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

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HAVE YOU MOVED?

If your present address differs from that shown on the address label, please send your new address to: Room 2A14, 5333 Westbard Avenue, National Institutes of Health, Bethesda, Maryland 20014, and attach your address label to your letter. Prompt notice of your change of address will prevent your name being removed from our mailing list.

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

Supplements, printed on yellow paper, are published by the respective awarding units concerning new projects, solicitations of sources, and requests for proposals.

BIOMEDICAL RESEARCH DEVELOPMENT

GRANT PROGRAM

A N N O U N C E M E N T

The Division of Research Resources, National Institutes of Health, announces the establishment of the Biomedical Research Development Grant (BRDG) Program. This program is intended to help establish significant involvement in biomedical and/or behavioral research in new, small, and developing institutions that need a strong research milieu to help assure that manpower for basic biomedical or behavioral research, clinical research, or other health professional areas will be well trained. The BRDG Program is a subprogram of the Biomedical Research Support Grant (BRSG) Program. Up to 10 percent of the funds available for the BRSG Program may be allocated for this new program. It is expected that 12 to 15 new awards will be made each year and that the program will be highly competitive. Prospective grantees will be expected to have a commitment to increasing and sustaining their biomedical or behavioral research capability, and to offer strong potential for ultimate biomedical and/or behavioral research excellence as a result of research development initiated with BRDG support.

Eligibility is limited to nonprofit and not-for-profit institutions which, during the latest 12-month period ending September 30, have received less than \$200,000 (direct and indirect costs) in Public Health Service (PHS) research grants. Each individual campus of a multi-campus university is considered as a separate "institution." Similarly, each health professional school is likewise considered an "institution," even though it may be a component of a university. Institutions that receive other PHS research development grant support (e.g. the Minority Biomedical Support Program) are not eligible for these new BRDG awards.

Applications may request up to three years of support, with average funding of no more than \$100,000 per year. Support may be extended by competitive renewal, but support to one institution may not exceed a total of six years or \$600,000.

Eligible institutions may obtain a PHS research grant application kit (form PHS 398) from the Division of Research Grants, Westwood Building, National Institutes of Health, Bethesda, Maryland 20014. The instructions for completing this application form should be followed except where they are modified by special instructions for the BRDG application. Requests for these special instructions, BRDG Program General Policy and Information Statement, advice on the preparation of applications, and information about eligibility or other matters should be addressed to:

Biomedical Research Development Grant Program
Division of Research Resources
Room 4B04, Building 31
National Institutes of Health
Bethesda, Maryland 20014

Telephone: (301) 496-6743

SPECIALIZED CLINICAL RESEARCH CENTERS

FOR PERIODONTAL DISEASE

A N N O U N C E M E N T

Introduction The National Institute of Dental Research (NIDR) announces a national competition to establish a limited number of clinical research centers devoted to periodontal diseases. The objectives of the proposed centers are to accelerate the development of new knowledge for the prevention, diagnosis, and treatment of periodontal diseases by bringing resources, facilities, and manpower into focus on these problems in a concerted way. It is expected that the centers will capitalize on findings accrued from recent microbiologic, immunologic, and pharmacologic investigations. This is the announcement of the NIDR's intent to establish clinical research centers and describes guidelines for developing the applications.

Background Periodontal diseases are a group of inflammatory conditions affecting the tissues surrounding the roots of the teeth. It is estimated that 94 million Americans have some form of periodontal disease, and 32 million of these have advanced disease. With age, the disease becomes more severe in the individual and more prevalent in the population. Thus, periodontal disease, in its various forms, constitutes a major health problem of increasing concern in our society. The current treatment methods are difficult and results are uncertain. Furthermore, periodontal therapy costs the American public approximately \$1.5 billion each year even though only a fraction of the individuals requiring treatment actually receive it.

Objectives The broad objective of the clinical research center is to translate basic concepts, especially those of microbiology, immunobiology, and pharmacology, into clinical investigations of patients with periodontal disease. Even though the main thrust of the center research should be clinical, it is recognized that the proper study of human subjects may encompass a laboratory component. Animal studies may also be appropriate. Specifically, the center should develop programs to accomplish some or all of the following tasks:

1. Establish the causative organisms in periodontal diseases,
2. Clarify the host response to these causative organisms,
3. Perform clinical studies of therapeutic techniques and regimens,
4. Develop preventive measures.

Although the substance of the research program may vary according to the local expertise, interest, resources, and recruitment possibilities, a proposed center should develop projects which relate to the above.

Characteristics of a Clinical Research Center The sponsoring institution is expected to have an adequate base of research. It should provide resources and services to support established research in areas such as microbiology, immunology, and pharmacology and develop relevant clinical investigations toward the establishment of such a center. The clinical research center should be an identifiable organizational unit within an institution or among a group of institutions and the sponsoring institution should be willing to make a commitment of its resources and staff to insure the development, operation, and function of the proposed center.

Mechanism and Length of Support The mechanism of support will be the grant, but differs from the regular research project grant in its emphasis, objectives, and the degree of coordination by the National Institute of Dental Research. Centers may receive support for a period of five years, with continuation beyond this period dependent upon a competing renewal application. Renewal applications will be reviewed in competition with new applications, on an equal basis.

Relationship to NIDR The award of clinical research center grants will establish a special cooperative relationship between the NIDR and the grantee institution. To accomplish this, a program officer will be designated by the NIDR to work closely with the staff of the clinical research center. The program officer will make regular visits to each clinical center to discuss progress and to provide assistance. In addition to the review of annual progress reports, project site visits to each center will be conducted on an annual basis.

Administrative Items and Costs The clinical research center director should be a respected scientist able to provide both scientific and administrative leadership. The director will be responsible for the organization and operation of the center and for communication with the NIDR on scientific and operational matters. The research program for each clinical center will be guided by its own internal review board consisting jointly of staff members and other expert consultants not part of the clinical center program. This board will advise the clinical center director of its assessment of progress on current projects and conduct an initial review of new initiatives.

The center grant may include pilot projects as well as a cluster of interrelated regular projects. Funds may be utilized for central support services, equipment, supplies, renovations, consultation services, travel, and publication costs. Funds may also be utilized for professional, technical, and administrative personnel. However, each participating scientist will be expected, within three years of joining the center, to obtain independent research support from sources other than the center grant. In this way, the center may continue to provide support for other scientists who enter the center program. Support for research-related costs of patient involvement and medical care may be authorized. The program cannot provide funds for new construction. For this first competition for periodontal disease clinical research centers, the Institute will reserve funds to initiate one or two centers during FY 77. There will be a limited expansion of the centers program during the next few years. The expected range of support should be \$150,000 - \$200,000 for the first year with modest increases in subsequent years.

Review Criteria Consideration for an award will be based upon demonstrable evidence that the applicant institution can provide a combination of factors including:

1. Quality research in basic microbiology, immunology, and/or pharmacology;
2. Competent clinical investigators;
3. Meritorious scientific projects which relate to a common theme;
4. Appropriate patient populations;
5. Adequate outpatient clinical facilities for clinical research; and
6. A favorable environment for research training.

The applications will be reviewed by the Dental Research Institutes and Special Programs Advisory Committee (DRISPAC) of NIDR.

Letter of Intent In order to facilitate planning for the review of applications, a "letter of intent" should first be submitted by the sponsoring institution. The letter of intent must deal briefly with each area specified (3.a-i below) to be included in the formal application. Letter of intent should be addressed to: Chief, Periodontal Diseases Program Branch, Extramural Programs, National Institute of Dental Research, Room 519, Westwood Building, National Institutes of Health, Bethesda, Maryland 20014.

Application Process Applications should be prepared on form PHS 398, "Application for Research Grant," and should include:

1. A table of contents;
2. A complete, consolidated first-year budget for the entire center (summarizing sub-budgets for the component projects and cores);
3. Expanded material for each item listed below:
 - a. Rationale and justification for the center,
 - b. A description of intended projects,
 - c. A description of available laboratory facilities,
 - d. A description of ongoing basic or clinical research related to periodontal disease,
 - e. A description of available clinical facilities,

- f. Specific information on patient availability,
- g. Availability of a statistical and data analysis capability,
- h. The academic positions and major research interests of the program director and his immediate staff, and
- i. Collaborative possibilities with other research groups and delineation of the roles and manner of anticipated interaction.

Timetable for Review

- A. Letter of intent due January 1, 1977.
- B. Deadline for receipt of applications, February 15, 1977.
- C. The earliest beginning date for award of grants, August 1, 1977.

The original and six copies of the completed application should be mailed to the Division of Research Grants, National Institutes of Health, Bethesda, Maryland 20014. In addition, it will be helpful for informational purposes to send two copies under separate cover to the Chief, Periodontal Diseases Program Branch, Extramural Programs, National Institute of Dental Research, Room 519, Westwood Building, National Institutes of Health, Bethesda, Maryland 20014.

REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA

A N N O U N C E M E N T

TITLE: *DIABETES IN PREGNANCY: EFFECTS ON MOTHERS AND OFFSPRING*

INTRODUCTION The Center for Research for Mothers and Children (CRMC) of the National Institute of Child Health and Human Development (NICHD) invites applications for grants to study pregnancies associated with pre-diabetes mellitus, gestational diabetes, and overt diabetes of either the adult or youth-onset type and to study the offspring of diabetic pregnancies. There is particular interest in feeding patterns and developmental factors related to the later appearance of obesity and of diabetes in these genetically predisposed individuals.

SCIENTIFIC PROGRAM REQUIREMENTS The CRMC seeks studies aimed at but not limited to understanding the pathophysiologic mechanisms which contribute to abnormalities encountered in the pregnant diabetic and her offspring. Research is encouraged on detection of pre-diabetes in the female population of childbearing age. Functional definition of optimal diabetic control during pregnancy is needed as well as determination of the optimal time and method of delivery as related to maternal and fetal status, and to the infant's adaptation to extrauterine life and maintenance of homeostasis. Investigations are requested to explain the aberrations in embryogenesis associated with the intrauterine environment in diabetic pregnancies as well as studies focused on developing better techniques to detect fetal distress. Studies should be directed toward clarifying mechanisms responsible for congenital malformations, stillbirths, neonatal deaths, and perinatal complications. Areas of particular interest include developmental studies of intermediary metabolism and hormonal interactions in offspring of diabetic, gestational diabetic, and nondiabetic women. Also of interest are studies on the impact of prepregnancy diabetes and gestational diabetes on the morphology, function, and metabolism of the placenta and on uterine blood flow.

Prevention of diabetes mellitus in genetically predisposed children is also a major concern. Studies of childhood feeding patterns and the development of dietary habits, tastes, and appetite are relevant, as are searches for other presently unrecognized developmental antecedents of diabetes and obesity. The CRMC also seeks studies of infants and children born of diabetic women which emphasize their physiologic, anatomic, or developmental aberrations. Interest also exists in exploring the eventual effect of the diabetic intrauterine environment on growth and development of the offspring.

SIGNIFICANCE TO NICHD AND CRMC PROGRAM GOALS An important goal of the CRMC is to understand mechanisms underlying normal growth and development and their distortion by transient or chronic events such as disease or functional disorder in the mother or in the fetus. Maternal diabetes has had major effects on perinatal mortality, on the outcome of pregnancy, and on infant morbidity. This metabolic disorder may also influence dietary habits and somatic conditions which could result in obesity. Developing new knowledge

about the complex processes by which maternal disease or dysfunction may affect the long-term health of the mother, her reproductive ability, and the well-being of her offspring is a major concern of the Center for Research for Mothers and Children.

APPLICATION REQUIREMENTS

1. Eligibility Nonprofit organizations and institutions, State and local governments and their agencies, authorized Federal institutions, and individuals according to NIH grants policies.
2. The Application Applicants should propose an individual project. Applicants may elaborate on the purposes, objectives, rationale, and significance stated in this announcement and must complete portions of the application pertaining to procedural details, the investigator's related experience, facilities available, budgets, and biographical information for key professional personnel. The application should also state the duration of time for which the support is requested. It is anticipated that the initial period will not exceed three years but may be renewable.
3. Submission Use the standard research grant application form NIH 398. In both the covering letter and at the top of the space provided for an abstract on page 2 of the application, clearly identify the application as being in response to this announcement by using its title and date of publication.
4. Receipt Date Applications should be submitted to meet the deadline dates established by the Division of Research Grants, NIH, for new research project grant applications.

REVIEW Upon receipt, applications will be reviewed for responsiveness to this announcement by the Division of Research Grants (DRG) in consultation with the NICHD staff. Applications judged responsive will be reviewed initially for scientific merit by DRG study sections and secondly by the NACHHD Council. Applications judged not responsive will compete in the regular research grant program and will be assigned for administration to an appropriate Institute.

FUNDING Although this program is included and provided for in the financial plans for fiscal year 1977, award of grants is contingent upon ultimate allocation of appropriated funds for this purpose.

NOTE For further information, potential applicants may contact:

Dr. Joseph C. Hwang
Center for Research for Mothers and Children
National Institute of Child Health and
Human Development
Bethesda, Maryland 20014

Telephone: (301) 496-1485

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