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For Grants and Contracts

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

Vol. 20, No. 19
May 17, 1991

NIH GUIDE - Vol. 20, No. 19, May 17, 1991

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

PREAPPLICATION MEETINGS: ADULT AIDS CLINICAL TRIALS UNITS

RFA: AI-91-07

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

National Institute of Allergy and Infectious Diseases

The Division of Acquired Immunodeficiency Syndrome of the National Institute of Allergy and Infectious Diseases (NIAID) is sponsoring three preapplication meetings for prospective applicants responding to RFA AI-91-07, Adult AIDS Clinical Trials Units (NIH Guide for Grants and Contracts, Vol. 20, No. 18, May 3, 1991). The purpose of these meetings is to provide a forum where prospective applicants may obtain information on the preparation and submission of applications in response to RFA AI-91-07.

NIAID staff will discuss the structure and function of the AIDS Clinical Trials Group and the structure of, and elements to be included in, the applications. NIAID program, review, and grants management staff will be available to answer questions.

The meetings will be held from 8:00 a.m. to 3:00 p.m. at the following locations:

(1) June 3, 1991 - Bethesda Hyatt Regency, Bethesda, MD
(2) June 4, 1991 - Hyatt Regency at the San Francisco Airport
(3) June 5, 1991 - Hyatt Regency at the Dallas Airport

For further information contact:

Frederick H. Batzold, Ph.D. or
Ms. Debra Cockrell
Clinical Research Management Branch
Division of AIDS
National Institute of Allergy and Infectious Diseases
Telephone: (301) 496-8214

Prospective applicants are encouraged to request a copy of and review the full RFA. Please submit any written questions to:

F.H. Batzold, Ph.D.
DAIDS/NIAID
6003 Executive Blvd.
Rockville, MD 20892

BIOLOGICAL FLUID DYNAMICS WORKSHOP: MODELING FLOWS WITH IMMERSED ELASTIC STRUCTURES

P.T. 42; K.W. 0710020

National Center for Research Resources

The Pittsburgh Supercomputing Center (PSC) is conducting a four-day workshop entitled, "Biological Fluid Dynamics Workshop: Modeling Flows with Immersed Elastic Structures," July 28-31, 1991. This workshop is funded by a grant from the Biomedical Research Technology Program, National Center for Research Resources, National Institutes of Health.

This workshop will familiarize biomedical researchers with computational methods for problems in biological fluid dynamics and provide practice in applying supercomputing resources such as the PSC's CRAY YMP/832 to such problems. Previous supercomputing experience is not necessary. The workshop will emphasize computer modeling of flow problems in which a fluid interacts with an elastic or muscular boundary. Examples of such problems will include aquatic animal locomotion, blood flow in the heart, and platelet aggregation. A common methodology will be presented that is applicable to problems of this type. The workshop leaders are Lisa Fauci, Tulane University; Aaron Fogelson, University of Utah; and David M. McQueen, New York University.

This workshop includes an optional half-day session the afternoon of Sunday, July 28, led by PSC staff members. Topics to be covered during the optional session include VAX/VMS and UNICOS, the Cray version of the AT&T System V Unix operating system.

Travel, meals, and hotel accommodations for U.S. academic participants are supported by the grant. Enrollment is limited to 20 participants. The deadline for submission of applications is June 14, 1991.

For application forms and further information on this workshop call or write:

Nancy Kiser
Biomedical Coordinator
Pittsburgh Supercomputing Center
4400 Fifth Avenue
Pittsburgh, PA 15213
Telephone: (412) 268-5206
Internet: kiser@psc.edu; Bitnet: kiser@pscwpsca

NOTICES OF AVAILABILITY (RFPs AND RFAs)

KIDNEY DISEASE AND HYPERTENSION IN BLACKS: PILOT STUDY

RFA AVAILABLE: DK-91-06

P.T. 34, FC; K.W. 0715115, 0755015, 0760013, 0760035, 0745070

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: September 5, 1991
Application Receipt Date: October 18, 1991

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) through the Division of Kidney, Urologic and Hematologic Diseases (DKUHD) invites cooperative agreement applications to establish clinical centers and a data coordinating center and supporting laboratories/distribution center directed at conducting a pilot study of antihypertensive drug therapy among persons with kidney disease due to high blood pressure. The primary study population will be Black Americans.

BACKGROUND

End-stage renal disease (ESRD) is an important health problem among Blacks Americans. The incidence rate of treated ESRD for Blacks is nearly four times that of Whites. The disparity between Blacks and Whites is especially striking for hypertension-related ESRD. The incidence rate of ESRD with a diagnosis of hypertension, the leading cause of renal failure among Blacks, is 6.5 times greater than in Whites. Since most, if not all, of the major antihypertensive clincal trials conducted to date have focused primarily on cerebrovascular and cardiovascular events, a randomized controlled clinical trial is necessary to define the clinical usefulness and possible renal protective effects of long-term therapy with the major blood pressure lowering drugs in patients, especially Blacks, with hypertension responsible for their impaired renal function.

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Health People 2000," a Public Health Service-led national activity for setting priority areas. This RFA, "Kidney Disease and Hypertension in Blacks: Pilot Study" is related to the priority area of Diabetes and Chronic Disabling Diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

OBJECTIVES AND SCOPE

The purpose of this Request for Applications (RFA) is to establish four Clinical Centers, one Data Coordinating Center and supporting laboratories and centers for drug distribution, kidney biopsy, and measurement of renal function (glomerular filtration rate or GFR). The Clinical Centers will recruit, provide treatment and follow-up patients with reduced kidney function caused by high blood pressure. The Data Coordinating Center will collect, store, and analyze data and specimens that are obtained. It is also expected that the Data Center will coordinate the activities of a Drug Distribution Center, Kidney Biopsy Laboratory, and Central GFR Laboratory.

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.

MECHANISMS OF SUPPORT

The support mechanism for this program will be the cooperative agreement (U01), which is similar to the traditional NIH research grant. It differs from a research grant in the extent and nature of NIH staff involvement.

As a result of this announcement, it is anticipated that five awards (four Clinical Centers and one Data Coordinating Center) will be made under this RFA, at a funding level of approximately $400,000 in total costs for the Data Coordinating Center, and approximately $150,000 in total costs for each Clinical Center. However, the funding of such applications is contingent on the actual availability of funds, and the receipt of applications of sufficient scientific merit. Support for successful applications will begin on July 1, 1992; total support for the project will be for 33 months. The current policies and requirements that govern the review, funding and performance of cooperative agreement programs of the NIH will prevail. Additional requirements for performance in this program are also set forth by NIDDK and are outlined in the full RFA.

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 appplicant. Those applications judged to be responsive 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 Disease Advisory Council will make recommendations regarding funding.

METHOD OF APPLYING

Applications must be submitted on form PHS 398 (revised 10/88) available in the Business or Research Grant Offices of most academic or research institutions, or 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 October 18, 1991. No extension will be granted on the application deadline.

INQUIRIES

Copies of the full RFA may be obtained from:

John W. Kusek, Ph.D.
Director, Clinical Trials Program
Division of Kidney, Urologic and Hematologic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 621
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7133

For fiscal and administrative matters, contact:

Nancy C. Dixon
Grants Management Office , DEA, NIDDK
Westwood Building, Room 649B
Bethesda, MD 20892
Telephone: (301) 496-7467

PROGRAM PROJECTS IN VASCULAR BIOLOGY AND MEDICINE

RFA AVAILABLE: HL-91-07

P.T. 34; K.W. 0705015, 0745020, 0745027, 0745070, 0705065

National Heart, Lung, and Blood Institute

Application Receipt Date: October 15, 1991

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Applications (RFA) on the above subject. The purpose of this initiative is to encourage development of program projects featuring innovative and interdisciplinary approaches to vascular biology and medicine. In particular, combined basic and clinical collaborative programs are required for translating the rapid advances in vascular biology into diagnostic, therapeutic, and preventive interventions for improving vascular health. This pertains to both the systemic and pulmonary circulations. For purposes of this solicitation, vascular biology is defined as the study of mechanisms of development and regulation of blood vessels and integration of the knowledge gained into an understanding of the physiologic dynamics of the vasculature. Vascular medicine concerns itself primarily with the clinical management of a wide variety of vascular diseases. Its objectives are: the clinical characterization of all vascular diseases including arterial, venous, and lymph in the cerebral, coronary, pulmonary, aortic, renal, and peripheral vascular beds; analysis of the pathogeneses of these diseases including atherosclerosis, lipid metabolic disorders, systemic and pulmonary hypertension, peripheral vascular disease, lymphedema, thrombosis, vasculitis, and vasospastic disorders; and the development of better diagnostic, therapeutic, and preventive approaches to these diseases. Investigators from a variety of disciplines including, but not limited to, atherosclerosis, cardiology, cell biology, hematology, hypertension, molecular biology, pulmonary medicine, radiology, vascular biology, vascular medicine, and vascular surgery are encouraged to form collaborations to meet the goals of the RFA.

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, 'Program Projects in Vascular Biology and Medicine,' is related to the priority area of Heart Disease and Stroke. 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 support mechanism for this program will be the Program Project grant. Although approximately $7 million in total costs for this program is included in the financial plans for fiscal year 1992, award of grants pursuant to this RFA is contingent upon receipt of funds for this purpose. It is anticipated that 5 grants will be awarded under this program. The specific number to be funded, however, will depend on the merit and scope of the applications received and the availability of funds.

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.

Inquiries regarding this program and requests for the complete RFA document should be addressed to the appropriate program administrator:

Dr. David M. Robinson
Associate Director for Scientific Programs
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 416
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-5656
FAX: (301) 496-9882
Bitnet: DRW@NIHCU

Dr. Carol H. Letendre
Associate Director for Scientific Programs
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 516
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-8966
FAX: (301) 402-1622

Dr. Carol E. Vreim
Associate Director for Scientific Program Operation
Division of Lung Diseases
National Heart, Lung, and Blood Institute
Westwood Building, Room 6A16C
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-7208
FAX: (301) 496-9886

For fiscal and administrative matters, contact:

Marie A. Willett
Chief, Heart and Vascular Grants Management Section
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A11C
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-7255

ONGOING PROGRAM ANNOUNCEMENTS

MEDICAL RELEVANCE OF HUMAN HERPESVIRUSES TYPES 6 AND 7

PA: PA-91-49

P.T. 34; K.W. 0715125, 1002045, 0755030

National Institute of Allergy and Infectious Diseases

Application Receipt Dates: June 1, October 1, February 1

PURPOSE

The National Institute of Allergy and Infectious Diseases invites investigator initiated research applications to explore possible etiological relationships, modes of transmission, and medical relevance of two newly recognized human herpesviruses, HHV-6 and HHV-7.

BACKGROUND

The isolation, in 1986, of HHV-6 from human white blood cells was followed in 1990 by the discovery of HHV-7 from a similar source. HHV-6 has been identified as the cause of roseola (exanthem subitum). Delayed primary infection can be accompanied by an ill-defined syndrome having persistent lymphadenopathy as its feature. Recent observations suggest an association of HHV-6 with pneumonia in transplant recipients and hepatitis in young infants; it has been suggested that HHV-6 can act as a cofactor in HIV pathogenesis. Thus, the full disease spectrum with which HHV-6 may be associated has not yet been recognized. Based on the behavior of other herpesviruses, it can be anticipated that HHV-6 and HHV-7 may cause morbidity and mortality in immunocompromised individuals. The little that is currently known about HHV-6 and -7 suggests that they could behave like CMV. If this is the case, the development of vaccines and antivirals would be needed.

RESEARCH OBJECTIVES

The goal of this program announcement is to encourage the submission of applications oriented towards the coordinate development of the reagents and information needed to assess the medical importance of HHV-6 and HHV-7. Thus, applications should propose at least one methodological approach, e.g. development of nucleic acid probes or immunological assays, and combine this approach with the assessment of clinical specimens. Epidemiological and clinical studies should be carefully designed so that etiological associations can be meaningfully made. Control populations should be carefully selected and matched with patient populations.

Among the issues (not all inclusive) that need to be addressed are: (1) assessment of the etiological role of these viruses in human disease, including clinical syndromes associated with primary, reactivated and chronic infection, as well as roles as cofactors in other diseases, (2) determination of the in vivo biological effects of these viruses, e.g., are they immunosuppressive, (3) identification of the site(s) of latency of these viruses, and (4) determination of protective immune responses. Applications

may focus on one or more of these issues or on other issues related to medical importance of these new human herpesviruses.

Applications whose sole emphasis is basic molecular biological studies, such as studies of genome structure, are not appropriate for this program announcement. Because issues of virology, epidemiology, and immunology may need to be addressed in a coordinate manner, collaborations among investigators having expertise in these disciplines are encouraged. Biostatistical input is recommended for applications where correlations between groups of individuals are proposed.

MECHANISM OF SUPPORT

This program will be supported through traditional research grants (R01). Awards will be administered under Public Health Service grants policy as stated in the PHS Grants Policy Statement, DHHS Publication No. (OASH) 82-50,000, revised January 1, 1987. The total project period for applications submitted in response to the Program Announcement should not exceed four years.

ELIGIBILITY REQUIREMENTS

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

GENERAL REQUIREMENTS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from either the GCRC program director or principal investigator could be included with the application.

APPLICATION PROCEDURE

Applications must be submitted on the grant application form PHS 398 (Rev. 10/88, reprinted 9/89) and will be accepted on the following receipt dates:

Receipt Date	Initial Review	Council Review
June 1	October/November	January/February
October 1	February/March	May/June
February 1	June/July	September/October

Application kits are available at most institutional business and grant/contract offices or may be obtained from: Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, Maryland 20892.

On the first (face) page, item 2, of the application, the word "YES" must be checked and the title and number of the announcement typed in the space provided: PA-91-49: MEDICAL RELEVANCE OF HUMAN HERPESVIRUSES TYPES 6 AND 7. A brief covering letter should accompany the application indicating that it is being submitted in response to this announcement. A copy of this letter must also be sent to the contact person listed below.

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

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCEDURE

Applications in response to this announcement will be reviewed in competition with other applications and in accordance with the applicable National Institutes of Health peer review procedures. The initial review for scientific and technical merit will be made by a review group of the Division of Research Grants, NIH; secondary review will be by an appropriate national advisory council. Funding decisions will be based upon relative scientific merit, program relevance, and the availability of appropriated funds.

INQUIRIES

Potential applicants are encouraged to contact:

Susan B. Spring, Ph.D.
Program Officer, Persisting Viral Diseases Virology Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 736
Bethesda, MD 20892
Telephone: (301) 496-7453
FAX: (301) 402-0804

For fiscal and administrative matters, contact:

Ms. Jane Unsworth
Grants Management Branch
National Institute of Allergy and Infectious Diseases
Westwood Building, Room 718
Bethesda, MD 20892
Telephone: (301) 496-7075

This program is described in the Catalog of Federal Domestic Assistance No. 93.856, Microbiology and Infectious Disease Research. Grants will be awarded under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations at 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.

MINORITY INSTITUTIONAL RESEARCH TRAINING PROGRAM

PA: PA-91-50

P.T. 44; K.W. 0720005, 0715040, 0715165, 0745027, 0785070

National Heart, Lung, and Blood Institute

Application Receipt Date: August 23, 1991

I. OBJECTIVES OF THE PROGRAM

The National Heart, Lung, and Blood Institute (NHLBI) announces a program to support full time research training for investigative careers at minority schools in areas related to cardiovascular, pulmonary, or hematologic* diseases. Minority schools seeking this support must have: (1) graduate students or (2) health professional students who will take a minimum of one year from his/her professional training or (3) postdoctoral students. The support mechanism will be the NIH institutional research training grant (T32). Copies of the program guidelines are currently available from staff of the NHLBI, listed below.

Grants in this program will be made to minority institutions, each of which will cooperate with a research center that has well-established cardiovascular, pulmonary, or hematologic research and research training programs. Each trainee will be placed with a mentor who is an accomplished investigator at the cooperating research center and who will assist the advisor at the minority institution in the trainee's development and research plan.

HEALTHY PEOPLE 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 Program Announcement, 'Minority Institutional Research Training Program,' is related to the priority area of Heart Disease and Stroke. 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).

II. BACKGROUND

Many studies have emphasized the need for minority individuals to participate in modern research activities to develop their investigative talents. There are existing programs at the National Institutes of Health that are designed to answer this need, such as the Minority Biomedical Research Support Program, the Minority Access to Research Careers Program, and the Minority Research Supplement Program. Even though these programs are successful in meeting their specific objectives and career development goals, it is believed that graduate students, health professional students, and postdoctoral students at minority schools need further opportunities to develop biomedical and behavioral research skills.

The Minority Institutional Research Training Program is designed to offer research training grant awards in cardiovascular, pulmonary, and hematologic research to minority schools to enable qualified graduate students, health professional students, and postdoctoral students to participate in research programs. It is expected to attract students in their developmental stages, increase their awareness of these diseases, and to acquaint them with career opportunities in research.

III. ELIGIBILITY

A. Minority School

The institution must be a medical or non-medical college, university, or equivalent school in which students of minority groups underrepresented in

biomedical research including Blacks, Hispanics American Indians, and Asian or Pacific Islanders comprise a majority or a significant proportion of the school enrollment.

The institution must have staff and facilities required for the proposed program. The program director at the minority school will be responsible for the selection and appointment of trainees and the overall direction of the training program.

B. Trainees

The individuals to be trained must be citizens of the United States, non-citizen nationals, or have been admitted to the United States for permanent residence at the time of appointment for training, and have a baccalaureate degree. Trainees must be training at the post-baccalaureate level in a relevant biomedical or behavioral science and have made a strong commitment to completing a doctoral degree, be enrolled in a minority health professional school, or have a doctoral degree or equivalent in a biomedical or behavioral science. The Minority Institutional Research Training Program may not support studies leading to a health professional degree. Research trainees in clinical areas are expected to devote their time to research training and to confine clinical duties to those that are a part of the research training.

C. Research Center

The minority institution must identify and collaborate with a research center (medical school or comparable institution) that has strong, well-established cardiovascular, pulmonary, or hematologic research and research training programs. Cooperation between institutions is needed to provide each trainee with a mentor who is recognized as an accomplished investigator in cardiovascular, pulmonary, or hematologic research and who will assist the advisor at the minority institution in the trainee's development and research plan. Plans for summer training, as well as academic year training, must be developed by the student and advisor at the trainee's home institution in collaboration with the mentor at the research center. It is expected that both advisor and mentor will guide the trainee through the initial training period and continue this interaction throughout the award.

IV. IMPLEMENTATION

Minority institutions will compete for research training grants of up to five years duration. Funds will be provided on an annual basis to develop and maintain a stable research training experience for qualified students. Awards recommended for the continuation years will be made contingent upon satisfactory progress during the preceding year, upon the availability of funds, and the requisite level of authorization for continued support of training activities. Successful applicants may compete for a second award of up to five years duration upon completion of the initial grant period. The minority institution will identify and complete arrangements with an established cardiovascular, pulmonary, or hematologic research center(s) before submitting an application. Graduate trainees appointed to the grant may receive support for up to five years. Postdoctoral trainees appointed to the grant may receive support for up to three years. Trainees will have a faculty advisory at the minority institution and together they will jointly select a faculty mentor at the research center. A written commitment to the training plan by potential faculty mentors at the research center and the department(s) involved, countersigned by both institutional officials, must be part of the application. The students may spend not more than 50 percent time at the research training center over the course of the year, including a period of intensive research training during the summer, but students are expected to pursue their research training on a full-time basis devoting no less than 40 hours per week as specified by the sponsoring institution in accordance with its own policies. Students will be expected to meet the degree requirements at their institution.

Because the research training environment provides a powerful context in which to promote responsible research practices, all competing Institutional National Research Service Award (NRSA) Research Training grant applications must include a description of formal or informal activities or instruction related to the responsible conduct of research that will be incorporated into the proposed research training program (NIH Guide for Grants and Contracts, Vol. 19, No. 30, August 17, 1990). It is expected that for the first 18 months (July 1, 1990 to December 31, 1991) of implementation of this requirement, institutions will be given considerable flexibility to develop innovative methods for providing training in scientific integrity.

V. PROVISIONS OF THE AWARD

The trainees may be appointed for 9 - 12 months at any time during the course of the budget period after he/she has been accepted as a full-time student. A strong interest in a cardiovascular, pulmonary, or hematologic research career must be evident.

Funds may be requested for:

A. Stipends - Current stipend level for graduate and health professional student trainees at all levels of experience is $8,800 per year. Stipend levels for postdoctoral trainees are dependent on relevant years of experience and are as follows:

Years of Experience	Per Annum Stipend
0	$ 18,600
1	19,700
2	25,600
3	26,900
4	28,200
5	29,500
6	30,800
7 or greater	32,300

B. Tuition, Fees, when necessary, and Medical Insurance (individual coverage), if regularly charged to all students regardless of their source of support, are allowable trainee costs. In addition, tuition and fees charged by the research center during the summer or off-quarter period are allowable.

C. Trainee Travel Costs - The institution may request funds to cover the costs of trainee travel, including attendance at scientific meetings that are necessary to the individual's training. Funds for commuting expenses that are clearly in excess of those incurred during the usual home to work travel of the trainee may also be requested.

D. Training-Related Expenses - Funds are provided to partially defray the cost of training such as staff salaries, equipment, research supplies, staff travel, and other expenses. The current level of training-related expenses is $1,500 per annum per full-time graduate student trainee or health professional student trainee and $2,500 per annum for postdoctoral trainees.

E. Indirect Costs - The award will provide indirect costs based on 8 percent of total direct costs, exclusive of tuition and fees.

F. Payback Agreement - A National Research Service Award Payback Agreement must be signed by each individual who is to receive a stipend through an institutional award. This form and the statement of appointment are submitted annually at the time of each appointment. These forms will be completed beginning with the initial period of support even though the first 12 months is excluded from the cumulative payback requirement.

VI. REVIEW PROCEDURES

All applications responding to this announcement will be reviewed for scientific and technical merit by the Research Training Review Committee of the Division of Extramural Affairs, NHLBI, followed by a second level review by the National Heart, Lung, and Blood Advisory Council.

Review Criteria

The factors to be considered in the evaluation of the proposed training program are:

- Adequacy of faculty, facilities, and resources for the proposed research training, both at the minority institution and the research center;
- Adequacy of the cooperative arrangements between the minority institution and the research program;
- Commitment of the relevant faculty and the two institutions to the goals of the training program;
- Procedures for evaluation of the impact of the program on the trainees involved.

VII. APPLICATION PROCEDURE

Submit applications on form PHS 398 (rev. 10/88) using substitute pages for the Institutional National Research Service Award. This form is available at the applicant institution's office of sponsored research. An application may also be obtained from the three program offices of the National Heart, Lung, and Blood Institute listed below. When submitting the application, identify the Minority Institutional Research Training Program on the face page. Special instructions for preparing the application are included in the program guidelines available from the NHLBI contacts listed below. Applicants are strongly encouraged to contact the appropriate individual listed under Program Information prior to the preparation of the application.

A. Letter of Intent

Applicants are asked to submit a letter of intent to the NHLBI at least one month prior to the announced receipt date to:

Scientific Review Administrator
Research Training Review Committee
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building, Room 550
Bethesda, MD 20892

A letter of intent is not binding and will not be considered in the review of any application submitted subsequently. The letter should list the applicant institution and program, the name of the Principal Investigator, the mentor at the research center, and the area of research training proposed.

B. Applications

Send the completed application and four (4) signed exact photocopies by the announced receipt date to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Two additional copies of the application must be sent to the Scientific Review Administrator of the Research Training Review Committee listed above.

Program Information

Information regarding this program may be obtained from:

John Fakunding, Ph.D.
Chief, Research Training and Development Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 3C04
Bethesda, MD 20892
Telephone: (301) 496-1724

Mary Reilly, M.S.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 640A
Bethesda, MD 20892
Telephone: (301) 496-7668

Helena Mishoe, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 5C04
Bethesda, MD 20892
Telephone: (301) 496-4186

For fiscal and administrative matters, contact:

Grants Operations Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A15C
Bethesda, Maryland 20892
Telephone: (301) 496-7255

* Within NHLBI, the term "hematologic" covers research on thrombosis and hemostasis, immunohematology, blood cell disorders, sickle cell disease, blood resources including blood component and derivative therapy, blood substitutes and blood resource management, aspects of AIDS products in AIDS prevention and treatment, and AIDS-related bone marrow and hematologic disorders. Other Institutes of the NIH are responsible for research on disorders of white cells, including the leukemias and other blood malignancies, and basic immunology related to the lymphoid system. Therefore, NHLBI cannot provide support for such studies.

This program is described in the Catalog of Federal Domestic Assistance numbers 93.837, 93.838, and 93.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations at 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.

MINORITY SCHOOL FACULTY DEVELOPMENT AWARD

PA: PA-91-51

P.T. 34; K.W. 0720005, 0715040, 0715165, 0745027, 0785070

National Heart, Lung, and Blood Institute

Application Receipt Date: August 23, 1991

I. OBJECTIVES OF THE PROGRAM

The Minority School Faculty Development Award is intended to:

1. Encourage the development of faculty investigators at minority schools in areas relevant to cardiovascular, pulmonary, and hematologic* diseases.

2. Stimulate cardiovascular, pulmonary, and hematologic disease research, prevention, control, and education by offering minority school faculty members the opportunity to enhance their research capabilities in these areas.

II. BACKGROUND

The proportion of biomedical investigators who are members of minority groups is strikingly lower than the percentage of minority U.S. citizens. While 12 percent of the population is Black, less than 0.25 percent of persons holding a Ph.D. in science are Black. The figures are even lower for Black Ph.D.s in the biomedical sciences. Furthermore, the number of doctorates, both M.D.s and Ph.D.s, in other ethnic minority groups (such as Native Americans or Hispanics) is proportionally lower than for Blacks. Vigorous recruitment is underway throughout the government, academic institutions, hospitals, research institutions, and industry.

One method of addressing this problem is by increasing capabilities of faculty members at minority schools. In so doing, the pool of biomedical and behavioral investigators in cardiovascular, pulmonary, and hematologic research will be increased. Furthermore, their graduate and undergraduate students, most of whom will be minority individuals, will become more cognizant of research opportunities in cardiovascular, pulmonary, and hematologic disease areas. The Minority School Faculty Development Program is designed to address this problem by providing research support to minority school faculty members who have the interest and capabilities of doing modern, sophisticated research in cardiovascular, pulmonary, or hematologic disease areas.

Despite a recent decline in the death rate from coronary heart disease, cardiovascular disease continues to be the number one cause of death in the United States. Arteriosclerosis and hypertension account for almost one million deaths annually. An estimated 40 million Americans have diseases of the heart and blood vessels, resulting in a large burden of acute and chronic

illness and disability. Heart and blood vessel diseases cost the economy more then $50 billion per year in wages, lost productivity, and expenses for medical care. A wide range of opportunities for research into the causes, diagnosis, treatment, and prevention of heart and vascular diseases has been enumerated in the 15th Report of the Director, National Heart, Lung, and Blood Institute, Volume 2, Heart and Vascular Diseases (NIH publication No. 89-2206).

Diseases of the lung constitute a major national health problem. About one in every five persons has some chronic respiratory problem resulting in an annual estimated cost to the nation of over $29 billion. In the newborn, the most common cause of death is neonatal respiratory distress syndrome (RDS). Neonatal RDS may be implicated in development of adult respiratory diseases as well. Of the adult respiratory diseases, emphysema and chronic bronchitis are the major causes of death. Fibrotic and immunologic lung diseases are major causes of lung problems in the young adult and may contribute to the development of chronic obstructive pulmonary diseases. Asthma, emphysema, and chronic bronchitis represent particularly pressing health problems affecting an estimated 17 million Americans. Moreover, the death rate and prevalence of these conditions have increased at an alarming rate over the past 15 years. As a disabling disease, emphysema is a leading cause of worker retirement on Social Security disability payments.

Disorders of the blood, including congenital and acquired disorders and deficiencies, are critical contributors to health problems of mankind. As a consequence, they are major causes of death and disability in the United States. Disorders of the blood affect not only the blood itself, but the tissues and organs through which it flows. Recent research findings have revealed the widespread involvement of thrombosis in the pathology of numerous disorders, including the development of atherosclerosis and coronary thrombosis. Aggressive therapy for cancer has resulted in the increased susceptibility of patients to bleeding disorders and has increased the demand for blood products for therapeutic purposes. A significant segment of the population has inherited disorders, such as sickle cell disease, hemophilia, or Cooley's anemia, that require life-long hematologic attention and support.

Other diseases may be acquired or represent temporary demands, such as replacement therapy as a result of surgical or accidental trauma. Research opportunities in blood resources and transfusion medicine range from basic to clinical. They cover such diverse topics as the development of new blood products, methods to improve and assure the stability and safety of these products, and ways to improve the benefits and safety of transfusion.

III. ELIGIBILITY

A. Minority School

A minority school is defined as a domestic medical or non-medical college, university, or equivalent school in which (1) students of minority ethnic groups, including Blacks, Hispanics, American Indians, and Asian or Pacific Islanders, comprise a majority or significant proportion of the school enrollment and (2) few or no members of its faculty are actively engaged in biomedical research. The commitment of the institution to the faculty candidate's research and development must clearly be presented in the application, including statement(s) from the sponsor and the department chairman.

B. Faculty Development Award Candidate

Candidates for this award are minority school faculty members who (1) are citizens of the United States, non-citizen nationals, or permanent residents at the time of application, (2) have a doctoral degree or equivalent in a biomedical or behavioral science, (3) wish to receive specialized training in cardiovascular, pulmonary, or hematologic research, and (4) have the background and potential to benefit from the training.

Applicants may not apply for, or accept, other Public Health Service research grant support or its equivalent at the time of Minority School Faculty Development Award application, nor may they apply concurrently for any other type of academic award. However, they may apply for, and accept, research grant support subsequent to award of the Minority School Faculty Development Award.

C. Mentor at Research Center

Each candidate must also identify and complete arrangements with a nearby mentor (within approximately 100 miles) who is recognized as an accomplished investigator in the research area proposed and who will provide guidance for

the awardee's development and research plan. Plans for the intensive training during the summer period (two to three months) as well as during the academic years must be developed with the mentor.

The commitment of the mentor and her/his institution to both the summer and academic year training period must be evidenced in the application. A commitment from the mentor's department chairman must be included in the application.

IV. IMPLEMENTATION

The awards will be made to the minority institution on behalf of the awardee. Each award will have a duration of five years and is non-renewable. These awards may not be transferred to another institution. Funding beyond the first year of the grant is contingent upon satisfactory progress during the preceding year.

The status of the minority school faculty development award program will be reviewed periodically from the date of the first award to determine whether the program should be continued. In addition, to assess the effectiveness of the program in fulfilling its objectives, the NHLBI intends to follow the progress of the recipient for a period of five years after completion of each grant to determine: (1) the investigator's professional affiliation(s), (2) his/her record of subsequent grant or contract support, (3) his/her record of scientific publications, and (4) the institution's research programs.

V. PROVISIONS OF THE AWARD

The mechanism of support will be the K14.

A. Salary

The awardee will receive salary support up to a maximum of $50,000 plus fringe benefits per year for five years. All funds must be used to support the original awardee. Support will be based upon the candidate's actual salary and must be consistent with the established salary structure of the minority institution for persons of equivalent qualifications, experience, and rank. The actual amount will be determined by the proportion of effort devoted to this program. Awardees must commit 100 percent of effort during summer and/or off-quarter periods and at least 25 percent of effort during the academic year.

Support for up to 10 percent of the mentor's salary during the summer experience may also be requested. Details of how or if this will be needed must be agreed upon by the mentor's institution and included in the application.

B. Research Support

Up to $20,000 per year will be provided for research support. Details regarding the apportionment of these funds between the minority institution and the research center must be worked out with the mentor at the research center and agreed to by representatives of both institutions. A statement of agreement must be provided in the application.

These research support funds may be used for:

Equipment: specialized research equipment essential to the proposed program, in accordance with PHS policy, title to such equipment will vest with the grantee institution;

Supplies: consumable supplies essential to the proposed program;

Travel: domestic travel for the awardee that is essential to the proposed program;

Tuition and fees: if essential to the awardee's individual research development program; and

Other: personnel, publication costs, computer costs, and other costs necessary for the research program.

Indirect costs will be provided at a rate of 8 percent of the total direct costs of each award, exclusive of tuition, fees, and expenditures for equipment.

VI. INCLUSION OF WOMEN IN STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognize that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to the policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.Clinical research findings should be of benefit to all persons at risk of the disease regardless of gender. If further clarification of the policy is needed or there are questions regarding the policy, please contact the NHLBI staff listed below.

VII. REVIEW PROCEDURES

All applications will be reviewed for scientific and technical merit by the Research Training Review Committee of the Division of Extramural Affairs, NHLBI, followed by a second level review by the National Heart, Lung, and Blood Advisory Council.

Review Criteria

The factors to be considered in the evaluation of the proposed training program are:

- the overall merit of the candidate's five-year plan for research and the development of research skills;
- the background and potential of the proposed candidate for development into an independent biomedical investigator;
- the candidate's commitment to a research career;

- o the ability of both the minority institution and the training center to provide facilities, resources, and opportunities necessary for the candidate's research development;

- o the qualifications, ability, and plans of the sponsor who will provide the candidate with the guidance necessary for career development in research.

VIII. APPLICATION PROCEDURE

Submit applications on the research grant application form PHS 398 (rev. 10/88). This form is available at the applicant institution's office of sponsored research. An application may also be obtained from the three program offices of the NHLBI listed below. When submitting the application, identify the NHLBI Minority School Faculty Development Award on line 2 of the application face page. Special instructions for preparing the application are included in the guidelines that must be obtained from the program staff listed below.

A. Letter of Intent

Applicants are asked to submit a letter of intent at least one month prior to the receipt date to:

Scientific Review Administrator
Research Training Review Committee
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building, Room 550
Bethesda, MD 20892

A letter of intent is not binding and will not be considered in the review of any application submitted subsequently. The letter should list the applicant institution and program, the name of the Principal Investigator, the mentor at the research center, and the area of research training proposed. Applicants are strongly urged to contact the appropriate individual listed under program information prior to submission of an application.

B. Applications

Send the completed application and four (4) signed exact photocopies by the announced receipt date to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Two additional copies of the application must be sent to the Scientific Review Administrator of the Research Training Review Committee listed above.

Program Information

Information regarding this program may be obtained from one of the following:

John Fakunding, Ph.D.
Research Training and Development Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 3C04
Bethesda, MD 20892
Telephone: (301) 496-1724

Joan Wolle, Ph.D.
Division of Lung Diseases
National Heart, Lung, and Blood Institute
National Institutes of Health
Westwood Building, Room 640
Bethesda, MD 20892
Telephone: (301) 496-7668

Helena Mishoe, Ph.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 504D
Bethesda, MD 20892
Telephone: (301) 496-6931

For fiscal and administrative matters, please contact:

Grants Operations Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A15C
Bethesda, Maryland 20892
Telephone: (301) 496-7255

* Within NHLBI, the term "hematologic" covers research on thrombosis and hemostasis, immunohematology, blood cell disorders, sickle cell disease, blood resources including blood component and derivative therapy, blood substitutes and blood resource management, aspects of AIDS products in AIDS prevention and treatment, and AIDS-related bone marrow and hematologic disorders. Other Institutes of the NIH are responsible for research on disorders of white cells, including the leukemias and other blood malignancies, and basic immunology related to the lymphoid system. Therefore, NHLBI cannot provide support for such studies.

This program is described in the Catalog of Domestic Assistance Nos. 93.837, 93.838, and 93.839. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410 as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulation 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.

RESEARCH ON MENTAL DISORDERS IN RURAL POPULATIONS

PA: PA-91-52

P.T. 34; K.W. 0715129, 0403004

National Institute of Mental Health

The National Institute of Mental Health seeks applications for the support of research and research demonstration projects on mental disorders in rural populations. This announcement supersedes the prior announcement issued in March 1990 for "Research on Mental Disorders in Rural Populations," and will govern competitive renewals for research and research demonstration projects funded under the prior announcement.

Research issues of interest include: the epidemiology of mental health problems in rural populations; the availability, responsiveness, effectiveness, and efficiency of delivery of clinical services to persons in rural areas with mental disorders; effective outreach forms of service delivery and mechanisms for coordinating diverse types of care in rural areas; the roles of the general medical care sector in serving mentally ill persons in rural areas; the structure and functioning of the mental health service system in rural areas of various types; economic and other stresses in rural areas and health-related behavior of rural populations; mental health problem prevention in rural populations; economic and financing issues concerning mental health related services in rural areas; special problems of distinctive rural subpopulations such as migrants, ethnic and cultural minorities, the elderly, persons with Alzheimer's disease, children and adolescents, the homeless mentally ill, and persons with co-occurring mental health and other types of disorders such as substance abuse and physical disorders; and distinctive methods needed for research in rural areas.

Applications for research demonstration projects must involve the transfer and application of interventions derived from a solid theoretical or research base, be designed to test effectiveness through a rigorous research design that measures the project's impact, and generate conclusions that are generalizable to other sites.

Applications may be submitted by any nonprofit or for-profit organization, including units of State and local governments.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

Preference will be given to projects consistent with the National Institute of Mental Health Public-Academic Liaison initiative (bringing together public sector service providers and academic researchers), those involving high-risk populations (e.g. homeless and severely mentally ill persons), and those that include females and minorities in study populations.

Support for research on rural mental health that does not include funds for demonstration services may be requested through applications for a regular individual research grant (R01), the First Independent Research and Transition (FIRST) award (R29), and a small grant (R03).

Support for research demonstration awards that include funds for services necessary for the conduct of the research may be requested through applications for research demonstration grants (R18). Research demonstration applications will be subject to review and comment by States, through

procedures that may be obtained from the State's single point of contact (SPOC). Criteria for the various grant mechanisms should be requested from the contact listed below.

Applications may request support for up to 5 years for research and research demonstration projects. Small grants are limited to 2 years and may not be renewed. FIRST awards may be made for up to 5 years, but are not renewable. Annual awards will be made, subject to continued availability of funds and progress achieved. During Fiscal Year 1990, the National Institute of Mental Health funded approximately $8 million for rural mental health research through all mechanisms.

The earliest receipt date is June 1, 1991. Applications submitted by that date, if complete at time of submission, will be eligible for an expedited review so that funding in September, 1991, is possible. Thereafter, the usual receipt dates of Oct. 1, Feb. 1, and June 1 and the usual review schedule apply.

Staff consultation to applicants during proposal development is available.

For further information and to request a copy of the full announcement, prospective applicants should contact:

Charles Windle, Ph.D.
Acting Director
Office of Rural Mental Health Research
Division of Applied and Services Research
Parklawn Building, Room 18C-14
National Institute of Mental Health
Rockville, MD 20857
Telephone: (301) 443-4233

Inquiries pertaining to grants management should be directed to:

Steven Hudak
Chief, Grants Management Section
Grants Management Branch
Parklawn Building, Room 7C-23
National Institute of Mental Health
Rockville, MD 20857
Telephone: (301) 443-4456

This program is described in the Catalog of Federal Domestic Assistance No. 93.242, Mental Health Research Grants. Under the authority of Section 301 of the Public Health Service Act (42 U.S.C. 241) and subject to availability of funds, the National Institute of Mental Health will accept applications in response to this announcement.

RESEARCH ON THE EFFECTS OF POWER FREQUENCY ELECTRIC AND MAGNETIC FIELDS

PA: PA-91-53

P.T. 34; K.W. 0725015, 1013026

National Institute of Environmental Health Sciences

The National Institute of Environmental Health Sciences (NIEHS), the National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute of Child Health and Human Development (NICHD) invite grant applications through a joint Program Announcement (PA) for basic studies on the effects of electric and magnetic fields. This solicitation is issued to encourage investigator-initiated research projects in areas of special programmatic interest to the National Institutes of Health (NIH). Applicants funded under the PA are supported through traditional research grants in accordance with Public Health Service (PHS) policies applicable to research grants. It is noted that only Research Project (R01, R29) grant applications will be considered to be responsive to this PA.

Grant applications in response to this announcement will be reviewed in accordance with the usual Public Health Service Peer Review Procedures.

BACKGROUND

The NIEHS is the principal NIH component for support of basic research on environmental factors that contribute to human health problems and disease. Major emphasis by NIEHS is placed upon research examining those physical and chemical substances to which humans are exposed in their general environment

as a result of human activities such as modern technologies and industrial and commercial processes. In addition to the NIEHS, the NINDS also supports research on those factors that impinge on the nervous and sensory systems. The NICHD is interested in factors such as EMF that may affect reproduction and development.

As a result of electrification of our homes and work places, people from all walks of life and of all ages are now exposed to power frequency (60 Hz) electric and magnetic fields. Increasingly scientists, regulators and lay people are asking whether human exposure to these fields involves risks to human health. Electromagnetic fields (EMF) cause biological effects in human beings, in laboratory animals, and in cells and tissues from humans and animals. However, the extant literature does not provide a basis for assessing the risks, if any, from exposure to these fields. Thus there is a need for additional research on the biological effects of EMF exposure particularly at the frequencies of power lines and electrically powered devices.

The results of studies on the biological effects of EMF are controversial. One reason for controversy is the finding of positive and negative effects in some similar studies. Also, there are scientists who believe that power frequency fields cannot cause biological effects other than the well known hazards of electrical shock and burn. This position is based on two points. One, the energy of a 60 Hz electromagnetic wave is too weak to break chemical bonds. Two, natural electric fields in the body are orders of magnitude greater than those induced by common EMF exposure.

On the other hand, there are reports of biological effects of EMF at many levels of biological organization. These studies have examined a wide range of endpoints but, for the most part, have been phenomenological rather than hypothesis based. For example, in vitro studies report effects on the cell membrane, DNA synthesis, RNA transcription, ornithine decarboxylase activity, calcium-ion efflux, cellular response to hormones and cancer cells. These responses to EMF at the cellular level display a considerable complexity including resonant responses in frequency and field strength, complex time dependencies, and dependence on the ambient DC magnetic field created by the earth.

Animal systems have been used for studies under a range of electric and magnetic field intensities for varied exposure conditions and durations. A few examples are studies of animal behavior with and without drugs, melatonin synthesis in the pineal gland, and circadian rhythms. In general, research is needed to determine if in vivo EMF exposure has a deleterious effect on animals and to define exposure conditions that may be effective.

The results of epidemiological studies are controversial because some studies report no association between residential EMF exposure and cancer while other work suggests a possible association. For example, a study published in 1979 reported increased incidence of leukemia and brain tumors in children exposed to EMF. Criticisms of the report led to a second study that addressed many of the study design problems. This work also found a weak association between EMF exposure and leukemia and brain tumors. However, another epidemiological study in 1980 failed to demonstrate an association between residential EMF exposure and childhood leukemia. In addition, some but not all studies of occupational exposure of electrical workers have suggested an increased incidence of leukemia and brain cancer; however, the causative agent for this pattern remains unknown.

RESEARCH OBJECTIVES AND SCOPE

This announcement is issued to encourage and foster investigator-initiated basic and applied research on the possible health effects of EMF. Because of the limited data on EMF biological effects it is anticipated that some projects may be more focused on identification of EMF effects than on the possible mechanisms of EMF actions. Such applications must state the means by which the information generated will be useful in risk assessment and/or developing mechanistic hypotheses. Collaborative research efforts among toxicologists, physicists, engineers, and scientists in closely related disciplines are encouraged to ensure quality in all aspects of the proposed study.

Research interests include, but are not limited to studies designed to:

A. Determine the effects/mechanisms of action of EMF on cellular responses such as DNA synthesis, modulation of ion binding, and interaction with hormones and growth factors.
B. Determine the effects on cancer processes in vivo and in vitro.

C. Determine the effects of EMF on reproductive/developmental and nervous systems in vivo and in vitro.
D. Development of well-characterized EMF exposure systems for assessing biological effects.

HEALTHY PEOPLE 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 Program Announcement, Research on the Effects of Power Frequency Electric and Magnetic Fields, is related to the priority area of environmental 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).

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES.

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, general and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognize that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial /ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks. Hispanics). The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the review will be deferred until the information is provided.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

MECHANISM OF SUPPORT

The mechanism of support for this activity will be the individual research grant (R01) or First Independent Research Support and Transition (FIRST) Award (R29) as applicable.

APPLICATION AND REVIEW PROCEDURES

Applications will be accepted in accordance with the usual receipt dates for new research grant applications; i.e., February 1, June 1, and October 1. The earliest possible award dates will be approximately nine months after the respective receipt dates. Applications received too late for one cycle of review will be held until the next receipt date.

Applications will be received by the NIH's Division of Research Grants (DRG) and referred to an appropriate study section for scientific and technical merit review. Institute assignment decisions will be governed by the normal programmatic considerations as specified in the NIH Referral Guidelines. The review criteria customarily employed by the NIH for regular research grant applications will prevail. Following the initial scientific review, the applications will be evaluated by an appropriate advisory council.

METHOD OF APPLYING

Applications must be submitted on form PHS 398 (revised 10/88) which is available in the business or contracts offices at most academic and research institutions and from the DRG. To identify the application as a response to this announcement, check "yes" in Item 2 on the face page of the application and enter the title "Research on the Effects of Power Frequency Electric and Magnetic Fields, PA-91-53."

The original and six (6) copies of the application must be directed to:

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

Inquires related to this Program Announcement should be directed to:

Dr. Michael J. Galvin, Program Administrator, Scientific Programs Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-7825

Dr. Eugene Streicher or Dr. W. Watson Alberts
Division of Fundamental Neurosciences
National Institute of Neurological Disorders and Stroke
Federal Building, Room 916
Bethesda, MD 20892
Telephone: (301) 496-5745

Dr. Felix de la Cruz
Chief, Mental Retardation and Developmental Disabilities Branch
National Institute of Child Health and Human Development
EPN, 631
Bethesda, MD 20892
Telephone: (301) 496-1383

Grants management inquiries should be directed to:

David L. Mineo, Chief, Grants Management Branch
Division of Extramural Research and Training
National Institute of Environmental Health Sciences
P. O. Box 12233
Research Triangle Park, NC 27709
Telephone: (919) 541-1373

This program is described in the Catalog of Federal Domestic Assistance Numbers 93.112, Characterization of Environmental Health Hazards, and 93.113, Biological Response to Environmental Health Hazards. Awards are made under the authority of Section 487, Public Health Service Act as amended (42 USC 288) and administered under PHS Grants Policies and Title 42 of the Code of Federal Regulations, Part 66. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

* U.S. G.P.O.:1991-281-826:20045