1,500,000 in direct costs has been set aside for the first year of these Cooperative Agreements, and it is anticipated that five meritorious applications, including the Data Coordinating and Analysis Center, will be funded.

The special terms of Award of Cooperative Agreement are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, DHHS grant administration regulations at 45 CFR Part 74, and other DHHS, PHS, and NIH grant administration policies. The NICHD review procedure in no way affects the right of a recipient of a cooperative agreement to appeal an adverse determination under the terms of PHS regulations at 42 CFR Part 50, Subpart D, and DHHS regulations at 45 CFR Part 16. Business management aspects of these awards will be administered by the NICHD Grants Management Branch in accordance with DHHS, PHS, and NIH grant administration requirements.

ADDITIONAL INFORMATION

Potential applicants should obtain a detailed RFA from:

Marian Willinger, Ph.D.
Health Scientist Administrator
Pregnancy and Perinatology Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Executive Plaza North, Room 643
Bethesda, MD 20892
Telephone: (301) 496-5575

Inquiries regarding grants management and administrative policy may directed to:

Douglas Shawver
Supervisory Grants Management Specialist
Grants Management Branch
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-1303

This program is described in the Catalog of Federal Domestic Assistance No. 93.865, 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 under the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SHORT-TERM CLINICAL TRAINING GRANTS IN DIAGNOSIS AND TREATMENT OF DEPRESSIVE DISORDERS

RFA AVAILABLE: MH-91-04

P.T. 34; K.W. 0720005, 0715072, 0745020, 0745060, 0745070

National Institute of Mental Health

Application Receipt Date: May 22, 1991

The National Institute of Mental Health seeks applications for programs of short-term (not to exceed 5 days' duration) continuing education. Each program will be carried out at multiple locations and will provide continuing education for primary care providers and mental health professionals. This initiative is intended to provide for the development of effective training that will give primary care providers and mental health professionals a didactic and experiential program to increase their capacity to recognize, diagnose, and treat clinical depression effectively, in a manner appropriate to their discipline.

Applications may be submitted by a department of psychiatry in or associated with a school of medicine or a free-standing mental health institution with an approved psychiatry residency program, a university-based department of

psychology or a school of professional psychology, a college or university school of nursing which offers a graduate program in psychiatric nursing, or a school of social work with a graduate program.

The mechanism of support for these awards will be the Continuing Education Grants (T15). The period of support is up to 3 years, although no firm commitment can be made beyond the first year. Therefore, activities in the first year must be significant with a minimum of six programs provided at six different sites in each grant year. It is expected that up to four awards may be made in fiscal year 1991, each award not to exceed \$125,000 total costs per award in fiscal year 1991.

The receipt date for applications is May 22, 1991. It is suggested that potential applicants send a brief letter of their intention to Harold Goldstein (see below). Dr. Goldstein is also available for consultations on program development, eligibility, and fiscal and administrative matters, contact:

Harold Goldstein, Ph.D.
Director of Training, D/ART Program
Prevention Research Branch
Division of Clinical Research
National Institute of Mental Health
Parklawn Building, Room 14C-02
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4140

SHORT-TERM GRANTS FOR TRAINING MEDICAL STUDENTS IN THE DIAGNOSIS AND TREATMENT OF DEPRESSIVE DISORDERS

RFA AVAILABLE: MH-91-05

P.T. 34; K.W. 0720005, 0715072, 0745020, 0745060, 0745070

National Institute of Mental Health

Letter of Intent Receipt Date: May 1, 1991
Application Receipt Date: May 22, 1991

The National Institute of Mental Health requests applications from medical schools to develop and implement training of predoctoral medical students in the diagnosis and treatment of clinical depression according to a basic curriculum presented in this request for applications. Support is available for the detailed development of this curriculum, its implementation, and evaluation of its educational effectiveness. The goal of the training is to prepare medical students to deal with depressive disorders as these disorders appear in medical settings.

Applications may be submitted by accredited schools of medicine and osteopathy, with a special interest in applications from departments of family medicine, internal medicine, obstetrics and gynecology, and other nonpsychiatric specialties.

The mechanism of support for these awards will be the Continuing Education Grants (T15). The period of support is 1 year. It is expected that up to 10 awards will be made, each award not to exceed \$15,000 total costs per award. To qualify for fiscal year 1991 funding, applications must be submitted for the receipt date of May 22, 1991.

It is suggested that a letter of intention be sent to Harold Goldstein, Ph.D., Director for Training, D/ART, to be received by May 1, 1991, at the address below. For questions of eligibility, fiscal and administrative matters and for assistance in developing applications, prospective applicants should consult Dr. Goldstein. His mailing address is:

Prevention Research Branch
Division of Clinical Research
National Institute of Mental Health
Parklawn Building, Room 14C-02
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4140

COOPERATIVE CLINICAL STUDIES FOR THE TREATMENT OF COGNITIVE IMPAIRMENT AND BEHAVIORAL DISORDERS ASSOCIATED WITH ALZHEIMER'S DISEASE

RFA AVAILABLE: AG-91-10

P.T. 34; K.W. 0715180, 0414005, 0715020, 0795005, 0740020

National Institute on Aging

Letter of Intent Receipt Date: April 1, 1991

Application Receipt Date: May 21, 1991

BACKGROUND

The National Institute on Aging (NIA) is inviting cooperative agreement (U01) applications from established clinical investigators to organize and conduct multi-site clinical studies on the efficacy of a number of compounds in ameliorating cognitive impairment and non-cognitive behavioral disorders of Alzheimer's disease. Each applicant should organize a group of investigators and institutions that is capable of screening and clinically evaluating compounds to determine those that should be studied in more formal and extensive double-blind clinical trials. The U.S. Congress, as part of the Fiscal Year 1991 appropriation for NIA, mandated that NIA "explore new treatment and management methods, including testing promising drugs such as nerve growth factor and acetylcarnitine, that could safely and effectively slow or reverse the symptoms of Alzheimer's disease."

RESEARCH OBJECTIVES AND SCOPE

The objective of this Request for Applications (RFA) is to support cooperative clinical studies to evaluate a number of compounds for efficacy in treating the symptoms of Alzheimer's disease and select the compounds that should go on to full-scale clinical trials. Because of the need for a large and diverse base for patient recruitment and study, it is expected that there will be one applicant site with a number of cooperating sites to be supported by subcontract or consortium agreements. Applications must contain a Clinical Data Coordinating Center to provide data management, reporting services, data analysis, and overall study coordination and management.

MECHANISM OF SUPPORT

The award will be made as a COOPERATIVE AGREEMENT (U01). NIA, in awarding the Cooperative Agreement, anticipates substantial involvement of a designated Program Administrator during performance of the award. It is anticipated that one award will be made for up to \$3,250,000 total cost per year for up to 5 years. The start date will be on or before September 30, 1991.

APPLICATION AND REVIEW PROCEDURES

In preparing applications, instructions for form PHS 398 (10/88 revision, reprinted 9/89), supplemental information available from NIA program staff, and additional instructions included in the full RFA must be used. Applications judged by staff to be nonresponsive to the RFA will be returned to the applicant without review. Responsive applications may then receive a preliminary review by a subcommittee of the review panel to establish those applications deemed to be competitive. Those judged noncompetitive for award will be withdrawn from further competition. Applications judged to be competitive will be given full review by a special review group convened by NIA. Following review by the initial review group, the applications will be considered by the National Advisory Council on Aging.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

Applicants should obtain the full RFA and supplemental information and discuss their plans with and direct any other inquiries to:

Neil Buckholtz, Ph.D.
NNA, NIA, NIH
Building 31, Room 5C35
Bethesda, MD 20892
Telephone: (301) 496-9350
FAX: (301) 496-1494

Inquiries regarding fiscal matters may be addressed to:

Mr. Joseph Ellis
Grants Management Officer
National Institute on Aging
Building 31, Room 5C07
Bethesda, MD 20892
Telephone: (301) 496-1472

Although not a prerequisite for applying, potential applicants are encouraged to submit a non-binding letter of intent by April 1, 1991 to Dr. Buckholtz at the address indicated above. Applications must be complete and received by May 21, 1991.

COOPERATIVE AGREEMENT FOR MULTI-SITE TRIALS OF BEHAVIORAL STRATEGIES TO PREVENT THE FURTHER SPREAD OF HIV INFECTION

RFA AVAILABLE: MH-91-06

P.T. 34; K.W. 0715008, 0755015, 0404000, 0745027

National Institute of Mental Health
National Institute on Drug Abuse
National Institute on Alcohol Abuse and Alcoholism
National Institute of Child Health and Human Development
Centers for Disease Control
Health Resources and Services Administration

Application Receipt Date: May 22, 1991

The National Institute of Mental Health is requesting applications for additional Extramural Research Groups (ERGs) to enter into an existing multi-site, multi-population collaborative study to test behavioral interventions to prevent the further spread of HIV infection. The purpose is to support a coordinated prevention trial to develop effective HIV-prevention strategies. The goals are to develop behavioral intervention strategies for groups that have not been reached effectively by existing prevention efforts, to assess existing interventions and improve the existing strategies that have shown some effectiveness, to develop an overall effective intervention program to promote behavioral change that will prevent the further spread of the HIV epidemic, and to establish causal links between behavioral interventions and behavioral change across populations.

Applications may be submitted by any public or private nonprofit or for-profit organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Applications from foreign institutions are accepted only if the data or other unique opportunities are not available in the United States. Women and minority investigators are encouraged to apply. For projects involving clinical research, NIH/ADAMHA requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

In fiscal year 1991, a minimum of \$1.5 million will be available for this entire Cooperative Agreement. It is expected that a minimum of three to five awards will be made to new ERGs in fiscal year 1991.

Applications must be received by May 22, 1991. The earliest possible start date will be September 1991.

Potential applicants should contact Dr. Isa Fernandez for consultation concerning submission of proposed projects in response to this request, at the address listed below:

Isa Fernandez, Ph.D.
Staff Collaborator, Office of AIDS Programs
National Institute of Mental Health
5600 Fishers Lane
Room 11C-18, Parklawn Building
Rockville, MD 20857
Telephone: (301) 443-7281

For fiscal and administrative matters, contact;

Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane
Parklawn Building, Room 7C-15
Rockville, MD 20857
Telephone: (301) 443-4414

STUDIES ON THE ETIOLOGY AND PATHOGENESIS OF POLYCYSTIC KIDNEY DISEASE

RFA AVAILABLE: DK-91-08

P.T. 34; K.W. 0785095, 0755030, 0765033

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: April 17, 1991
Application Receipt Date: May 15, 1991

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) through the Division of Kidney, Urologic and Hematologic Diseases (DKUHD), invites research grant applications directed at defining and further characterizing the etiology and pathogenesis of Polycystic Kidney Disease (PKD).

BACKGROUND

Polycystic Kidney Disease is the most common genetic disease, affecting 500,000 Americans, and 7,000 new patients are recognized each year. Since 1982, the number of newly diagnosed patients has risen steadily, with a compound annual rate of 5.7 percent. Each child of an affected parent has a fifty percent chance of inheriting the gene. Two major types of PKD are recognized, autosomal dominant PKD and autosomal recessive PKD.

Polycystic Kidney Disease ranks first among the inherited and congenital conditions leading to end-stage renal disease (ESRD); it ranks fourth as a primary cause of ESRD and as a basic diagnosis among newly identified ESRD patients. Males and females are affected equally, and its worldwide distribution appears to demonstrate that it affects all races.

OBJECTIVES AND SCOPE

The purpose of this Request for Applications (RFA) is to stimulate high quality research studies to further the understanding of the etiology and pathogenesis of PKD. Applications proposing clinical trials are not requested at this time.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional, individual, investigator-initiated Research Grant (R01) Application.

Approximately \$1.2 million in total direct and indirect costs are anticipated to be available to fund applications submitted in response to this RFA. However, the funding of such applications is contingent on the actual availability of funds, and the receipt of applications of sufficient scientific merit. It is anticipated that five to seven awards will be made, for up to an average of 4 years per award. Support for successful

applications will begin on September 30, 1991. The current policies and requirements that govern the review, funding, and performance of research grant programs of the NIH will prevail.

APPLICATIONS AND REVIEW PROCEDURES

Applications will be reviewed initially by the Division of Research Grants (DRG) for completeness and will be assigned to a special NIDDK review group. Evaluation for responsiveness to the RFA is an NIDDK program staff responsibility. Applications that are judged non-responsive will be returned to the applicant but may be resubmitted as investigator-initiated applications at the next receipt date. Those applications judged to be both responsive and competitive will be evaluated for scientific/technical merit by an appropriate initial review group convened by the NIDDK Review Branch. The second level of review by the National Diabetes, Digestive and Kidney Advisory Council will make recommendations regarding funding.

METHOD OF APPLYING

Applications should be submitted on Form PHS 398 (revised 10/88) available in the Business or Research Grants Offices of most academic or research institutions, and from the Office of Grants Inquiries, Division of Research Grants, Room 449, Westwood Building, 5333 Westbard Avenue, National Institutes of Health, Bethesda, Maryland, 20892. Applications will be accepted until close of business on May 15, 1991. No extensions will be granted on the application deadline.

INQUIRIES

Copies of the full RFA may be obtained from:

Gladys H. Hirschman, M.D.
Director, Chronic Renal Diseases Program
National Institute of Diabetes and Digestive and Kidney Diseases
Federal Building, Room 102
Bethesda, MD 20892
Telephone: (301) 496-8218

For fiscal and administrative matters, contact:

Ms. Donna Huggins
Grants Management Specialist
Grants Management Branch
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 653
Bethesda, MD 20892
Telephone: (301) 496-7467

COOPERATIVE SPECIALIZED INFERTILITY RESEARCH CENTER PROGRAM

RFA AVAILABLE: HD-91-06

P.T. 34; K.W. 0413002, 0745020, 0745070

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: March 29, 1991

Application Receipt Date: June 17, 1991

OVERVIEW

The National Institute of Child Health and Human Development (NICHD) invites applications from investigators willing to participate with the NICHD under a cooperative agreement in a multicenter cooperative research program aimed at developing new approaches for the diagnosis and/or treatment of infertility. Recognizing that the complexity of infertility research severely limits the progress that can be achieved by individual investigators working alone, the NICHD will establish at least two (2) Specialized Infertility Research Centers to conduct accelerated preclinical and clinical research and development studies on promising new leads in infertility research. The cooperating Specialized Infertility Research Centers will also serve as national resources for the career development of young scientists electing to pursue research in high priority areas of infertility research. Grantee institutions in the continental United States that meet the requirements stated are eligible to participate.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA for a Cooperative Specialized Infertility Research Centers Program is related to the priority area of Family Planning. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

RESEARCH GOALS AND CENTER REQUIREMENTS

The research goals pursued by these Centers will focus on the early diagnosis and/or therapy of infertility. The scope of this RFA includes those female factors most often contributing to infertility or undesired surgical sterility (endometriosis, chronic ovulatory dysfunction, or uterine myomata-related dysfunctional bleeding) or those male factors associated with ineffective sperm production (quality or quantity).

Center requirements include an experienced Principal Investigator of recognized ability who is committed to and involved in human infertility research, the local or consortium availability of competent and experienced scientific experts to direct the Center's individual research projects or cores, access to the technical resources and facilities necessary for the conduct of the proposed experimental protocols, a research environment conducive to the training of young investigators in infertility research, a willingness of the investigators to participate in a coordinated, cooperative research program involving two or more Centers with multiple interactive research projects and substantive evidence of departmental and institutional support and commitment to the proposed Center.

MECHANISM OF SUPPORT

The funding mechanism to be used to assist the scientific community in undertaking this Program of basic and applied research will be the U54 cooperative agreement mechanism between participating Centers and the NICHD. It is expected that up to two (2) applications will be funded for a five (5)-year period, contingent upon the receipt of a sufficient number of meritorious proposals, within the total cost limit of \$1,000,000 available for the first year of this Program. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of an NICHD staff Research Coordinator above and beyond the levels required for traditional Program management of grants.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or inadequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

REVIEW PROCEDURES

An administrative review of the content of applications meeting the above NIH guideline will also be done by NICHD staff upon receipt of the application. Any application that does not meet the minimal requirements for a center project as specified in this RFA will be judged to be unresponsive to this RFA and will be returned to the applicant without technical review.

Applications that are complete and responsive may be subjected to a triage procedure by peer review to determine their general competitiveness. In accord with NIH policy, brief summary statements will be provided to the Principal Investigator of applications judged to be noncompetitive for award. Applications judged to be competitive for awards will be reviewed in detail in accordance with established NIH peer review procedures for research grants. Project site visits are neither planned nor a prerequisite of the scientific merit review procedure. Peer review will be conducted first for scientific and technical merit by a special review committee convened specifically for this purpose by the Division of Scientific Review, NICHD. This will be followed by a second-level review by the National Advisory Child Health and Human Development Council in September 1991.

APPLICATION PROCEDURES

Interested applicants should contact the Chief, Reproductive Sciences Branch (RSB) for an advisory consultation regarding Cooperative Specialized Infertility Research Center (U54) grants. If an applicant intends to apply, it is strongly recommended, but not mandatory, that applicants send a letter of intent by March 29, 1991 to the Chief, RSB at the address listed below. This letter should indicate the title of the proposed center and the names of the key investigators for the proposed subprojects. Applicants are encouraged to send it as soon as they decide to apply for the grant so that the RSB staff can be of maximum assistance in the application process.

Applications must be submitted on form PHS 398 (revised 10/88, reprinted 9/89), which is available in most institutional business offices or from the Division of Research Grants, Office of Grant Inquiries, NIH, Westwood Building, Room 449, Bethesda, Maryland 20892 or calling NIH (301/496-7441).

ADDITIONAL INFORMATION

Potential applicants are encouraged to request a detailed Request for Applications by contacting:

Michael E. McClure, Ph.D.
Chief, Reproductive Sciences Branch
Center for Population Research
National Institute of Child Health and Human Development
National Institutes of Health
Executive Plaza North, Room 603
Bethesda, MD 20892
Telephone: (301) 496-6515

For further information concerning administrative policy, contact:

Ms. Melinda Nelson
Office of Grants & Contracts
National Institute of Child Health and Human Development
National Institutes of Health
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-5481

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards will be made under the authority of the Public Health Service Act 301 (42 USC 241) and 441 (USC 289d) and administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

COOPERATIVE CONTRACEPTIVE DEVELOPMENT RESEARCH CENTERS PROGRAM

RFA AVAILABLE: HD-91-07

P.T. 34; K.W. 0413002, 0750020, 0710100

National Institute of Child Health and Human Development

Letter of Intent Receipt Date: March 25, 1991

Application Receipt Date: June 17, 1991

OVERVIEW

The National Institute of Child Health and Human Development (NICHD) invites applications from investigators willing to participate with the NICHD under a Cooperative Agreement in establishing a Centers program designed to conduct comprehensive research to develop new methods to regulate fertility. The aim of these Centers will be to conduct a wide range of research activities that, with time, will result in clinically useful products. The scope of the proposed program must involve the concurrent development of at least three projects. Each project comprises activities related to the development of a specific method for fertility regulation. Thus, research dealing with the development of a compound for male fertility regulation would be classified as a single project. Investigators are invited to propose development of methods, other than abortion related, that can serve the needs of the American public.

It is the intent of NICHD to establish three Contraceptive Development Research Centers. Grantee institutions in the United States that meet the requirements are eligible to participate.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Cooperative Contraceptive Development Research Centers Program, is related to the priority area of Family Planning. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

MECHANISM OF SUPPORT

The funding mechanism to be used to assist the scientific community in establishing these Centers will be the US4 Cooperative Agreement between the participating Centers and NICHD. The major difference between a Cooperative Agreement and a research grant is that there will be substantial programmatic involvement of NICHD staff above and beyond the levels required for traditional program management of grants. It is expected that up to three (3) applications will be funded for a five (5) year period, contingent upon the receipt of a sufficient number of meritorious proposals, within the total cost limit of \$2,000,000 available for the first year of this program.

REVIEW PROCEDURES

A preliminary review will be done by NICHD staff upon receipt of the applications. Any application that does not meet the minimal requirements of this RFA will be judged to be unresponsive to this RFA and will be returned to the applicant without technical review. Applications that are complete and responsive may be subjected to a triage procedure by peer review to determine their general competitiveness. Applications judged to be competitive for awards will be reviewed in detail in accordance with established NIH peer review procedures for research grants. Project site visits are neither planned nor a prerequisite of the review procedure. The review will be conducted first for scientific and technical merit by a special review committee convened specifically for this purpose by the Division of Scientific Review, NICHD. This will be followed by a second-level review by the National Advisory Child Health and Human Development Council in September 1991.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

Application Procedures:

Applications must be submitted on form PHS 398 (revised 10/88, reprinted 9/89), which is available in most institutional business offices and from the Office of Administrative Management, Division of Research Grants, NIH, Office of Grants Inquiries, Westwood Building, Bethesda, Maryland 20892, (301) 496-7441.

Additional Information:

Potential applicants are encouraged to request a detailed RFA by telephoning:

Gabriel Bialy, Ph.D.
Contraceptive Development Branch
National Institute of Child Health and Human Development
Executive Plaza North, Room 600
Bethesda, MD 20892
Telephone: (301) 496-1661

After receipt of the RFA, Principal Investigators who plan to respond to this RFA should indicate so by writing to the above address as soon as possible, but not later than March 25, 1991. The Intent letter should provide the names of the Principal Investigator, other key investigators and organizations that will be part of the Center's application.

This program is described in the Catalog of Federal Domestic Assistance No. 93.864, Population Research. Awards will be made under the authority of the Public Health Service Act 301 (42 USC-241) and 441 (USC289d) and administered under PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

EFFECT OF SPECIFIC COMPONENTS OF HUMAN MILK ON THE NURSING

RFA AVAILABLE: HD-91-10

P.T. 34; K.W. 0750015, 0775015, 1003008, 0760020, 0760025

National Institute of Child Health and Human Development

Application Receipt Date: July 24, 1991

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This RFA, Effect of Specific Components of Human Milk on the Nursing, is related to the priority areas of Nutrition and Maternal and Infant Health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

The Endocrinology, Nutrition, and Growth Branch of the Center for Research for Mothers and Children of the National Institute of Child Health and Human Development (NICHD) invites research grant applications on the effects of specific components of human milk on the nursing infant with respect to nutrition, physiological maturation of specific tissues or organ systems, and susceptibility to infection and malignancies, endocrinopathies, and degenerative disorders. Of particular interest are studies designed to determine the mechanisms of these effects.

BACKGROUND

Over the last twenty years we have become aware that human milk is a complex mixture which contains many substances besides those which meet the classical nutritional requirements of newborn infants. Many of these substances are not present in cow milk or infant formula or are present there only in much lower concentrations. They include enzymes, hormones, growth factors, antibodies, specific proteins of other classes, non-protein nitrogenous substances, and oligosaccharides. Some of these substances which are of large molecular size can nevertheless be absorbed intact from the immature gastrointestinal tract. Many of them have powerful biological actions in other in vivo and in vitro contexts, but for only a few have we learned the physiological import of their presence in milk. Whether the others have significant developmental effects on the nursing infant or are only incidental passengers of the milk secretion process is unknown.

RESEARCH GOALS

Most full-term infants thrive on artificial formulas which lack high concentrations of the human milk-specific components. Their development apparently proceeds satisfactorily without any specific stimulation these substances may provide. On the other hand, the maturation of low birth weight infants proceeds less smoothly, and is complicated by conditions such as the respiratory distress syndrome, bronchopulmonary dysplasia, and necrotizing enterocolitis which seem to result from maturational deficiencies. An understanding of how human milk components influence intestinal maturation, lung function, intellectual development, specific or nonspecific immunity, and other variables in the neonatal period could lead to specific therapeutic uses of these components in physiologic or pharmacologic doses in undersized, ill, or developmentally delayed infants. Such studies could also provide important, broadly applicable information about the biological functions of these components.

This RFA is issued to encourage investigators to undertake clinical studies of the role of specific components of human milk in normal development and disease resistance, and to develop animal or organ/tissue models when studies in humans are impractical or unethical. Nonclinical model studies must focus on the effects of components of human milk. Studies of these topics are expected to increase our understanding of the physiologic role and pharmacologic potential of human milk components, and lead to improved formulas for artificially fed infants. This is an underinvestigated area of

research on maternal-infant interactions, with potentially important clinical applications.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

Applications in response to this RFA will be funded through the traditional individual research award (R01) program of the NIH. This announcement is for a single competition with the application receipt deadline of July 24, 1991. The earliest possible start date for these grants is March 1, 1992. It is anticipated that four (4) grants will be awarded under this program, contingent upon receipt of a sufficient number of meritorious applications and the availability of funds. \$600,000 has been set aside to fund these grants.

REVIEW PROCEDURES AND CRITERIA

Applications will be reviewed by NICHD staff for responsiveness to the RFA. Applications judged to be nonresponsive will be returned. The applicant may resubmit the application and have it assigned for review in the same manner as unsolicited grant applications. If the application submitted in response to this RFA is substantially similar to a research grant application already submitted to the NIH for review, but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. Therefore, an application cannot be submitted in response to this RFA that is essentially identical to one that has already been reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

Criteria for the initial review will include the significance and originality of research goals and approaches; the feasibility of research and adequacy of the experimental design; the research experience and competence of the investigator(s) to conduct the proposed work; the adequacy of investigator effort devoted to the project; and the appropriateness of the project duration and cost relative to the work proposed. Following review by the Initial Review Group, applications will be evaluated by the Institute's Advisory Council for program relevance and policy issues before awards for meritorious proposals are made.

INQUIRIES

Requests for copies of the complete RFA should be directed to:

Ephraim Y. Levin, M.D.
Medical Officer, Endocrinology, Nutrition and Growth Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Executive Plaza North, Room 637
Rockville, MD 20852
Telephone: (301) 496-5593

For fiscal and administrative matters, contact:

Mr. E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 501
Rockville, MD 20852
Telephone: (301) 496-1303

This program is described in the catalog of Federal Domestic Assistance No. 93.865, 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.

MINORITY ONCOLOGY LEADERSHIP ACADEMIC AWARD

RFA AVAILABLE: CA-91-11

P.T. 34, FF; K.W. 0785140, 0745020, 0745027, 0745070, 0755030, 0795003

National Cancer Institute

Letter of Intent Receipt Date: April 5, 1991

Application Receipt Date: May 17, 1991

PURPOSE

The Comprehensive Minority Biomedical Program, Division of Extramural Activities, National Cancer Institute (NCI), invites academic health centers or schools and other health professional schools that employ, educate or serve a preponderance of minority faculty, staff, trainees and communities, to submit applications for the support of an individual to pursue leadership activities in the development of research and training programs in clinically oriented cancer research (defined as including population research; surgical, medical or radiation oncology; cancer prevention and control; epidemiology and biostatistics; nutrition; clinical pharmacology and clinical trials; behavioral medicine and related areas of cancer research).

GOALS AND SCOPE

This award is aimed at encouraging and assisting a designated leader in any of the minority health professional schools to increase his/her institution's efforts in clinical cancer research in the areas such as medical oncology, prevention, etiology, diagnosis, treatment, and control; and to aid in establishing a cadre of faculty and staff capable of developing new research protocols and of participate in intervention studies and clinical trials in these areas.

These awards offer opportunities for supporting start-up expansion of such activities, and are intended to meet needs that have not been addressed by other types of awards available from the NCI or other Federal Agencies. Priority is given to those minority institutions with an interest in and commitment to expansion of clinical cancer research-related activities in local populations.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health grant-in-aid (K07). Applicants will be responsible for the planning, direction, and execution of the proposed project. Up to \$350,000 in total costs per year will be committed specifically to fund applications submitted in response to this RFA. It is anticipated that between 2 and 4 awards will be made from the competition for this K07 solicitation. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The earliest feasible start date for the initial award is September 30, 1991. Awards may be requested for a period of 3 to 5 years.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 5, 1991, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted. The letter of intent is of great benefit to the NCI in planning for and implementing the review process although it is not required, is not binding, and does not enter into the review of subsequent applications.

The letter of intent should be sent to the NCI Program Director:

Dr. Lemuel Evans
Comprehensive Minority Biomedical Program
Division of Extramural Activities
National Cancer Institute
NIH Building 31, Room 10A04
Bethesda, MD 20892
Telephone: (301) 496-7344
FAX: (301) 402-0062

For information regarding budgetary/administrative issues related to this RFA, please contact:

Mr. Leo Buscher, Jr.
Chief, Grants Administration Branch
National Cancer Institute
National Institutes of Health
Executive Plaza South, Room 216
Bethesda, MD 20892
Telephone: (301) 496-7753

INQUIRIES

Requests for a complete copy of the RFA, written or telephone inquiries concerning the objectives and scope of this RFA, or inquiries about whether or not specific proposed research would be responsive should be directed to Dr. Lemuel Evans at the above address. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants.

CLINICAL INVESTIGATOR AWARD FOR RESEARCH ON SPECIAL POPULATIONS

RFA AVAILABLE: CA-91-12

P.T. 34; K.W. 0715035, 0411005, 0715020, 0785055, 0785140, 0785210, 0745062

National Cancer Institute

Letter of Intent Receipt Date: April 5, 1991
Application Receipt Date: May 17, 1991

PURPOSE AND BACKGROUND

The Comprehensive Minority Biomedical Program, Division of Extramural Activities, National Cancer Institute (NCI) announces the availability of Clinical Investigator Awards for Research on Special Populations. This program is intended to:

- o Encourage newly trained clinicians to develop research interests and skills in the basic and applied sciences relevant to cancers and risks for cancers that have a high prevalence or incidence in special populations that may be underserved by limited access to current knowledge and medical care.
- o Increase the pool of cancer physician-investigators, particularly in medical oncology, epidemiology, nutrition, behavioral medicine, surgical oncology, preventive oncology and diagnostic and therapeutic radiology, who are committed to investigation of the unique problems facing special populations.
- o Provide the opportunity for clinically trained physicians with a commitment to research to develop into independent biomedical research investigators.

The term "special populations" refers to those population segments which may experience or are known to experience high cancer rates and are underserved in terms of: cancer prevention and control programs (e.g., smoking or health screening programs); diagnostic and treatment modalities; study for special risk factors or underlying biological differences; and who may have limited access to regular medical care. This definition is taken to include: African Americans, Alaskan Natives, American Indians, Asian Americans, Pacific Islanders, the elderly, Hispanics, and low-income groups.

HEALTHY PEOPLE FOR THE YEAR 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This PA/RFA, "Clinical Investigator Award for Research on Special Populations (K08)", is related to the priority area of cancer research. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (Telephone 202-783-3238).

GOALS AND SCOPE

The award will enable candidates to undertake from three to five years of specialized study and supervised research experience tailored to individual needs with a sponsor (or sponsors) competent to provide research guidance. This award is intended to cover the transition between postdoctoral experience

and a career in independent investigation, and to acquaint the candidate with the often unique challenges and circumstances involved in designing research protocols directed toward improving the health of groups comprising a significant and often disproportional percentage of individuals at risk from high cancer morbidity and mortality rates.

This award differs from the NIH Research Career Development Award (RCDA) in that it seeks to develop research ability in individuals with a clinical background early in the candidate's career rather than to promote the further development of research skills of individuals already demonstrating significant research achievement. A major purpose of this award is to increase the number of cancer-oriented research physicians in the United States with research interests and experience focused specifically on the unique needs of special populations and the broad array of issues at the biological, behavioral, social, economic and medical levels that render such populations at increased risk for cancer and for mortality from cancer.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and/or minorities are not included or adequately represented in study populations proposed for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health grant-in-aid (K08). Applicants will be responsible for the planning, direction, and execution of the proposed project. Applicants may request three to five years of support. Awards are non-renewable and non-transferable from one awardee to another. Funding beyond the first year of the grant is contingent on satisfactory progress during the preceding year. Future program interest in this initiative will be announced through the NIH program announcement mechanism.

It is anticipated that in a majority of cases the experience and results achieved by awardees as a result of this special grant program will provide the basis for their successful competition in the research support programs of the NCI.

Up to \$300,000 has been set-aside in FY 1991 to fund meritorious applications received in response to this competition. Depending on the merit and distribution of applications received, approximately 1 to 3 Clinical Investigators will be funded with a start date of September 30, 1991. Meritorious applications received for this competition that cannot be funded at that time may be held over for possible funding in fiscal year 1992.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 5, 1991, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted. The letter of intent is of great benefit to the NCI in planning and implementing the review process although the letter is not required, is not binding, and does not enter into the review of subsequent applications. The letter of intent must be sent to the NCI Program Director:

Dr. Lemuel Evans
Division of Extramural Activities
Comprehensive Minority Biomedical Program
National Cancer Institute
Building 31, Room 10A04
Bethesda, MD 20892
Telephone: (301) 496-7344

For information regarding budgetary/administrative issues related to this RFA, please contact:

Mr. Leo Buscher, Jr.
Chief, Grants Administration Branch
National Cancer Institute
National Institutes of Health
Executive Plaza South, Room 216
Bethesda, MD 20892
Telephone: (301) 496-7753

INQUIRIES

Requests for a copy of the complete RFA, written or telephone inquiries concerning the objectives and scope of this RFA or inquiries about whether or not specific proposed research would be responsive should be directed to Dr. Lemuel Evans at the above address. The program director welcomes the opportunity to clarify any issues or questions from potential applicants.

MINORITY SCHOOL FACULTY DEVELOPMENT AWARD

RFA AVAILABLE: CA-91-13

P.T. 34, FF; K.W. 0715035, 0710030

National Cancer Institute

Letter of Intent Receipt Date: April 5, 1991
Application Receipt Date: May 17, 1991

PURPOSE

The Comprehensive Minority Biomedical Program, Division of Extramural Activities, National Cancer Institute (NCI), invites academic health centers or schools and other health professional schools that employ, educate or serve a preponderance of minority faculty, staff, trainees and communities to submit applications for support of activities directed at the development of faculty investigators at minority schools in areas relevant to cancer. The intent of the award is to provide the awardee with increased access to research opportunities through collaborative arrangements with outstanding cancer research scientists, usually at institutions within a 100 mile radius of the applicant organization.

BACKGROUND

Despite a variety of efforts to increase minority faculty representation, the percentage of minority faculty in U.S. medical and other health professional schools has remained at consistently low levels. The continuation of this deficiency is projected by observing the discrepancies between the proportion of underrepresented minorities in the medical school population and the general population. While 12 percent of the U.S. population is African American, less than 1 percent of persons holding a Ph.D. in science are African American and the percentages for other minority groups are correspondingly small.

The proportion of minority biomedical investigators, especially those receiving funding support from agencies of the Federal government, is strikingly low. This program is designed to offer support for cancer related research to minority school faculty members at the M.D., Ph.D. or equivalent level who have the interest and capabilities of doing state-of-the-art research in this area.

GOALS AND SCOPE

The objective of this Request for Applications (RFA) is to broaden the experience of faculty members at minority schools, increase the pool of biomedical and behavioral investigators in cancer research, and have graduate and undergraduate students, most of whom will be minority individuals, become more cognizant of research opportunities in cancer research.

MECHANISM OF SUPPORT

Support of this program will be through the National Institutes of Health grant-in-aid (K14). Applicants will be responsible for the planning, direction, and execution of the proposed project. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in Public Health Service Grants Policy Statement, HHS Publication No. (OASH) 90-50,000, revised October 1, 1990. Applicants may request three to five years of support. Awards are non-renewable and nontransferable from one awardee to another. Funding beyond the first year of the grant is contingent

on satisfactory progress during the preceding year. Future program interest in this initiative will be announced through the NIH program announcement mechanism.

A set-aside of approximately \$300,000 in total costs per year has been designated for this group of applications, which should request a starting date of September 30, 1991. It is anticipated that three to four awards will be made. This funding level is dependent upon the receipt of a sufficient number of applications of high scientific merit. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

LETTER OF INTENT

Prospective applicants are asked to submit by April 5, 1991, a letter of intent that includes descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted. The letter of intent is of great benefit to the NCI in planning and implementing the review process.

INQUIRIES

Requests for a copy of the complete RFA, written or telephone inquiries concerning the objectives and scope of the RFA or inquiries about whether or not specific proposed research would be responsive should be directed to:

Dr. Lemuel A. Evans
Director
Comprehensive Minority Biomedical Program
National Cancer Institute
Building 31, Room 10A04
9000 Rockville Pike
Bethesda, MD 20892

For information regarding budgetary/administrative issues related to this RFA, please contact:

Mr. Leo Buscher, Jr.
Chief, Grants Administration Branch
National Cancer Institute
National Institutes of Health
Executive Plaza South, Room 216
Bethesda, MD 20892
Telephone: (301) 496-7753

The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants, and to aid in identification of institutions and potential mentors appropriate to the interests of the applicant.

RESEARCH UNITS ON PELVIC INFLAMMATORY DISEASE AND ITS SEQUELAE

RFA AVAILABLE: AI-91-08

P.T. 34; K.W. 0715026, 1002004, 1002027, 0710070

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: April 15, 1991

Application Receipt Date: October 21, 1991

The Sexually Transmitted Disease Branch of the Division of Microbiology and Infectious Disease of the National Institute of Allergy and Infectious Diseases (NIAID) invites grant applications for program project grants to be initiated in FY 1992 that focus on pelvic inflammatory disease (PID) and its sequelae. In recognition of the severe impact of PID on the health of women, the NIAID wishes to expand research in this area and to place greater emphasis on investigations that are likely to lead to reduction of the incidence and severity of long-term sequelae such as infertility, ectopic pregnancy and chronic pelvic pain syndrome. The Research Units on PID and its Sequelae will provide a strong, interdisciplinary approach to PID research which will draw upon expertise in clinical, epidemiological, behavioral, and basic sciences. Although a broad range of PID research issues will be addressed, research in the following three areas is particularly enthusiastically encouraged:

- 1) Long-term sequelae - Characterization of the immunopathological and behavioral determinants of the development of long-term sequelae of PID and use of animal models to evaluate interventions to reduce these sequelae;
- 2) Atypical PID - Development of methods to detect atypical infections and definition of the epidemiology of this portion of the PID spectrum;
- 3) Diagnostic Approaches - Development and assessment of non-invasive methods to diagnose PID.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. This RFA, Research Units on Pelvic Inflammatory Disease and its Sequelae, is related to the priority area of Sexually Transmitted Diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

RESEARCH OBJECTIVES AND SCOPE

The goal of this program is to encourage investigators to undertake research that will provide the microbiological, immunological, clinical, epidemiological and behavioral information needed for the eventual control of PID and its long-term sequelae. In addition to other important research issues, data that are needed to design and conduct intervention trials to reduce the incidence and severity of sequelae of PID are of high priority. It should be understood that such a trial is not a component of this solicitation nor has the NIAID developed specific plans for such a trial at this time. However, one of the major purposes of this RFA is to stimulate exceptionally high quality, multi-disciplinary research on those aspects of the epidemiology, pathogenesis and detection of PID that are likely to be critical in the design of such trials.

In addition to the importance of utilizing a multi-disciplinary approach, specific programmatic requirements and constraints are as follows:

- o Structure: Each program project must consist of at least three individual subprojects that are synergistically inter-related. Each subproject should clearly describe research objectives and each should be headed by a Principal Investigator, with a research staff and a separately identifiable budget.
- o Clinical Facility: In order to bridge the basic research and clinical arenas, the PID program project must offer a strong clinical facility with accessible patient populations that are appropriate to answering PID research questions. Adolescents and inner city minority groups should be considered for special attention in the context of these program project grants.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES - For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. By the nature of this program, subjects will consist largely of women. Applicants are urged to give added attention, where feasible and appropriate, to the inclusion of minorities in study population for PID program project grants. If minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

A broad range of research questions is potentially relevant to the goal of this program. Specific research areas of high priority include but are not limited to microbiology, pathogenesis, epidemiology, behavioral determinants, and diagnosis of PID and are addressed in greater detail in the RFA.

MECHANISM OF SUPPORT

Successful applicants funded under this RFA will be supported through program project (P01) grants. This type of funding mechanism is utilized when it is desired to encourage multi-disciplinary investigator-initiated research on a broad range of problems which are linked by a common theme. NIAID anticipates making three program project grant awards as a result of this RFA. The final number of awards to be made is dependent upon the availability of funds.

Requests for support should be limited to no more than \$800,000 total costs for the initial year of funding. This solicitation represents a single competition with a specified deadline for receipt of applications. Awards will be made for a project period of up to four years. Although there are no present plans to reissue this RFA at any future time, NIAID may invite competitive renewal applications upon expiration of the initial funding period, contingent on the availability of funds for this purpose.

ELIGIBILITY - ONLY DOMESTIC INSTITUTIONS ARE ELIGIBLE TO APPLY.

APPLICATION PROCEDURE

Before preparing an application, the prospective applicant must request a copy of the RFA and the NIAID Information Brochure on Program Project Center Grants from:

Dr. Judith Wasserheit
Chief, Sexually Transmitted Diseases Branch
Westwood Building, Room 749
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 402-0443

Letter Of Intent

Prospective applicants are asked to submit, by April 15, 1991, a letter of intent that includes a descriptive title and the names and affiliations of the proposed key investigators for each of the proposed research projects.

This letter must be sent to:

Dr. Olivia Preble
Chief, Microbiology and Immunology Review Section
Program and Project Review Branch
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Westwood Building, Room 3A10
Bethesda, MD 20892
Telephone: (301) 496-8208

Questions regarding fiscal matters should be addressed to:

Mr. Todd Ball
Grants Management Branch
Division of Extramural Activities
NIAID, NIH
Westwood Building, Room 726
Bethesda, MD 20892
Telephone: (301) 496-7075