

NIH GUIDE

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U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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HAVE YOU MOVED?

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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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PROPOSALS INVOLVING RECOMBINANT DNA

REVISED
PROCEDURE NOTICE

THIS IS A REPUBLICATION OF A PROCEDURE NOTICE THAT APPEARED IN THE *NIH GUIDE FOR GRANTS AND CONTRACTS*, Vol. 8, No. 9, July 6, 1979, WITH THE EXCEPTION OF THE LAST PARAGRAPH, WHICH HAS BEEN REVISED.

The current NIH Guidelines for Research Involving Recombinant DNA Molecules, The Administrative Practices Supplement, and announcements of modifications and changes to the Guidelines are available from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20205. All research involving recombinant DNA techniques which is supported by the National Institutes of Health (NIH) must meet the requirements of these Guidelines, which were developed in response to the concerns of the scientific and the lay communities about the possible effects of recombinant DNA research. Their purpose is to specify practices for the construction and handling of recombinant DNA molecules and organisms or viruses containing recombinant DNA. As defined by the Guidelines "recombinant DNA" corresponds to (1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules which result from the replication of a molecule described in (1) above.

Several types of studies involving recombinant DNA are exempt from the Guidelines while others are prohibited by the Guidelines. For the remainder it is required that the applicant organization shall establish and implement policies that provide for the safe conduct of the research in full conformity with the Guidelines. This responsibility includes establishing an Institutional Biosafety Committee to review all recombinant DNA research to be conducted at or sponsored by the applicant organization, and to approve those projects it finds are in conformity with the Guidelines. For each approved project, a valid Memorandum of Understanding and Agreement shall be submitted for review by the NIH Office of Recombinant DNA Activities. The Memorandum of Understanding and Agreement is considered approved after acceptance by the NIH Office of Recombinant DNA Activities.

Grant application forms are being revised to include a check block indicating whether or not recombinant DNA research subject to NIH Guidelines is involved. Until such time as these forms are available, the applications concerned should show in capital letters at the bottom of the first page "THIS APPLICATION INVOLVES RECOMBINANT DNA RESEARCH SUBJECT TO NIH GUIDELINES." Labeling the face page of the application will assist in expediting the processing of the application.

Consult section II-c of the Administrative Practices Supplement, June 1979, for procedures for submitting a Memorandum of Understanding and Agreement for different classes of grant applications and awards.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

NIH-NIAID-80-1

ANNOUNCEMENT

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

TITLE: *ASTHMA AND ALLERGIC DISEASE CENTERS FOR
IMMUNODERMATOLOGIC STUDIES*

Application receipt date, February 15, 1980

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for grants to be initiated during FY 1980 for participation in the ongoing Asthma and Allergic Disease Centers (AADC) program for studies specifically directed to allergic and immunologic aspects of skin diseases.

BACKGROUND INFORMATION

A. AADC Program

The Allergy and Clinical Immunology Branch of the Immunology, Allergic and Immunologic Diseases Program of NIAID sponsors fundamental and clinical research grants and contracts and the procurement and distribution of research reference reagents concerned with asthma, allergic, and immunologic diseases and with relevant mechanisms of hypersensitivity and inflammation. This request for applications is intended to encourage the development of proposals from clinical investigative groups in immunodermatology meeting the criteria and requirements for an Asthma and Allergic Disease Center.

Since its inception in 1971, the AADC program has progressively expanded with the gradual addition of new Centers on an open application basis. In accordance with established policy announced in the *NIH Guide for Grants and Contracts*, Vol. 7, No. 8, p. 1, June 9, 1978, proposals for AADCs are received only periodically and at designated times. Applications for both renewal of existing AADCs and creation of new Center programs will be expected to compete for funds available through the periodically announced awards.

The AADC program currently consists of 15 Centers. Each year several are scheduled to terminate and may compete for renewal. During FY 1980, in addition to the scheduled awards for 4 Asthma and Allergic Disease Centers (per RFA announcement Vol. 8, No. 8, June 5, 1979, page 11), NIAID expects to make 2 additional awards for new AADCs with programs specifically directed to the study of allergic and immunologic aspects of skin disorders.

Legislative authority for this program is found in Section 301 of the Public Health Service Act (Public Law 78-410, 42 USC 241). The Catalog of Federal Domestic Assistance Number is 13.855. Awards will be administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74.

NIAID's fundamental objective in continuing the AADC program remains unchanged - the accelerated application of emerging knowledge from immunology and other relevant biomedical sciences to clinical investigations of asthma, allergic diseases, and hypersensitivity disorders. The requisite factors within a participating institution are quality research in basic sciences and clinical investigation; adequate clinical facilities; access to appropriate patient study populations; staff expertise in diagnosis and management of asthmatic and allergic patients; and a suitable academic/investigative setting designed to favor multidisciplinary interaction.

B. Studies in Immunodermatology

As a product of both basic and clinical investigations, the role of hypersensitivity and immune-related inflammatory mechanisms has become increasingly evident in disorders of the skin. The recognition of the socio-economic impact of allergic skin disorders has provided another stimulus to further major efforts in this field. As a result, allergic-immunologic research in Dermatology is increasing at many universities and medical centers.

Clinical immunologists are in a position to take advantage of the ready access of the skin for in vivo studies of immune mechanisms operative in both local lesions and systemic immunopathologic diseases with manifestations at cutaneous sites.

NIAID views with favor the entrance of researchers from immunobiology, immunochemistry, and immunogenetics into clinically relevant studies leading to advances in the diagnosis, prevention, and treatment of allergic and immunologic diseases. These studies in skin diseases would be consistent with our programmatic interests and activities in the mission of this Institute of Allergy and Infectious Diseases.

RESEARCH GOALS AND SCOPE

1. As a fundamental prerequisite, there should be an indication by the sponsoring university or medical institution of its preparedness to commit resources to insure the development and operation of the proposed center for allergic and/or immunologic skin disorders.
2. A prospective center should be in a position to bring diverse institutional strengths to bear upon the study of major problems in allergic skin disease(s) and/or pathophysiologic mechanisms underlying these disorders. Prerequisites are experience, orientation, laboratory and clinical facilities, scientific and professional staff, support personnel, and the expertise to design and execute protocols representing a multifaceted long-term approach to immunodermatology.
3. The institution's achievements in basic science and clinical research should have reached that stage of development where laboratory techniques and findings can be expanded and integrated at the clinical level with the ultimate goal of developing new and improved methods for diagnosis, prevention, and treatment of allergic or immunologic skin diseases.

4. Suitable subjects for study within the provisions of this program may include those relevant to:
 - a. The study of immune mechanisms in cutaneous disorders; the application of investigative approaches in biochemistry, microbiology, genetics, pathology and pharmacology to humoral and cell mediated functions associated with involvement of the skin.
 - b. Studies to identify disorders and their mechanisms where skin may be primarily involved as target tissue by immune humoral and/or cellular reactants, or where cells of the integument may serve as natural sources of specific antigens in immune processes (erythema nodosum, erythema multiforme, pemphigus, bullous pemphigoid, dermatitis herpetiformis, herpes gestationis, lupus erythematosus, viral exanthems and vasculitides).
 - c. Studies to differentiate allergic skin disorders that arise as a result of:
 - (a) IgE related mechanisms.
 - (b) Cell mediated immunity/delayed hypersensitivity.
 - (c) Inflammation emerging from activation of the complement cascade and the effects of chemical mediators, in order to effect corresponding methods of treatment.
 - d. Atopic dermatitis - definition of possible interacting etiologies (e.g., immediate hypersensitivity, T cell disorders, neurogenic abnormalities, environmental irritants and genetic predisposition) that may influence the development and course of allergic eczema as a multifactorial disease.
 - e. Urticaria and angiodema - investigations to detect and define those allergenic triggers, neurogenic factors, chemical mediators, immunoglobulines and immune complexes, complement deficiencies, and abnormalities of the microcirculation that result in heterogeneous disorders of identical clinical presentation.
 - f. Contact hypersensitivity - further efforts to delineate the nature of normal components of the skin that can be converted to antigenic determinants as a result of interaction of cutaneous cells with sensitizing agents and the determination of critical structural characteristics of these agents, in order that manufacturers can be guided in the development of safer products for human usage.
 - g. Infection - studies directed to immune responses to both pathogenic and saprophytic flora of the skin in order to understand and control primary infections and hypersensitivity reactions due to antigens derived from bacteria, viruses, fungi, and parasitic organisms.

5. Animal models will be considered acceptable as a partial segment or adjunct to a Center's program only if in support of a major project of the center.
6. A Center should not rely upon its ability to conduct research activity solely within the confines of a single discipline, but rather should have established participatory associations of workers in pertinent biomedical fields and medical specialties, e.g., immunobiology, biochemistry, microbiology, genetics, pathology, physiology, pharmacology, biostatistics, bioinstrumentation and computer science; and the clinical subspecialties, e.g., allergy, clinical immunology, dermatology, rheumatology, infectious diseases, etc.
7. More than one avenue of research may be pursued within a center with provision for unified operation and coordination of component projects and collaborative investigators.
8. Designation of a Center Director should be based upon accomplishments as a senior scientist and ability to assume both leadership of the investigative group and responsibility for scientific, professional, and administrative functions.
9. The Center Director will be expected to communicate freely with NIAID and other AADC Centers for effective exchange of new information, to interact with scientists working in other Centers on related investigative problems, and to present progress reports and share experimental data with other Centers through scientist exchanges and attendance at NIAID sponsored meetings.

MECHANISMS OF SUPPORT

In fiscal year 1980, the NIAID plans to award two Asthma and Allergic Disease Center grants for immunodermatology. Each grant will have a duration of not more than five years but may be renewed, depending on program needs at that time and competitive review. Funding beyond the first year of the grant will be contingent upon satisfactory progress during the preceding year.

Grant funds may be utilized to support the research activities of scientific and professional personnel, administration, consultation services, central support services, equipment, supplies, travel, and publication costs. Support for research-related costs of patient involvement and medical care may be authorized. Since the program cannot provide funds for new construction, adequate physical facilities must be available for the primary needs of the Center. However, moderate alterations or renovations to enhance clinical facilities may be allowed if they are necessary to meet objectives of the Center's program.

Only those institutions that can demonstrate excellence in both basic and clinical areas and can direct their resources toward a multifaceted attack on immunodermatology can be supported under the provisions of this RFA.

REVIEW PROCEDURES AND CRITERIA

Applications must be received by February 15, 1980. They will undergo initial review by the Allergy and Clinical Immunology Research Committee in spring 1980 and subsequent review by the National Advisory Allergy and Infectious Diseases Council in summer 1980. September 1, 1980 will be the earliest starting date for successful applicants.

Criteria for Review

The center grant application should include a justification for the appropriateness of that granting mechanism. Review criteria include evaluation of the following, not necessarily in order of importance:

- The scientific merit of the program as a whole, as well as that of each individual project. Each project should be supportable on its own merit.
- The significance of the overall program goals and the development of a well-defined central research focus.
- The cohesiveness and multidisciplinary or multifaceted scope of the program and the coordination and interrelationships among the individual projects and core(s). The relationship of each core(s) to the central focus of the overall program.
- The qualifications, experience, and commitment of the investigators responsible for the individual research projects or core(s) and their contribution to the program, including their ability to devote adequate time and effort to the program.
- Accomplishments of the program to date (for renewal applications).
- The academic and physical environment in which the research will be conducted, including the availability of space, equipment, patients, and the potential for interaction with active scientists from other departments and/or institutions.
- A sound administrative and organizational structure that facilitates attainment of the objective(s) of the program.
- Arrangements for internal quality control of on-going research, allocation of funds, day-to-day managements, internal communications and cooperation among the investigators involved in the program, contractual agreements, and replacement of the Center Director, if required, on an interim or permanent basis.

CONSEQUENCES OF LACK OF RESPONSIVENESS TO THE RFA OR LATE SUBMISSION

Formal applications that are not responsive to the RFA or are not received by February 15, 1980, will not be accepted for review and will be returned to the applicant.

METHOD OF APPLYING

For preliminary screening by NIAID staff, a "letter of intent" must first be prepared by the prospective Center Director.

Letters of intent should cover the following points:

1. A brief description of the intended project;
2. The academic positions and major research interests of the Center Director and professional staff proposed for the Asthma and Allergic Disease Center;
3. A brief description or reference to published research works by the investigators in allergy, immunology and dermatology;
4. A brief description of ongoing basic immunological and clinical research relating to allergy and dermatology;
5. A description of available laboratory facilities;
6. A description of all clinic facilities available for use by the proposed center;
7. Specific information on the institution's present patient load and projections for patient involvement in clinical investigation;
8. Proposed collaborative arrangements with other area laboratories and investigators and delineation of the roles and interaction of the principal investigators and collaborators.

Letters of intent are due no later than December 15, 1979, and upon receipt will be screened by NIAID staff to determine the eligibility and suitability of the projected proposals for the Asthma and Allergic Disease Centers program.

Based upon the letter of intent, potential applicants will be promptly advised whether or not their proposal is found to be within the research goals and scope of the program as defined in this RFA. Applicants will then have an opportunity to correct deficiencies or weaknesses and to restructure their submissions accordingly.

Before preparing an application, the prospective applicant should request from NIAID program staff a copy of the NIAID Information Brochure on Program Projects which contains details on the requirements for multi-disciplinary grant applications and the review criteria.

Use the standard research grant application form PHS 398 which is available in institutional Application Control Offices or may be obtained from the Division of Research Grants. In addition to following accompanying format instructions for the development of a Center application, include expanded

material listed above under the eight points for the "letter of intent." For purposes of identification and processing the words "ASTHMA AND ALLERGIC DISEASE CENTER" should be typed on the face page of the application and a brief covering letter should be attached indicating submission is in response to this NIAID announcement.

Forward to:

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

Please forward a copy (not the original) of the cover letter and the application face page to: (1) Chief, Allergy and Clinical Immunology Branch, to alert NIAID to the submission of the proposal, and (2) Chief, Program and Project Review Branch, NIAID, Room 704, Westwood Building, National Institutes of Health, Bethesda, Maryland 20205.

Inquiries and letters should be directed and addressed to:

Robert Goldstein, M.D., Ph.D.
Chief, Allergy and Clinical Immunology Branch
National Institute of Allergy and
Infectious Diseases
Room 755, Westwood Building
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-7104

ACQUIRED CRANIOFACIAL DEFECTS

RESEARCH GRANT APPLICATIONS

SOUGHT BY THE

NATIONAL INSTITUTE OF DENTAL RESEARCH

ANNOUNCEMENT

The National Institute of Dental Research (NIDR) has a continuing interest in laboratory and clinical research which is relevant to acquired craniofacial defects. General areas of concern are the effects of trauma on appearance, function, and growth of the craniofacial region. Of particular interest are epidemiological studies related to an understanding of the nature and the extent of the problem of traumatic injury to the craniofacial structures. Studies having potential for improving treatment of injuries and alleviating the impact of ablative surgery involving these structures are encouraged. This research may include such areas as emergency care, diagnostic techniques, surgical methods, secondary infection, and studies of wound healing, including basic research. Applicants are also encouraged to address the behavioral research problems of acquired facial disfigurement. Similarly more knowledge is needed on the associated speech disability and treatment, as well as growth of the injured child. NIDR is also interested in studies of biomaterials and prosthetic procedures used in the rehabilitation of patients with acquired craniofacial defects.

The deadlines for the receipt of research grant applications by the Division of Research Grants are March 1, July 1, and November 1. Review and award of such applications will be through the usual NIH procedures governing research project grants.

Inquiries regarding this program may be addressed to:

Dr. Richard L. Christiansen, Chief, or
Dr. Jerry D. Niswander
Craniofacial Anomalies Programs Branch-EP
National Institute of Dental Research
National Institutes of Health
Room 520, Westwood Building
Bethesda, Maryland 20205

Telephone: (301) 496-7807

This program is described in the Catalog of Federal Domestic Assistance Number 13.842. 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.

BURN AND TRAUMA RESEARCH AND RESEARCH TRAINING

APPLICATIONS SOUGHT BY

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

ANNOUNCEMENT

The National Institute of General Medical Sciences (NIGMS) wishes to emphasize its program interest in research and research training and invites applications from interested investigators to expand the basic knowledge of the body's total response to accidental injury including burn injury.

I. BACKGROUND INFORMATION

Trauma, including burns, is the fourth leading cause of death in the United States and the number one killer in the 1-44 year age group. Each year more than 10 million Americans are involved in accidents of whom 100,000 die and 400,000 endure some degree of permanent injury. During the first 24 hours after injury, systemic responses frequently culminate in respiratory and cardiovascular collapse, metabolic dysfunction, and overwhelming infection, all of which can lead to death or disability. In order to increase the survival rate, it is essential to discover the underlying pathophysiologic mechanisms for these disturbances.

II. GOAL AND SCOPE

The NIGMS invites applications for support of research and research training relating to basic studies of the underlying mechanisms of the body's systemic response to trauma and burns. Coordinated basic and clinical investigations are intended to foster more rapid application to patients of research advances in the areas of biochemistry, physiology, cell biology, biomedical engineering, and behavioral sciences. Examples of selected topics include the following:

- Fluid balance studies: ideal composition, toxicity, and sodium content, and the post resuscitative effects.
- Factors leading to altered vascular permeability.
- Release of mediators from cell injury during septic and burn shock.

This program is described in the Catalog of Federal Domestic Assistance, 13.821. Awards will be made under the authority of the Public Health Service Act, Section 301(c) and Section 444; Public Law 78-410, as amended; 42 USC 241; 42 USC 289g. Public Health Service Act, Section 472; Public Law 78-410, as amended: 42 USC 2891-1. Grants will be administered under PHS grants policies and Federal Regulations 42 CFR Part 52, 45 CFR Part 74 and 42 CFR Part 66, as applicable.

- Immunosuppressive agents and their role in infections.
- Mechanisms to stimulate host defenses prior to irreversible sepsis.
- Hormonal imbalance following injury and its effects on metabolism.
- Mechanisms involved in producing a protein catabolic state after injury.
- Tools for the diagnosis of parenchymal damage following smoke inhalation.

Applications in response to this announcement are not limited to the specific topics mentioned above.

III. MECHANISMS OF SUPPORT, FUNDING

The NIGMS will accept applications for research center grants, program project grants, research project grants, research career development awards, new investigator awards, and institutional and individual postdoctoral National Research Service Awards with the following stipulations.

Research Center Grants (P50) are intended to foster collaboration between basic and clinical scientists on a variety of closely interrelated research projects which are focused on solving biomedical problems in the field of burns and trauma. A research center grant application should consist of five to eight projects with a total budget not exceeding \$500,000 (direct costs) per year. A letter of intent should be submitted at least three months prior to formal submission of an application. (For additional information consult the *NIH Guide for Grants and Contracts*, Vol. 7, No. 4, March 10, 1978). Deadlines for receipt of applications are February 1, June 1, and October 1.

Program Project Grants (P01) foster collaboration of several investigators with differing expertise related to a specific problem that thus may be solved more expeditiously. They are usually investigator-initiated and are smaller in scope and budget than the average research center grant. Applicants should avail themselves of staff consultation prior to submission. (For additional information consult the *NIH Guide for Grants and Contracts*, Vol. 8, No. 1, January 19, 1979). Deadline for receipt of applications are February 1, June 1, and October 1.

Research Project Grants (R01) provide opportunity for a broad range of indepth studies on specific aspects of burns and trauma such as biochemical and physiological changes induced by severe injury, the fundamental aspects of wound healing and biological repair, nutritional requirements of patients, factors leading to life-threatening infections, and rehabilitation of the injured. Deadlines for receipt of applications are March 1, July 1, and November 1.

Research Career Development Awards (RCDA) are given only to individuals who wish to develop careers directed toward bridging the gap between basic and clinical sciences. Candidates for these awards must be actively engaged in research but at a level which requires additional experience in an active research environment before being considered independent scientists. Since the rank of associate professor or the successful competition for more than one substantial research grant usually indicates that the candidates have been judged to be independent investigators, preference in selection of NIGMS awardees will be given to individuals whose achievements at the time of application have not been so recognized. (For additional information consult the *NIH Guide for Grants and Contracts*, Vol. 6, Nos. 11, June 3, 1977). Deadlines for receipt of applications are February 1, June 1, and October 1.

Special Grants for New Investigators (R23) are offered to physicians in an attempt to facilitate the transition from research training to productive scientific investigation in the field of burns and trauma. The grant is given in the amount of \$30,000 annually for a three year period. (For additional information consult the *NIH Guide for Grants and Contracts*, Vol. 6, No. 11, June 3, 1977). Deadline for receipt of applications are March 1, July 1, and November 1.

Individual and Institutional Postdoctoral National Research Service Awards (institutional training grant or individual fellowship) are research training programs for postdoctoral scientists intended to enhance their capability of advancing the knowledge of the body's complex reaction to burns and trauma. The supervisory staff of such trainees should include trauma surgeons and/or burn specialists as well as basic scientists and emphasis will be placed on basic training for at least two years in such departments as physiology, immunology, biochemistry, and microbiology. (For additional information consult the *NIH Guide for Grants and Contracts*, Vol. 6, No. 3, February 4, 1977). Deadlines for receipt of applications are February 1, June 1, and October 1.

The support mechanisms referred to in this announcement will be grants-in-aid and such grants are contingent upon availability of appropriated funds for this purpose. Funding beyond the first year will be contingent on satisfactory progress during the preceding year.

IV. REVIEW PROCEDURES AND CRITERIA

- A. Application Review. Upon receipt all applications will be assigned by the Division of Research Grants according to accepted Referral Guidelines to an initial review group for assessment of scientific merit and to the NIGMS for final review by its National Advisory Council.
- B. Review Criteria

Applications for research center grants should be preceded by letters of intent which should include the following items:

1. How a research center grant would fulfill the above stated purpose of an NIGMS center grant.
2. A statement of the scientific focus or unifying theme.
3. The research goals with identification of the proposed individual projects.
4. The overall goal and how each individual project will contribute to it.
5. The names and curricula vitae of responsible investigators.
6. Existing research resources and requested renovations.
7. An estimate of the necessary level of support.

Applicants for program project grants should consult with program staff and provide similar information prior to formal submission.

The other types of applications previously mentioned must be relevant to the goals of this announcement. The factors considered in evaluating all applications are:

1. The scientific merit of the research.
2. The qualifications of the principal investigator and proposed staff to carry out the research objectives.
3. A strong commitment by the applicant institution to provide patient beds, laboratory facilities, and the personnel required for the particular type of application submitted.
4. Appropriateness of the duration of the project in relation to the proposed research.

V. METHOD OF APPLYING

Applications must be submitted on the appropriate form for the award mechanism, i.e., Research grants - PHS 398
Research career development awards - PHS 398
New investigator awards - PHS 398
NRSA institutional award - PHS 6025
NRSA individual fellowship - PHS 416

These forms may be obtained from the applicant institution's business office or by writing to:

Office of Grant Inquiries
Division of Research Grants
National Institutes of Health
Bethesda, Maryland 20205

The face page of the original copy and the folder in which it is sent should be clearly labelled "NIGMS BURN AND TRAUMA PROGRAM."

Identification of contact point. All inquiries and correspondence should be addressed to:

Assistant Director for Clinical Research
National Institute of General Medical Sciences
Room 925, Westwood Building
5333 Westbard Avenue
Bethesda, Maryland 20205

Telephone: (301) 496-7373

METHODS FOR QUANTIFYING THE SIZE AND EVALUATING
THE FUNCTION OF ISCHEMIC AND INFARCTED MYOCARDIUM
NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

ANNOUNCEMENT

In 1971, the National Heart, Lung, and Blood Institute (NHLBI) initiated a research program for the development and assessment of methods for quantifying the size of ischemic, infarcted, healing, and/or scarred myocardium, suitable for use in the clinical setting. The program was competitively expanded and renewed in 1975 for the development of methods which would be useful in the evaluation of the acutely ill patient, and was again competitively renewed in 1977, with 10 awards made for the development and utilization of various radiopharmaceuticals and the evaluation of electrocardiographic techniques.

In the past, the program has supported research projects which have developed and evaluated several techniques for quantifying infarct and ischemic zone size, ranging from laboratory in vitro and in vivo animal studies to the use of the techniques in the clinical setting of acute myocardial infarction both in the acute state and during recovery. Some examples of these are electrocardiographic mapping, serial serum enzyme measurements, assessment of ischemic zone size with thallium 201 and quantification of infarct size with technicium 99 pyrophosphate.

More recently initiated investigative techniques have broadened this scope through their potential for the assessment of physiologic and metabolic dysfunction. Among these are, but not necessarily limited to the following: computerized tomography using contrast agents, two-dimensional echocardiography, multi-gated blood pool scanning, positron labelling and imaging using carbon-11 fatty acids and nitrogen-13 amino acids and nuclear magnetic resonance technique involving phosphorous-31 and carbon-13.

The NHLBI continues to be interested in a broad scope of investigations to detect and quantify the size of ischemic or infarcted myocardium directly or through the evaluation of regional ventricular function and to expand our knowledge of the pathophysiology of these disorders. Some methods may be of significant diagnostic use in the acute state of myocardial infarction and during recovery. They may also be of considerable use in the earlier detection of sub-clinical stages of ischemic heart disease, in the serial evaluation of therapeutic interventions to limit the size of ischemic and infarcted myocardium, and in the serial assessment of chronic disease states. Some of these methods - or new methods not yet developed - may be of significant value through their accuracy, reproducibility, specificity, and sensitivity, ease of use and economy.

This program is described in the Catalog of Federal Domestic Assistance Number 13.837. 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.

The Institute encourages investigators to submit grant applications to develop and evaluate, in the laboratory or clinical setting, or both, a method(s) for quantifying the size and evaluating the function of ischemic and/or infarcted myocardium. Such techniques should have the potential capability of assessing and/or predicting derangments in myocardial function, such as segmental wall motion abnormalities and dyskinesia, alterations in ventricular stroke volume and ejection fraction and disturbances in the metabolic energy generation and utilization systems. This listing is intended only to provide examples.

Application Submission and Review

Application receipt dates are the regular application receipt dates of March 1, July 1, and November 1. 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 responses to this announcement, the statement "SUBMITTED IN RESPONSE TO NHLBI PROGRAM ANNOUNCEMENT ON METHODS FOR QUANTIFYING THE SIZE AND EVALUATING THE FUNCTION OF ISCHMIC AND INFARCTED MYOCARDIUM" should be written at the top of the face sheet of those grant applications conforming to the topics identified therein. The completed application should be mailed to:

Division of Research Grants
Room 240, Westwood Building
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
Room 3C06, Federal Building
Bethesda, Maryland 20205

Telephone: 496-1081

BEHAVIORAL AND SOCIAL SCIENCE

RESEARCH IN MENTAL RETARDATION

NATIONAL INSTITUTE OF CHILD HEALTH

AND HUMAN DEVELOPMENT

ANNOUNCEMENT

I. BACKGROUND INFORMATION

The National Institute of Child Health and Human Development (NICHD) carries a primary responsibility for the conduct and support of basic, clinical and applied biomedical, social, and behavioral research in mental retardation and related aspects of human development.

In the fulfillment of this mandate, the NICHD recognizes the critical role of behavioral and social sciences in the prevention and amelioration of mental retardation, delineation of causes and processes of dysfunction, and development of treatment modalities.

II. GOALS AND SCOPE

This announcement is intended to encourage the stimulation and expansion of research into social-environmental factors affecting behavior and development in the mentally retarded, the interactive effect of biologic and social forces on cognitive development and social competence and the effect of mental retardation on interpersonal relationships and attitudes.

In support of the development of research activities specified below, the NICHD has sought the advice and guidance of the scientific community through consultation and conferences on important issues and gaps in knowledge on the behavioral and social aspects of mental retardation. The areas selected for emphasis in encouraging research grant applications are:

A. Prevention of MR in Children from Psychosocially Disadvantaged Homes

The large majority of retarded persons have no demonstrable central nervous system damage and are heavily concentrated in subsegments of our most disadvantaged population. The families are generally characterized by low intelligence in mothers and siblings. Child-focussed strategies and other models for intervention have, thus far, proven only marginally successful in sustaining intellectual

This program is described in the Catalog of Federal Domestic Assistance Number 13.865. 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.

gains over time. Studies are needed to determine the processes and mechanisms within the family environment that depress intellectual development and impair adaptive behavior and how parents can be helped to become more effective agents for teaching and socialization in these children.

B. Impact on Development and Behavior of Recent Trends and Changes in Living Arrangements and Specific Settings for Retarded Persons

In view of the national commitment to integrate retarded persons into community life, it is essential that these programmatic efforts proceed from a sound, scientific base. To achieve this goal more satisfactorily than at present, studies are needed to determine:

1. The specific behavioral or personality traits or family and environmental variables and their interactions which can be used to predict successful community adjustment.
2. The impact of mainstreaming on the self-concepts, behavior patterns, coping skills and adjustment of retarded persons; the effect on teacher and parental attitudes and expectations; and the effect of stigma and labelling processes.
3. The effect of alternative patterns of community care (own homes, group care, apartment living, foster family homes, small group structures and variations in grouping arrangements) on the development and behavior of subgroups of retarded persons.
4. The degree to which opportunities are actually provided to subgroups of the retarded and the relationship of such "normalizing" experiences to subsequent behavior and development, family attitude, and community acceptance.

C. Intervention with Children at Biological Risk for Retardation

Children suffering from such complications of pregnancy as anoxia, premature pregnancy, or low birthweight, and in the absence of severe neurological damage, develop normally in average homes. However, such children when raised in seriously disadvantaged families are highly vulnerable to mental retardation, learning problems and other behavior disorders. Studies are needed to determine the effects of such conditions, including prolonged care in intensive care units, on parent-child interactions, cognitive and social development in these children and the kind of post-natal experiences that might prevent these adverse outcomes.

D. The Effect of Mental Retardation on Caretaking Behavior and Interpersonal Relationships

An increasing range of persons--single parents, foster parents, group home operators, apartment supervisors, ward attendants--

are involved in caretaking responsibility for retarded persons. There is limited information on how such caretakers perceive and interact with retarded persons, their motivations, desirable personality traits for caretaker roles and the effect of caretaker attitudes and behavior on development.

E. Development of Methodologies for Assessing the Effects of Social Environment on Cognitive and Social/Emotional Development of Retarded Children

Studies are needed on the nature of the processes that constitute cognitive development and dysfunction in retarded children and the social environmental factors which influence them. Work could include early and more predictive measures of cognition; language and social competence; improved methods for measuring mother-child interactions; information processing; learning strategies. Environmental factors could focus on parent-child dyads, family systems and social institutions.

F. The Impact of Teratogens on Behavior, Cognitions and Social Functioning

The extensive use and misuse of pharmaceutical drugs, chemical agents, and alcohol during pregnancy are known to have teratogenic effects on offspring, resulting in a variety of congenital malformations and physiologic abnormalities. However, such exposure in less severe form may result in intellectual and behavioral impairment without evidence of morphological change, as in cases of low lead levels. Studies are needed to identify teratogenic substances that can be related to depressed mental performance and disordered behavior.

G. The Role of Genetics in the Learning and Behavior of Persons with Specific Mental Retardation Syndromes

Knowledge about genetic influences in human intelligence and behavior is still inconclusive. Some forms of mental retardation which are manifested later in childhood have strong genetic components. There is also some evidence that certain types of learning disorders are associated with specific syndromes and chromosomal abnormalities. Elucidation of such gene-behavior relationships could have meaningful implications for the development of special education technologies.

III. MECHANISMS OF SUPPORT AND FUNDING

The support for this program will be the traditional NIH research project grant. Applicants are expected to plan and execute their own research programs. Support of grants, pursuant to this announcement, is contingent upon budget capabilities.

IV. REVIEW PROCEDURES AND CRITERIA

A. Application Review

Upon receipt, all applications will be assigned by the Division of Research Grants according to accepted Referral Guidelines to an Initial Review Group for scientific merit review and to an appropriate Institute or Division for final review by their National Advisory Council/Board.

B. Review Criteria

Applications must be relevant to the goals of this announcement. The factors considered in evaluating applications are:

1. Scientific merit of the research design, approaches, and methodology;
2. Adequacy of existing and proposed facilities and resources;
3. Qualifications and experiences of the principal investigator and proposed staff for the conduct of the proposed investigations;
4. Reasonableness of the budget and duration in relation to the proposed research;
5. Adequacy of time to be devoted by proposed project staff.

V. METHOD OF APPLYING

A. Application Procedure

Use the standard research grant application form PHS 398. If the institution's Business Office or Central Application Control Office does not have this form, a copy can be requested by writing to the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, or by calling (301) 496-7441.

Type the phrase "NICHD BEHAVIORAL AND SOCIAL SCIENCE RESEARCH IN MENTAL RETARDATION" on the face page of the application. Enclose a covering letter stating that the application is in response to this announcement. Send the NICHD a copy (see below).

Follow the instructions with the application form PHS 398, making sure that items noted in Section IV of this announcement are covered appropriately. Forward to:

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

Receipt dates for research grant applications in response to this announcement are no later than: March 1, July 1, and November 1.

VI. INQUIRIES AND CORRESPONDENCE

Inquiries and correspondence should be directed to:

Center for Research for Mothers
and Children
National Institute of Child Health
and Human Development
7910 Woodmont Avenue
Landow Building
Bethesda, Maryland 20205

BIOMEDICAL RESEARCH SUPPORT GRANT

DIVISION OF RESEARCH RESOURCES

ANNOUNCEMENT

The Biomedical Research Support Grant (BRSG) Program is specifically designed to complement other forms of biomedical research support. Its main thrust is to strengthen, balance, and stabilize public health-supported biomedical and behavioral research studies that develop new knowledge about fundamental processes related to health. A distinguishing feature of this program is that it provides opportunity for the grantee institution to exercise on-site judgment in decisions regarding emphasis and specific direction of their research activities. It enables institutions to respond quickly and effectively to new opportunities and unpredictable requirements, to enhance creativity, to encourage innovation, to provide for pilot studies and initial support of new investigators, and to improve research resources--both physical and human. Awards are used to support short-term, nonrecurring, low-cost or core resource support needs that are not feasibly or appropriately supported by other PHS grant programs.

Health professional schools; academic institutions other than health professional schools; hospitals; state and municipal health agencies; and non-profit non-academic research organizations that have received a minimum of three allowable PHS biomedical and/or health-related behavioral research grants, totaling \$200,000 (including direct and indirect costs), awarded during FY 1979 (October 1, 1978 through September 30, 1979) are eligible to apply for an FY 1980 BRSG. Federal institutions and institutions located in a foreign country are not eligible.

BRSG applications will be mailed on or about November 30 to all current BRSG grantees and to those institutions that appear to be eligible according to NIH/PHS records.

If an institution believes that it is eligible to apply for a BRSG and does not receive an application by December 10, please write or call:

Biomedical Research Support Program
Division of Research Resources
Office of Grants and Contracts Management
National Institutes of Health
Bethesda, Maryland 20205

Telephone: (301) 496-5131

EXTENSION OF DEADLINES FOR BIOPHARMACEUTICS

RFAs (HFD 79-3 and 79-4)

NOTICE

Vol. 8, No. 12, dated September 26, 1979, of the *NIH Guide for Grants and Contracts* included two FDA RFAs entitled "The Bioavailability and Pharmacokinetics of Oral Dosage Forms in Newborn and Infant Human Patients" on page 35 and "The Pharmacokinetics and Bioavailability of Drugs in Disease States" on page 39 with application receipt dates of November 15, 1979.

The deadlines for these two RFAs are hereby extended to December 15, 1979, to provide additional time for responses.