NIH GUIDE for GRANTS and CONTRACTS

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

No. 14, November 29, 1971

MANAGEMENT OF AND ACCOUNTABILITY FOR EQUIPMENT ACQUIRED UNDER NIH GRANTS (NIH 5602)

ANNOUNCEMENT

The effective date of NIH Guide for Grants and Contracts Issuance No. 9, pages 1 through 6, July 29, 1971, subject as above, is changed from July 1, 1971 to July 1, 1972.

Consequently, submission of NIH Forms 1754, Equipment Acquired with NIH Grant Funds - Accountability and Disposition, will not be required until after July 1, 1972.

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 programs administered by the National Institutes of Health.

Reporting of Inventions Supported by Research Career Awards, Research Career Development Awards, and Research Training Grants

PROCEDURE NOTICE

1. Applicants for continuation or renewal support of NIH research career awards, (Form PHS 2557-2), research career development awards, (Form PHS 2557-2), and research training grants, (Form PHS 2499-2) need no longer submit the Annual Inventions Statement (PHS 3945). Until such time as the proper application forms are revised, the following certification is being stamped on the first page of each application form:

"Inventions (See Special Instruction)
A. ☐ NO B. ☐ YES - Not previously reported
C. ☐ YES - Previously reported"

2. Each applicant should check the appropriate box. If the answer is "No," this entry on the official, signed application constitutes a certification that no inventions were conceived or first actually reduced to practice during the course of the work under this project. If the answer is "Yes," and the inventions were not previously reported to the Department of Health, Education, and Welfare, list the titles of all such inventions, and the names of inventors on a separate sheet and submit with the application.

3. All references to the requirement for Annual Invention Statements in instructions for completing application forms should be disregarded and the procedures outlined herein should be followed.

4. This procedure does not preclude the requirement for timely submission of OS Form 489, Final Invention Statement, at the close of the project period.

Sources Sought for Epidemiological Studies of Cancer

ANNOUNCEMENT

The National Cancer Institute (NCI), National Institutes of Health, is seeking research and development sources qualified to design, carry out, and analyze epidemiological studies on U.S. Blacks and Spanish Americans relevant to their special risks for cancer of the large bowel. The incidence of this disease in Blacks was once only about 60 percent of that of Whites but now has risen above white rates in some population groups. It is expected that rates in the Spanish American population are undergoing the same shifts. Contracts are contemplated to determine the relation of dietary and other environmental factors to this changing risk and to test hypotheses about specific causal factors. Contractors will be expected to be responsible for the study design and creation and validation of the questionnaires, taking into account priority items furnished by NCI staff. Information submitted must be pertinent and specific for the following: (1) Experience: submit evidence of ability to handle project including outline of work previously performed; (2) Personnel: Name, professional qualifications, and specific experience of scientists and technical personnel who would be assigned to the project; (3) Facilities: Population sources, (size, characteristics, suitability) cooperating groups, data processing capabilities; (4) Existence of pretested questionnaires and/or other resources that might speed the multiple OMB clearances required for development and use of governmental questionnaires; types of information that could and would be gathered. In case of collaborative efforts the information to be furnished shall include evidence that agreement has been reached to make available the necessary personnel or facilities. This synopsis is not a request for proposal and responses shall not state any proposed pricing but should indicate conceptual design thinking. Only those sources deemed fully qualified for the specific requirement under consideration will be invited to submit proposals when Requests for Proposals are issued.

Ten copies of resumés of experience and capabilities must be submitted to Mr. George Brandner, Chief, Research Contracts Branch, Office of the Director, National Cancer Institute, National Institutes of Health, Bldg. 31, Room 10-A-11, Bethesda, MD 20014, so as to be received no later than the close of business, 5:00 p.m. local time at the place designated for receipt of resumés, December 15, 1971. Telephone inquiries will not be honored and all inquiries must be directed to the office listed above.

SOURCES SOUGHT FOR PREPARATION OF VITAMIN D METABOLITES

ANNOUNCEMENT

The National Institute of Arthritis and Metabolic Diseases (NIAMD) is interested in organizations having a capability and interest in the preparation and assay of non-commercially available vitamin D analogs and metabolites. Of immediate interest is the compound, 1,25 - dihydroxy cholecalciferol (1,25 - DHCC). Other analogs and metabolites of vitamin D may be within the scope of future interest. Resumes are invited from organizations having the above capabilities.

Resumes should contain information which will: 1) establish the organization's qualifications, experience and achievements in the area, 2) provide background on personnel available for the project, 3) describe equipment and facilities available for the project, 4) outline the approach to be used for preparation of 1,25 - DHCC.

It is emphasized that expression of interest must relate to this specific project. Compilation of organizational reports, C.V.'s, and general expression of capabilities will not suffice.

This synopsis is not a request for a proposal. Only those sources deemed fully qualified for this project will be considered when requests for proposals are solicited. The decision to request proposals for the conduct of the project will be based on evaluation by NIAMD staff and consultants of the responding organization's prior experience in this field and the feasibility of their outlined approaches. Other respondents will not be notified of the results of the evaluation. Five copies of the resume of experience and capabilities should be submitted to:

Contract Officer
National Institute of Arthritis
and Metabolic Diseases
Building 31, Room 10A52
National Institutes of Health
Bethesda, Maryland 20014

before close of business, no later than 15 days from date of this publication.

Collaborative (Contract) Blood Resource Programs, National Heart and Lung Institute

The National Blood Resource Branch supports contract research in blood banking systems, thrombosis and hemorrhagic disease, and sickle cell disease. In addition, the clinical evaluation of promising drugs and treatments is occasionally undertaken by the Branch as a direct operation. In the blood banking area the Branch has supported studies of the feasibility of automated systems for tracking blood inventory and distribution in large metropolitan areas. Other work is aimed at improving the technology of blood fractionation, prolonging the storage period of blood and blood components, and eliminating safety hazards in blood transfusion, particularly the transmission of hepatitis. Recently, in recognition of the fragmented nature of the nation's blood industry, the Branch has initiated a management study which is intended to identify and describe the key operational aspects of blood banking in this country.

Thrombosis is a major public health problem and hemorrhagic diseases place great demand on the nation's blood supply. Since thrombotic and hemorrhagic processes often are an inseparable tandem, the National Blood Resource Branch supports and conducts research in both areas. Current research in thrombosis includes clinical trials of thrombolytic (clot dissolving) agents in pulmonary embolism and acute myocardial infarction, studies in the epidemiology of venous thrombosis and in the standardization of tests to detect venous thrombosis. Studies of agents which may prevent thrombosis are envisioned. Work on hemorrhagic processes centers on hemophilia. Current research is aimed at standardizing the cryoprecipitate method of extracting clotting factor VIII from blood and at improving methods of obtaining high-purity factor VIII in high yield. Clinical studies are envisioned to assess the value of prophylactic treatment and self-treatment with factor VIII.

Present studies in sickle cell disease are designed to evaluate several regimens in the treatment of painful sickle "crisis." Support will be forthcoming for more fundamental studies of the sickle cell and of the pathophysiological events surrounding the sickle "crisis."

Collaborative (Contract) Myocardial Infarction Programs, National Heart and Lung Institute

The objectives of the Myocardial Infarction Program are the planning and support of research leading to a reduction of death or disability from acute myocardial infarction, chronic coronary heart disease, and sudden cardiac death. It includes investigations on disease detection, pathophysiological mechanism, and prophylactic, acute, and rehabilitative therapy.

The Program was established in 1966. In 1967 five large, clinically focused, multidisciplinary groups were established for a comprehensive investiation of the pathophysiology and therapy of acute myocardial infarction. There are now nine such Myocardial Infarction Research Units. They use certain protocols in common, but the bulk of their research represents individual projects. Relevant fundamental studies support the clinical investigations. Techniques for clinical investigation are being developed in these MI Research Units; in addition, in response to a separate solicitation, techniques are being developed for quantifying the extent of ischemic or infarcted myocardium suitable for clinical use.

A program of research on sudden cardiac death was initiated in 1970 and expanded in 1971. Four groups are working on the comprehensive, clinical-pathological correlation of sudden cardiac death. Five groups are investigating the early therapy of patients with suspected myocardial infarction, using atropine and/or lidocaine. About a dozen additional projects attack a variety of topics directly or fundamentally related to sudden cardiac death. The goals of these studies collectively include the development of methods for identifying those chronically at high risk, the recognition of better premonitory warning signs, the elucidation of possible precipitating factors and pathophysiological processes, and the development and assessment of very early therapy of acute myocardial infarction and of chronic prophylactic therapy.

Research on chronic coronary heart disease will encompass the development and assessment of pharmacological, surgical, and other techniques for the prevention of acute coronary heart disease and/or the amelioration of symptomatic chronic heart disease.

Physiological and biochemical processes fundamental to new therapeutic methods are under investigation. The present six projects focus upon characterizing these processes in ischemic myocardium and designing interventions to prevent the progression of ischemic to irreversible damage. Future topics might include investigation of myocardial scar formation, the fundamental problems of arrhythmias associated with coronary heart disease, non-occlusive pathophysiological mechanisms, and the comparison of the pathophysiology and therapeutic response of atherosclerotic and non-atherosclerotic animals.

Special programs have included the support of a symposium of research on myocardial infarction; future symposia on broad and narrow topics are planned. In addition, the development of large-scale data bases on myocardial infarction are contemplated.

COLLABORATIVE (CONTRACT) CLINICAL APPLICATIONS PROGRAMS, NATIONAL HEART AND LUNG INSTITUTE

The Clinical Applications Program undertakes research into the etiological factors relating to cardiovascular and respiratory diseases in general population groups and evaluates the therapeutic effectiveness of new drugs, products, or measures which may have promise for the prevention or treatment of cardiovascular and respiratory diseases. It conducts or cooperates in clinical trials or controlled therapeutic evaluations of new agents or measures for the prevention or treatment of cardiovascular and respiratory diseases; and following confirmation of effectiveness, develops and demonstrates special techniques for preventive or therapeutic applications.

The Clinical Applications Program utilizes grants, contracts, P.L. 480 counterpart currency, and direct funds to support its activities. Three major segments comprise the program: the Epidemiology Branch, the Therapeutic Evaluations Branch, and the Biometrics Research Branch.

The Epidemiology Branch conducts a coordinated research program (U.S. and foreign population studies) to identify etiological factors which determine the rates of cardiovascular, cerebrovascular, and obstructive pulmonary disease in natural populations; and conducts such field investigations into the frequency, geographic distribution, and other demographic characteristics of such diseases as may be necessary to evaluate relative significance of factors affecting the incidence and prognosis of particular cardiovascular and pulmonary diseases. Such investigations have been conducted by the branch for many years in Framingham, Mass., and in Honolulu, Hawaii, as direct operations, and in Puerto Rico, Israel, Yugoslavia, and Japan through other funding mechanisms.

The Therapeutic Evaluations Branch serves as a focal point for the evaluation of new diagnostic techniques, therapeutic measures, new drugs, and/or new devices which have potential importance for the prevention or treatment of cardiovascular disease; implements operational clinical trials which require cooperative efforts of multiple centers; provides a final testing area for drugs, agents, or devices which have passed through the preliminary evaluation procedures and warrant definite testing in large-scale clinical trials; and develops and demonstrates special techniques for application of new measures for the prevention or treatment of cardiovascular disease. Studies supported by this branch include the Hypertension Clinical Trials, a coordinated program for the detection and follow-up of hypertensive persons in the population at large, in an effort to determine the degree to which morbidity and mortality from hypertension can be reduced under special regimens of management by anti-hypertensive drugs; and the Coronary Drug Project, a coordinated program designed to determine whether or not drugs which reduce the levels of cholesterol and other blood lipids will improve the survival rate of men who have coronary heart disease.

The Biometrics Research Branch provides a central resource for statistical consultation and other biometrical assistance to all segments of the National Heart and Lung Institute; in collaboration with the Epidemiology and Therapeutic Evaluations Branches initiates studies of the statistical role of various biologic factors in the incidence of and mortality from cardiovascular and respiratory diseases, and undertakes responsibility for collection and analysis of data from such studies; collaborates with intramural and extramural scientists in the design and analysis of laboratory experiments, clinical investigations, and field studies; and conducts theoretical investigations leading to new biometric methods of use in medical research.

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CUMULATIVE CONTENTS

Assoc. Dir. for Extramural Research and Training
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Bethesda, Maryland 20014

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