NIH GUIDE

for GRANTS

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

Vol. 3, No. 13, September 3, 1974

RESEARCH GRANT SUPPORT IN THE AREA OF DIGESTIVE DISEASES

ANNOUNCEMENT

The National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD), a division of NIH, provides financial support for biomedical research on the cause, prevention, diagnosis, and treatment of diseases of the various hollow organs of the gastrointestinal tract and its accessory organs such as the exocrine pancreas, salivary glands and including the liver and biliary tract.

There is a sparsity of research effort in certain areas of the Digestive Diseases program; exocrine pancreatic disease, inflammatory bowel disease, diarrheal disease, and esophageal disease. Well-conceived research efforts in these areas, in both basic and clinical projects, are encouraged. The next deadline for applications is October 1, 1974.

All research grant proposals submitted to the NIAMDD are reviewed on a competitive basis by scientific merit review committees of the NIH and then by the National Arthritis, Metabolism, and Digestive Diseases Advisory Council. Applications for NIAMDD research grant support can be funded only if recommended for approval by the National Advisory Council.

Further information can be obtained from:

Digestive Diseases Program
National Institute of Arthritis,
Metabolism, and Digestive Diseases
National Institutes of Health
Bethesda, Maryland 20014

The GUIDE is published at irregular intervals to provide policy, program, 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 Institues of Health.

FETAL RESEARCH MORATORIUM



The following public notice, establishing a moratorium on certain types of fetal research, has been prepared for publication in the Federal Register. The Institutional Relations Branch (IRB), Division of Research Grants, National Institutes of Health, which is responsible for implementation of DHEW policy for the protection of human subjects, will be the focal point to assure consistency in the interpretation of the term "living human fetus" as it applies to any particular research project. Questions relating to this notice should be directed to: Dr. Donald T. Chalkley, Chief, Institutional Relations Branch, Division of Research Grants, National Institutes of Health, Bethesda, MD 20014. Phone: 301-496-7005

P.L. 93-348, "The National Research Act," became law on July 12, 1974. Title II of this act, which is concerned with the protection of human subjects, mandates the establishment of a "National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research."

Section 202(b) of Title II states:

"The Commission shall conduct an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research has been undertaken, and alternative means for achieving such purposes. The Commission shall, not later than the expiration of the 4-month period beginning on the first day of the first month that follows the date on which all the members of the Commission have taken office, recommend to the Secretary (of Health, Education, and Welfare) policies defining the circumstances (if any) under which such research may be conducted or supported."

Section 213 states:

"Until the Commission has made its recommendations to the Secretary pursuant to Section 202(b), the Secretary may not conduct or support research in the United States or abroad on a living human fetus, before or after the induced abortion of such fetus, unless such research is done for the purpose of assuring the survival of such fetus."

Thus, in compliance with Section 213, neither the Department of Health, Education, and Welfare nor any of its components may conduct directly or support through grant or contract any research on a living human fetus, unless such research is done for the purpose of assuring the survival of such fetus. Subject to the limitations of Section 213, this moratorium will remain in effect until the Secretary has determined that it should be lifted.

Each grantee and contractor whose present research project involves studies prohibited by Section 213 must discontinue such activities immediately and advise the awarding Agency of the Department of Health, Education, and Welfare how it proposes to comply with the moratorium. Each proposed plan for such compliance must be approved by the Agency head or his designee.

NIH ADDENDA TO PHS GRANTS POLICY STATEMENT (OS) 74-50,000



A number of questions from grantee institutions are arising concerning the new PHS Grants Policy Statement as parts of it are intended to apply specifically to NIH grants. The following is in answer to some of the inquiries:

Page 8 - Administrative Increases

For NIH grants where the project is located in an organizational component that receives an NIH General Research Support or an NIH Biomedical Sciences Support Grant, no supplemental funds will be provided by NIH for administrative increases which take effect during a current budget period. Requests for supplemental funds may be included in the application for continuation support.

Page 17 - Pre-award Costs

NIH defines "pre-award" as being before the new or competing renewal award. Therefore, NIH will continue to allow a grantee, at its own risk, to incur obligations and expenditures prior to the beginning date of a continuation award, if they are considered essential to the conduct of the research. The NIH awarding unit will allow reimbursement from the continuation grant when awarded, provided the items concerned are incorporated in the approved budget of the continuation grant and that, when required for restricted categories, prior approval was obtained.

Page 22 - NIH allows no indirect costs on Research Career Development Awards.

Page 28 - Termination for Cause

Termination for cause action is reserved to the Director, NIH, following recommendation of the awarding component.

Page 50-55 - Property Management Standards

For all grants whose <u>project period terminates</u> after July 1, 1974, NIH will not require submission of form NIH-1754 (Equipment Acquired with NIH Grant Funds).

Page 58 - Rebudgeting

- 1. The prior approval requirements do not apply to the General Research Support grants, except in the case of use of funds for motion picture production.
- On training grants, prior approval of the awarding unit is required for rebudgeting which increases or decreases the total amount budgeted for training stipends.
- 3. Alterations and renovation costs over \$1,000 require prior approval of the awarding component.

NIH MANPOWER REPORT



- 1. <u>PURPOSE</u> This issuance states the NIH's policy for submission of the Manpower Report form as a requirement for continued grant or contract support. It supersedes the announcement made in the NIH GUIDE, Vol.3, No.8, May 24, 1974.
- 2. <u>APPLICABILITY</u> This policy is applicable to all NIH grants which are completed by all principal investigators, program directors, or contractors for each separate research grant or contract submission.
- 3. <u>BACKGROUND</u> The report provides basic data needed for an annual assessment of the impact that NIH research support has on the Nation's biomedical and health-related manpower. It is used in the decision-making process related to National health programs and policies. Initially a special procedure was instituted to establish a useable data base for grants active as of June 30, 1973 (see NIH GUIDE Vol.2, No.9, November 23, 1973). Subsequently, the procedure for submission of the report was set forth as follows.
- 4. <u>PROCEDURE</u> The principal investigator or program director of an NIH research project, program project or center that is not in its terminal year will complete the report and return it with the Application for Continuation Grant forms submitted for the next period of committed support. The Manpower Report should be for the current budget period and must coincide with the period covered in the Summary Progress Report. Since submission of the report is required several months prior to the end of the current budget period, reasonable estimates for the remaining time will be satisfactory. Blank forms will be included in the application kit for continuation grants.

The principal investigator or program director of an NIH research project, program project, or center whose grant is in its terminal year—the last year of noncompeting support—will be supplied a copy of the Manpower Report form 30 days prior to the project end date and will return the completed form within 30 days after close of the terminal budget period. The report will cover the last budget period of the project.

NIH contractors will complete the Manpower Report for the current contract period and will submit it as part of the annual report. The requirement for submission of this report by all appropriate contractors has been a part of each contract as such contracts were renewed subsequent to September 1, 1973. Additional copies of blank forms may be obtained from the contracting NIH Institute or Division.

5. <u>EFFECTIVE DATE</u> This policy has been in effect for all research projects, program projects, center grants and contracts as of May 24, 1974.

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