# NIH GUIDE

## for GRANTS

### and CONTRACTS

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

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REQUEST FOR APPLICATIONS - NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Major research program grants to promote and support multidisciplinary research pertaining to the health of pregnant women, infants, and children in areas where knowledge gaps are not being sufficiently addressed by ongoing research or where there are needs to stimulate or intensify efforts in promising research areas 'ML \$ 1976

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

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.

#### REQUEST FOR RESEARCH GRANT APPLICATIONS: RFA ANNOUNCEMENT

TITLE: MAJOR RESEARCH PROGRAM GRANTS

INTRODUCTION The National Institute of Child Health and Human Development (NICHD), through the Center for Research for Mothers and Children (CRMC), invites program grant applications to develop new knowledge about diseases and disorders of pregnancy and of infants and children.

Major Research Program grants (MRP) will be used to promote and support multidisciplinary research efforts in areas where (a) knowledge gaps are not being sufficiently addressed by ongoing research, or (b) there are needs to stimulate or intensify efforts in promising research areas. Research areas for Major Research Program grants have been and will continue to be identified by CRMC with the help of outside advisors.

Major Research Program grants will be supported through the customary NIH grant-in-aid, and management of applications will be governed by the policies for program grants. Applications will be reviewed by the Maternal and Child Health Research Committee, CRMC, NICHD, and the National Advisory Child Health and Human Development Council. An on-site visit will be a part of the initial review. Applications will be evaluated on a continuing basis in accordance with established review schedules for initial review groups and the National Advisory Child Health and Human Development Council. A health scientist administrator in the CRMC will advise a prospective MRP applicant on the relevance of proposed concepts to the needs of the CRMC and the feasibility of an outlined program before a formal application is submitted.

BACKGROUND A major goal of the Center for Research for Mothers and Children is the prevention of diseases and disorders during pregnancy, infancy, and childhood. The complexity of the health problems which need to be addressed requires a variety of integrated, multidisciplinary approaches involving the behavioral and natural sciences in clinical and laboratory settings. Among several problems of major concern, one example is that of low birth weight infants; such infants are major contributors to the unnecessarily high infant mortality rate in the United States. Each year nearly a quarter million infants are born too soon, or too small for their gestational age; about 45 thousand of these babies die, but an even larger number sustain lifelong disabilities, including mental retardation. One in every four low birth weight infants is born to a teen-age mother. If we could ensure that all newborns were free of defects and mature enough to cope during the first month of life, much of this Nation's infant mortality and morbidity could be eliminated.

An associated concern of the CRMC is achieving an understanding of acute and chronic disabilities associated with the processes of human development, in order to find means of preventing these disabilities. There is increasing evidence that many of these problems have antecedents in uterine life. Also, social and behavioral contributions to problems of maternal and child health continue to be poorly understood.

RESEARCH SCOPE Areas of concern include, but are not necessarily limited to, the following:

#### A. Infants at Risk for Mortality and Morbidity

Areas for research could include diseases and disorders of pregnancy; normal and abnormal mechanisms determining the time and character of the onset of labor; and nutritional, social, and behavioral problems contributing to low birth weight and other high risk conditions in infants; problems of mortality and morbidity confronting the low birth weight infant before, during, and after birth; and developmental conditions contributing to the sudden infant death syndrome.

#### B. Birth Defects

Genetic, embryologic, pharmacologic, developmental, and social factors and mechanisms which contribute to birth defects and to disabling conditions in childhood and later life.

#### C. Disorders of Growth and Development

Studies of the impact of nutritional imbalances and excesses on child health and development, including immunologic competence, obesity, and the relationship of nutrition to disease in adult life; problems of excessive or retarded growth or of deviant growth rates; problems of the development of human communicative processes with special emphasis on dyslexia and related language dysfunctions and learning disorders; problems of adolescents including normal and abnormal sexual development and adaptation to adult status; impact of the chronic illness of one family member upon the other members of the family; and social and behavioral problems associated with each of the above.

#### D. Accidents and Poisonings

Biomedical, behavioral, and social studies aimed at identifying causes and developing means of preventing accidents and poisonings, presently the leading causes of death in children after the first year of life.

#### APPLICATION REQUIREMENTS

- A. <u>Eligibility</u> Nonprofit organizations and institutions, State and local governments and their agencies, and authorized Federal institutions.
- B. <u>Letter of Intent</u> Prospective applicants for MRP grants must first submit a brief letter indicating interest and including an outline of the proposed research program.

Applicants desiring the earliest possible action on a definitive application (see section D. below) should submit a letter of intent by August 1, 1976, to:

Dr. Jonathan T. Lanman
Director
Center for Research for Mothers
and Children
National Institute of Child Health
and Human Development
Room C-703, Landow Building
Bethesda, Maryland 20014

Enclosed with the Netter should be a succinct and informative outline of the proposed program.

A letter of intent is not binding. Its purpose is:

- 1. To assure that the prospective proposal falls within the scope of priorities defined by the CRMC as eligible for support under the MRP.
- 2. To avoid wasted effort by an applicant in preparing a definitive proposal inappropriate for support under the MRP.
- 3. To alert the CRMC of a potential application at an early stage of its development so that the CRMC can designate a Program Officer. The Program Officer will be a staff scientist assigned to work with the applicant with a view to developing the best and most appropriate request possible in order to meet the rather special requirements of the MRP.
- C. The Application After the CRMC has determined that a prospective application lies in an appropriate area for MRP support, the applicant should prepare a definitive application on research grant application Form NIH 398. The CRMC urges strongly that the application be developed in close cooperation with the Program Officer assigned by the CRMC.

Applications should be identified by typing in the words MAJOR RESEARCH PROGRAM GRANTS and the date of publication of the NIH Guide containing the official announcement of the MRP Program. This information should be put on page 2 of the application at the top of the space provided for an abstract.

In addition, a brief covering letter should accompany the application indicating in the same way that it is in response to this RFA. A copy of the covering letter should be sent to the Director, Center for Research for Mothers and Children, at the address given in section B. above.

MRP awards will be made initially for a period of not less than three years and no more than five years with option for renewal. An important consideration in making a renewal award will be substantive evidence, in the form of a plan, that the MRP will serve as a nucleus for growth of research activities which will be supported from other sources, both private and public.

The proposal for each component project of the MRP and for core support must include sufficient information to permit their evaluation independently and as contributing parts of a research program. Any core activities or equipment or centralized laboratories (i.e., those shared by several or all investigators) must be described to show how they will support the proposed research. Facilities must be available for the primary needs of the MRP and require no more than modest alteration and/or renovation. Funds for new construction are not available.

D. Receipt Date - Applications received on or before November 1, 1976, will be processed for review by the National Advisory Child Health and Human Development (NACHHD) Council in May 1977. Applications received after November 1, 1976, will be reviewed in order of receipt by the Council at its regularly scheduled meetings.

#### SPECIAL CONSIDERATIONS

- A. Responsibility of the MRP Director The MRP Director must be a scientist who can provide strong, effective administrative and scientific leadership. The Director will be responsible for the organization and operations of the MRP and for communication with the NICHD on all scientific and operational matters.
- Responsibilities of the CRMC The CRMC has a responsibility to maintain close and continuing contact with each MRP to assure that the program develops along lines compatible with the objectives of the original proposal and of the MRP. A Program Officer assigned to each MRP will afford whatever help or guidance is possible and appropriate in both scientific and administrative problems.

In addition, the research program of the MRP must be evaluated at the end of two years by a review panel consisting of NICHD staff members and consultants. This panel will advise the MRP director of its assessment of progress and will conduct an initial review of major changes in budget allocation and/or direction of effort. Informal staff reviews will be made at the end of the third and fourth years unless these are terminal years.

Responsibilities for Each MRP - Active collaboration between scientists working in an MRP-supported program is considered a necessity for an effective MRP. Each MRP should submit a plan, as part of the application, to assure the interaction of MRP staff members, so that all will be kept aware of progress and problems in achieving research objectives.

MRP awardees must operate within the workscope of the approved program, but they may pursue promising new leads through pilot studies. The initiation of such pilot studies must be approved by the Program Officer responsible for the MRP and his/her immediate superior.

D. Relationship among MRP's - It is a major goal of the NICHD to promote active collaboration among MRP's that are concerned with a particular health problem. To accomplish this goal, directors of MRP's with related scientific concerns will meet, when CRMC staff consider it advisable, to review progress, plan collaborative efforts, and discuss administrative problems. This meeting will be attended by key MRP and NICHD staff, representatives from the NICHD Maternal and Child Health Research Committee and other appropriate and selected investigators having mutual scientific interests.

#### METHOD AND CRITERIA FOR REVIEW

- A. Upon receipt, applications will be reviewed by the Division of Research Grants and NICHD staff for responsiveness to this announcement. Applications judged responsive will be reviewed by the Maternal and Child Health Research Committee and the NACHHD Council. Those applications judged not responsive will be returned to the applicant organization in care of the Principal Investigator.
- B. Review Criteria The factors to be considered in evaluating each MRP application are:
  - The pertinence of the proposed program to the goal of this CRMC effort.
  - The scientific merit of the research design, approaches and methodology.
  - The research experience and competence of the staff to carry out the proposed investigations.
  - Adequacy of time (effort) to be devoted to the project by investigators and technical staff.

- The adequacy of the organizational arrangements for scientific direction.

<u>FUNDING</u> 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 write to:

Dr. Jonathan T. Lanman
Director
Center for Research for Mothers and Children
National Institute of Child Health
and Human Development
Room C-703, Landow Building
Bethesda, Maryland 20014

or call Mr. Jehu Hunter, (301) 496-1877, Center for Research for Mothers and Children, NICHD.