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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

NATIONAL INSTITUTES OF HEALTH
BETHESDA, MD. 20014
AREA CODE 301 TEL: 656-4000

February 21, 1966

Dear Sir:

Proposed regulations for the Regional Medical Programs are being cleared for publication in the Federal Register. For 30 days after publication, suggestions and comments will be invited. Modifications in the proposed regulations could affect the final form of program guidelines. Therefore, in order to allow prospective applicants to go forward without delay in the development and organization of information which will be necessary for the submission of an application for planning funds, we are forwarding these tentative guidelines. We have taken this step in response to many requests.

The law provides for two types of grants--planning and operational. Guidelines for operational grants are not included. It is anticipated that planning grants and operational grants will overlap in many instances, and that concomitant applications might be submitted. Guidelines for operational grants will be forwarded as soon as they are completed.

Sincerely yours,

Robert Q. Marston, M. D.
Associate Director, NIH, and
Chief, Division of Regional Medical Programs

Enclosure

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
DIVISION OF REGIONAL MEDICAL PROGRAMS

TENTATIVE PROGRAM GUIDELINES

FOR PLANNING GRANTS

General Considerations

Title IX of the Public Health Service Act (P.L. 89-239), "Education, Research, Training, and Demonstrations in the Fields of Heart Disease, Cancer, Stroke, and Related Diseases," sets forth the purposes and requirements for grants made under this Title. The purposes are:

"(a) Through grants, to encourage and assist in the establishment of regional cooperative arrangements among medical schools, research institutions, and hospitals for research and training (including continuing education) and for related demonstrations of patient care in the fields of heart disease, cancer, stroke, and related diseases;

"(b) To afford to the medical profession and the medical institutions of the Nation, through such cooperative arrangements, the opportunity of making available to their patients the latest advances in the diagnosis and treatment of these diseases; and

"(c) By these means, to improve generally the health manpower and facilities available to the Nation, and to accomplish these ends without interfering with the patterns, or the methods of financing, of patient care or professional practice, or with the administration of hospitals, and in cooperation with practicing physicians, medical center officials, hospital administrators, and representatives from appropriate voluntary health agencies."

The requirements stated in the Act are further defined and interpreted in the regulations. The applicant for a planning grant for a Regional Medical Program as authorized and supported by Title IX must comply with the requirements of the law and regulations.

NOTE: DISCRIMINATION PROHIBITED--Title VI of the Civil Rights Act of 1964 states: "No person in the United States shall, on the ground of race, color or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." Therefore, the grant and award programs of the Public Health Service, like every program or activity receiving financial assistance from the Department of Health, Education, and Welfare, must be operated in compliance with this law.

The Division of Regional Medical Programs of the National Institutes of Health has developed these Program Guidelines to assist in the preparation of applications for planning grants and in the subsequent conduct of planning activities and feasibility studies supported by such grants. These guidelines are intended to cover most of the foreseeable questions and problems. However, in view of the anticipated wide variety of needs, problems, and opportunities in different regions of the Nation, it is expected that many unforeseen questions will arise. Discussions, conferences, and other communications with the Division are expected and encouraged.

Each Regional Medical Program should be initiated, planned, and developed by local cooperating agencies in accordance with local needs and opportunities, which are expected to vary widely in different regions. Achievement of the objectives of a Regional Medical Program requires that the planning and subsequent development encourage and support local cooperative efforts, jointly developed plans, and joint implementation of these plans.

The guidelines for the application for a planning grant are designed to provide appropriate planning flexibility. The applicant is encouraged to describe the background; participating institutions, organizations, and advisory groups, and their current and anticipated resources; the existing relevant activities and sources of support; and presently planned relationships, functions, responsibilities, and activities of each of the participants in the proposed Regional Medical Program.

A complete and fully informative application will facilitate and expedite the review of the application. When necessary in the judgment of staff or consultants, additional information or justification may be required, either by supplemental documents or by conferences and visits.

Specific Requirements

Application Form. The application must be submitted on the official form for planning grants for Regional Medical Programs and must be fully completed. If the form does not provide sufficient space, additional, properly identified pages should be attached.

Required Signatures. The application must be signed by the individual authorized to act for the applicant and to commit the applicant to comply fully with all of the obligations specified in the terms and conditions of the grant. The application must also be signed by the individual who will be responsible for the continuing coordination of activities to be supported by the grant and other related activities.

Eligible Applicants. The applicant may be a public or nonprofit private university, a medical school, a research institution, or other public or nonprofit private agency authorized to represent the component groups who propose to plan and operate a Regional Medical Program.

The applicant should describe the basis for his representation of the proposed region.

Participating Institutions and Organizations. The proposed cooperating institutions and organizations must be described, giving their nature, functions, program, size, facilities, staff size and composition, intended role in the cooperative program, and other relevant information.

Regional Advisory Group. The individual members of the Regional Advisory Group must be listed and identified with affiliations, where applicable. The advisory group must include practicing physicians, medical center officials, hospital administrators, representatives from appropriate medical societies, other health professions, voluntary health agencies, and representatives of other organizations, institutions, and agencies concerned with activities of the kind to be carried on under the program, and members of the public familiar with the need for the services provided under the program.

The Regional Advisory Group should participate in the planning program from the initial steps onward. It should be actively involved in the review and guidance and in the coordinated evaluation of the ongoing planning functions.

The Regional Advisory Group has an advisory responsibility to the entire Regional Medical Program including the participating institutions and organizations as well as the applicant. It should be particularly concerned with continuing review of the degree of relevance of the planning activities to the objectives of the Regional Medical Program and to the effectiveness of these activities in attaining the objective of improved patient care.

The Regional Advisory Groups should be constituted to encourage cooperation among the participating institutions and interested organizations. Individuals should be chosen who will provide a broad background of experience, attitudes, and knowledge to give continuing advice in formulating and carrying out the plan for the establishment and operation of the proposed Regional Medical Program. The projected functions of the advisory group, its planned methods of operation, and continuity of participation must also be given.

Region Defined. A region is defined as a geographic area which forms an economic and socially related region, taking into consideration such factors

as present and future population trends and patterns of growth; location and extent of transportation and communication facilities and systems; and presence and distribution of educational, medical, and health facilities and programs. The relationships to adjoining regions should be described including a report of communications with these regions. The extent of expected participation of the potential eligible institutions or organizations within the region must be described. The proposed region should be functionally coherent. It should follow, where appropriate, existing relationships among institutions and existing patterns of patient referral and continuing education. It should encompass a sufficient population base for effective planning and use of expensive and complex diagnostic and treatment techniques. The clearer definition of the region and its relationships to adjacent regions should emerge from the planning process, which may modify the originally conceived region.

Feasibility Studies. The purpose of feasibility studies under planning grants is to allow the applicant to undertake such activities as gathering data to determine practicability of an idea or proposed cooperative relationships; exploring approaches to determine whether it is desirable to incorporate them in the program; and evaluating factors which may limit sound operational program development. Feasibility studies will not be supported which are in effect premature components of an operational grant. They are to be distinguished from pilot projects supportable under operational grants. A pilot project initiates the operational phase of a regional medical program. Feasibility studies under these planning grants must be related clearly to the planning function.

Plans for Interrelationships Among Research, Education, and Diagnosis and Treatment. The application should reflect the emphasis given to the functional interrelationships among medical research, education, and improved patient care.

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Preventative*

An application for a regional medical program planning grant must include specific aspects concerning the program-related education and training of health personnel. Continuing education should receive particular emphasis as an integral part of the total regional medical program. Meritorious programs of continuing education presented in the absence of, or unrelated to, plans for a sound regional program cannot be supported by grants under this program. Therefore, the relationship of continuing education to other aspects of a proposed planning activity must be described.

The application for a planning grant should also include a discussion of the proposed relationship of ongoing research activities in the fields of heart disease, cancer, stroke, or related diseases to the other proposed activities under the regional medical program. This discussion should describe such research activities, present or proposed, the sources of support or proposed sources of support, and how the applicant intends to approach the need to maintain an effective interaction between ongoing research activities and other aspects of a regional medical program so

as to assure that the activities specifically directed toward the goal of improved diagnosis and treatment may receive the benefits of future research advances. *T. Howell*

Program Evaluation. The application should include a statement of how the applicant plans to incorporate into the planning activity a continuing evaluation process.

Budget. Each category of proposed expenditure must be fully justified. The justification should indicate the relationship of the categories of expense to the proposed planning activities. Proposed personnel positions should be listed and the functions of these positions described in the detail necessary to indicate the need for the positions in the planning activity. When available, list the names of individuals already identified for a particular position at the time of application.

Funds requested for support of contracts and consultant services should be fully justified in terms of the descriptions of types of activities, the necessity or desirability for the use of contracts and consultants rather than the direct employment of personnel under the grant, and identity of proposed contractors and consultants if known at the time of application. Methods for maintaining fiscal accountability by the applicant must be clearly indicated, both for funds expended by the applicant and in those programs where funds are separately expended by several participating institutions or organizations.

The initial planning grants may be for any period up to June 30, 1969. The period of time during which grant support is requested and the projected phasing of planning program expenditures should be indicated.

Progress Reports. A grantee supported by a regional medical program planning grant is required to submit an annual progress report. The report should contain sufficient detail to inform the reader of the planning accomplishment with particular respect to the objectives originally set forth. In addition, grantees are encouraged to report significant developments promptly at any time and may be required to supply other information needed for the guidance and development of the national program.

Comprehensive Description. The purpose of the final section of the application form is to provide all the information required by law and regulations as presented in the program guidelines for Regional Medical Programs, including a comprehensive statement of the background, nature, present status, objectives and plans for further development of the proposed regional medical program. This section should present the concepts, rationale, current commitments of the participants in the joint

activity, probable roles of each of the participants in the cooperative program, expected administrative structure, and plans for effective communications among the participants. Relationships to other Federal and nonfederal grants for planning, research, training, health services, or facilities should be described. This information will provide the basis for the initial review of the application and for subsequent review and recommendation to the Surgeon General by the National Advisory Council on Regional Medical Programs. The applicant should discuss the proposed activity as an interrelated functional whole with especial reference to aspects expected to lead to improved patient care through continuing education programs and similar educational efforts. The application should also present an estimate of the expected eventual effects of the Regional Medical Program for which the planning grant is sought.

ADDITIONAL SPECIFIC INFORMATION NEEDED FOR APPLICATION FORM

The application form for Regional Medical Program planning grants is in preparation and will be distributed as soon as available. The application will require the following specific items of information in addition to the descriptive material required by the program guidelines:

Title of proposal;

Dollar amount requested;

Period of time requested;

Name, title, address and other relevant data of person to be responsible for coordination of the planning program;

Name, address and type of applicant;

Name, title and address of official to whom checks should be mailed;

Names and addresses of anticipated component institutions and organizations;

Definition of proposed region in terms of geographic boundaries, governmental units included, and population characteristics;

Names, titles and addresses of advisory group;

Complete budget data presented in terms of funds requested for personnel (by individual positions), consultant services, movable equipment, supplies, travel, publication costs, and other items needed by the proposed planning activity; and

The support available and expected for support of the proposed planning activity from PHS, other Federal agencies, and nonfederal agencies.