

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 indi-
viduals and organizations who need to
be kept informed of opportunities,
requirements, and changes in extra-
mural programs administered by the
National Institutes of Health.

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NOTICES

NIH/FDA REGIONAL WORKSHOPS - PROTECTION OF HUMAN SUBJECTS

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in biomedical and behavioral research. The workshops are open to everyone with an interest in research. The meetings should be of special interest to those persons currently serving or about to begin service as a member of an IRB. The current schedule includes:

o Dates: June 1-2, 1989

Location: Indianapolis, Indiana

Title of Workshop: "Protection from Research Risks: Whom Are We Protecting?"

Contact:

Mrs. Roxanne Loomis
Research Risk Coordinator
Indiana University
355 Lansing Street
Administration Building, Room 126
Indianapolis, Indiana 46202
Telephone: (317) 274-8289

o Dates: June 15-16, 1989

Location: Philadelphia, Pennsylvania

Title of Workshop: "NIH/FDA Regional Workshop on the Protection of Human Subjects"

Contact:

Mrs. Ruth Clark
Assistant Director for Regulatory Affairs
University of Pennsylvania
The Office of Research Administration
133 South 36th Street, Suite 300
Philadelphia, Pennsylvania 19104
Telephone: (215) 898-2614

o Dates: July 10-11, 1989

Location: Syracuse, New York

Title of Workshop: "Research Involving Human Subjects"

Contact:

Dr. Eric Holzwarth
Syracuse University
College of Arts and Science
300 Hall of Languages
Syracuse, New York 13244-1170
Telephone: (315) 443-2201

Additional workshops will be announced later. For further information regarding human subjects education programs contact:

Darlene Marie Ross
Education Program Coordinator
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 5B62
9000 Rockville Pike
Bethesda, Maryland 20892
Telephone: (301) 496-8101

SHARED INSTRUMENTATION GRANTS

P.T. 34; K.W. 0735000, 1014002

National Institute of General Medical Sciences

The National Institute of General Medical Sciences (NIGMS) announces the termination of its Shared Instrumentation Program announced in the November 5, 1982 issue of the NIH Guide for Grants and Contracts, Vol. 11, No. 12. The final receipt date for applications was February 15, 1989; applications received for that receipt date will be considered for funding from the FY 1990 budget. NIGMS grantees in need of new equipment or desiring to update existing major research instruments are advised to avail themselves of the Shared Instrumentation Program of the Division of Research Resources or to discuss their needs with their NIGMS Program Administrator. Applications for this program will no longer be accepted by NIGMS.

DATED ANNOUNCEMENTS (RFPs AND RFAs)

MAINTENANCE AND OPERATION OF SYNTHETIC PEPTIDE FACILITY

RFP AVAILABLE: NICHD-CD-89-22

P.T. 34; K.W. 0780000, 0780017, 0760060, 1003006

National Institute of Child Health and Human Development

The Contraceptive Development Branch of the Center for Population Research, National Institute for Child Health and Human Development, has a requirement for maintenance and operation of a synthetic peptide facility capable of synthesizing gram-scale quantities (1-50 grams) of peptides for toxicology studies, primate testing and clinical investigation, as well as smaller quantities (5-100 milligrams) of new peptides for initial biological testing in small animals.

Offerors should have expertise in the synthesis of peptides (by solid phase techniques), especially those of MW>1000, on a small scale and on a large scale as noted above. Specific assignment of peptides and quantities to be prepared will be determined by the Project Officer. Major emphasis will be on the preparation of peptides on a gram-scale (1-50 grams). The Contractor's facilities must meet the requirements for Good Manufacturing Practices (GMP) inasmuch as GMP must be followed for all peptides prepared for toxicology and clinical studies. The Contractor may be required to supply all gram-scale batches (1-50 grams) of peptides at a minimum purity of 97 percent. The minimum purity requirements for small quantities (5-100 mg) of peptides is anticipated to be 93 percent. The Contractor shall furnish, package, and distribute all peptides synthesized under the contract, as requested by the Project Officer, in the amounts designated, together with evidence of purity and characterization including but not limited to HPLC, TLC, optical rotation, quantitative amino acid analysis, mass spectral analysis, NMR, and mixed and parallel chromatograms of the peptide(s) against the standard peptide(s) to be furnished by the Project Officer. A functional group analysis by TLC spray reagent, and evidence of electrophoretic homogeneity may also be required as well as sequence analysis of the peptides. An additional requirement for peptides prepared under GMP will be water, salt and C, H, & N analysis (including ash content) and an estimation of peptide content. No subcontracting will be permitted.

As a minimum requirement, the Contractor's facilities must meet the requirements for current Good Manufacturing Practices (GMP) required by the U.S. Food and Drug Administration and must meet requirements in compliance with OSHA for protection of its workers.

The Government estimates the effort to be approximately 3.0 technical staff years annually. The Principal Investigator should be an established peptide chemist and should devote approximately 15 percent effort to this project. All responsible sources may submit a proposal which will be considered by the agency.

One 5-year cost-reimbursement, incrementally funded contract is expected to be awarded, beginning November 29, 1989, as a result of this RFP. The RFP represents a recompetition of the project "Maintenance and Operation of a Synthetic Peptide Facility" currently being performed by the Salk Institute for Biological Studies, San Diego, California.

This is not a Request for Proposals. RFP-NICHD-CD-89-22 will be issued on or about May 19, 1989. Proposals will be due approximately 60 days thereafter. Copies of the RFP may be obtained by sending written requests to Mr. Paul J. Duska at the address listed below. Requests may also be made by FAX Telephone (301) 496-0962.

Paul J. Duska, Contracting Officer
Contracts Management Section, OGC
National Institute of Child Health and Human Development
Executive Plaza North, Room 610
9000 Rockville Pike
Bethesda, Maryland 20892

LARGE-SCALE ANIMAL CELL PRODUCTION FACILITY FOR BIOMEDICAL RESEARCH

RFA AVAILABLE: 89-RR-01

P.T. 34; K.W. 0780005, 0780015, 0760045, 1002045

Division of Research Resources

Application Receipt Date: August 22, 1989

The Biological Models and Materials Resources Section (BMMRS), Animal Resources Program, Division of Research Resources (DRR), invites applications for a cooperative agreement to support a cell culture center providing large quantities of animal cells and cell products, such as viruses and monoclonal antibodies, to biomedical investigators who are unable to produce such quantities in their own laboratories. One center may be supported in response to this announcement.

BACKGROUND

The BMMRS, DRR, is developing a focus for the NIH's activities in the development and support of nonmammalian models for biomedical research. The Section also provides critical biological materials through support of centers that make such materials available to the biomedical research community.

The DRR seeks to continue support of a national facility for the production of large quantities of cells or their products. This facility will provide a customized service to biomedical investigators whose research demands a scale-up from normal laboratory cell production operations.

ELIGIBILITY

Any of the following types of organizations are eligible to apply: Non-profit and for-profit organizations and institutions; State and local governments and their agencies; and authorized Federal institutions.

MECHANISM, SCOPE AND SCALE OF SUPPORT

The award will be made as a Cooperative Agreement which is an assistance relationship involving cooperation by the BMMRS staff. The major difference between a cooperative agreement and a research grant is that there is substantial programmatic involvement of the NIH staff above and beyond that which normally occurs for traditional program management of grants. The awardee has the authority and responsibility to initiate, develop and implement the project activities.

Support may be requested for a period of up to 5 years. Annual awards will be made subject to continued availability of funds and progress achieved. The total direct costs requested for the first year may not exceed \$200,000.

APPLICATION PROCEDURES

Applications must be received by August 22, 1989. An application not received by this date will be considered ineligible.

THE RFA LABEL FOUND IN THE PHS 398 KIT MUST BE AFFIXED TO THE BOTTOM OF THE FACE PAGE OF THE ORIGINAL COMPLETED APPLICATION FORM, PHS 398, AND DUPLICATED ON ALL COPIES. FAILURE TO USE THIS LABEL COULD RESULT IN DELAYED PROCESSING OF YOUR APPLICATION SUCH THAT IT MAY NOT REACH THE REVIEW COMMITTEE IN TIME FOR REVIEW.

The original and four copies of the application should be sent or delivered to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, Maryland 20892

Two copies of the application should be mailed to the address given below.

COMPLETE REQUEST FOR APPLICATION AND INQUIRIES

A complete Request for Application and further information may be obtained from:

James D. Willett, Ph.D. (301) 496-5507
Louise E. Ramm, Ph.D. (301) 496-5175
Biological Models and Materials Resources Section
Division of Research Resources
Westwood Building, Room 8A07
Bethesda, Maryland 20892

This Program is described in the Catalog of Federal Domestic Assistance, Number 13.306, Laboratory Animal Sciences and Primate Research Program. Cooperative Agreements will be awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241), and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This Program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency Review.

COMMUNITY CLINICAL ONCOLOGY PROGRAM

RFA AVAILABLE: 89-CA-13

P.T. 34; K.W. 0715035, 0785035, 0795003, 0403004

National Cancer Institute

Letter of Intent Receipt Date: June 15, 1989

Application Receipt Date: August 22, 1989

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications from domestic institutions for cooperative agreements to continue its Community Clinical Oncology Program (CCOP). New community applicants and currently funded programs, and new research base applicants, are invited to respond to this Request For Applications (RFA).

This issuance of the CCOP RFA seeks to build on the strength and demonstrated success of the CCOP over the past six years by: 1) continuing the program as a vehicle for supporting community participation in treatment and cancer control clinical trials through research bases (clinical cooperative groups and cancer centers supported by NCI, and public health departments); 2) expanding and strengthening the cancer control research effort to equal that of cancer treatment; 3) utilizing the CCOP network for conducting NCI-assisted cancer control research; and 4) evaluating on a continuing basis CCOP performance and its impact in the community.

BACKGROUND INFORMATION

Over 80 percent of patients with cancer are treated in the community. The CCOP was initiated in 1983 to bring the benefits of clinical research to cancer patients in their own communities by providing support for physicians to enter patients onto treatment research protocols.

In response to the RFA issued in July 1982, 62 community programs in 34 states were funded. In the first three years, approximately 14,000 patients were entered onto NCI-approved treatment clinical trials through the CCOP. The CCOP contributed approximately one fifth of all patients accrued to clinical trials through the cooperative groups. The data from CCOP participants met or exceeded all the quality control standards of the cooperative groups.

The CCOPs clearly were very effective in accruing patients to treatment clinical trials. The second RFA, issued in 1986, expanded the focus to include cancer control research. As a result of the second RFA, 52 community programs in 30 states received three-year awards in June 1987, with approximately 240 hospitals participating. To date, approximately 9000

patients, or 4500 patients per year, have been entered onto treatment clinical trials through the CCOP; approximately 3000 patients/subjects per year have been enrolled in cancer control studies. The CCOP contributes approximately one third of all patients accrued to clinical trials through the cooperative groups.

The development of cancer control research in the CCOP network has been increasing steadily since funding was begun in 1987. Protocols are developed by the research bases and reviewed by DCPC's Cancer Control Review Committee (CCRC). Protocols cover the full spectrum of cancer control research, including chemoprevention, marker studies, smoking cessation studies, screening and early detection, and pain control and other supportive care interventions aimed at reducing cancer incidence, morbidity, and mortality.

RESEARCH GOALS AND SCOPE

The CCOP initiative is designed to:

- o Bring the advantages of state-of-the-art treatment and cancer control research to individuals in their own communities by having practicing physicians and their patient/subjects participate in NCI-approved treatment and cancer control clinical trials;
- o Provide a basis for involving a wider segment of the community in cancer control research;
- o Increase the involvement of primary health care providers and other specialists with the CCOP investigators in treatment and cancer control research;
- o Facilitate wider community participation, including minority groups and underserved populations, in treatment and cancer control research approved by NCI; and
- o Reduce cancer incidence, morbidity, and mortality by accelerating the transfer of newly developed cancer prevention, early detection, treatment, patient management, rehabilitation, and continuing care technology to widespread community application.

MECHANISM OF SUPPORT

CCOP and research base awards will be made as Cooperative Agreements. The cooperative agreement is an assistance mechanism involving cooperation by NCI staff as described in the RFA. Depending on individual costs and available funds NCI anticipates making up to 80 awards, with total funding not expected to exceed \$12 million per year. Awards will be for three, four, or five years as described in the RFA.

STAFF CONTACT

Leslie G. Ford, M.D.
Community Oncology and Rehabilitation Branch
Executive Plaza North, Room 300-D
Division of Cancer Prevention and Control, NCI
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-8541

TROPICAL MEDICINE RESEARCH CENTERS

RFA AVAILABLE: 89-AI-15

P.T. 34; K.W. 0785215, 0765023, 1002032, 1002003, 0710070, 0745005, 0745045

National Institute of Allergy and Infectious Diseases

Application Receipt Date: February 15, 1990

The National Institute of Allergy and Infectious Diseases (NIAID) invites applications for Tropical Medicine Research Center (TMRC) grants to be initiated in FY 1991. The TMRC will be located in or near an area of endemic tropical disease. It will be directed by a resident Project Director who will be responsible for the development of programs in clinical, epidemiological and basic or applied research in one or more tropical disease areas such as parasitology, medical entomology, and bacteriology and virology of tropical diseases and related to the biology and immunology of host-parasite relations, pathogenesis, diagnosis,

immunotherapy and immunoprophylaxis, chemotherapy and chemoprophylaxis, vector biology and control. Research projects at the TMRC will provide opportunities for U.S. and foreign scientists to gain new knowledge and research experience in an endemic tropical disease area.

The RFA label available in the 9/86 revision of Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

It is anticipated that up to four (4) awards will be made, although the number of grants awarded will depend upon the quality of the approved grant applications.

INQUIRIES

Copies of the RFA and additional information may be obtained from:

Dr. Harley G. Sheffield
Acting Chief, Parasitology and
Tropical Diseases Branch
Microbiology and Infectious Diseases Program
National Institute of Allergy and
Infectious Diseases
National Institutes of Health
Westwood Building, Room 737
Bethesda, Maryland 20892
Telephone: (301) 496-7114
FAX: (301) 480-3780

This program is described in the Catalog of Federal Domestic Assistance, Microbiology and Infectious Diseases Program, Number 13.856. Grants or Cooperative Agreements are awarded under the authority of the Public Health Service Act, Section 301 (42 USC 241) (or other authority as pertinent) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.