NIH GUIDE for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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The GUIDE is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

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REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIEHS-EP-81-2

STUDIES RELATING HUMAN HEALTH EFFECTS TO PBB

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Application receipt date: April 15, 1981

I. BACKGROUND INFORMATION

Polybrominated biphenyls (PBBs), originally synthesized for use as a fire retardant and in the manufacture of electronic parts and plastics, have made their way into the environment as exemplified in Michigan and are of concern because of their toxicity. These compounds, which are resistant to metabolism or excretion, will bioaccumulate in man. Analysis of existing information on the human health effects of PBBs indicate a need for additional research. Although epidemiologic studies in human populations have failed to demonstrate a definitive cause-effect relationship between PBB exposure and human disease, laboratory and field studies have shown the toxicity of the commercial preparations. Extrapolation of the effects in animals to man is precluded by the lack of information concerning specific compound structure/activity relationships, possible synergistic, antagonistic or additive effects and the metabolic fate or biotransformation of these compounds.

II. GOALS AND SCOPE

The objective of these proposed studies is to provide information which will aid in the assessment of the real and potential dangers to man from exposure to commercial preparation of PBBs and their component compounds in the environment such as has occurred in Michigan.

In assessing the need for additional information to shed light on the human health effects of PBBs, the following areas of research have been identified:

1. Information relative to the toxicity of PBB congeners for humans, including aspects of storage, metabolism, and excretion.

This program is described in the Catalog of Federal Domestic Assistance, number 13.892, Prediction, Detection and Assessment of Environmentally Caused Diseases and Disorders. 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 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

2. Additive, synergistic or otherwise interactive reactions with other pollutants such as PCBs, DDT and its residues, and other persistent halogenated hydrocarbons widespread (i.e., beyond Michigan) in the environment.

3. Since all studies of immune functions in residents exposed to PBBs in Michigan have been limited to those older than 18 years, further studies in children born during or shortly after the exposure seem warranted. Such studies might focus on the examination of immunological functions such as delayed cutaneous hypersensitivity (DCH) to standard recall antigens and antibody titers to the standard childhood immunogens. This group is especially appropriate for study since its members (1) have higher body burdens than adults and (2) were exposed through transplacental passage of PBBs, and PBB-contaminated breast milk or products from contaminated farms during periods under which the immune system is undergoing development and maturation and may be the most vulnerable to toxic insult.

4. At the present time there is no known therapy which effectively promotes the elimination of PBBs to reduce the body burden. Research is therefore needed to increase the knowledge base useful for general application in development of means for clearing the body of these and structurally similar compounds.

5. Since children exposed in utero to PBBs are now reaching school age, further exploration of the hypothesis of delayed or altered central nervous system development is warranted. In concert with such investigations, questions potentially relevant to the acquisition of body burden (i.e., breast feeding, farm status) as well as other factors thought to affect development (i.e., stressor events, socioeconomic status) should be considered.

Since similar studies are and have been carried out in this area, proposals should reflect cognizance of prior work in the field and provide specific plans for coordination of the research effort to complement the efforts of universities, as well as local, State and Federal agencies now involved.

III. MECHANISM OF SUPPORT

The support mechanism for this program will be the NIH research project grant. This type of announcement (the RFA) is used when an Institute--with the concurrence of its National Advisory Council or another appropriate advisory group--wishes to stimulate investigator interest in a particular research problem that is important to its program. The RFA solicitation represents a single competition with usually one specified deadline for receipt of applications. All applications in response to an RFA are reviewed by the same initial review group in competition with each other, usually for a designated amount of funds or number of awards.

The RFA identifies the scope of the Institute's interest but does not require that the proposal conform to a specific research protocol. Thus it is expected that each successful applicant will plan, direct, and carry out the research program. As with any research grant, the recipient must obtain prior approval for any major change in the scope or objectives of the approved project. Applicants should be aware that this general requirement is particulary pertinent when, as in the case of RFA solicitations, the awarding Institute has committed funds in response to a specific program need.

It is anticipated that $600,000 will be allocated for this program during the first year; however, award of grants is contingent upon the availability of funds. The project period should adequately reflect the time required to accomplish the stated goals and be consistent with the NIH policy for grant support.

IV. REVIEW PROCEDURES AND CRITERIA

A. Review Procedure

Proposals in response to this solicitation will be reviewed in competition with each other on a nationwide basis. The initial review will be for scientific merit and will be carried out by an appropriate peer review group. The secondary review for relevance and responsiveness to the announcement will be made by the National Advisory Environmental Health Sciences Council. Applicants will be informed of the results of the competition as soon as possible after the October 1981 meeting of the Council.

B. Review Criteria

Applications must be responsive to the RFA and, therefore, relevant to the program goals of the sponsoring institute. Those applications considered to be unresponsive to the RFA will be returned to the applicant. Those factors considered to be important for review include a demonstrated knowledge of the applicable science, adequacy of facilities and commitment, availability of subject population when applicable and in-depth knowledge of the state-of-the-art to which the RFA is directed. The application will be judged upon the overall scientific merit, adequacy of methodology, facilities and resources, commitment of time, and cost effectiveness of proposal. The sponsoring institution should indicate a commitment of facilities and resources to the program.

V. METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application form for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division of Research Grants, NIH. The original and six

copies of the application must be received by April 15, 1981. Applications must be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

The face page of the application should be labeled "**In response to RFA-NIH-NIEHS-EP-81-2.**" One copy of the application should be sent to:

Dr. Edward Gardner, Jr.
Program Director
Regular Research Programs Section
Scientific Programs Branch
Extramural Program
National Institute of Environmental
Health Sciences
P.O. Box 12233
Research Triangle Park, North Carolina 27709

VI. STAFF CONTACT

Questions relating to this announcement may be directed to Dr. Edward Gardner, Jr. (address above) or (919) 755-4021.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

RFA-NIH-NHLBI-81G-C

INVESTIGATION OF BASIC MECHANISMS INVOLVED IN SUDDEN CARDIAC DEATH

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Application receipt date: April 15, 1981

The Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute invites grant applications for research leading to a better understanding of the fundamental mechanisms of the processes which convert chronic ischemic heart disease into an acutely progressive state resulting in ventricular fibrillation and sudden death.

The Institute will use the grant-in-aid as the support mechanism, but it will differ from other research grants both in its goal orientation and in the degree of participation by the National Heart, Lung, and Blood Institute. While it is expected that each successful applicant will plan, direct, and execute his/her own research project, any subsequent substantial modifications must be mutually agreed upon by the participant and the National Heart, Lung, and Blood Institute. The present announcement is for a single competition with a specified deadline of April 15, 1981 for receipt of applications. It is open to all interested investigators, including those who are already the recipients of investigator-initiated research grants from the NHLBI in this area. Applications should be prepared and submitted in accordance with the aim and requirements described in the following sections.

It is important to call attention to the fact that the RFA application differs from that for the regular research grant in that it is requested that a letter of intent to submit an application be sent by March 2, 1981, and that the applications be received by the April 15, 1981 deadline. More detailed instructions are provided under Section V, Method of Applying.

This program is described in the Catalog of Federal Domestic Assistance, number 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

I. BACKGROUND INFORMATION

A. The Coronary Heart Disease Program

The Division of Heart and Vascular Diseases of the National Heart, Lung, and Blood Institute has the responsibility for the design and administration of a National Research Program leading to the reduction in death and disability from ischemic heart disease. The program fosters the development of new knowledge and the translation of results into methods which will have wide clinical application.

The program is structured with planned areas for support. It includes clinical and fundamental research directly related to the problems of myocardial infarction, angina pectoris, sudden cardiac death and other facets of ischemic heart disease. Because it is a program in which the various elements have relevance to one another and may depend upon each other, free communication is expected between participants. The program may foster such communication in part through the conduct or support of workshops and conferences. The Program Office has a direct interest in being informed of the scientific experience and results of each project it supports, as well as in its operational aspects.

The major components of the present program are the Specialized Centers of Research in Ischemic Heart Disease, research on Sudden Cardiac Death, Animal Models of Protecting Ischemic Myocardium, the National Unstable Angina Pectoris Study, Collaborative Studies on Coronary Artery Surgery, and the Multicenter Investigation for Limitation of Infarct Size.

B. Historical Perspective

The Sudden Death Program was begun in 1970-71 with the award of 19 contracts to develop methods for identifying subgroups in the population at high risk for sudden death, to develop the means of recognition of premonitory warning signs, to identify and characterize possible precipitating factors and pathological processes, to characterize underlying chronic and acute pathology, to develop clinical-pathological correlations, and to develop and assess means of early therapy to prevent sudden death. Competition was reopened in 1975 and the mechanism of support changed from a contract to a grant mechanism. Fifteen institutions were funded for investigations in this area, including studies of lethal arrhythmias. The special grant program was competitively renewed in 1978 with the award of 13 grants for a three-year period. Emphasis was on the understanding of fundamental mechanisms of the processes causing sudden death, the definition of high risk individuals, development of preventive measures, and refinement of early therapy.

II. RESEARCH GOALS AND SCOPE

Sudden cardiac death does not have a single definition that is useful for all purposes. Broadly defined, it is death due to a primary cardiac cause or mechanism occurring within 24 hours of the onset of acute illness. Those with recognized ischemic heart disease, including previous myocardial infarction, are not excluded; however, in contrast to those with advanced and severely symptomatic heart disease, the definition is probably best restricted to those thought to be free of heart disease or with asymptomatic or moderately symptomatic heart disease.

This research program is concerned with that phenomenon occurring in individuals with chronic coronary heart disease whereby a chronic, sometimes asymptomatic or even unrecognized condition is converted to an acutely and rapidly progressive process associated with severe ischemic episodes, lethal arrhythmias and sudden death. The ultimate objective of this research is to provide a basis for effective prevention of these events in individuals with coronary artery disease.

Considerable progress has been made both in the identification of persons at risk and in the investigation of the basic electrophysiology of ischemic myocardium. It has, for example, been established that ischemic heart disease is the major cause of sudden cardiac death, with over 80 percent of sudden cardiac deaths being associated with severe stenosis of one or more of the coronary arteries. Although subgroups of patients at high risk can be identified, it now appears likely that sudden death, even though due to ventricular fibrillation terminally, is influenced to a marked degree by a wide variety of underlying, contributing, and precipitating factors. Since the details of these factors remain obscure, the choice of anti-arrhythmic drugs or other interventions must be made empirically and there is presently no reliable means of tailoring preventive therapy to individual patients. An understanding of the basic mechanisms of such events as reentry, pacemaker abnormalities, and conduction defects remains essential to the application of preventive therapy on a rational, selective basis.

A workshop was held by the Cardiac Diseases Branch in April, 1980 to make an in-depth assessment of the current knowledge concerning sudden cardiac death, and to identify opportunities and needs for future research.* The discussions of the workshop indicated that although substantial progress has been made in a number of areas, it does not appear that definitive therapies for preventing sudden death are in the immediate future. It was the consensus that the lack of adequate information regarding basic mechanisms has limited progress in the formulation of new therapeutic hypotheses.

*Copies of the summary of the Workshop on Sudden Cardiac Death may be obtained by contacting the NHLBI staff person listed at the end of this announcement.

In recognition of the importance of an improved understanding of the fundamental mechanisms involved in sudden cardiac death to the development of more effective prophylactic and therapeutic measures, the competitive continuation of this program has been recommended by the Cardiology Advisory Committee and the National Heart, Lung, and Blood Advisory Council.

Applications are invited for studies in laboratory animals or in the clinical setting which will develop and explore new hypotheses concerning the fundamental mechanisms involved in sudden cardiac death. It is recognized that the expertise of many disciplines can be brought to bear in the investigation of this problem area. Accordingly, proposals involving multidisciplinary research efforts are encouraged. For illustrative purposes, some general areas of relevant research effort are listed below. Other areas may occur to the applicant which would be appropriate to the objectives. New concepts and approaches are encouraged. In all instances, the perceived relationship and importance of the proposed work to the improved understanding, prevention and treatment of sudden cardiac death should be made explicit.

These studies may be concerned with the factors and pathophysiological mechanisms precipitating the acute lethal progression of ischemic heart disease or they may be specifically directed to the mechanisms underlying the genesis of lethal arrhythmias in the context of ischemic myocardium. They may be concerned, for example, with alterations in the biochemical milieu at the cellular and subcellular levels including metabolic effects of ischemia, abnormalities in electrophysiological properties and associated morphological changes especially of the conduction system and its blood supply, brain-heart interactions including the roles of stress and the autonomic and central nervous systems, and the assessment of the roles of vasospasm and electrolyte abnormalities such as hypokalemia and hypomagnesemia. These general areas for study are listed only to provide an indication of the breadth of this solicitation.

Applications should identify the hypothesis and clearly outline the questions proposed for investigation. The description of the proposed studies should include the research design and methodology, including procedures for the analysis and interpretation of data.

While this research program has considerable breadth of scope, research effort in several areas is not sought. Specifically, proposals solely concerned with the development of animal models, the evaluation of drugs, the epidemiology of sudden cardiac death or the clinical evaluation of survivors of ventricular fibrillation will not be considered to be responsive to this announcement.

Potential applicants should review their research proposals in the context of the enunciated program goals and review criteria to reassure themselves that their application is truly responsive; if the relevance and responsiveness of a research proposal to these goals and criteria are

tenuous, the application should be considered for submission as a regular research grant application. It should be recognized that the existence of a targeted program and the distribution of a request for grant applications does not pre-empt the topic from the regular research grant program.

Because this program is one in which the various elements have relevance to one another and may depend upon each other, free communication is expected between the participants. Institute staff will attempt to foster such communication in part through the conduct or support of workshops and conferences. In the preparation of the budget for the grant application, applicants should request travel funds for one, two-day research conference each year, most likely to be held in Bethesda, Maryland.

III. MECHANISMS OF SUPPORT

The support mechanism for this program will be the NIH research project grant. This type of announcement (the RFA) is used when the Institute--with the concurrence of its National Advisory Council--wishes to stimulate investigator interest in a particular research problem that is important to its program. The RFA solicitation represents a single competition with one specified deadline for receipt of application. All applications in response to an RFA are reviewed by the same initial review group usually for a designated amount of funds or number of awards.

The RFA identifies the scope of the Institute's interest but does not require that the proposal conform to a specific protocol. Thus it is expected that each successful applicant will plan, direct, and carry out the research program. As with any research grant, the recipient must obtain prior approval for any major change in the scope or objectives of the approved project. Applicants should be aware that this general requirement is particularly pertinent when, as in the case of RFA solicitations, the awarding Institute has committed funds in response to a specific program need.

In addition, Institute staff will serve to foster communication and coordination among the successful applicants and, in doing so, staff will establish relationships with investigators and grantees that are closer than those that exist in the traditional research grant program. Ongoing evaluation may include periodic visits and the review of formal progress reports.

Applicants are requested to furnish their own estimates of the time required to achieve specific objectives of the proposed work and an outline of the phases or segments into which the proposed project can be logically divided. The total project period should not exceed three years in duration; it is desirable, but not mandatory, that a September 30, 1981 starting date for the project be requested.

Although this announcement is included and provided for in the financial plans for Fiscal Year 1981, support of grants pursuant to this Request for

Applications is contingent upon ultimate receipt of appropriated funds for this purpose. The total annual funding level for the program is estimated at $800,000. A variety of approaches would be responsive to this solicitation; accordingly, it is anticipated that there will be a range of costs among the individual grants awarded. It is anticipated that 6-8 awards will be made if a sufficient number of high quality applications is received; this should be considered in the preparation of the scope of work and budget.

Unless specifically stated to the contrary, herein all policies and requirements which govern the grant program of the PHS apply, including the requirement for cost sharing.

IV. REVIEW PROCEDURES AND CRITERIA

Applications will be reviewed in a national competition with each other. Primary review will be conducted by an Initial Review Group composed primarily of non-Federal scientific consultants. Secondary review will be by the National Heart, Lung, and Blood Advisory Council. Applicants will be informed of the results of the competition as soon as possible after the September, 1981 meeting of the Council.

The major factors considered in evaluating each application will be:

1. The scientific merit of the application, that is, the questions proposed for study, the research design and approaches, the methodology, and the analysis and interpretation of data.

2. The likelihood of arriving at meaningful and useful data to accomplish the goal of this solicitation.

3. The research experience and competence of the staff to carry out the proposed investigations and the time they will devote to the program.

4. The adequacy of existing and proposed facilities and resources.

5. In applications containing more than one project, the integration of various projects into an effective total program.

6. The organizational and administrative structure of the proposed program.

7. The evidence of institutional commitment to the program.

8. Willingness to work cooperatively with other participants in the program and with the National Heart, Lung, and Blood Institute.

9. The cost of the proposed research.

V. METHOD OF APPLYING

A. Letter of Intent

Prospective applicants are asked to submit a brief, one-page letter of intent which includes a very brief synopsis of the proposed areas of research and identification of any other participating institutions. This letter should be sent no later than March 2, 1981, to Dr. Charles L. Turbyfill, Review Branch, Division of Extramural Affairs, National Heart, Lung, and Blood Institute, National Institutes of Health, Westwood Building, Room 553, 5333 Westbard Avenue, Bethesda, Maryland 20205.

The Institute requests such letters for the sole purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding, and it will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for application.

B. Format for Applications

Applications should be submitted on form PHS 398, the application form for a regular research grant. This form is available at the applicant's institutional control office or from the Division of Research Grants, NIH. The conventional format of research grant applications should be utilized, ensuring that the points identified under "Review Procedures and Criteria" (see Section IV, above) are fulfilled. Specific attention is directed towards the inclusion of a statement indicating the willingness of the applicant to work cooperatively with other participants in the program and with the National Heart, Lung, and Blood Institute.

C. Application Procedure

The completed application and thirty (30) copies thereof should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

To ensure their review, applications must be received by April 15, 1981. Applications not received by this deadline will be considered ineligible and, after discussion with the applicant, may be considered as a regular research grant application. Concerning applications that are non-responsive to this announcement, applicants will be contacted to determine if they wish to have the proposal returned or reviewed as a regular research grant.

The outside of the mailing package and the top of the face page of the applications should be labeled **"Response to RFA NIH-NHLBI-DHVD-81G-C."**

Applications will be accepted and reviewed as follows:

Application Receipt	Initial Review	Council Review	Start Date
April 15	June	September	September 30

VI. IDENTIFICATION OF CONTACT POINTS

Inquiries may be directed to Dr. James V. Dingell, Cardiac Diseases Branch, Division of Heart and Vascular Diseases, National Heart, Lung, and Blood Institute, Federal Building, Room 3C06, Bethesda, Maryland 20205; Telephone: (301) 496-1081.

AVAILABILITY OF REQUEST FOR APPLICATIONS (RFA)

CLINICAL CENTERS FOR A COLLABORATIVE CLINICAL TRIAL ON THE RELATIONSHIP BETWEEN BLOOD GLUCOSE CONTROL AND VASCULAR COMPLICATIONS OF INSULIN-DEPENDENT DIABETES MELLITUS

NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM AND DIGESTIVE DISEASES

Application receipt date: May 1, 1981

The National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) announces the availability of a Request for Applications (RFA) inviting proposals for Clinical Centers to participate with the NIAMDD under **cooperative agreements** in a multicenter collaborative clinical trial to determine whether strict control of blood glucose concentration is effective in preventing or ameliorating the vascular complications of insulin-dependent diabetes mellitus. The assistance mechanism which will be used to support this study, the cooperative agreement, is similar in many respects to the traditional NIH research grant; however, it differs from a research grant principally in the extent and nature of the involvement of NIAMDD staff. The staff of the NIAMDD will be substantially involved as an active partner in all aspects of the scientific and technical management of this trial above and beyond the levels required for administration of traditional research grants.

This clinical trial will utilize a randomized design and is planned to consist of four sequential phases in which the experience and results of each phase will determine whether and how the next phase will be undertaken. The general phases will include those of planning, limited feasibility testing, conduct of the full-scale collaborative trial, and data analysis and reporting. Phase I will be concerned with the collaborative development of the detailed protocols, including the therapies, measurements of control and endpoints of pathologic complications which will be applied in Phase II. Phase II will utilize the protocols developed in Phase I, and will be a limited array of studies to determine:

- whether a randomly allocated, strict control treatment regimen can be used in a group of insulin-dependent diabetic patients to establish and

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This program is described in the Catalog of Federal Domestic Assistance, number 13.847, Diabetes, Endocrinology and Metabolism Research. Cooperative Agreements will be awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically, 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

maintain blood glucose control that differs significantly, both clinically and statistically, from that achieved in a similar group receiving a more conventional treatment;
- whether these therapies can be effectively and safely applied in a randomized manner to a population of insulin-dependent diabetic patients;
- whether sufficiently high rates of patient acceptability can be achieved with these therapies; and
- whether the effects of these therapies on selected biochemical and pathological endpoints can be adequately and reliably assessed.

If the results of Phase II demonstrate feasibility and indicate the likelihood that a long-term trial can be conducted in a manner which will allow meaningful conclusions to be reached regarding the relationship between control of blood glucose concentration and the vascular complications of diabetes mellitus, a full-scale multicenter collaborative clinical trial will be undertaken in Phase III. That full-scale clinical trial should focus concurrently on two categories of insulin-dependent diabetic patients: those who have no evidence of background retinopathy (primary intervention trial) and those who already have minimal background retinopathy (secondary intervention trial). Thus, Phase III of the study will consist of separate but parallel trials in which each participating Clinical Center should have two treatment groups within each category of patient. In each of the patient categories there will be a treatment group randomized to a strict control regimen and another group randomized to a more conventional therapy. There will be coincident assessment of selected biochemical and pathological endpoints in all groups to determine the effects of the two therapies on the development and/or progression of certain of the vascular complications of insulin-dependent diabetes mellitus. During Phase IV, analysis and reporting of the data generated in the Phase III study will be completed.

The approximate timetable for the study will be as follows:

Phase I	-	6 months
Phase II	-	2 years
Phase III	-	7-10 years
Phase IV	-	1 year

An RFA is available which outlines the proposed study in more detail, the requirements for participation as a Clinical Center, and the method of applying. This request is an invitation for **Clinical Centers to participate in all four phases** of this multicenter collaborative clinical trial. However, since this study will proceed through four distinct phases, applications reflecting participation in only the first two phases are being requested at this time; a performance review of applications for continuation support will be conducted between Phase II and Phase III. Clinics selected for participation in Phases I and II should expect to continue to participate in Phases III and IV provided their performance in Phases I and II has been acceptable. It is anticipated that approximately 20 Clinical Centers will take part in all four phases of this clinical trial, and an institution wishing to participate must make application in accordance with the guidelines specified in the RFA. The deadline for receipt of applications for Clinical Centers is May 1, 1981. Applications received after this date will not be

considered. Logistics and managerial practicality necessitate that institutions in only the United States and Canada are eligible to apply. Additional information and copies of the RFA can be obtained from:

Carolyn Siebert, M.P.H.
Clinical Trial Coordinator
Diabetes, Endocrinology and Metabolic Diseases
National Institute of Arthritis, Metabolism and
Digestive Diseases, NIH
Westwood Building, Room 607
Bethesda, Maryland 20205
Telephone: (301) 496-7595

A Data Coordinating Center will participate with the Clinical Centers and Institute staff during the entire clinical trial. The Coordinating Center is being sought under separate competition.

ANNOUNCEMENT

CRANIOFACIAL ANOMALIES

NATIONAL INSTITUTE OF DENTAL RESEARCH

The National Institute of Dental Research (NIDR) invites applications for support of basic research relevant to the Craniofacial Anomalies Program. Of particular interest are fundamental studies related to normal and/or abnormal prenatal craniofacial growth and development.

Approaches that have been identified as particularly appropriate for support by the NIDR include studies directed toward:

1. Identifying intrinsic and extrinsic factors which cause or increase susceptibility to craniofacial defects.

2. Identifying biological processes in craniofacial development (such as cell proliferation, cell death, cell differentiation, cell migration, and tissue interactions during morphogenesis) including those which are particularly susceptible to abnormal genetic and environmental influences.

3. Identifying the molecular, cellular, and organismic bases for normal growth and genetic predisposition to abnormal development.

4. Identifying molecular, cellular, and organismic changes resulting from environmental factors causing abnormal development.

5. Developing appropriate animal models and in vitro techniques to investigate specific developmental processes directly related to defective human craniofacial morphogenesis.

6. Identifying genetic and environmental interactions resulting in abnormal development.

Applicants are encouraged to address any specific aspects of the areas presented above. However, NIDR also would be receptive to any creative proposals which offer a molecular approach toward understanding normal and abnormal development of the craniofacial region.

This program is described in the Catalog of Federal Domestic Assistance, number 13.842, Craniofacial Anomalies Research. 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 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

REVIEW PROCEDURES

The initial review of applications for scientific and technical merit will be by an appropriate study section of the DRG; secondary review will be by the National Advisory Dental Research Council. Applicants will be informed of the outcome of the review shortly after each Council meeting.

APPLICATION PROCEDURE

Applications should be prepared on research grant application form PHS 398, available in the business or grants and contracts offices of most academic and research institutions. Applications must be received on or before the regular receipt dates of March 1, July 1, or November 1. Applications should be sent to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
5333 Westbard Avenue
Bethesda, Maryland 20205

STAFF CONTACT

Preliminary drafts of the proposals and other inquiries regarding this program may be addressed to either Dr. Richard L. Christiansen, Chief, or Dr. Jerry D. Niswander, Craniofacial Anomalies Program Branch, National Institute of Dental Research, National Institutes of Health, Westwood Building, Room 520, Bethesda, Maryland 20205. Telephone: (301) 496-7807.

ANNOUNCEMENT

RESEARCH GRANTS IN NEONATAL BRAIN DISORDERS RESEARCH

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

The Developmental Neurology Branch (DNB), Neurological Disorders Program (NDP) of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), encourages the submission of program project research grant applications (P01) on neonatal brain disorders.

BACKGROUND

Neonatal brain disorders are receiving new and intensified research attention. They are an important cause of mortality and morbidity. New technologies available to study such disorders have provided a rapidly expanding knowledge base. At this time it is appropriate that a well-focused and integrated research effort be supported on the etiology, diagnosis, treatment, consequences, and prevention of neonatal brain disorders.

RESEARCH GOALS

Program project research grant applications on neonatal brain disorders must focus on clinical research, but related basic research components supporting the clinical effort would be appropriate. Of particular interest are intracranial hemorrhage in low birthweight infants, neonatal seizures, hypoxic/ischemic encephalopathy in the full-term infant, and metabolic disorders relevant to brain function. However, applications need not be limited to these conditions. Research should be directed at developing knowledge and understanding of the etiology and pathogenesis of neonatal brain disorders expanding the capability for early and precise diagnosis, and correlating detected pathology and dysfunction with clinical course. Research also should be directed at evaluating and refining current therapies and developing new ones, precisely and accurately assessing and defining mortality and chronic neurologic disability with the goal of developing strategies for the prevention of the initial disorder and/or for preventing or ameliorating the long-term chronic disabilities which may be associated with the initial disorders. Investigations into the refinement of currently used diagnostic techniques and development of new techniques are encouraged.

This program is described in the Catalog of Federal Domestic Assistance, number 13.852, Neurological Disorders Research. 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 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

For most of the conditions considered, it may be necessary to assess their impact on the neurologic quality of survival by following affected children. The availability of well-defined population bases will be extremely important. Because some of the conditions under evaluation (e.g., severe asphyxia in term infants) and some of the outcomes (e.g., cerebral palsy) occur with low frequency, cooperation among neonatal nurseries, or wide referral nets for out-born infants, may be necessary to assemble clinical populations in sufficient numbers to answer questions related to these conditions or outcomes.

Program project research grant applications on neonatal brain disorders should focus on pediatric neurology. However, the development of multidisciplinary teams is encouraged to include other appropriate clinical specialties, as well as related disciplines of basic neuroscience. It is the intent that the program projects would provide, through the individual components, a comprehensive, integrated, and cohesive approach to neonatal brain disorders.

Although some areas of research interest have been indicated above, the application is by no means restricted to any one or more of these areas. Any investigational aspect related to neonatal brain disorders, that pertains directly or indirectly to the etiology, diagnosis, treatment, consequences and prevention of neonatal brain disorders, is encouraged.

ETHICAL ISSUES

Some specific research projects on neonatal brain disorders may present complex ethical issues. In such instances, applicants are expected to include a thorough and precise discussion of specific ethical issues as they relate to the given project.

MECHANISM OF SUPPORT

Applications may be submitted for program project research grants (P01). Program project applications may be multi-institutional or have cooperating units. If a grant application includes research activities that involve institutions other than the sponsoring organization, the program is considered a consortium effort. Such cooperative activities may be included in a program project grant application, but it is imperative that a consortium application be prepared so that the programmatic, fiscal, and administrative considerations are explained fully. Potential applicants should contact the institute representative listed below as early as possible in the planning stages to receive detailed written guidelines for preparing P01 applications. Deadlines for receipt of P01 applications are annually on June 1, October 1 and February 1.

REVIEW PROCEDURES AND CRITERIA

Applications should be prepared on form PHS 398 following instructions contained in the application kit and those specified in the NINCDS Guidelines for Program Project Grant Applications. Application kits are available from most institutional business offices or from the Division of Research Grants, NIH. The applications will be judged solely on scientific merit in accordance with NIH policy and procedures involving peer review. Initial review will be by one of the Neurological

Disorders Program Project Review Committees. The final review will be by the National Advisory Neurological and Communicative Disorders and Stroke Council.

The phrase **"Prepared in Response to NINCDS Invitation for Research Grants in Neonatal Brain Disorders"** should be typed across the top of the first face page of the application. The original and 6 copies of the application should be mailed to the following address:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, Maryland 20205

One copy of the application is to be sent to the address below.

For further information and copies of the NINCDS Guidelines for Program Project Applications, contact:

Joseph S. Drage, M.D.
Chief, Developmental Neurology Branch
Neurological Disorders Program
National Institute of Neurological and
Communicative Disorders and Stroke
Federal Building, Room 816
Bethesda, Maryland 20205
Telephone: (301) 496-6701

ANNOUNCEMENT

RESEARCH FUNDAMENTAL TO PROTECTING ISCHEMIC MYOCARDIUM

THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

In 1971, the National Heart, Lung, and Blood Institute (NHLBI) began a research program of investigations of the fundamental physiology and biochemistry of ischemic myocardium. It was augmented in 1972 with additional laboratory investigations to delineate the cellular derangements in injured myocardium. The program was expanded, by an open competition in 1975, to include research involving the application of laboratory findings to the clinical setting. In 1978, the program emphasis shifted to investigations of the fundamental understanding of the basic mechanisms and processes associated with myocardial ischemia and its reversibility and irreversibility. In 1979, five additional awards were made to develop and validate standardized experimental protocols for models of experimental myocardial infarction, to be used to assess interventions to protect ischemic myocardium.

These investigations have been part of the Coronary Heart Disease program of the National Heart, Lung, and Blood Institute. In addition to the above-mentioned research programs, the NHLBI is also conducting a multi-center clinical trial, the Multicenter Investigation of the Limitation of Infarct Size (MILIS), in order to assess the efficacy of two drugs, propranolol and hyaluronidase, to limit the size of an infarct when administered within 18 hours of the onset of symptoms of presumed myocardial infarction. The NHLBI has also supported, as part of the Ischemic Heart Disease Specialized Centers of Research (SCOR) program and the investigator-initiated research grant program, a substantial number of laboratory and clinical investigations concerning the pathophysiology of myocardial ischemia and therapeutics aimed at limiting infarct size.

The above-mentioned research activities provide strong evidence that, in recent years, the number of research projects supported by the NHLBI in the area of research concerning myocardial ischemia has increased significantly. A substantial increase is evident in the number of basic research projects specifically involving investigations of the concept of the limitation of infarct size. The growth in the number of research projects in this area indicates that the special grant program, described above, has been most successful in stimulating

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This program is described in the Catalog of Federal Domestic Assistance number 13.837, Heart and Vascular Diseases Research. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC 241) and administered under PHS grant policies and Federal Regulations, most specifically 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

the conduct of research in an area of significant research need and opportunity. Accordingly, the NHLBI, following the recommendation of the Cardiology Advisory Committee and the National Heart, Lung, and Blood Advisory Council, has decided that there will be no special set-aside funds for this program following the expiration of the present program in June, 1981.

However, the NHLBI continues to be interested in a broad scope of investigations aimed at elucidating the fundamental mechanisms associated with ischemic myocardium and infarct size limitation. Although a considerable amount of information has been learned and a number of techniques have been developed which offer considerable potential for clinical efficacy, additional information is required to extend the understanding of the fundamental mechanisms and processes of ischemic myocardium and infarct size limitation. Thus, the NHLBI encourages investigators to submit research projects in these areas of investigation. They will be considered as applications for the regular research grant program, without a special set-aside of funds.

These investigations may involve studies at the molecular and subcellular level, the cellular level, in vitro, in vivo or in the intact animal. It is both desired and anticipated that these studies will be useful for the development of therapeutic interventions in experimental animals and in man. However, the development and/or evaluation of the efficacy of therapeutic regimens is not the sole goal of this request. For example, a promising approach would be to incorporate studies which attempt to investigate concurrently basic mechanisms and processes associated with infarct size limitation and the preclinical assessment of efficacy of promising therapeutic interventions aimed at limiting infarct size. Recent basic studies have yielded much information concerning the mechanism of action of various classes of therapeutic agents, including, but not necessarily limited to, calcium antagonists, adrenergic blockers, and the non-steroidal anti-inflammatory agents. The clinical utility of these and other drugs has yet to be fully established; accordingly, coordinated attempts to secure additional knowledge of the mechanism of action and the preclinical assessment of efficacy of these drugs would be an important research undertaking.

Application Submission and Review

Application receipt dates for new applications are the regular application receipt dates of March 1, July 1, and November 1 (February 1, June 1, and October 1, for Competing Renewal Applications). Applications received after any one receipt date are considered and reviewed together with those received by the next receipt date. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application form (PHS 398) which is available at the applicant's institutional application control office or from the Division of Research Grants, NIH.

A program announcement is designed to focus attention upon a topic or problem and is not intended to discourage investigators from their pursuit of promising ideas in related or unrelated topics. However, in order to identify the response to this announcement, **check "yes" and put "Research fundamental to protecting**

ischemic myocardium" under Item 2 on those grant applications conforming to the topics identified herein. The completed application should be mailed to:

Division of Research Grants
Westwood Building, Room 240
National Institutes of Health
Bethesda, Maryland 20205

The Division of Research Grants will assign applications to study sections for review according to the NIH process for regular research grant applications. Approved applications will compete for available funds with all other approved grant applications assigned to the National Heart, Lung, and Blood Institute. Additional information may be obtained by contacting:

Dr. Richard P. Schwarz, Jr.
Cardiac Diseases Branch
Division of Heart and Vascular Diseases
National Heart, Lung, and Blood Institute
Federal Building, Room 3C06
7550 Wisconsin Avenue
Bethesda, Maryland 20205
Telephone: (301) 496-1081

ANNOUNCEMENT

RESEARCH TRAINING AND DEVELOPMENT AREAS AND TYPES OF AWARDS AVAILABLE

THE DIVISION OF BLOOD DISEASES AND RESOURCES

THE NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

This announcement consolidates and summarizes the current research training and development areas of the Division of Blood Diseases and Resources; it is not an announcement of new programs or initiatives. (The number of new awards made annually depends on the merit of proposals and the availability of funds.)

The Division of Blood Diseases and Resources (DBDR) of the National Heart, Lung, and Blood Institute (NHLBI) has a mandate to support the training of investigators who will be capable of conducting exemplary programs in basic and clinical research in blood diseases and blood resources. Examples of appropriate research areas are provided below but the list is not meant to exclude other topics related to blood diseases and blood resources.

* Thrombosis
* Hemostasis
* Red Blood Cell Diseases
* Sickle Cell Disease
* Blood Resources
* Blood Banking Sciences

The Research Training and Development Program of the DBDR is intended to achieve the following objectives through established NIH mechanisms of support.

* To encourage qualified individuals at different levels of professional development to direct, or redirect, their research interests and investigative skills toward problems in blood diseases and blood

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These programs are described in the Catalog of Federal Domestic Assistance number 13.839, Blood Diseases and Resources Research. Awards will be made under the authority of the Public Health Service Act, Section 472 (42 USC 289-1), administered under PHS grants policy and Federal Regulations 42 CFR Part 66, and Section 301 (Public Law 78-410, as amended; 42 USC 241), administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. These programs are not subject to A-95 Clearinghouse or Health Systems Agency Review.

resources. This action will create a pool of highly qualified investigators with experience and skills in the disciplines needed to understand and explore effectively problems in blood diseases and blood resources.

* To provide support for qualified individuals at different levels of professional development to pursue a program of research in various fundamental and clinical research disciplines related to blood diseases and blood resources.

MECHANISMS OF SUPPORT

The mechanisms summarized in this announcement may be used for the support of individuals interested in advancing the state-of-the-art of hematology through basic and clinical research on problems relevant to blood diseases and blood resources. (See also Special Announcement of a Special Emphasis Research Area (SERA) for the "Development of Investigators, Blood Transfusion Sciences," **NIH Guide for Grants and Contracts,** Vol. 9, No. 9, July 18, 1980, p. 19.)

Only citizens and non-citizen nationals are eligible for support under the following programs.

RESEARCH TRAINING

I. National Research Service Award (NRSA) - Individual and Institutional

These awards provide support for individuals at various levels of career development who wish to gain additional experience in biomedical and behavioral research related to problems in blood diseases and blood resources.

A. NRSA Individual Fellowship Award

* Post-doctoral fellowships are awarded to individuals having an appropriate sponsor and institution.
* Selection by national competition.
* Stipend is $13,380-$18,780 based on years of relevant postdoctoral experience.
* Training period is not less than one year nor more than three years.
* Stipend supplementation is allowed from non-federal funds.
* Institutional allowance (IA) of $5,000 may be requested to defray fellowship expenses (e.g., tuition and fees, medical insurance, research supplies and equipment, and travel to scientific meetings). Federal laboratories may request $2,000 for IA.
* Each month of NIH-financed training requires one month of payback, which can be fulfilled by teaching and/or conducting research.

* Receipt dates:	Starting dates:
- February 1	- September
- June 1	- February
- October 1	- May

* Use application form PHS 416-1.

B. NRSA Institutional Research Training Award

* Up to 5-year pre- and postdoctoral awards are made to institutions on behalf of a training program director.
* Selection of training institution by national competition.
* Trainee selection results from local review established by training program director at the grantee institution.
* Stipend is $13,380-$18,780 based on years of relevant postdoctoral experience. Stipend is $5,040 per year for predoctoral trainees. Support may be requested for tuition, fees, medical insurance and travel.
* Training period for each trainee is not less than one year. Postdoctoral support for not more than three years; predoctoral support for up to five years.
* Stipend supplementation is allowed from non-federal funds.
* Institutional allowance of $5,000 per postdoctoral and $3,000 per predoctoral trainee may be requested to defray trainee expenses (e.g., personnel, research supplies and equipment, and staff travel). Indirect costs of 8 percent of total direct costs or actual rate, whichever is less, may be requested.
* Each month of NIH-financed training requires one month of payback which can be fulfilled by teaching and/or conducting research.

* Receipt dates:	Advisory Council Review:	Starting dates:
- February 1	October	- July 1
- June 1	February	- July 1
- October 1	May	- July 1

* Use application form PHS 6025.

II. NRSA for Senior Fellows

Provides support to experienced scientists who have at least 7 years of relevant postdoctoral research or professional experience and wish to make major changes in the direction of their scientific careers, or wish to enhance and enlarge their research capabilities in order to conduct research on problems in blood diseases and blood resources.

* Fellowships are awarded to individuals having an appropriate sponsor or institution.
* Selection by national competition.
* Stipend may be negotiated up to $30,000 per year.

* Training period is normally twelve months.
* Stipend supplementation is allowed from non-federal funds.
* Institutional allowance of $5,000 may be requested to defray fellowship expenses (e.g., tuition and fees, medical insurance, research supplies and equipment, and travel). Federal laboratories may request $2,000 for IA.
* Each month of NIH-financed training requires one month of payback which can be fulfilled by teaching and/or conducting research.
* Receipt dates: Starting dates:

  - February 1 - September
  - June 1 - February
  - October 1 - May

* Use application form PHS 416-1.

III. NRSA for Short-Term Training: Students in Health Professional Schools

Provides support for promising students in health professional schools who are interested in blood diseases and blood resources. Awardees are expected to be exposed to a structured research training experience for periods up to three months during off-quarters or summer vacation.

* Up to 5-year awards are made to institutions in behalf of a training program for no fewer than four, nor more than 32, off-quarter students per year.
* Selection of training institution by national competition.
* Trainee selection by grantee institution.
* Training period is not less than 8 weeks nor more than 12 weeks.
* Stipend support for Trainees ($420 per month) and may be supplemented from non-federal funds.
* Institutional allowances of $250 per month per student may be requested.
* Indirect costs of 8 percent of total direct costs or actual rate, whichever is less, may be requested.
* No payback is required for training periods of up to three months.
* One application to NIH per professional school is accepted.
* Receipt date: Advisory Council Review: Starting date:

  - May 1 February - April 1

* Use application form PHS 6025, with special instructions.

RESEARCH CAREER DEVELOPMENT

I. Clinical Investigator Awards (CIA)

These awards provide support to newly trained physicians, usually with not less than three years of clinical training nor more than six years of total postdoctoral, clinical and research experience by the time an award is

made. The objective is to encourage them to develop clinical and basic research interests in blood diseases and blood resources.

* Award is made to institution on behalf of a candidate who has an appropriate sponsor willing to assume responsibility and provide guidance for candidate's research program.
* Selection by national competition.
* Salary of up to $25,000 plus fringe benefits for first year, with annual increases of salary up to $30,000.
* Research support is provided up to $10,000 per year.
* Training period is five years; full-time effort; non-renewable.
* Salary supplementation is allowed from non-federal funds.
* Indirect costs of 8 percent of total direct costs or actual rate, whichever is less, may be requested.
* Annual receipt date is **August 1** for starting date of July 1 of the following year.
* Use application form PHS 398, with special CIA instructions.

II. Research Career Development Award (RCDA)

Provides salary only for investigators with at least three years of relevant postdoctoral experience by the time an award is made to encourage acquisition of the skills and experience needed for an independent research career in blood diseases and blood resources. Support must be available to carry out the research project for which the RCDA salary is provided. This award may not substitute for other sources of support since the objective is to provide relief from responsibilities that prevent full-time (not less than 75% clinical or basic research) pursuit of an academic research career. Untried or established investigators are ineligible.

* Candidate is nominated by and award is made to an institution on behalf of the candidate, with selection by national competition.
* Salary is up to $30,000 plus fringe benefits.
* Award period is five years; non-renewable.
* Salary supplementation is allowed from non-federal funds.
* Indirect costs of 8 percent of total direct costs or actual rate, whichever is less, may be requested.
* RCDA application may be submitted concurrently with a regular research grant application but must not be submitted concurrently with other development awards, such as, New Investigator Research Award, Clinical Investigator Award, academic and teacher investigator award, research scientist development award, and postdoctoral and special fellowships.
* Receipt dates: Advisory Council Review: Starting dates:

Receipt dates:	Advisory Council Review:	Starting dates:
- February 1	October	- December 1
- June 1	February	- April 1
- October 1	May	- July 1

* Use application form PHS 398, with special RCDA instructions.

III. New Investigator Research Award (NIRA)

Provides research support for newly emerging investigators (including those who have interrupted early promising careers) in basic or clinical science disciplines. This research grant award is intended to bridge the transition from training status to that of independent investigator by helping them to establish independently their research interests and capabilities in blood diseases and blood resources.

* Principal Investigators (P.I.s) usually have no more than five years of research experience after completion of formal training and must not have been a P.I. on a PHS grant.
* Three-year, non-renewable grants are awarded to institutions on behalf of the principal investigators; selection by national competition.
* Total direct costs of up to $107,500 may be requested for the three-year period; no more than $37,500 may be requested in any one year.
* Salary of up to $25,000 and fringe benefits may be requested. Salary is proportional to percent time or effort on the research project.
* Fifty percent or more time must be committed to the research project.
* Technical support, supplies, publication costs, limited equipment, and necessary travel may be requested as direct costs.
* Indirect costs are allowed in accordance with HHS policies for research grants.
* Three letters should be submitted from former supervisors attesting to the P.I.'s potential for conducting independent research.
* P.I.s are expected to provide NIH with information on their scientific achievements and professional status for a period of six years following termination of the NIRA.
* The P.I. should be prepared to compete for regular research grants after completion of the NIRA.
* Receipt dates: Advisory Council Review: Starting dates:

Receipt dates:	Advisory Council Review:	Starting dates:
- March 1	October	- December 1
- July 1	February	- April 1
- November 1	May	- July 1

* Use application form PHS 398, with special NIRA instructions.

MINORITY ACCESS TO RESEARCH CAREERS (MARC)

The Division of Blood Diseases and Resources, in cooperation with the National Institute of General Medical Sciences, provides support for faculty members and students of minority institutions interested in research involving diseases of the blood, in the use of blood, and in the management of blood resources. This activity operates through a faculty fellowship and a visiting scientist program. The purpose of these programs, as supported by the Division of Blood Diseases and Resources, is to increase the number of minority scientists in the fields of blood diseases and blood resources and to develop and strengthen research training programs in institutions which enroll significant numbers (50%) of minority students.

Applications may come from four-year academic institutions, for the programs summarized below, on behalf of a citizen or non-citizen national. Applicant institutions must 1) have a significant minority student enrollment; 2) have a demonstrated commitment to further the careers of ethnic minority faculty, students, and investigators; and 3) be located in the U.S., or in a U.S. territory.

A. MARC Faculty Fellowship Program

Provides support through the National Research Fellowship to faculty from institutions having a significant minority student enrollment for the purpose of acquiring advanced research training on problems in blood diseases and resources. The setting for this training should be in institutions known for their training programs.

* Award is made to the minority institution on behalf of a fellow who is nominated from the faculty of that institution; selection by national competition.
* Doctorate degree or Ph.D. candidacy is required.
* Training period is up to 3 years
* Fellow must be prepared to return to sponsoring institution following completion of training where he or she will conduct research or teach.
* Stipend is based on current salary up to $25,000 per year.
* Stipend supplementation is allowed from non-federal funds.
* Institutional allowance of $5,000 may be requested to defray fellowship expenses (e.g., tuition and fees, medical insurance, research supplies and equipment, and travel to scientific meetings).
* Each month of NIH-financed training requires one month of payback which can be fulfilled by teaching and/or conducting research at the sponsoring institution.
* Receipt dates:
  - February 1
  - June 1
  - October 1

  Starting dates:
  - September
  - February
  - May

* Use application form PHS 416-1.

B. Visiting Scientist Program (MARC)

Provides support to established outstanding scientists to conduct in-residence teaching, research, and/or science counseling in the fields of blood diseases and blood resources at the invitation of the applicant minority institution. The purpose is to strengthen the research and teaching programs in blood diseases and blood resources at the institution.

* Scientist is invited by a minority institution which receives the award on behalf of the visiting scientist; selection of institution by national competition.
* Awards are made for up to 1 year.
* Visiting scientist must be accomplished investigator and teacher.
* Stipend is based on current salary of the applicant.
* Stipend supplementation is allowed from non-federal funds.
* Institutional allowance of $5,000 may be requested to defray visiting scientist expenses (e.g., medical insurance, research supplies and equipment, and travel to scientific meetings).
* Receipt dates:
  - February 1
  - June 1
  - October 1

  Starting dates:
  - September
  - February
  - May

* Use application form PHS 416-1.

Applications: MARC Program

To request application kits, assistance and/or additional information, please write or call:

Mr. Elward Bynum
Minority Access to Research Careers Program
National Institute of General Medical Sciences
National Institutes of Health
Bethesda, Maryland 20205
Phone: (301) 496-7941

Applications: All Programs Except MARC Program

Application forms and detailed instructions specific to the summarized programs are available from the business office of most institutions or from the Division of Research Grants, NIH. Please forward to the addess below a **copy of the face page** of all applications sent in response to this program summary for Investigators in Blood Diseases and Blood Resources.

Fann Harding, Ph.D.
Special Assistant to the Director
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland 20205
Phone: (301) 496-1817

ANNOUNCEMENT

PULMONARY ACADEMIC AWARD

The Division of Lung Diseases, National Heart, Lung, and Blood Institute, invites national competition for Pulmonary Academic Awards, which have the dual purpose of improving the quality of pulmonary curricula and of fostering research careers in the respiratory field. Each school of medicine or osteopathy in the United States or its possessions and territories is eligible for such an award. (Awards will be limited to one for each eligible school, for a project period up to five years.)

The Division has initiated the Pulmonary Academic Award program to provide a stimulus for development of a pulmonary curriculum in those schools that do not have one and to strengthen and improve the pulmonary curriculum in those schools that do. Awards provide support to individual faculty members for their educational development, and for implementation of the pulmonary curriculum.

The specific objectives of the Award are to:

* encourage development of a quality pulmonary curriculum that will attract outstanding students to pulmonary research and medical practice;
* ensure superior learning opportunities in pulmonary medicine;
* develop promising young faculty whose interest and training are in pulmonary medicine;
* facilitate interchange of educational ideas and methods among awardees and institutions; and
* develop at the grantee institution the ability to strengthen continuously the improved pulmonary curriculum, with local funds, subsequent to the award.

Applications must be received no later than April 1, 1981 for review at the September (1981) meeting of the National Heart, Lung, and Blood Advisory Council. Awards will be made with a beginning date of June 1, 1982.

The complete program announcement and guidelines for applications may be obtained from:

Barbara Marzetta Liu
Prevention, Education, and Manpower Branch
Division of Lung Diseases, NHLBI
Westwood Building, Room 6A10
Bethesda, Maryland 20205
Telephone: (301) 496-7668

This program is described in the Catalog of Federal Domestic Assistance, number 13.838, Lung Diseases Research. 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 Section 413 (42 USC 287b) and administered under PHS grants policy and Federal Regulation 42 CFR Part 66. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

ANNOUNCEMENT

MINORITY ACCESS TO RESEARCH CAREERS (MARC) PROGRAM

MARC PREDOCTORAL FELLOWSHIP

The National Institute of General Medical Sciences (NIGMS) is accepting applications for Individual National Research Service MARC Predoctoral Fellowships under authority of Section 472 of the Public Health Service Act as amended (42 USC 2891-1) and to be administered under PHS grants policy and Federal Regulations 42 CFR Part 66. This program is described in the Catalog of Federal Domestic Assistance, number 13.880, Minority Access to Research Careers. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

The MARC Predoctoral Fellowship Program provides support for research training leading to the Ph.D. degree in the biomedical sciences for selected students who are graduates of the MARC Honors Undergraduate Research Training Program.* It is expected that such training will be conducted in graduate-degree programs of the highest quality.

Support is not available for individuals enrolled in medical or other professional schools, unless they are enrolled in a combined-degree (M.D.-Ph.D.) program.

Awards are conditional upon acceptance into a specified doctoral (Ph.D.) degree program in biomedical research.

MARC Predoctoral Fellows are selected on a highly competitive basis. Applications will be evaluated by the Minority Access to Research Careers Review Committee of NIGMS. A maximum of up to five years of support may be recommended, based on the merit of the application and evidence of satisfactory progress in the doctoral program in which a successful applicant is enrolled.

Annual Stipends and Allowances

The annual stipend for MARC Predoctoral Fellows will be $5,040. This stipend is a pre-established level of support to help provide for the fellow's living expenses during the period of training. The stipend is not a payment for services performed. Fellows supported under individual awards are not considered to be employees either of PHS or of their sponsoring institution. For fellows sponsored by domestic non-Federal institutions, the payment of the stipend will be made through the sponsoring institution.

*Schools having MARC Honors Undergraduate Training Programs are four-year colleges, universities and health professional schools in which student enrollments are drawn substantially from ethnic minority groups such as American Indians, Blacks, Hispanics, and Pacific Islanders.

The National Institute of General Medical Sciences will provide funds of up to $4,000 per 12-month period to the sponsoring institution to help defray such trainee expenses as tuition and fees, research supplies, equipment, travel to scientific meetings, and related items.

Application Receipt Date	Results Announced By
February 1	September
June 1	January
October 1	May

Further information regarding eligibility and required payback provisions may be found in the **NIH Guide for Grants and Contracts,** Vol. 5, No. 9, July 4, 1978.

Application forms may be obtained from Mr. Elward Bynum, Director, MARC Program, National Institute of General Medical Sciences, NIH, Bethesda, Maryland 20205; Telephone (301) 496-7941. If there are any questions regarding the preparation of applications, applicants seeking support should contact Mr. Bynum.

ANNOUNCEMENT

AVAILABILITY OF CLINSPEC GAS CHROMATOGRAPHY-MASS SPECTROMETRY FACILITIES

CLINSPEC, a project funded by the Division of Research Resources of the National Institutes of Health, is designed to encourage the application of gas chromatography-mass spectrometry in the clinical research process.

Through its General Clinical Research Centers Program, the Division of Research Resources funds 75 General Clinical Research Centers at teaching hospitals and universities throughout the country. These small hospital units, which meet the pressing need for discrete study units where ideally controlled conditions produce the most reliable research results, enable clinical scientists to investigate research protocols that relate directly to human health conditions.

CLINSPEC makes available to investigators using General Clinical Research Center facilities the gas chromatography-mass spectrometry capabilities of the Medical University of South Carolina. The program provides access, training, and assistance pertaining to the use of gas chromatography-mass spectrometry in clinical research applications. It also can assist General Clinical Research Center program directors, principal investigators, and individual investigators in establishing gas chromatography-mass spectrometry facilities at their own institutions.

Gas chromatography-mass spectrometry uses high technology instrumentation to provide clinical investigators with the opportunity for both rapid and highly accurate qualitative and quantitative analysis of compounds.

Qualitatively, gas chromatography-mass spectrometry can reveal the structure of new compounds and the presence of known compounds by separating and analyzing the individual components of a complex biological sample mixture. Examples of such use include the study of biotransformation of both endogenous and exogenous compounds and the identification of abnormal metabolic products.

Quantitatively, gas chromatography-mass spectrometry can be used to determine the levels of endogenous or exogenous compounds, as well as to establish enrichment in compounds. This type of use finds particular application in kinetic studies and allows the use of stable, non-radioactive isotope tracers.

The CLINSPEC process involves proposal submission, informal review, project approval, consultation with the investigator, previsit preparation, carrying out the proposed and approved project on site in Charleston, South Carolina, and a postvisit consultation. In addition to the use of the gas chromatography-mass spectrometry facilities at the Medical University of South Carolina, the program pays for travel to and expenses at the CLINSPEC laboratory in Charleston for the duration of the research project.

For more information on CLINSPEC or to submit a proposal, contact in writing Dr. Daniel Knapp, Department of Pharmacology, Medical University of South Carolina, Charleston, South Carolina 29403.

ANNOUNCEMENT

AVAILABILITY OF ANIMALS FOR FLUORIDE STUDIES

NATIONAL INSTITUTE OF DENTAL RESEARCH

The Soft Tissue Stomatology and Nutrition Program Branch of the National Institute of Dental Research maintains a special colony of mice on long term low and high fluoride diets. Subgroups of the colony have been maintained on a defined diet containing either less than 0.5 parts per million or 50 parts per million fluoride for at least ten generations. Starter animals are **available at no charge** to investigators wishing to study the biological effects of long term dietary exposure to high and/or low fluoride.

Individuals wishing to conduct relevant studies who already have funds to carry out either full scale or pilot studies may obtain animals by sending a request accompanied by a synopsis of their research proposal to the official listed below. The synopsis should be no more than three pages in length and consist of:

* Title
* Background
* Specific aims of the proposal
* Outline of the approach to achieve the aims
* Evidence of availability of adequate funding and facilities
* Requested starting date

Requests for animals accompanied by a synopsis of the research proposal will be reviewed by NIDR program staff and applicants will be notified within thirty (30) days. Successful applicants will receive breeding stock from the colony as they become available.

In order to determine future needs for this resource, individuals wishing to use these animals for a research project which is not yet funded must submit a Letter of Intent. For those seeking funds from NIDR through the regular project grant system, the Letter should state the type of study contemplated, estimate of budget needed and the date an application will be submitted to NIH. If funds to support the research project are being sought from non-NIH sources, the Letter of Intent should be followed by a synopsis of the proposal, as described in the preceeding paragraph, at least thirty (30) days prior to the expected funding date.

Support for those applying for NIDR funds will be through a grant-in-aid. The legislative authority is Section 301 of the Public Health Service Act (PL. 78-410 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. The Catalog of Federal Domestic Assistance number is 13.878, Soft Tissue Stomatology and Nutrition Research. This program is not subject to A-95 Clearinghouse or Health Systems Agency Review.

The deadline for acceptance of applications will be in accordance with dates published for new applications. The receipt dates for the next three review cycles are:

March 1, 1981
July 1, 1981
November 1, 1981.

Additional information about the program's interest in fluoride research may be found in the **NIH Guide for Grants and Contracts,** Vol. 8, No. 9, July 6, 1979. Questions concerning the animal colony or NIDR's interest in fluoride research may be obtained from:

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