NIH GUIDE

For Grants and Contracts

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

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NOTICES

DATED ANNOUNCEMENTS (RFPs AND RFAs AVAILABLE)

NOTICES

NONCOMPETING CONTINUATION GRANT APPLICATIONS -- TIMELY AND COMPLETE SUBMISSION

P.T. 34; K.W. 1014002

National Institutes of Health

The purpose of this notice is to emphasize to NIH research grant recipients the importance of submitting noncompeting continuation grant applications (Form PHS 2590) that are both timely and complete.

Grantees are asked to submit noncompeting continuation applications directly to the awarding unit eight weeks before the begin date of the scheduled budget period so that the awarding unit may issue the Notice of Grant Award two weeks before the start of the budget period. Applications that are late or incomplete sometimes result in late awards, which put a burden on both NIH staff and grantees. NIH staff cannot issue a noncompeting continuation grant award until the required information regarding budgetary detail, progress report, human subjects, animal welfare, or the appropriate Financial Status Report has been received and reviewed. Greater cooperation in this regard will facilitate the timely issuance of Notices of Grant Award.

NIH POLICY ON THE HUMANE CARE AND USE OF LABORATORY ANIMALS
NIH REGIONAL WORKSHOP

P.T. 42; K.W. 0201011, 1014003

National Institutes of Health

The National Institutes of Health, (NIH), Office for Protection from Research Risks, (OPRR) is continuing to sponsor a series of workshops on implementing the revised Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the NIH Guide for the Care and Use of Laboratory Animals. The Workshops are open to institutional administrators, members of animal care and use committees, laboratory animal veterinarians, investigators and other institutional staff who have responsibility for high-quality management of sound institutional animal care and use programs.

Date: March 12 - 13,1987

Location: Portland, Oregon

Contact:

Ms. Nancy Praskell
Administrative Assistant
Department of Animal Care
Oregon Health Sciences University - L110
3181 S. W. Sam Jackson Park Road
Portland, Oregon 97201
Telephone: (503) 225-8427)

Date: March 30, 1987

Location: Miami, Florida

Contact:

Ms. Cynthia Stingone or
Ms. Margaret Moncure
Mannheimer Primatological Foundation
20255 S. W. 360 Street
Homestead, Florida 33034
Telephone: (305) 547-6803 or
(305) 245-1551

DATED ANNOUNCEMENTS (RFPs and RFAs AVAILABLE)

HUMAN LIVER CELL CULTURE FACILITY -- SOURCES SOUGHT

P.T. 36; K.W. 0780015, 0780020

National Institute of Diabetes and Digestive and Kidney Diseases

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, is seeking to identify organizations that are interested in and have the ability to provide a facility where (1) the science of culturing human liver cells would be highly developed and studied and (2) where such cells would be available for use by other investigators either in the culture facility or through shipment of cultures.

A development phase of no longer than one year is envisioned, so that respondents to this announcement must already be heavily involved and highly experienced in this cell culture system. Experience with animal cell culture systems, though not as relevant as human cell culture experience, will be considered if the ability to procure the tissues and successfully make the transition is documented.

At the completion of the development phase, the culture facility must be able to provide cell cultures to qualified investigators, most of whom would come to the facility to perform their experiments. Therefore, adequate space and common laboratory equipment would need to be available for their use. Any special needs or requirements would have to be prearranged and the costs would have to be borne by the investigator. In addition, a user charge to cover part of the expense of maintaining the facility would be levied for its use. Investigators to whom cell cultures were shipped for use in their own facilities might require initial training in the establishment of their cultures and in quality control procedures.

Stringent characterization of the cell cultures and quality control procedures would have to be maintained.

Capability Statements are invited from those organizations interested in serving as a human liver cell culture facility. Statements should contain: (1) information which establishes the organization's qualifications, experience and achievement in liver cell culture; (2) information about personnel, space and equipment available for the project; and (3) a brief statement of probable approach, awareness of problems and factors involved in long-term human liver cell culture. The entire Capability Statement should not exceed three (3) pages single-spaced.

This announcement is not a Request for Proposals. There is no commitment by NIDDK to issue a Request for Proposals but if such a request is issued, those answering this Sources Sought announcement will be so notified.

Two copies of the Capability Statement as itemized above should be submitted to:

Patrick M. Sullivan
Contracting Officer
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 602
National Institutes of Health
Bethesda, Maryland 20892

Capability Statements must be received no later than close of business, 5:00 p.m. local time, January 16, 1987.

RESOURCE FOR PROCUREMENT OF HUMAN TISSUES FROM DONORS WITH AN EPIDEMIOLOGICAL PROFILE

RFP AVAILABLE: RFP-NCI-CP-71013-58

P.T. 36; K.W. 0780005, 0785055

National Cancer Institute

The National Cancer Institute (NCI) has a requirement for: 1) collection of nontumorous and tumorous lung, bronchus, colon and pleural mesothelium human tissue at the time of surgery; 2) delivery, by contractor-specified means, of viable human tissue and cells promptly (within 2 hours of excision) to Laboratory of Human Carcinogenesis (LHC) at National Institutes of Health, (NIH) Bethesda, Maryland; 3) provision of an epidemiological profile of the donors obtained by trained

interviewers using a form provided by NCI. This procurement is restricted to contractors located within 90 minutes by land of NIH. The incumbent contractor is Georgetown University, contract NO1-CP-31007. The RFP will be available on or about December 15, 1986 and proposals will be due January 15, 1987. All requests should reference RFP NCI-CP-71013-58 and be directed to:

Ms. Diane M. Smith
Contract Specialist
CECS, RCB, NCI
Blair Building, Room 119
9000 Rockville Pike
Bethesda, Maryland 20892

COLLECTION, STORAGE, QUALITY ASSURANCE AND DISTRIBUTION OF BIOLOGICAL RESPONSE MODIFIERS

RFP AVAILABLE: NCI-CM-73710-18

P.T. 36; K.W. 0780005, 0755010, 0710100

National Cancer Institute

The Biological Response Modifiers Program (BRMP) Division of Cancer Treatment, National Cancer Institute, seeks a contractor to: 1) provide the facilities, including space and equipment, to operate a computerized inventory system and repository for the acquisition, receipt, storage and distribution of biological reagents and tumor cell lines. The facilities shall be adequate for the storage of 100 to 150 specific biological response modifiers (BRMs) ranging in amount from 1 to 2,000 vials each; 2) perform assays of BRMs for microbiological agents by performing tests for fungal, bacterial, mycoplasma and cytopathic viral contaminations as requested by the Project Officer. These tests need to conform to FDA specifications pertaining to testing sterility of biologicals (21 CFR 610.12). The Limulus Lysate assay for endotoxin level quantitation and pyrogen testing in rabbits shall be available. Mouse antibody production (MAP) and intracerebral LCM test capacity shall also be available; 3) perform General Safety Test on biologics intended for clinical use in compliance with the requirements of 21 CFR 610.11; 4) carry out vialing and labeling, and potency and purity testing of BRM agents obtained in bulk form that are intended for clinical use. Because of the need and value of frequent communication between the Principal Investigator and the Project Officer, and the need for pick-up from BRMP of Biologicals with a short half-life, offerors must demonstrate the capability to pick up biologics from or deliver them to the Frederick Cancer Research Facility, Frederick, MD within 2 hours.

This is a recompetition of a contract currently held by Meloy Laboratories, Inc. One award for a five-year period is anticipated.

All responsible sources may submit a proposal which shall be considered by the agency. It is anticipated that RFP NCI-CM-73710-18 for the work described above will be available to interested offerors on or about 12/15/86, with a due date for receipt of proposal on 02/01/87.

Copies of the RFP may be obtained by sending a written request to:

Catherine V. Baker
Contract Specialist
Research Contracts Branch
National Cancer Institute, NIH
Blair Building, Rm. 212
Bethesda, MD 20892

STRUCTURAL BIOLOGY AS APPLIED TO THE PROBLEM OF TARGETED DRUG DESIGN FOR THE TREATMENT OF AIDS

RFA AVAILABLE: 87-NIH-01

P.T. 34; K.W. 0755025, 0790000, 1003008, 0710100, 1002008, 0715120

National Institutes of Health

Application Receipt Date: March 23, 1987

BACKGROUND

The National Institutes of Health (NIH) announces that new funds are available to apply modern techniques of molecular structure determination and analysis in a pilot program for the purpose of developing antiviral drugs in the treatment of Acquired

Immunodeficiency Syndrome (AIDS). It seems clear that advances in several fields are generating a level of knowledge such that it may soon be possible to design drugs that are targeted against viral nucleic acids, specific viral proteins, or their cellular binding sites. This approach to designing drugs requires a knowledge of the macromolecular structures that might be involved in interactions with these substances, and an understanding of structure-function relationships in the molecules of interest. The central disciplines required for such an effort are in the area of structural biology, particularly x-ray crystallography and theoretical chemistry as related to molecular modeling. To be effective, these must be aided, and to some degree guided, by modern research in molecular biology and pharmacology.

This capability to develop specifically designed antiviral drugs is still more in the realm of speculation than reality. Because of the urgency to find a way to combat AIDS, the NIH is attempting to stimulate progress in this area by encouraging the formation of multidisciplinary research teams organized around the disciplines of structural biology, which are prepared to work on human immunodeficiency virus (HIV) and related viruses.

RESEARCH GOALS

- To stimulate the organization of a multidisciplinary research group centered around studies related to structural biology, in order to develop approaches to targeted drug design.

- To carry out studies of the structure of the AIDS virus, viral proteins, and other molecules of importance to the understanding of AIDS. It is recognized that large quantities of working materials such as virus stocks, viral proteins, nucleic acids and other reagents will be required. Lack of a source of such materials should not be a deterrent to interested groups of investigators since, if not available from other sources, these may be obtained from a central resource through NIH.

- To provide an environment for research training of both graduate students and postdoctoral scientists to think creatively about the problems of targeted drug design.

ELIGIBILITY FOR AWARD

It is expected that the applicant groups will have particular strengths in several areas, including, but not limited to, crystallography, molecular modeling, drug design and synthesis, and virology. Proposals involving more than one organization, including industrial groups, will be considered as long as an appropriate level of collaboration and interaction can be demonstrated.

MECHANISM OF SUPPORT

The administrative and funding mechanism will be the Program Project Award. This award can support both research projects and a core facility.

The start date for funded projects will be approximately September 1, 1987. NIH anticipates that about 3-5 awards will be made, for a period of five years. The total funds available for all awards will be between $4 and $6 million in the first year. Informal interactions and exchange of information between all the groups in the program is expected. A yearly conference of all participants is planned.

For further information and for copies of the complete RFA, contact:

Marvin Cassman, Ph.D.
Director, Biophysics and Physiological
Sciences Program
National Institute of General Medical Sciences
National Institutes of Health
Westwood Building, Room 909
5333 Westbard Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-7463

IMPROVING CANCER PATIENT MANAGEMENT THROUGH THE TUMOR CONFERENCE

RFA AVAILABLE: 87-CA-17

P.T. 34; K.W. 0715035, 1004017, 0795000

National Cancer Institute

Application Receipt Date: March 18, 1987

The National Cancer Institute (NCI) invites applications for research projects designed to improve the educational benefits of tumor conferences through controlled interventions that increase the transfer of state-of-the-art cancer patient management information. A successful tumor conference enhances both patient management and health professional education.

BACKGROUND

A survey at 1,330 hospitals holding regular tumor conferences was conducted by the NCI in cooperation with the American College of Surgeons (ACOS). The results showed that tumor conferences are heterogeneous in their organization, format and handling of recommendations directed toward the management of individual cancer patients.

Tumor conferences are an established part of the cancer care system in the U.S. The majority of hospitals conduct some type of tumor conference because the ACOS requires these educational patient management discussions as part of their approval for hospital cancer programs. Over 300,000 patients are presented at tumor conferences every year. Based on reported attendance, length and meeting frequency, an estimated 1.25 million physician man-hours are allocated annually for the cancer conference. This well-established system provides a unique opportunity to explore ways to accelerate the delivery of state-of-the-art cancer patient information.

OBJECTIVES AND SCOPE

The purpose of this RFA is to invite applicants to design and conduct research on interventions for enhancing the educational impact of the tumor conference. Through this effort it is anticipated that the increased quality of information transferred will affect physician behavior and lead to improvements in cancer patient management. The interventions should be developed with the intent of providing recommendations at the completion of the study that will make it possible for the American College of Surgeons and tumor conferences to utilize the most effective educational methods.

Tumor conferences selected for study should represent the most common formats, as shown by the NCI/ACOS hospital survey, so that the study results will apply to the largest number of institutions possible. (For a copy of the NCI/ACOS survey report see Section on "Staff Contact"). The applicant must classify participating hospitals according to size and teaching status as defined by the American College of Surgeons in its Hospital Cancer Program. Applicants must demonstrate the applicability of their proposed interventions to a larger universe of hospitals.

In order to evaluate the effect of the intervention, the offeror must develop plans to obtain baseline data and data from control institutions from which to judge the success of the intervention. Such data should be relevant to the intervention being tested and may be derived from patterns of care studies, reviews of treatment decisions, analysis of referral patterns, and/or data relating to the frequency with which the tumor conference recommendations are followed, or the role of the consultant in treatment recommendations.

Applicants must specify procedures for implementing the interventions as well as managing data from multiple participating institutions. Analytic techniques should be adequate to allow the applicant to reach relevant conclusions for the purpose of providing pertinent recommendations.

STAFF CONTACT

A summary of the tumor conference survey conducted by NCI/ACOS and the full RFA may be obtained from:

Donald E. Henson, M.D.
Program Director
Community Oncology and Rehabilitation Branch
Division of Cancer Prevention and Control
National Cancer Institute
Blair Building, Room 701
Bethesda, Maryland 20892 4200
Telephone: (301) 427-8708

Prospective applicants are encouraged to submit a one-page letter of intent that includes a synopsis of the proposed research and identification of the participating institutions. The NCI requests such letters by February 1, 1987 for the purpose of providing an indication of the number and scope of applications to be received. A letter of intent is not binding, it will not enter into the review of an application and in fact is not a required antecedent to the application. Letters of intent and inquiries should be directed to Dr. Henson at the address above.

USE OF HYDROXYUREA IN PATIENTS WITH SICKLE CELL ANEMIA

RFA AVAILABLE: 86-HL-25-B

P.T. 34; K.W. 0785035, 0785070, 0710100, 0755015

National Heart, Lung, and Blood Institute

Application Receipt Date: April 1, 1987

The Sickle Cell Disease Branch of the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute (NHLBI) announces the availability of a Request for Application (RFA) on the above subject. Copies of the RFA are currently available from staff of the NHLBI.

This program will support a cooperative effort to determine the optimum dose, schedule, and short-term toxicities of hydroxyurea in severely affected adults with sickle cell disease. It is the expectation that expertise in clinical hematology, pharmacology, sickle cell disease, and design and implementation of collaborative studies will be included. The program will utilize the cooperative agreement mechanism and will support several clinical centers, one of which will serve as the coordinating center and central laboratory.

Request for copies of the RFA should be addressed to:

Marilyn Gaston, M.D.
Sickle Cell Disease Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
Federal Building, Room 508
7550 Wisconsin Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-6931

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