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NIH GUIDE for GRANTS and CONTRACTS

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

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DISTRIBUTION OF NIH GUIDE FOR GRANTS AND CONTRACTS

ANNOUNCEMENT

The *NIH GUIDE FOR GRANTS AND CONTRACTS* was initiated in April, 1971, to increase the opportunities for the biomedical research community to learn about contractual activities conducted by NIH. Although the mailing lists for the *GUIDE* include about 5,000 names, many investigators do not see it and are unaware of NIH contract-supported activities.

The purpose of this announcement is twofold: First, to expand the mailing list for general issuances of the *GUIDE*, which describe program announcements and policy matters for both grants and contracts; and secondly, to identify investigators who would be interested in receiving announcements of contractual projects as they are developed. These project announcements, prepared and issued individually by the component Institutes and Divisions of NIH, are published as "sources sought" synopses or announcements of the availability of "requests for proposals" as supplements to the *GUIDE*. The mailing lists for these announcements should be more specialized than those for the general *GUIDE* issuances because they will relate to specific disciplines and areas of research.

We are therefore publishing in this issue of the *GUIDE* revised descriptions of research programs of NIH which use contracts as the method of support of research or for provision of research services, reagents, etc., or for developmental activities. Please use the tear sheet (p.35) to provide necessary information for both general and special mailing lists for distribution of the *GUIDE* and its supplements. It may be replicated by xerography or any other method available and distributed to the research personnel in your institution. Please be selective in your requests. For example, only deans, vice-presidents for research, and administrative personnel responsible for sponsored research should request both the regular *GUIDE* and all supplemental issues. We would expect that individual investigators will limit their choices to selected programs within their areas of interest. Please complete the tear sheet even though the GUIDE or SUPPLEMENTS may have been requested in recent months.

Your cooperation and any suggestions for further improvements in this service will be appreciated.

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 Institutes of Health.

HANDBOOK ON THE RESEARCH CONTRACTING PROCESS — ANNOUNCEMENT

1. The Office of Contracts and Grants has issued a handbook furnishing information on the initiation, award and administration of research contracts supported by the National Institutes of Health.

2. Entitled *A Guide to the NIH Research Contracting Process,* the handbook provides general guidance to assist potential contractors and the scientific community in obtaining an overall picture of the NIH contracts program.

3. Copies of the handbook are available to interested institutions and may be obtained upon request addressed to the Director, Office of Contracts and Grants, National Institutes of Health, Bethesda, Maryland 20014.

NIH Biomedical Research Contracts (NIH 6000-3-60.4)

POLICY

1. *PURPOSE AND APPLICABILITY* This issuance states the policy concerning the selection and use of the contract mechanism for the support of biomedical research by the National Institutes of Health.

2. *BACKGROUND* In addition to support of research and research training through the grants mechanism, with which the biomedical research community is well acquainted, NIH accomplishes its several missions through work conducted in its own facilities and support of mission-related activities in other institutions, Federal and non-Federal. Work supported in other Federal laboratories is arranged by interagency agreements and appropriate transfer of funds. This represents only a small fraction of funds available for contracts, but is nevertheless significant in that it makes available the talents and expertise existent in other Governmental laboratories. The major part of contractual activities are conducted in universities, research foundations, and commercial and industrial organizations across the Nation.

Contracts are identified in NIH reports as "collaborative research and development." This is because NIH seeks collaboration with other organizations and fosters collaboration among a number of other institutions to accomplish certain research goals.

3. *BASIC CRITERIA* Contracts are used for support of research and development when one or more of the following considerations obtain:

a. the awarding Institute or Division has identified a need for certain research work to accomplish its mission and has determined that the work must be done outside its own facilities and the initiative for undertaking the activity originates primarily within the awarding unit (Institute or Division) of NIH;

b. the objective is the acquisition of a specified service or end product;

c. the collaboration of a number of institutions must be obtained, and work must be coordinated or carried on in a comparable manner by all of these so that the data collected can be combined for statistical analysis; or

d. the NIH awarding unit participates to the degree necessary to accomplish its mission in the direction and control over the manner of performance or timing of the work.

4. *COROLLARY CRITERIA* used to define the contract as the preferred instrument of support may be:

a. there is in addition a requirement for extensive participation by the staff of the awarding unit in the program design, direction, methodology, and evaluation;

b. a need to capitalize immediately on information through directed initiation or changes in particular research and developmental projects.

5. *MANDATORY USE OF CONTRACTS* When awards are made to commercial or industrial profit-making corporations, or when payment of an amount in excess of actual costs (i.e., profit or fee) is intended, the use of the contract as the instrument of support is required.

6. *SELECTION OF CONTRACTORS* It is the policy of NIH to advertise its requirements for research and development contract projects as widely as possible. Participation in such projects is sought from all segments of the biomedical scientific research community and from engineering development organizations, where the expertise for the performance of specialized work may reside. Such advertising is conducted through the medium of *COMMERCE BUSINESS DAILY*[1/] and notices in general or specialized scientific journals. It is also the policy of NIH to encourage possible contractors to submit statements of competence and interest in regard to contract programs which will be announced in general terms, henceforth, in this publication. Such statements will serve as the basis for the compilation of lists of "sources." These sources may be requested directly to submit proposals on individual projects as they are developed within a specific program.

NIH policy is to assure that awards of contracts are based on scientific and technical ability and judgment, availability of facilities, and other such factors as displayed in the contract proposal, as well as on price. Scientific review of proposals is conducted by advisory panels including non-NIH members from the scientific community. Contracts proposed for award by such bodies receive further review by a senior staff group of the awarding unit.

7. *DESCRIPTIONS OF THE COLLABORATIVE PROGRAMS* of the NIH awarding units appear in this issue of the *NIH GUIDE FOR GRANTS AND CONTRACTS*. It will be the policy of NIH to assure that all new collaborative programs are announced in this manner, as well as through other media. The *GUIDE* also will provide information on the contract programs of the NIH awarding units as well as furnish information on procedural and administrative policy matters.

8. *RESCISSION* This statement supersedes *GUIDE* No. 6, Vol. 1, April 26, 1971.

1/ *COMMERCE BUSINESS DAILY* available on an annual subscription rate of $40 plus an additional $30.25 for airmail service. To order, send remittance plus full mailing address to: Superintendent of Documents, Government Printing Office, Washington, D. C. 20402.

References

(1) DHEW Grants Administration Manual, Chapter 1-10, Considerations in Selecting Award Instrument--Contract or Grant.
(2) Office of Management and Budget Circular A-101, January 9, 1971.

COLLABORATIVE (CONTRACT) ACTIVITIES OF THE NATIONAL CANCER INSTITUTE

This issuance provides a summary of programs in treatment, in cause and prevention, and in diagnosis and cancer biology currently conducted by the National Cancer Institute (NCI). The contract mechanism is used as at least a partial means of pursuing the objectives of each of the programs described below.

CANCER TREATMENT

The objective of the Division of Cancer Treatment is the development of drugs which singly or in combination with other drugs or modalities are efficacious in producing complete remissions of clinical cancer at safe and tolerable dosages, and in extending the disease-free interval so that the patients' life expectancy approaches or equals that of the normal comparable populations. This program is implemented in laboratories and clinics in Bethesda, Baltimore, Washington, and Kampala, Uganda, by NCI scientists and at universities, commercial organizations, and other institutions under contract agreements with the NCI.

The Division of Cancer Treatment had its beginning as the Chemotherapy Program in 1955 with the establishment of the Cancer Chemotherapy National Service Center. In 1965, a thorough study of the previous 10 years' experience in drug development was undertaken and, as a result of that study, a linear array was developed and the logical steps from drug acquisition through screening to clinical trials were outlined. The program was then reorganized into three major segments along the lines of the linear array.

The first of these major segments is the Drug Research and Development area which is responsible for the input of chemical compounds and natural products for screening, drug formulation, and for drug scheduling studies. The second segment is Experimental Therapeutics where toxicology and pharmacologic disposition of drugs are studied. Those compounds that pass these first two segments successfully then undergo clinical trials in man in the Medical Oncology area of the program, either in the Clinical Center or in clinical resources under contract. In addition, the Cancer Therapy Evaluation Branch of the Division implements and monitors a comprehensive therapy clinical contract program designed to provide for clinical trials of anti-cancer drugs and studies of combined modality therapy. This unit is also responsible for the communication and filing of all information required by the Food and Drug Administration in connection with the drug development program of the Division of Cancer Treatment.

Clinically active, safe drugs eventually are cleared by the FDA and become commercially available for use by practicing physicians for the control of cancer. There are now 40 anti-tumor drugs which have either been licensed or are in clinical trial. There are currently ten types of cancer in which treatment with drugs, either singly or in combination with other drugs or with radiation or surgery may result in life expectancy approaching the normal for a comparable group in significant numbers of patients. These cancers are the more rapidly growing types but many of the drugs are effective in inducing impressive tumor regressions in the more slowly growing cancer.

The strategy for the future includes studies attempting to explain the differences between rapidly growing and slowly growing tumors, and perfection of animal models for slowly growing tumors; the continuation of a broad screening operation involving chemicals and natural products obtained through developments in university

laboratories, industry, and other institutions in this country and abroad as well as those selected on the basis of biochemical or biological rationales; in vitro biochemical screens as well as the use of slowly and rapidly growing animal tumor models to select the best drugs, schedules, and combinations; increased toxicologic and pharmacologic studies in animals and man; and the organization of clinical trials to study each new agent in representative rapidly and slowly growing tumors. Clinical trials of drug combinations and combinations of drugs with other modalities including surgery, radiotherapy, and immunotherapy are also sponsored. Finally, there are extensive basic and clinical studies of the biology of cancer, and of the supportive care of patients, particularly those at high risk to infection as a consequence of cytotoxic therapy. This includes studies of granulocyte transfusions, bone marrow transplants, and laminar flow protected environments. For further information write Assoc. Director for Program, DCT, National Cancer Institute, Bethesda, Md. 20014.

CANCER CONTROL

The Cancer Control Program (CCP) was established as an integral part of the National Cancer Program under the National Cancer Act of 1971. With contracts to a wide variety of public and private organizations, CCP supports activities designed to reduce cancer incidence, mortality and disability through more effective application of knowledge about cancer, particularly new research findings. Examples of CCP-supported activities include demonstrations to health professionals and/or the general public of the nature and value of new methods of cancer control that are ready for wide application; activities to stimulate broader acceptance of existing and/or new knowledge, methods and techniques which are not in general use; improvements in the primary (undergraduate) education of selected allied health professionals in cancer-related subjects and skills; education of the cancer patient and/or his family in cancer-related skills; education of the general public relative to cancer; continuing education for health professionals; and graduate education for selected allied health professionals. CCP generally does not support laboratory or clinical research or field-testing. Contractors are encouraged, however, to pursue meritorious research opportunities which may develop in the course of cancer control projects, provided the research does not interfere with the cancer control projects themselves and does not result in significant increases in costs to CCP. CCP can provide full support for research expected to lead to improved application of cancer-related knowledge in medicine and public health. Examples would include research on motivation to participate in cancer detection programs or research on more effective ways to deliver rehabilitation services.

CCP conducts most of its activities through competitive contracts. Projects are advertised in Commerce Business Daily and other publications. Existing or proposed Cancer Centers are encouraged to compete for advertised CCP projects.

Comprehensive or Specialized Cancer Center grantees or applicants may also apply for noncompetitive CCP contract funds, to expand their cancer control activities beyond usual levels, in accordance with these guidelines:

A. The cancer control work must constitute an integral part of the Center's framework of activity
B. It must be administratively and scientifically compatible with the Center's principal objectives
C. It must derive its basic support from the facilities and personnel funded under the Cancer Center Support Grant
D. It must be directed specifically toward cancer control and conform with CCP guidelines.

All noncompetitive contracts require special justification and CCP should be queried before fully developed unsolicited proposals are submitted. For further information, write Director, Cancer Control Program, National Cancer Institute, Bethesda, Md.20014.

CANCER BIOLOGY AND DIAGNOSIS

The Division of Cancer Biology and Diagnosis carries out intramural research in three general aspects of the cancer problem: Cancer Biology, Tumor Immunology, and Clinical Research. Cancer Biology includes the efforts of the National Cancer Institute's Laboratories of Biology, Biochemistry, Molecular Biology, Physiology, Pathophysiology and Theoretical Biology. Tumor Immunology includes the Laboratory of Cell Biology and the Immunology Branch, and Clinical Research includes the work of the Surgery, Radiation, Metabolism and Dermatology Branches and the Laboratory of Pathology.

The Division of Cancer Biology and Diagnosis also plans and manages collaborative contract research programs in three areas, Tumor Immunology, Cancer Diagnosis and Breast Cancer. The Tumor Immunology contract research program is divided into three general areas, tumor immunobiology, cancer immunodiagnosis, and the immunotherapy of cancer. The contract program in Cancer Diagnosis has two goals, the development of screening tests for the early detection of cancer, and the improvements of methods for the localization of cancer once detected. Present efforts include work on hormonal and other biochemical screening tests, as well as immunological tests; the application of cytologic methods in cancer screening; and the development of automated methods for reading cytologic specimens. In the future it is hoped to develop improved radiologic methods for cancer diagnosis, and improved instruments for localization of the disease. The Division of Cancer Biology and Diagnosis manages the contract program of the Institute's Breast Cancer Task Force. This broadly conceived approach to cancer of this organ site is divided into four subprograms in the epidemiology, experimental biology, diagnosis, and treatment of the disease.

For further information write to Associate Director for Program Planning, DCBD, National Cancer Institute, Bethesda, Maryland 20014.

CANCER CAUSE AND PREVENTION

General The Division of Cancer Cause and Prevention is responsible for planning and executing a broad research program on etiology and prevention of cancers. Experimental and epidemiologic research is conducted on potential and actual viral, chemical, and radiologic carcinogenic agents and on their combinations. Evaluations of carcinogenic hazards and studies on mechanism of cancer induction are included. Biometric and epidemiologic investigation of cancers are conducted in populations, and extensive demographic data are continually compiled. The various areas of research complement each other, with data from one area providing input for another area in the planning, conduct and evaluation of research programs. Laboratory findings provide leads that must be evaluated in human populations; observed associations of cancer with other factors determined in epidemiologic studies require further clarification in experimental investigations.

The Division of Cancer Cause and Prevention is divided into three program areas, each headed by an Associate Director. The Viral Oncology area is concerned with determining the significance of viruses in the induction of cancers in man and with developing means for preventing these cancers with virological, immunological, and other techniques. The Carcinogenesis area is concerned with determining the significance of chemical agents in the induction of cancer in man and with developing means of preventing these cancers. The Field Studies and Statistics area is concerned with continued monitoring of populations for cancer incidence, prevalence, and mortality; identification of groups with different risks of cancers and determination of associated internal and external environmental and genetic factors; conduct of observational research in situations where society or nature has provided experiments on cancer, such as studies on occupational groups, migrant populations, groups with other diseases, etc.; studies on diagnosis and therapy, including design and evaluation of therapeutic trials, end results of the therapies, diagnostic and detection studies, etc.; and collaboration in a variety of investigations requiring epidemiologic, demographic, statistical and mathematical expertise.

The program is conducted through in-house research and through research contracts for a nationwide effort of the integrated programs in the three areas. The Division of Cancer Cause and Prevention staff are responsible for planning, coordination, evaluation of the contract-supported efforts as well as for the conduct of in-house investigations, with major scientific and review input from the scientific community at large. These efforts are coordinated with investigations conducted by NCI grantees.

Viral Oncology The Viral Oncology program is responsible for the Institute's research into the role of viruses in the causation of cancer in man and animals, intended ultimately to prevent and control neoplastic diseases of viral etiology. The three branches within the Office of the Associate Director for Viral Oncology are responsible for the planning and supervision of broad programs of basic, developmental, and applied research directed toward these objectives, as well as for the management of similarly directed special programs of national scope under the direct operations activities of the NCI.

The many disciplines and skills needed to study problems of viral causation of cancer are located in three branches and are available for deployment in varying combinations for collaboration in problem-solving approaches to disease entities at the program and project levels. This type of collaborative utilization of research capabilities and disciplines has served to unify research efforts and to reduce unnecessary duplication to a minimum.

The mission-oriented research of the Virus Cancer Program started in 1964 with a special Congressional appropriation of $10 million. Launching of the Program was predicated upon the underlying belief that at least one virus is causally related to human leukemia and lymphoma and persists in the diseased individual. Management of this Program was under the Leukemia and Lymphoma Branch. Increased evidence of a relationship of viruses to the etiology of solid tumors led to additional funding and the launching of a Solid Tumor Virus Program in 1967, under the management of the Viral Carcinogenesis Branch. The growth of both programs and their many common interfaces led to their merger in 1968 into the Special Virus Cancer Program, which now embraces viral etiological research on cancers of all types. The program now employs a research convergence technique to provide coordination of objectives, personnel, resources, and information under the general direction of the Office of the Associate Director for Viral Oncology.

All organizational units under the Office of the Associate Director for Viral Oncology, as well as members of other organizational units in the Division of Cancer Cause and Prevention, participate in the program. The resources of the Institute are strongly complemented by the numerous academic and industrial research groups collaborating in this effort. This integration has made possible the sharing of information resulting from the examination and treatment of large numbers of leukemic patients without which it would be difficult or impossible to conduct significant research programs directed to the etiology, prevention, and control of this disease. It has also made possible concurrent studies on the leukemia sarcoma complex in animals, particularly those common to the human environment. Such studies are expected to yield answers to the possible interrelationships of these diseases and to provide models for the study of the counterpart human studies.

Carcinogenesis The Carcinogenesis area is responsible for planning, implementing, and managing the coordinated research program of the NCI on carcinogenesis by chemical and physical factors and on cancer prevention.

Intramural research and a contract-supported collaborative program, directed by the scientific staff, encompass an integrated effort for the identification of population groups at different risks to cancers, the selection of chemical agents for bioassay with emphasis on suspected environmental carcinogenic hazards, the development and

selection of biological models for carcinogenesis bioassays and studies, the identification of carcinogenic activity to selected chemicals by bioassay, and the identification of processes required for the carcinogenic action of selected agents as target points for prevention or inhibitory measures. Processes studied include the penetration of chemicals into the organism and their molecular logistics, metabolic pathways and enzymatic mechanisms of activation, interaction with cell constituents, neoplastic transformation, growth regulation of transformed cells, and immunological control.

The newly established Lung Cancer Branch conducts investigations to identify carcinogenic agents and biological factors involved in the development of lung cancer and attempts to determine means by which these factors may be inhibited or prevented. It develops, designs, and standardizes biological and chemical assay systems for testing the carcinogenic and/or synergistic effects of chemical and physical agents involved in lung cancer causation.

Field Studies and Statistics The Field Studies and Statistics area has three major functions: (a) research into the etiology of cancer in free-living populations, largely but certainly not exclusively human; (b) consultation and support in mathematics, statistics (including experiment design and analysis) and system analysis in problems of cancer research; (c) development of the basic data of cancer incidence, prevalence, and mortality in the United States sufficiently precise to permit administrators and research workers to measure their successes (and failures) in preventing, diagnosing, or treating cancer. The two Branches (Biometry and Epidemiology) within the Office of the Associate Director for Field Studies and Statistics supplement and support each other in these activities.

Objectives for 1973 The major objectives in the Virus Cancer Program are: (a) the determination of cancer-causing activity in animals by viruses already isolated from human cancers; (b) relating this activity, and other characteristics of the candidate viruses, to cancer in man; (c) the determination of the entire sequence of molecular events, including specific enzymatic activities (e.g., polymerases) in viral replication and tumor induction; and (d) relating this information to the control of cancer in man.

The Carcinogenesis area will give high priority to the identification of chemical-viral interaction mechanisms, the role of various chemicals and dusts in the induction of lung cancer, short term in vitro carcinogenesis bioassay, and the establishment of data collection and retrieval systems to improve efficiency in coordinating information generated by the program and disseminating it to the scientific community.

In Field Studies and Statistics, epidemiology studies will be made in human populations of the role of viruses and chemicals in cancer initiation. In 1973, the activities of the Third National Cancer Survey will shift from analysis of the initial data to the setting up of a permanent data collection and analysis system.

For further information write to Associate Director for Program, DCCP, National Cancer Institute, Bethesda, Maryland 20014

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COLLABORATIVE (CONTRACT) ACTIVITIES OF THE NATIONAL EYE INSTITUTE

In 1971 and 1972, the National Eye Institute (NEI) initiated a program for targeted research and development in glaucoma. In 1973, the NEI continued this effort and initiated similar undertakings in the study of retinal disease. For 1973, the NEI is planning to establish a targeted research program for the development and clinical application of new knowledge related to corneal disorders.

Opacification, painful injuries, and irregularities in curvature impair or destroy the optical properties of the cornea. Corneal disorders cause approximately 3% to 4% of the blindness in the United States.

Although many corneal disorders are congenital, degenerative, or due to nutritional deficiencies, one of the most common causes of opacification and subsequent visual loss or blindness to an individual is the scarring that follows injuries resulting from infections, lacerations, heat burns, and chemical burns. In addition to the impairment of an individual's visual capacity, concern is expressed for the considerable industrial and economic loss resulting from numerous small injuries or external diseases involving the cornea which render individual workers nonproductive for extended periods of time (without rendering them legally blind), deprive society of their earning power, and force these individuals to become dependent on others.

General areas of interest to the NEI are: immunology and immunopathologic mechanisms of corneal diseases, infectious diseases involving the cornea, opacification and edema, and tear film.

This announcement is not a request for proposals and does not commit the government to award any contracts. Proposals may be solicited on a competitive basis through published announcements by the NEI. Further information is not available until the solicitation is published. However, specific areas of investigation to be pursued are being identified, and the NEI will make every effort to keep all interested parties informed of developments concerning this program through announcements in the Commerce Business Daily, NIH Guide for Grants and Contracts (Supplement), and by direct mail.

For further information write Dr. Thomas C. O'Brien, Scientific Programs Branch, National Eye Institute, Bethesda, Maryland 20014.

COLLABORATIVE (CONTRACT) ACTIVITIES OF THE NATIONAL HEART AND LUNG INSTITUTE

BLOOD DISEASES AND RESOURCES

The Division of Blood Diseases and Resources (DBDR) supports contract research in blood banking systems, thrombosis and hemorrhagic diseases, and sickle cell disease. In addition, the clinical evaluation of promising drugs and treatments is occasionally undertaken by the Division as a direct operation. In the blood banking area the Division 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. In recognition of the fragmented nature of the nation's blood industry, the Division continues management studies which are 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 Division of Blood Diseases and Resources supports and conducts research in both areas. Current research in thrombosis includes planning for studies of clot-dissolving agents in the treatment of myocardial infarction, and monitoring progress of science relating to drugs which inhibit platelet aggregation with the intention of mounting definitive trials when feasible. 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 usefulness of Factor VIII derived from animal sources in the treatment of hemophilia patients who have an inhibitor for the human factor, and 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."

For further information write Dr. James M. Stengle, Chief, Blood Resources Branch, DBDR, National Heart and Lung Institute, Bethesda, MD 20014.

ISCHEMIC HEART DISEASE

The Myocardial Infarction Program is a part of the Clinical Cardiac Diseases Branch of the Institute. Its objectives 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 mechanisms, and prophlyactic, acute, and rehabilitative therapy. The Program was established in 1966.

In 1967 five large, clinically focused, multidisciplinary groups were established for comprehensive investigation of the pathophysiology and therapy of acute myocardial infarction. There are now nine such Myocardial Infarction Research Units. The clinical investigation is supported by relevant laboratory and fundamental investigations, and the development of the necessary instrumentation systems.

In addition, specific techniques needed for clinical investigation, particularly techniques for quantifying the size of infarcted or ischemic myocardium suitable for use in living man, are currently being developed.

A program of research on sudden cardiac death and the onset of myocardial infarction was initiated in 1970 and expanded in 1971. It includes prophylactic and early therapeutic techniques, investigation of pathophysiological mechanisms and possible precipitating factors, the recognition of high risk individuals, and laboratory and clinical investigations fundamental to these objectives.

Physiological and biochemical processes fundamental to new therapeutic methods are under investigation. A dozen projects, half initiated in 1971 and the balance in 1972, are focused upon characterizing these processes in ischemic myocardium and designing interventions to prevent the progression of ischemia to irreversible damage.

Experimental interventions and studies fundamental to the control of lethal arrhythmias associated with coronary heart disease are under investigation with six projects initiated in 1972.

Currently, a collaborative study is being initiated on coronary artery surgery which is to utilize both a patient registry and randomized studies on specific, sharply defined subsets of patients.

Special programs have included the support of symposia on research on myocardial infarction and on emergency medical care.

For further information write Dr. Peter L. Frommer, Associate Director, Division of Lung Diseases, National Heart and Lung Institute, Bethesda, Maryland 20014.

LUNG DISEASE

In the Spring of 1971, the Division of Lung Diseases was organized. The various branches, Pathophysiology Branch, Etiology and Epidemiology Branch and Special Programs and Resources Branch, of this Division foster fundamental and applied collaborative research and development programs that are timely and that hold promise of leading to results of immediate and practical significance in the prevention of respiratory disease. Research addressed to environmental diseases of the lung, diseases of the airways, interstitial and diffuse pulmonary diseases, pulmonary vascular diseases, pediatric and adult respiratory distress syndromes, development of devices for pulmonary assistance, diagnosis, monitoring, and control, as well as investigation of the structure and function of the lung are of interest to the Division.

The Pathophysiology Branch fosters a program of basic and applied, clinical and non-clinical research on the lung and respiratory system in normal and diseases states. Contracts presently being sponsored by this Branch include: Oxygen Therapy vs. Oxygen Toxicity and Methods of Ventilatory Assistance; Smoking and Chronic Airways Obstruction; Chronic Pulmonary Disease and Smoking (Animal Models); Extracorporeal Support for Respiratory Insufficiency; and Studies on Normal Lung Cell Separation Culture and Morphology.

The Etiology and Epidemiology Branch directs a program concerned with the etiology of respiratory diseases and the factors affecting their natural history. Epidemiology is the primary approach to achieving the Branch's programmatic goals. Representative contract activities include Alphal Antitrypsin Deficiency & Chronic Respiratory Disease; Population Studies on Respiratory Disease; and Control Studies on Host Factors as Determinants of COPD Susceptibility.

The Bic ngineering Program of the Special Programs and Resources Branch fosters a program of bioengineering relevant to respiratory disease, including the analytical and theoretical description or modeling of the physiological functions associated with lung function in health and disease. This includes the development of devices used for lung disease prevention, monitoring and control of lung function, and the therapeutic and case management of lung disease. Presently this Branch sponsors contracts dealing with: Instrumentation for Development and Utilization of Medical Devices and for Patient Diagnosis and Monitoring.

Additional requests for proposals by a l branches will supplement current programs.

For further information write Dr. Claude J. M. Lenfant, Associate Director, Division of Lung Diseases, National Heart and Lung Institute, Bethesda, Maryland 20014.

TECHNOLOGICAL APPLICATIONS

The National Heart and Lung Institute's Division of Technological Applications has as its goal the reduction of deaths and disability from circulatory and respiratory diseases through the development of materials, instruments, and devices for the diagnosis, monitoring, and treatment of such diseases.

Requirements for materials of interest include compatibility with the various tissues involved, durability, strength, and suitability for a wide range of specific implantation needs. Instruments sought are those that will aid in the diagnosis and treatment of circulatory and respiratory diseases, with emphasis on instruments that offer non-invasive techniques for early diagnosis and monitoring of these diseases. Devices to be developed include a variety of therapeutically effective, safe, and reliable circulatory and pulmonary assist and replacement devices. The biological and physical problems involved are being identified and attacked at both the basic and applied levels by research and development groups in academic and industrial settings working under contract to the Division of Technological Applications. The primary monitoring of the scientific and technical aspects of these contracts is at a scientist-to-scientist level with close contact between the scientific staff of the Division and the principal investigators of the various research groups.

The Division of Technological Applications (1) outlines an over-all plan based on the establishment of long-range and intermediate goals; (2) identifies problems related to the achievement of those goals; and (3) supports work designed to solve those problems in a timely, effective manner. In accordance with the program plan, which is subject to constant updating, the Division issues Requests for Proposals (RFPs) directed at the solution of specific problems related to the achievement of the program goals. Responses to such RFPs in the form of research and development proposals are selected for award of contracts on the basis of their likelihood of contributing to the solution of the identified problems, all factors considered.

For further information write Dr. Clarence Dennis, Associate Director, Division of Technological Applications, National Heart and Lung Institute, Bethesda, Maryland 20014.

CLINICAL APPLICATIONS AND PREVENTION

Primary research interests and activities in this area are directed toward the conduct of epidemiological studies, clinical trials, biometrics research and research into the prevention of heart and vascular diseases. Mechanisms of support are through direct operations, research grants, research contracts and a limited number of international studies in countries where P.L. 480 counterpart funds are available.

Preventive Cardiology Branch The research conducted and supported in this Branch is directed toward studies of preventive measures to reduce morbidity and mortality from atherosclerosis, hypertension, and stroke. An example of these prevention studies is the Hypertension Detection and Follow-up Program in 14 communities to determine the extent to which mortality from hypertension can be reduced in the general population. Intervention studies on risk factors for coronary disease are also in progress.

Clinical Trials Branch Cooperative clinical trials supported by grants are the primary responsibility of this Branch. The largest of these is the Coronary Drug Project which involves 53 clinical centers and 8400 men to determine whether or not lipid-lowering drugs can reduce recurrences of myocardial infarction and deaths from coronary heart disease. Medical and biometrics staff of the Branch maintain direct liaison with the involved investigators through the duration of these trials.

Epidemiology Branch Conducts epidemiological studies of the heart and vascular diseases in populations within the United States and in cooperation with medical investigators in other countries. The Framingham Heart Disease Epidemiology Study and other prospective studies in Puerto Rico, Japan, Honolulu, Israel and Yugoslavia are examples of such investigations conducted with direct funds, contract funds and P.L. 480 counterpart currencies.

Biometrics Research Branch Provides consultation to intramural investigators of the NHLI in the design and analysis of laboratory experiments, collaborates with the staff of the Epidemiology, Clinical trials and Preventive Cardiology Branches in the research programs conducted in these Branches.

For further information write Associate Director for Clinical Applications and Prevention, DHVD, National Heart and Lung Institute, Bethesda, Maryland 20014.

LIPID METABOLISM

General Description In December 1970 the Lipid Metabolism Branch was created in the National Heart and Lung Institute's Collaborative Research and Development Program. Its aim is to help implement a primary goal of the National Heart and Lung Institute--the prevention of premature atherosclerosis through the diagnosis and treatment of hyperlipedemia.

The Lipid Metabolism Branch is responsible for the planning, developing, and directing of a collaborative program of research into the structure, metabolism, and functions of lipids and lipoproteins as they relate to atherosclerosis, and coordinating a national research program designed to increase knowledge related to the diagnosis and management of lipid disorders, especially those associated with premature vascular disease.

The Lipid Metabolism Branch plans to implement its program goals in part by the establishment of (1) a network of twelve Lipid Research Clinics and (2) a Patient Registry and Coordinating Center, a Lipid Standardization Laboratory, a Central Exercise Laboratory, and a Central Clinical Chemistry Laboratory. The Lipid Research Clinics' program serves to improve the diagnosis and management of

hyperlipoproteinemia and establish opportunities for further research, including determination of prevalence of abnormalities, their causes and treatment, and the effect of this treatment on premature atherosclerosis. The coordinated ventures of the Clinics require common study protocols, comparable patients, random assignment, double blind evaluation, placebo control, long-term observation and central collection, editing and monitoring of data.

Objectives The objectives of the Lipid Research Clinics' Program include:

1. Evaluation of current techniques for the diagnosis of hyperliproproteinemia and the development of better ones.

2. Improvement of detection, diagnosis, and medical care for hyperlipidemic patients by providing guidance and assistance to physicians on the management of these patients.

3. Testing and development of improved therapy (both dietary and drug) for specific disorders.

4. Design and implementation of an intervention study to test the lipid hypothesis in high-risk patients: i.e., will lowering blood lipids reduce cardiovascular mortality and morbidity in patients with specific types of hyperlipoproteinemia? Will it delay the development and/or progression of cardiovascular disease?

5. The standardization of methodology, techniques, and definitions dealing with hyperlipoproteinemia and its diagnosis.

The first task of the Lipid Research Clinics was to set up and standardize basic techniques for the evaluation of hyperlipidemia. They have succeeded in validating the basic lipid techniques needed to define hyperlipoproteinemia. New and simpler techniques will be evaluated collectively. Now that methodology is established the clinics seek to determine the prevalence of hyperlipoproteinemia in the United States.

Ultimately the high risk subjects defined and registered by the Lipid Research Clinics will provide the ideal populations to gain the answer to the fundamental question as to whether the lowering of lipids will reduce the development and/or progression of coronary vessel disease.

In the future the branch hopes to be able to support through the contract route additional areas of study in lipid metabolism including the development of animal models of the human dyslipoproteinemias and study of the determinants of cholesterol absorption.

For further information write Dr. Robert I. Levy, Chief, Lipid Metabolism Branch, DBDR, National Heart and Lung Institute, Bethesda, Maryland 20014

520-715 O - 73 - 3

COLLABORATIVE (CONTRACT) ACTIVITIES OF THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

OBJECTIVES

The National Institute of Allergy and Infectious Diseases, through its collaborative research activities provides and evaluates a variety of essential research resources and develops associated research methodology and information. Activities include: the production and distribution of virus reagents and tissue typing materials; development and testing of vaccines, and antiviral substances; and support of research on methodology in selected areas of transplantation immunology. These are projects through which specific needs of medical research and delivery of health services can be met. Information on program is published in the *NIH GUIDE FOR GRANTS AND CONTRACTS* and made available through announcements in scientific journals. Progress reports are either published in journals or deposited in the National Technical Information Service.

Collaborative programs are designed, through use of contracts, to be flexible and responsive. When an activity reaches an appropriate stage of development, efforts are made for other Federal agencies or the private sectors to assume responsibility for delivery and utilization. New programs are initiated in response to demands of public health needs and related opportunities resulting from research breakthroughs.

PROGRAM AREAS

Within Collaborative Research are four operating branches--Research Resources, Transplantation and Immunology, Infectious Disease, and Geographic Medicine--each designed to carry out a facet of a broad mission of meeting vital health research needs. The programs of these four branches are described below:

Geographic Medicine Branch The Geographic Medicine Branch was created in 1968 to manage several programs transferred to the NIAID from the former Office of International Research. This Branch currently supports contracts under the United States-Japan Cooperative Medical Science Program within the following selected areas: cholera, leprosy, the parasitic diseases schistosomiasis and filariasis, immunology and pathogenesis of tuberculosis, and the viral diseases dengue and rabies. Each of the foregoing scientific areas of interest are further delimited to afford a very specific program focus. In addition, under direct cognizance of the National Institute of Arthritis, Metabolic and Digestive Diseases, the Branch supports research on selected aspects of malnutrition, including the relationship between malnutrition and infection. Finally, under the sponsorship of the National Institute of Environmental Health Sciences, research is conducted on methods to evaluate environmental mutagenesis and carcinogenesis.

Another activity managed by the Geographic Medicine Branch is the International Centers for Medical Research (ICMR) Program. This Program has no NIAID contract support, but rather it is funded through four research project grants.

Infectious Diseases Branch The Institute's Infectious Disease Branch functions in concert with intramural scientists of the NIAID and the Bureau of Biologics, FDA. It also benefits from the experience of advisory groups and the collaboration of university and drug industry scientists. Within this framework, the branch promotes targeted research leading to the development and evaluation of promising prophylactic and therapeutic agents for the control of selected infectious diseases. A vaccine development program was set up in 1962 to conduct collaborative vaccine studies,

particularly against acute respiratory infections. A rubella (German measles) vaccine program, undertaken in 1965, resulted in a licensed vaccine in 1969.

Current interests include development and evaluation of vaccines against pneumococcal pneumonia, meningococcal and Hemophilus influenzae meningitis, influenza, respiratory syncytial virus and parainfluenza virus infections, and streptococcal infections. Another Infectious Disease Branch program is designated to bring interferon and other promising antiviral substances into clinical application. A recently initiated program in hepatitis sponsors developmental studies on hepatitis B antigens and antibodies, experimental infections in animal models, epidemiologic surveillance in high-risk groups and clinical evaluation of hyperimmune hepatitis B antibody gamma globulin for the prevention of infection following parenteral inoculation of possible infectious material.

Research Resources Branch The Research Resources Branch was established in 1962 and conducts a collaborative program for the support of research by stimulating the production, testing and distribution of a wide-range of reagents. These reagents for health research purposes include viral and mycoplasma seed cultures and their corresponding antisera, allergens and interferons. All reagents are characterized by appropriate microbiological, immunological and biochemical methods and provide the recipients with well-characterized reference materials. Reagents for most of the important viruses and mycoplasmas involved in infections of the respiratory and gastrointestinal tracts are available for distribution. Reagents are also available to selected arthropod-borne viruses and for the antigens of hepatitis B. The reagents related to allergic diseases have recently received greater emphasis and this expanded program will result in the acquisition of reagents for ragweed, ryegrass and ascarid allergens. The program also provides support for research requiring biophysical separation, purification and concentration procedures. These facilities and procedures are needed in the preparation of antigen subunits used for newer, more sophisticated reagents for research in virology.

Transplantation and Immunology Branch The program of the Transplantation and Immunology Branch was started in 1964 to encourage research and provide resources designed to solve the immunological problem of graft rejection in organ transplantation.

From the beginning, the Transplantation and Immunology Committee, made up of experts in the field, has identified objectives to be pursued through contracts with selected laboratories. The Branch's program now includes developing and providing standardized reagents useful in tissue typing; providing technical advise and information on reagents, techniques and transplants through workshops and publications; investigating biological immunosuppressive agents which help slow graft rejections; developing methods for recognition of early graft rejection, and investigating techniques for organ preservation.

Contracts to acquire information on human clinical studies are in progress. This information is focussed on the evaluation of tissue matching as an appropriate predictor of graft survival, and the efficacy of anti-thymocyte globulin in abrogating graft rejection during the first three years of graft implantation. These informational studies are designed to establish a better understanding of the graft rejection process and its circumvention.

For further information write Associate Director for Collaborative Research, National Institute of Allergy and Infectious Diseases, Bethesda, Maryland 20014.

COLLABORATIVE (CONTRACT) ACTIVITIES OF THE NATIONAL INSTITUTE OF ARTHRITIS, METABOLISM AND DIGESTIVE DISEASES

The Artificial Kidney-Chronic Uremia Program was established by the National Institute of Arthritis, Metabolism and Digestive Diseases in the fall of 1965 with funds earmarked by Congress for a target-oriented, planned program of research and development in chronic uremia, dialysis, and the artificial kidney. The goals of this program are achieved through contracts placed with universities, non-profit research laboratories, and industrial concerns. Currently about 70 contracts are in effect for carefully selected research and development program elements. Research contract proposals to the Artificial Kidney-Chronic Uremia Program are reviewed for scientific merit and program relevance by two levels of peer review in a manner similar to the double peer review which characterizes NIH's extramural research grant operation.

Research and development in the program includes studies in the pathophysiology of uremia, blood access and clotting mechanisms, dialyzers and dialysate delivery systems, therapy and its evaluation, and membranes and other materials. Studies in pathophysiology are directed toward minimizing some of the complications of dialysis patients as well as developing a better understanding of the mechanisms of the disease in order to design improved therapy.

Toward these goals, studies are underway in biochemistry and metabolism, anemia, bone disease, neurological and psychological disorders of uremia, gastrointestinal pathophysiology and hyperlipidemia of uremia.

High program priorities are in studies of therapy and its evaluation particularly with the view of quantitating dialysis therapy and various measurements of patient well-being especially in the known parameters of complications of dialysis. Blood access problems continue to be of moderately high priority.

At present, about 8,500 patients in the United States are being maintained by chronic dialysis. Estimates are that 10,000 new patients each year will be suitable candidates for artificial kidney therapy or for renal transplants when they reach a stage where their own kidneys no longer can support them. The NIAMDD Artificial Kidney-Chronic Uremia Program is one of the major efforts to create the technology to enable these persons to attain a higher level of rehabilitation at lower cost.

At present, opportunities for new contracts are limited; when they are feasible again they will be announced in the *GUIDE*.

For further information write Dr. Robert J. Wineman, Associate Chief, Artificial Kidney Program, National Institute of Arthritis, Metabolism, and Digestive Diseases, Bethesda, Maryland 20014.

COLLABORATIVE (CONTRACT) ACTIVITIES IN POPULATION RESEARCH, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

OBJECTIVES

The Institute uses the contract mechanism when the initiative for carrying out a research project, including design, direction, and methodology, originates primarily within the National Institute of Child Health and Human Development (NICHD) or when the research requires extensive participation by staff in its development. Contracts are used (1) to stimulate research in gap areas; (2) to develop resources, methodology, instrumentation, or specific products; (3) to provide services to investigators; (4) when staff can function as both stimulator for collaborative efforts and coordinator of research among a number of investigators; (5) to provide for innovative, creative, pioneering projects which may be of general value to the scientific community; (6) to give coherence to a relatively unstructured field; (7) to support organizational activities such as conferences which are program or mission oriented and provide for information exchange or the development of methods.

PROGRAM AREAS

The Center for Population Research, NICHD, currently has contracts in the following areas:

Contraceptive Development

1. Development of new potential contraceptive drugs including the synthesis and biological evaluation of novel steroids, unique prostaglandin analogs, novel analogs of luteinizing hormone releasing factor (LRF), and other miscellaneous non-steroids to determine the extent and nature of their possible antifertility activity.

2. Development of systems and/or materials for uninterrupted administration of antifertility drugs aimed at improving the safety and efficacy of presently available drugs; and evaluation of biological evidence concerning slow and constant release of contraceptive drugs.

3. Development of methods for permanent and reversible sterilization in females and reversible sterilization in males. Design of devices that are safe and effective, easily implantable, and acceptable to various population groups; testing and evaluation of these devices.

4. Studies of how sperm mature and acquire the capacity to fertilize ova; functions of the male duct system and accessory glands; factors affecting the transport of sperm to the site of fertilization; the survival and movement of sperm in the female tract; study of enzymes of sperm.

5. Development of techniques for observing the normal function of segments of the oviduct in ovum pick-up and transport, and studies of the effect of hormones and physical factors on the oviduct.

6. Studies of hormones involved in reproduction and of methods for measuring them; the role of hormones in the initiation and maintenance of pregnancy; regulation of the function of the corpus luteum; and studies to elucidate the control of ovulation.

7. Studies of the ovum, including maturation and ovulation; the biochemistry and physiology of egg membranes and their possible alteration for contraceptive purposes; biochemical function of the fertilized egg before implantation; and the dynamics of decidualization and implantation.

Evaluation of Existing Contraceptive Methods

1. Clinical and laboratory studies of selected subjects (particularly long-term oral contraceptive users) which will elucidate elements of excess risk, estimates of extent of risk, unique properties of presently available drugs, and interaction between steroid drugs and commonly used prescription drugs.

2. *In vitro* and *in vivo* (human and animal) studies of the absorption, metabolism, and excretion of steroid contraceptive drugs.

3. Studies to clarify further the effects of oral contraceptives on blood pressure, including extent and magnitude of risk, characteristics of high-risk subpopulations; unique properties of certain contraceptive formulations; physiological mechanism of production of increased blood pressure; and desirable methods of treatment.

4. Human studies which will lead to a more precise estimation of the minimal dose of a drug which will provide acceptable contraceptive effect and/or minimal biochemical or toxic effects; evaluation of potentially toxic effects may be done in animal models.

5. Studies of the effects of oral contraceptives on dietary nutrients.

6. Studies to ascertain whether vasectomy is a relatively innocuous surgical procedure or whether it may be associated with acute adverse effects and/or significant long-term medical complications.

Social Science Research Related to Population

1. Studies of the interrelations between social change and population size, structure, and distribution with particular emphasis upon the social, economic, and other determinants and consequences of population change.

2. Analyses of trends in fertility as affected by age at marriage, divorce, abortion, and related variables; studies of the interrelations of fertility and other socioeconomic variables, such as income, education, religion, and residence; and the relationship between trends in fertility and broad socioeconomic changes such as level of economic activity, women's participation in the labor force, etc.

3. Studies of interrelations between family structure, sexual behavior, and fertility, illegitimacy and abortion; motivations and decisions which determine a couple's number and spacing of children; attitudes toward methods of fertility control and use-effectiveness of various methods among various subgroups of the population; and alternatives to child-bearing which couples perceive and how these perceptions affect fertility.

4. Social, economic, and psychological consequences for both parents and children of various childbearing patterns, size of family, etc.

5. Evaluation of policies aimed at regulating population and of policies which indirectly affect population growth or distribution. Past and present policies--including family allowances, direct incentives and family planning programs--are evaluated for their impact on population.

For further information write: Director, CPR, National Institute of Child Health and Human Development, Bethesda, Maryland 20014.

COLLABORATIVE (CONTRACT) ACTIVITIES OF THE NATIONAL INSTITUTE OF DENTAL RESEARCH - NATIONAL CARIES PROGRAM

Most of the collaborative (contract) research in the National Institute of Dental Research relates to the National Caries Program. The development of means to reduce further the universal disease of tooth decay was identified by the Administration as a special initiative area of biomedical research. Substantially increased funds were made available for that purpose in the beginning of fiscal year 1971, with $3,500,000 allocated to collaborative research.

Primary emphasis is placed on projects which encompass the application of existing knowledge and which will prove or disprove the findings of earlier laboratory and animal studies when applied to man; projects which seek new preventative modalities that are feasible, effective, and less demanding of the time of scarce professional manpower; and projects which assess new, promising variations of current approaches. In short, most of the collaborative research in the caries area will be targeted to the acceleration of the development of preventive methods for decreasing the incidence of caries and making this disease almost completely preventable. The collaborative program also recognizes the need for, and will support, a certain amount of caries-related basic research to fill in important gaps in knowledge.

Three factors, all of which interact, are implicated in caries: (1) susceptibility of teeth to the demineralizing action of acids, (2) presence of caries-inducing bacteria, and (3) a diet which favors the colonization and destructive activity of cariogenic organisms. Because of the complex nature of caries, it is unlikely that any one approach will completely solve the problem of its control and prevention. Efforts are therefore directed to depressing the effects of all factors to a minimum and utilizing a combination of techniques instead of concentrating on one.

Each proposal is reviewed for technical merit by an ad hoc initial review group composed mainly of nongovernmental scientists, and then for policy compliance and funding priority by the NIDR Contracts Review Group.

All "Sources Sought" or "RFP Available" announcements appear in the *COMMERCE BUSINESS DAILY* and the *NIH GUIDE FOR GRANTS AND CONTRACTS SUPPLEMENT*.

For further information write Chief, Office of Collaborative Research, National Institute of Dental Research, Bethesda, Maryland 20014.

COLLABORATIVE (CONTRACT) ACTIVITIES OF THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

The mission of the National Institute of Environmental Health Sciences is directed to definition and explanation of toxicologic mechanisms and effects induced by environmental stressors as related to human health. The NIEHS collaborative research program is limited to support of research efforts intrinsic to the mission of the Institute. Collaborative projects, including both research contracts and interagency agreements, are activities which by virtue of required expertise or logistics lie beyond the scope of the NIEHS intramural program and require NIEHS initiative and participation.

Contract proposals are solicited on a competitive basis, through published announcements and direct contract with research groups of recognized competency. Proposals are subject to competitive evaluation by an ad hoc technical committee and final evaluation by the NIEHS Contract Review Committee.

The current and projected scope of the NIEHS collaborative research program includes efforts in areas of heavy metals toxicity, chemical mutagenesis, biological effects of microwaves and noise, and environmental factors associated with defects of reproduction and development. Future contract research needs, in the aforementioned or other areas, will be published through the usual mechanisms.

For further information write to Special Assistant for Program Planning and Development, NIEHS, P.O. Box 12233, Research Triangle Park, North Carolina 27709.

Collaborative (Contract) Activities of the National Institute of General Medical Sciences

The Institute awards contracts for research and development in three principal areas. This notice is being published for informational purposes, since no active solicitation for sources or proposals is planned at present.

Automation of the Clinical Laboratory Research, development, and evaluation of rapid, reliable automated systems and instruments, for potential application in all aspects of clinical laboratory sciences, including clinical chemistry, toxicology, hematology, microbiology, virology, blood banking, etc. Subject areas of interest include sample collection and labelling techniques, new or improved analytical methods, data handling and reduction techniques for compact computers, miniaturized and portable test systems for emergency use, all intended to increase reliability, throughput, and clinical significance.

Pharmacology/Toxicology Research, development, and evaluation in all aspects of therapeutic drug use, including synthesis, testing, assays in body fluids, and surveillance for effectiveness, side effects, and drug interactions. The principal aim is to promote safer and more effective use of drugs. Related problems include dose-response patterns, kinetics of uptake, distribution, and elimination, metabolic transformations of administered drugs, and quantitative analytical methods and instruments for identification and assay.

Genetics and Genetic Chemistry Research, development, and production in areas where technological constraints impede progress in genetics research. Representative problem areas include isolation, synthesis, separations, purification, and production procedures for material and synthetic genetic materials such as nucleic acids, related enzymes, tissue culture cells, genetically determined animals, etc.

For further information write Special Assistant to the Director, National Institute of General Medical Sciences, Bethesda, Maryland 20014.

COLLABORATIVE (CONTRACT) ACTIVITIES OF THE NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE

PURPOSE OF RESEARCH CONTRACT ACTIVITIES

The National Institute of Neurological Diseases and Stroke (NINDS) identifies specific research areas within its sphere of interest which are not receiving the necessary investigative attention required for the development of knowledge leading to the prevention or cure of disease and disabilities of major and general concern to the public. It is not always possible for the Institute using its own resources exclusively to mount a complete research program to promote knowledge in the required areas. In such situations, NINDS relies upon negotiated research contracts to support such required research.

The use of the research contract as a mechanism for research support implies a significant role for the supporting Institute (NINDS) in the framing of project goals and the parameters within which work will be carried out, in the monitoring of research underway, and often in the dissemination or further utilization of the research results. Contract-supported research is undertaken only when such research can and will be carefully monitored by a Project Officer or Project Officers from the full-time scientific staff of the Institute.

ONGOING PROGRAMS

Currently, NINDS supports approximately 100 research contracts in a broad variety of scientific areas. Research is supported at a number of institutions, including academic institutions, hospitals, not-for-profit research organizations, and commercial research and development organizations. Contractors are widely distributed geographically. Current contract-supported programs include the following general program areas:

The Collaborative Perinatal Project A comprehensive analysis is being made of data collected on 50,000 pregnancies and the resultant neurological and mental development of the offspring. Contractors capable of developing and applying sophisticated analytic techniques to highly specialized and complex clinical phenomena will be offered opportunities to participate in t is closely coordinated data analysis effort. Twenty specific areas for major nd minor data analysis efforts have been identified.

Infectious Diseases A varied research program on infectious diseases of the nervous system, particularly related to early life and development, is being conducted.

Epilepsy and Convulsive Disorders A program of investigation of promising anticonvulsant compounds is being supported, as are highly focused studies into methodology for the improvement of the diagnosis, therapy, and rehabilitation of epileptics.

Head Injury and Stroke NINDS has initiated a carefully directed research effort designed to elucidate the processes of brain damage due to trauma or circulatory infarction.

Epidemiologic Studies Measures of the incidence and prevalence of neurologic and sensory diseases, require a variety of surveys depending on the methodology employed. Surveys involving prospective or retrospective approaches include demographic as well as genetic and environmental components. Research contracts support activities which are a direct extension of in-house studies, or independent studies of direct interest to the Institute.

Communicative Disorders NINDS has initiated programs of applied research on improved methods of detecting and diagnosing hearing loss in infants and children; on developing, refining and testing new speech analytic techniques and hearing aid systems; and on the specific etiology of hearing loss.

Biomedical Engineering and Instrumentation NINDS recognizes the need for overall coordination in the development of needed neurologically useful diagnostic and therapeutic instrumentation through all the stages of developmental research, prototype development, and clinical evaluation. The in-house efforts of NINDS laboratories and clinics are supplemented by directed research projects supported by contract in laboratories of other institutions where the necessary expertise and facilities are available.

Neural Prostheses NINDS has embarked on a multidisciplinary study of basic physiology and biophysics of neural transmission, and of applied engineering problems involved in developing and utilizing artificial mechanisms to replace sensory and neuromuscular activity. Contracts for various phases of such development are being awarded.

Supporting Services In order to conduct a broad variety and scope of complex research activities in various laboratories and clinics, NINDS must from time-to-time seek supporting research and services outside of the NIH. Such supporting research and services are varied in nature and complexity but include such activities as long-time holding of research animals; production and delivery of specific biological reagents, cell cultures and antigens; provision of data processing and information storage and retrieval services; and, the provision of specialized professional and technical services.

For further information write Associate Director, C&FR, National Institute of Neurological Diseases and Stroke, Bethesda, Maryland 20014.

Collaborative (Contract) Activities of the Division of Research Resources

Biotechnology Resources Program The Biotechnology Resources Branch (BRB) uses the contract mechanism to fund activities that enhance the effectiveness of its grant supported programs, facilitate program planning and evaluation, or further develop technological advancements of potential benefit to BRB's clientele. For example, the need for and importance of a national high voltage electron microscopy program was established through a contract awarded to the United States Steel Corporation to provide time on their one million volt electron microscope to biomedical research scientists. Also, a contract to the University of Iowa enabled the BRB to improve on the design of a low-cost computer graphics terminal developed in one of its grant-supported resources. As a result of this contract, prototype units were constructed and evaluated.

For further information write to Dr. W. R. Baker, Jr., Asst. Chief, Biotechnology Branch, Division of Research Resources, Bethesda, MD 20014.

Chemical/Biological Information-Handling (CBIH) Program The CBIH Program is concerned with providing biomedical scientists with the research support capabilities they most need to pursue their investigations effectively. The focus specifically is on (a) designing and developing computer-based information-handling tools important to studies of chemical/biological interactions (a line of inquiry relevant to almost every major medical area); (b) making these tools available to the national scientific community in an easy-to-use and highly reliable form; and (c) collaborating with the users of these tools in order not only to refine and extend them but also to develop deeper insights into the investigative process itself. Particular emphasis is placed on questions of where and how computer technology and information science can catalyze the emergence of predictive capabilities regarding the interactions of chemical substances and living systems.

For further information write to Dr. W. F. Raub, Chief, Biotechnology Branch, Division of Research Resources, Bethesda, MD 20014.

Animal Resources Program (ARB) The overall objective of the ARB is to support resource projects that provide or enable biomedical scientists to effectively use animals in human health related research. Special attention is given to those animal resource activities that are broadly supportive of the missions of the various NIH components. The Branch objectives are accomplished through a Primate Research Centers Program, a Laboratory Animal Science Program, and Research Contracts. The ARB has used the research contract mechanisms as an adjunct to its resource grant programs to support specific, essential services or to initiate activity in vital resource areas that have not responded or are not eligible to respond to the grant mechanism.

For further information write to Dr. Charles McPherson, Chief, Animal Resources Branch, Division of Research Resources, Bethesda, MD 20014.

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- 1703 ☐ Parasitic Diseases
- 1704 ☐ Research Resources
- 1705 ☐ Transplantation and Immunology

1800 ☐ National Institute of Arthritis, Metabolism and Digestive Diseases (All Programs)

1900 ☐ National Institute of Child Health and Human Development (All Programs)
- 1901 ☐ Contraceptive Development
- 1902 ☐ Evaluation of Existing Contraceptive Methods
- 1903 ☐ Social Science Research Related to Population

2000 ☐ National Institute of Dental Research (All Programs)

2100 ☐ National Institute of Environmental Health Sciences (All Programs)
- 2101 ☐ Environmental Physical Factors
- 2102 ☐ Mutagenesis
- 2103 ☐ Pharmacology and Toxicology
- 2104 ☐ Reproduction and Development

2200 ☐ National Institute of General Medical Sciences (All Programs)
- 2201 ☐ Automation of the Clinical Laboratory
- 2202 ☐ Pharmacology/Toxicology
- 2203 ☐ Genetics and Genetic Chemistry

2300 ☐ National Institute of Neurological Diseases and Stroke (All Programs)
- 2301 ☐ Collaborative Perinatal Project
- 2302 ☐ Infectious Diseases
- 2303 ☐ Epilepsy and Convulsive Disorders
- 2304 ☐ Head Injury and Stroke
- 2305 ☐ Epidemiologic Studies
- 2306 ☐ Communicative Disorders
- 2307 ☐ Biomedical Engineering and Instrumentation
- 2308 ☐ Neural Prosthesis
- 2309 ☐ Supporting Services

2400 ☐ Division of Research Resources (All Programs)

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