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

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NOTICES

The following two notices describe the main features of new procedures intended to expedite the review of investigator-initiated AIDS research grant applications. Additional details about these procedures will be published in future issues of the NIH GUIDE. Applicant investigators, institutional business officials, and others concerned with the submission of funding requests for AIDS research are encouraged to watch the NIH GUIDE for additional information.

EXPEDITED REVIEW OF INVESTIGATOR-INITIATED AIDS RESEARCH GRANT APPLICATIONS

P.T. 34; K.W. 0715120, 1014002

National Institutes of Health

The National Institutes of Health (NIH) has begun an expedited referral, review, and award process for contract proposals and grant applications in Acquired Immune Deficiency Syndrome (AIDS) research. Specific AIDS initiatives that will be solicited, utilizing any of the current mechanisms (contract, cooperative agreement or grant), will be announced at appropriate times in the NIH Guide for Grants and Contracts. These announcements, which in addition may also appear in selected scientific journals as well as the Commerce Business Daily, will carry specific information regarding receipt dates, review processes, and Institute requirements.

The plan for expediting the review of intended AIDS research also applies to unsolicited investigator-initiated research project grant applications (R01 and R29). This process, which began in a limited way February 1, 1988, extends throughout the various funding components of the NIH and is described in this announcement: **THE FOLLOWING APPLIES ONLY TO UNSOLICITED INVESTIGATOR INITIATED R01 AND R29 GRANT APPLICATIONS ON AIDS RESEARCH.**

This announcement establishes three new receipt dates for all unsolicited new and competitive renewal AIDS research grant applications submitted to the Division of Research Grants, NIH. The dates selected are JANUARY 2, MAY 1, and SEPTEMBER 1 of each year, beginning MAY 1, 1988.

All applications received on or before these receipt deadlines, if determined to be AIDS research, will undergo an accelerated review to award process lasting approximately six months. In order to be considered for this accelerated process, the following conditions must be met:

a. APPLICATIONS MUST BE DIRECTLY APPLICABLE TO AIDS (etiology, epidemiology, natural history, diagnosis, treatment or prevention of AIDS, or the various sequelae specifically associated with the syndrome. Preparation and screening of anti-AIDS agents as well as vaccine development, including both preclinical and clinical studies, are considered to be directly applicable). For example, not all research applications examining various influences on T-lymphocytes nor all applications dealing with retroviruses will be appropriate for this expedited review process that will involve initial scientific merit review by experts in AIDS. Applications only indirectly related to AIDS will be evaluated by established initial review groups (study sections) appropriate to the scientific discipline during regular NIH review cycles and should not be submitted in response to the new AIDS receipt dates.

b. Applicants are requested to indicate "AIDS Research" in Block 2 of the PHS-398. All other instructions for investigator-initiated research grant applications, including the special requirements of the FIRST award (R29), also apply to these applications.

c. The completed application, as described above, and 6 copies should be sent to the following address; unique to AIDS applications:

DRG AIDS Coordinator
Division of Research Grants, NIH
Westwood Building, Room 9
Bethesda, Maryland 20892**

REVIEW AND AWARD SCHEDULE FOR AIDS APPLICATIONS

Receipt of AIDS Investigator- Initiated Applica- tion in DRG	Scientific Merit Review by AIDS Study Sections	Second Level Review by Institute Council or Board	Earliest Possible Start of Grant
May 1 *	July 10-20	Sept./Oct.	Nov.
Sept. 1 *	Nov. 15-25	Jan.	Feb.
Jan. 2 *	March 15-25	May	June

* Because of the expedited review cycle, late applications will not be accepted.

NOTE: In addition to the expedited review cycle outlined in this announcement, AIDS applications may also be submitted for the regular research grant receipt dates established for all applications (February 1, June 1, October 1 for new applications and March 1, July 1, and November 1 for competing continuation applications). Such submissions will undergo the usual referral process, and be assigned to the most appropriate DRG study section for that particular application. This alternative may be considered by any investigator who decides that an expedited review cycle has no particular advantage, because for example, current support for an ongoing AIDS research effort continues for another year.

EXPEDITED REVIEW AND AWARD OF INVESTIGATOR-INITIATED AIDS GRANT APPLICATIONS

P.T. 34; K.W. 0715120, 1014002

Alcohol, Drug Abuse, and Mental Health Administration

INTRODUCTION

The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) has begun an expedited referral, review, and award process for grant applications and contract proposals applicable to Acquired Immune Deficiency Syndrome (AIDS). Specific AIDS initiatives that will be solicited utilizing any of the current mechanisms (grant, contract, or cooperative agreement) will be announced at appropriate times in the NIH Guide for Grants and Contracts or the Commerce Business Daily. These announcements, which may also be published in scientific journals, will carry specific information regarding receipt dates, review processes, and Institute requirements.

In ADAMHA, the following procedures apply only to unsolicited (i.e., not in response to an RFA) investigator-initiated research, research scientist development/award, and research training grant applications (i.e., R, P, K, T, and F activity codes).

APPLICATION RECEIPT, REVIEW, AND AWARD SCHEDULE

This notice establishes three new receipt dates for all unsolicited NEW AND COMPETING renewal AIDS grant applications submitted to the Division of Research Grants, NIH for review by ADAMHA. The special AIDS receipt, review, and award cycle is outlined below:

Receipt of AIDS Invest.- Initiated Applications	Scientific Merit Review	Second Level Review	Earliest Possible Start of Grant
May 1*	June/July	Sept./Oct.	Nov.
Sept. 1*	Oct./Nov.	Jan./Feb.	Feb.
Jan. 2*	Feb./Mar.	May/June	June

* Because of the expedited review cycle, late applications will not be accepted.

ADAMHA will accept unsolicited investigator-initiated new and competing renewal AIDS applications only on the special AIDS receipt dates. ADAMHA will not accept AIDS applications for the regular PHS receipt dates (June 1, October 1, and February 1). Applications received on or before the regular PHS receipt deadlines, if determined to be applicable to AIDS, will be held

for the next special AIDS review cycle. All applications determined to be applicable to AIDS will undergo an accelerated review to award process lasting approximately six months.

In order to be considered for this accelerated process, applications must be applicable to AIDS. (The National Institute on Alcohol Abuse and Alcoholism supports research on all issues pertinent to alcohol and AIDS including the potential modification of normal host defense mechanisms against HIV by alcohol, the contribution of alcohol to risk-taking behavior directly related to HIV acquisition (and the prevention of such behaviors), and the impact of alcohol in altering the efficacy of treatment for HIV or opportunistic disease consequent to AIDS. The National Institute on Drug Abuse supports research on all aspects of drug abuse and AIDS, including a wide range of subjects from the effects of illicit drugs on the immune system to the treatment, prevention/ intervention of AIDS in populations at special risk, e.g., intravenous drug abusers. The National Institute of Mental Health supports research on the neuropsychiatric and neuropsychological aspects of AIDS and AIDS dementia; research on the biopsychosocial aspects of stress and immune function as related to HIV infection; and psychosocial research on high-risk behaviors and strategies for motivating behavior change in populations at high risk for AIDS.)

APPLICATION SUBMISSION INSTRUCTIONS

1. Applicants will be responsible for submitting an original grant application form PHS 398 (Rev. 9/86) and 6 legible copies. Fellowship applicants should submit an original application form PHS 416-1 (Rev. 6/85) and 2 legible copies.
2. Applicants are requested to indicate "AIDS Research" in Block 2 of the PHS 398 (Block 3 of the PHS 416-1) and on the container used to mail the application. All other instructions for investigator-initiated research, research scientist development/award, and research training applications, including the special requirements of the FIRST award (R29), also apply to these applications.
3. The completed application, as described above, and 6 copies (2 copies for fellowships) should be sent to the following address which is unique to AIDS applications:

DRG AIDS Coordinator
Division of Research Grants, NIH
Westwood Building, Room 9
Bethesda, Maryland 20892**

DATED ANNOUNCEMENTS (RFPs AND RFAs)

STUDIES OF CHEMICAL DISPOSITION IN MAMMALS

RFP AVAILABLE: NIH-ES-88-04

P.T. 34; K.W. 1003008, 0765020

National Institute of Environmental Health Sciences

The purpose of this project is to obtain detailed chemical disposition data from approximately 5 (five) studies per year of selected environmental contaminants or model compounds. Most of these studies will be required in laboratory rats (Fischer 344); however, some studies may be required in other laboratory species. Most studies will address the disposition of organic chemicals or environmental contaminants; however, studies of inorganic compounds may also be requested. Individual studies may vary in complexity from preliminary investigations of chemical absorption to detailed studies of all phases of chemical disposition and metabolism. This project will cover a five-year period. The Government estimates that the project will require approximately 1.5 professional person years and 3.0 technical person years per contract year.

This is an announcement of an anticipated Request for Proposals. RFP NIH-ES-88-04 will be issued on or about March 14, 1988, with a closing date for receipt of proposals set for April 29, 1988.

Requests should reference RFP NIH-ES-88-04 and should be forwarded to:

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

DIETARY SURVEYS AND FOOD COMPOSITION DATA

RFP AVAILABLE: NCI-CN-87077-42

P.T. 34; K.W. 0710095, 0715035, 0404021

National Cancer Institute

The primary goals of this procurement are: to obtain existing dietary survey and food intake data on individuals in various international populations and to establish a classification scheme, computerized data base, and retrieval software for these data; and to maintain a data exchange standard based on an international food language, convert various food component data sources to the standard, and develop a retrieval network.

These efforts will provide valuable research resources for better understanding the relationship between diet and cancer.

The RFP is tentatively scheduled for release around March 2, 1988, and responses will be due on approximately April 21, 1988. One award is anticipated and a three-year incrementally funded cost-reimbursement (completion) type contract is expected to be awarded to the successful offeror.

Copies of the RFP may be obtained by sending a written request to:

Joanne S. Feldman
Blair Building, Room 2A07
National Cancer Institute, NIH
Bethesda, Maryland 20892
Telephone: (301) 427-8745

CRANIOFACIAL ANOMALIES RESEARCH CENTERS

RFA AVAILABLE: 88-DE-03

P.T. 04; K.W. 0785055, 1002008, 1002019, 1002059, 0775030, 0710030

National Institute of Dental Research

Application Receipt Date: December 1, 1988

The National Institute of Dental Research (NIDR) invites applications from United States institutions for support of Craniofacial Anomalies Research Centers to conduct multidisciplinary, fundamental and epidemiological research on genetic aspects of the etiology of craniofacial anomalies.

BACKGROUND

Approximately five percent of babies born in the United States require treatment for various malformations. Single mutant genes and major chromosomal abnormalities are associated with about 13.5 percent of these malformations; combinations of genetic and environmental factors are implicated in a further 20 percent of cases. Three quarters of congenital malformations affect the head and neck and thus represent a major public health problem of interest to the NIDR. Cleft lip with or without cleft palate and isolated cleft palate are the most common and extensively studied birth defects of the craniofacial region, occurring in approximately one in every 600 live births. One in every 1,600 live babies in the United States are affected with craniofacial anomalies other than cleft lip and/or palate. Nearly fifty percent of U.S. children are affected by dentofacial malrelations that warrant treatment and about five percent have sufficiently severe orthodontic or orthognathic problems that they are handicapped functionally and psychosocially. Genetic factors are also implicated in determining tooth size, morphology and number. At the molecular level, genes coding for proteins contributing to tooth structure and mineralization and also for production of collagens and other proteins of cartilage and bone have been

characterized. Mutations of these genes may be responsible for inherited conditions such as amelogenesis- and osteogenesis-imperfecta.

Recent advances in molecular biology and genetics have provided the molecular basis for interpreting epidemiological and biochemical information on many human inherited disorders, permitting studies on their etiology, diagnosis, treatment and prevention. These advances have created opportunities for research on developmental disorders of genetic origin affecting human craniofacial structures. The objective of this RFA is to solicit center grant applications, which will capitalize on recently developed techniques and information on molecular biology and genetics and create multidisciplinary teams to address problems of normal and abnormal human craniofacial development.

RESEARCH GOALS AND SCOPE

The following research areas and approaches may be appropriate for inclusion in applications for support. However, these are intended as examples only, no priorities are implied and they should not constrain applicants from proposing other research topics on the molecular biology and genetic aspects of craniofacial development and the etiology of congenital craniofacial anomalies.

- o Obtain epidemiological genetic data and use gene mapping techniques to locate genes responsible for specific craniofacial anomalies.
- o Develop genetic and physical maps of selected chromosomal segments deemed important in craniofacial development.
- o Examine the genetic and biochemical control of morphogenesis of the skull, face and oral structures. The genes responsible for determining craniofacial form may be analogous to the homeotic genes.
- o Develop and use model systems to determine the genetic control of susceptibility to the major teratogens responsible for craniofacial anomalies.
- o Determine the importance of genetic and biochemical factors in cellular differentiation, migration and interactions during craniofacial development.

It is likely that some of the information gained will ultimately lead to improvements in clinical treatment. However, it is not intended that center resources will be used to support research on surgical treatment or clinical management and rehabilitation of patients with craniofacial anomalies. The NIDR is already directing considerable resources to those aspects of research through existing programs.

FUNDING MECHANISM

The centers will be supported by specialized center research grants (P50) for a period of five years, commencing as early as August 15, 1989. Subsequent support will be contingent upon program needs and successful competitive reviews. Applicants may request up to \$500,000 in direct costs for the first year. It is anticipated that a minimum of two awards may be made, if a sufficient number of high quality applications are received. However, award of grants for this program is contingent upon receipt of appropriated funds for this purpose. Policies governing research grant programs of the National Institutes of Health will prevail.

REVIEW

Major factors to be considered in the evaluation of applications will be the extent to which the center will promote advances in knowledge of the etiology of craniofacial anomalies, which could not be achieved or which would be achieved more slowly, if the component projects were funded separately; the institutional commitment to research on the molecular biology and genetics of craniofacial development; the scientific merit of each subproject.

METHOD OF APPLICATION

Center grants will only be made to United States institutions. Applications should be prepared on form PHS-398 (Rev. 9/86), Application for PHS Grant, which can be obtained from the Division of Research Grants (DRG), NIH, or from the institution's application control office. The RFA label available in the 9/86 revision of form PHS-398 must be affixed to the bottom of the face page.

Failure to use this label could result in delayed processing of an application such that it may not reach the review committee in time for review.

Requests for copies of the full RFA and all inquiries should be directed to:

John D. Townsley, Ph.D.
Chief, Craniofacial Anomalies,
Pain Control and Behavioral Research Branch
National Institute of Dental Research
Westwood Building, Room 506
Bethesda, Maryland 20892-4500
Telephone: (301) 496-7807

INTERNATIONAL TRAINING GRANTS IN EPIDEMIOLOGY RELATED TO AIDS

RFA AVAILABLE: 88-TW-01

P.T. 44; K.W. 0785055, 0715120, 0720005

Fogarty International Center

Application Receipt Date: May 2, 1988

The Fogarty International Center (FIC), National Institute of Health (NIH), invites applications from U.S. institutions with interest in developing international training programs in epidemiology related to AIDS for foreign health scientists, clinicians, and allied health workers.

A major goal of the International Training Grants in Epidemiology Related to AIDS Program is to increase the self reliance and capacity of scientists in other countries to effectively deal with the AIDS epidemic through epidemiologic research, clinical trials, and AIDS prevention research programs. This training program will help to: (1) establish the necessary research and medical expertise needed in countries affected by AIDS and facilitate new research efforts which supplement or complement U.S. AIDS research, and (2) establish cooperative relationships between U.S. and foreign research groups and support cooperation between U.S. academic research centers and foreign scientists. Collaborations established through this effort will help to facilitate standardized screening and monitoring of clinical trial subjects and prepare for the coordinated conduct of scientifically valid and ethically sound clinical trials on an international basis.

Funds will be awarded to provide training in epidemiology for individuals preparing for or involved in AIDS research and AIDS prevention research programs. Applicants are encouraged to relate training to ongoing research efforts in developing countries.

OBJECTIVES:

The purposes of this program are to increase the capability of scientists in foreign countries and especially in developing countries to conduct their own epidemiologic research related to AIDS and to utilize epidemiology in clinical trials and prevention research; these activities will complement ongoing NIH AIDS research efforts. Specifically the program is designed to:

- o Increase expertise in epidemiology through short- and long-term training at U.S. institutions which may lead to M.S. and Ph.D. degrees in epidemiology;
- o Increase laboratory expertise of technical assistants in foreign countries who are engaged in epidemiological studies related to AIDS through in-country, short-term, didactical and technical training; and
- o Expand ongoing collaborative epidemiological research in AIDS between U.S. and foreign scientists.

Grants will be made only to U.S., nonprofit private or public institutions for five years. The total allowable cost (direct and indirect) per grant for the first year of this five-year award must not exceed \$600,000. The intent is to award up to 5 grants depending on the availability of funds and the quality of approved grant applications.

A review will be conducted in accordance with expedited review procedures established for AIDS programs at the NIH. Upon receipt, the FIC staff will administratively review all applications for their responsiveness to the RFA. All applications considered responsive will be reviewed for scientific merit

by an initial review group convened by the FIC. Upon advice from the FIC Advisory Board, the Director FIC, will make the final funding decisions.

The RFA label (found in the 9/86 revision of application form PHS 398) must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing of your application such that it will not reach the review committee in time for review.

STAFF CONTACT

For further information and a copy of the RFA contact:

Kenneth Bridbord, M.D.
Chief
International Studies Branch
Building 38A, Room B2N13
Fogarty International Center
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-2516

DEVELOPMENTAL RESEARCH IN SPECIAL POPULATIONS

RFA AVAILABLE: 88-CA-09

P.T. 34, FF; K.W. 0715035, 0745000, 0745055, 0403004

National Cancer Institute

Application Receipt Date: June 17, 1988

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites applications for developmental studies which: 1) assess cancer control needs, 2) determine barriers to cancer control, and/or 3) validate intervention methods and assessment instruments in special populations--i.e. Alaska Natives, American Indians, Asian Americans, Blacks, blue-collar groups, the elderly, Hispanics, low-income groups, and Native Hawaiians. These studies are limited to applicants from within the United States.

RESEARCH GOALS AND PROGRAM DEFINITIONS

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 screening programs. Special populations include Alaska Natives, American Indians, Asian Americans, Blacks, elderly, Hispanics blue-collar groups, low-income groups, and Native Hawaiians.

Cancer control is defined as the reduction of cancer incidence, morbidity, and mortality through an orderly sequence from research on interventions and their impact in defined populations to the broad, systematic application of the research results.

Cancer control research studies are classified in the five phases which represent the orderly sequence progression noted in the above definition: I) hypothesis development, II) intervention methods development and testing, III) controlled intervention trials to establish cause and effect relationships, IV) research in defined human populations, and V) demonstration and implementation studies.

The research of interest in this RFA falls into either Phase I or Phase II studies. Hypothesis development (Phase I) studies should focus on the assessment of cancer prevention and control needs in communities or organizations with large special populations (as previously described); or studies which identify barriers to cancer prevention and control in special populations. Methods development and testing studies (Phase II) should focus on: 1) validating the use of existing intervention methods (e.g. dietary modification, health services, tobacco cessation) as applied in the special populations described above; 2) the development and pilot testing of unique methods which are sensitive to the needs of the special populations described above; or 3) the development and validation of assessment instruments to measure the cancer control related needs of special populations or for use in evaluating the effectiveness of intervention methods in special populations.

The paucity of data on effective cancer prevention and control intervention methods in special populations reflect both a dearth of effective interventions and a dearth of validated instruments to evaluate their effectiveness. The need for the development of sensitive intervention methods and assessment instruments has to be established in many areas in health (e.g., mental health, vascular diseases, and heart diseases) and other sectors (e.g., education).

PROGRAM AREAS OF INTEREST

The National Cancer Institute has announced a goal and objectives for achieving a 50 percent reduction in the cancer mortality rate by the year 2000 (Greenwald, P. and Sondik, E. Cancer Control Objectives for the Nation: 1985-2000. NCI Monograph No. 2, 1986).

Cancer Control Program areas appropriate for research grants include human research in the following areas:

- o Assess cancer prevention and control needs in communities with large special populations (e.g., Blacks, Native Americans, Hispanics, Asian Americans, low-income groups, blue-collar groups, and elderly).
- o Identify barriers to cancer prevention and control in special populations.
- o Validate the use of existing intervention methods (e.g., dietary modification, health service, tobacco cessation) as applied in special populations.
- o Develop and pilot test unique intervention methods sensitive to the needs of special populations.
- o Develop and validate assessment instruments (e.g., dietary intake, risk factor surveys, etc.) to measure the cancer control related needs of special populations and to evaluate the effectiveness of intervention methods in special populations.

EXCLUSIONS

Studies to determine the efficacy of chemotherapy, surgery, radiotherapy, and other primary treatment interventions are not considered developmental intervention research under this RFA. Other animal studies are not allowed.

ELIGIBILITY

Applicants may be established researchers, new investigators, and qualified staff of public health departments and collaborating agencies.

MECHANISMS OF SUPPORT

This RFA will use the NIH Grant-in-Aid mechanism. Approximately \$1.0 million has been set aside for direct costs for all projects for the first year. This level of activity is dependent on the receipt of a sufficient number of applications of suitable, scientific merit. Funding under this RFA is limited to a maximum of three years.

INQUIRIES

Copies of the complete RFA and additional information may be obtained from:

Gregory Christenson, Ph.D.
Director of Evaluation
or
Patricia Von Bargen, M.P.A.
Program Director for Developmental Research
Special Populations Studies Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building, Room 1A01
9000 Rockville Pike
Bethesda, Maryland 20892-4200
Telephone: (301) 427-8597

Prospective applicants are strongly encouraged to discuss their ideas with the Program Director to determine whether they fit within the definition and program guidelines of cancer control. PLEASE CONTACT THE PROGRAM DIRECTOR(S) BEFORE SUBMITTING A GRANT IF THERE IS ANY UNCERTAINTY ABOUT MEETING THE CRITERIA.

**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