

NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific
initiatives and provides policy and
administrative information to indivi-
duals 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

PROPOSED MODEL FEDERAL POLICY FOR THE PROTECTION OF HUMAN RESEARCH SUBJECTS

P.T. 04, 34, 44; K.W. 0783005

NATIONAL INSTITUTES OF HEALTH

On June 3, the proposed Model Federal Policy for the Protection of Human Subjects was published in the Federal Register, Part V, Office of Science and Technology Policy (OSTP), pages 20204 through 20217. The proposed Model Federal Policy was published with Federal responses to other recommendations of the President's Commission for the study of Ethical Problems in Medicine and Biomedical and Behavioral Research made in the First Biennial Report on the Adequacy and Uniformity of Federal Rules and Policies and Their Implementation for the Protection of Human Subjects in Biomedical and Behavioral Research.

The proposed Model Federal Policy, derived from and based on regulations of the Department of Health and Human Services at Title 45 Code of Federal Regulations Part 46 (45 CFR 46), Subpart A, was drafted by the Interagency Human Subjects Coordinating Committee, composed of representatives of 20 Federal components. Public comments will be received for 60 days from date of publication prior to consideration of a final Model Federal Policy and implementing regulations for affected Federal departments and agencies.

Comments may be addressed to:

Dr. Joan P. Porter
Office for Protection from Research Risks
National Institutes of Health
Building 31, Room 4B09
Bethesda, Maryland 20892

NEW INVESTIGATOR RESEARCH AWARD

P.T. 34; K.W. 0413000

OFFICE OF POPULATION AFFAIRS

The Office of Population Affairs (OPA) will continue to utilize the New Investigator Research Award (R23) until such time as modified guidelines can be implemented to increase the maximum amount of funds that can be awarded under this mechanism. The three-year limit for NIRA awards will continue to apply.

Information about NIRA as currently utilized by OPA is available from:

Office of Grants Management
Office of Population Affairs, OASH, DHHS
Hubert H. Humphrey Building, Rm. 755D
200 Independence Avenue, S.W.
Washington, D.C. 20201
Telephone: (202) 245-0146

DATED ANNOUNCEMENTS (RFPs and RFAs AVAILABLE)

RFP AVAILABLE: RFP-NIH-NIAID-MIDP-87-9

P.T. 34; K.W. 0710080, 0715125, 1003006

THE DEVELOPMENT OF ADDITIONAL DRUGS FOR TREATMENT OF PNEUMOCYSTIS CARINII

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The Parasitology and Medical Entomology Program of the Microbiology and Infectious Diseases Program of the National Institute of Allergy and Infectious Diseases has a requirement for the development of additional drugs for the treatment of Pneumocystis carinii. The successful offeror must have the capabilities, appropriate technical approach and facilities to evaluate approximately thirty (30) compounds a year in an animal model using a systematic scheme to evaluate their effectiveness against Pneumocystis carinii.

This is an announcement for an anticipated Request for Proposal (RFP). RFP-NIH-NIAID-MIDP-87-9 will be issued on or about July 21, 1986, and proposals will

be due by close of business September 17, 1986. Requests for the RFP should be directed to the Chief, Contract Management Branch, NIAID, NIH Westwood Building, Room 707, Bethesda, Maryland 20892. Please provide this office with two (2) self-addressed mailing labels. All responsible sources may submit a proposal which will be considered by NIAID.

This advertisement does not commit the Government to award a contract.

RFP AVAILABLE: RFP-NIH-NIAID-MIDP-87-10

P.T. 34; K.W. 0710080, 0715125, 1003012

DEVELOPMENT OF ANTIVIRAL DRUGS FOR TREATMENT OF HUMAN CYTOMEGALOVIRUS (HCMV) INFECTIONS, PARTICULARLY IN AIDS AND OTHER IMMUNOSUPPRESSED PATIENTS.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

The Development and Applications Branch of the Microbiology and Infectious Diseases Program of the National Institute of Allergy and Infectious Diseases, National Institutes of Health, has a requirement for the development of antiviral drugs for the treatment of human cytomegalovirus (HCMV) infections. The successful offeror must have capabilities, appropriate technical approach and facilities to chemically synthesize one or more compounds which will inhibit the replication of human CMV.

This is an announcement for an anticipated Request for Proposal (RFP). RFP NIH-NIAID-MIDP-87-10 will be issued on or about July 25, 1986 with a closing date for receipt of proposals of September 25, 1986. To receive a copy of the RFP, please supply this office with two (2) self-addressed mailing labels. Telephone inquiries will not be honored and all inquiries must be in writing and addressed to the following office: Ms. Jacqueline C. Holden, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5333 Westbard Avenue, Westwood Building, Room 707, Bethesda, Maryland 20892.

All responsible sources may submit a proposal which will be considered by the NIAID.

This advertisement does not commit the Government to award a contract.

RFP AVAILABLE RFP-NIH-NHLBI-HB-86-13

MAINTENANCE OF CHIMPANZEES FOR HEPATITIS OR AIDS RESEARCH

P.T. 36; K.W. 1002002

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

The National Heart, Lung, and Blood Institute plans to continue the maintenance of a colony of chimpanzees to be utilized in nondestructive experiments judged most likely to advance hepatitis or acquired immune deficiency syndrome (AIDS) research. The chimpanzees are presently located at the site of the incumbent Contractor, the Southwest Foundation for Biomedical Research, San Antonio, Texas. The NHLBI colony currently comprises forty-seven (47) experimental animals (adult and juvenile). The offeror shall furnish housing and veterinary medical support to maintain and feed the forty-seven (47) NHLBI-owned chimpanzees. These chimpanzees shall be made available for use (under separate contracts) in experimental studies of viral hepatitis or AIDS with on-site laboratory and technical support to be furnished to and paid by the NHLBI-authorized user under separate contract between the user and the offeror.

This is an announcement for a Request For Proposals (RFP). RFP NIH-NHLBI-HB-86-13 will be available on or about August 1, 1986, with proposals due October 15, 1986. This is a five-year program. One (1) award is anticipated by the Government. Your written request should include three (3) labels, self-addressed with your mailing address, and must cite RFP No. NHLBI-HB-86-13.

Requests for copies of the RFP should be sent to the following address:

Jack E. Jackson, Contracting Officer
Blood Resources Branch, BDR Contracts Section
National Heart, Lung, & Blood Institute
Federal Bldg., Room 5C14
Bethesda, MD 20892

RESEARCH CENTERS IN MINORITY INSTITUTIONS AWARD

P.T. 34, FF; K.W. 0710030, 0735000, 0780000, 0785000

NATIONAL INSTITUTES OF HEALTH

Application Receipt Date: October 1, 1986

The National Institutes of Health (NIH) is pleased to re-announce the Research Centers in Minority Institutions (RCMI) Award. Its purpose is "to establish research centers in those predominantly minority institutions which offer doctoral degrees in the health professions or the sciences related to health..." (Report of the House/Senate Conferees on the Fiscal Year 1985 Appropriation for the Office of the Director, NIH).

The RCMI Program is managed by the Office of the Director, Division of Research Resources. The program is designed to provide grants of up to \$1,000,000 per year, for five years, to help eligible institutions enrich their research environments via selected improvements in their human and physical resources. For example, the funds awarded could be used for the salaries of key research and research-support personnel, instrumentation, and alteration and renovation of facilities. Such expenditures would complement ongoing and planned research activities (e.g., projects funded by Minority Biomedical Research Support grants, Minority Access to Research Career awards, traditional NIH and ADAMHA research projects, and individual and institutional research fellowships).

To be eligible to compete for an RCMI award, an institution must have more than 50 percent minority enrollment and offer doctoral degrees in the health professions or the sciences related to health. This program is open only to institutions within the United States and its territories.

Eligible institutions who need additional information (e.g., program guidelines) should contact:

Dr. Sidney A. McNairy, Jr.
Director, RCMI Program
Division of Research Resources
Building 31, Room 5B19
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-6341

AVAILABILITY OF REQUEST FOR APPLICATIONS (RFA) - 86-RR-02

DEVELOPING AND IMPROVING INSTITUTIONAL ANIMAL RESOURCES

P.T. 14, 36; K.W. 1002002

DIVISION OF RESEARCH RESOURCES

Application Receipt Date: October 13, 1986

BACKGROUND

As part of its mission to create, develop and maintain animal resources needed by NIH-supported biomedical investigators throughout the nation, the Division of Research Resources (DRR) is continuing its competitive grant program to help institutions upgrade and develop their animal facilities. DRR anticipates that \$3.981 million may be available to support such improvement grants in Fiscal Year 1987.

RESEARCH GOALS AND SCOPE

Institutional animal resource improvement projects are awarded to assist biomedical research and educational institutions to upgrade their animal facilities and develop centralized programs of animal care. A major objective is to enable institutions to comply with the USDA Animal Welfare Act and DHHS policies on the care and treatment of animals. This improvement is limited to alterations and renovations to improve laboratory animal facilities and related equipment, such as animal cages and cage washers. It is not the purpose of the improvement grant to provide general operating costs for the resource; e.g., funding for personnel, consumable supplies for routine animal care, etc. The projects are supported for one year, after which the applicant institution is expected to assume complete financial responsibility for its basic animal resource.

To gain approval and support, both the need for resource improvement and a sound plan to meet the requirements of the Public Health Service Policy on Humane Care and

Use of Laboratory Animals must be presented and described in the context of the biomedical research and research training program of the institution. Alteration, renovation and equipment grant requests, per se, will not be acceptable; i.e., requests for such needs will be considered only in relationship to the overall project plan to improve institutional animal resources.

ELIGIBILITY AND REVIEW

Any domestic public or nonprofit institution, organization, or association is eligible to apply. Applicants are expected to develop a single animal resource improvement proposal for campus-wide service.

Applications will be received by the NIH Division of Research Grants. Applicants must use PHS Form 398, "Application for Public Health Service Grant." A receipt date of October 13, 1986 has been established. Applications received after this date will not be accepted for review in this competition. All applications submitted in response to this RFA will be reviewed by the Animal Resources Review Committee for scientific merit review and the National Advisory Research Resources Council of the DRR for program considerations.

MECHANISM OF SUPPORT

Awards will be made as competitive resource grants for a project period limited to one year. It is expected that from 10 to 20 awards will be made in Fiscal Year 1987. The number of grants and the specific amount of awards will depend on the merit and scope of the applications received and the availability of funds. All policies and requirements which govern the grant programs of the PHS apply.

TERMS OF AWARD

Alterations, renovations and equipment are limited to a maximum award of \$500,000 from this grant program. Equal matching funds from nonfederal sources are required for both A&R and equipment. Support for new construction is not authorized. Funds awarded for alterations and renovations may not be obligated until final drawings, specifications, and updated cost estimates are received and approved by the Division of Research Resources.

INQUIRIES

A copy of the complete RFA, which provides background information, research goals and scope, terms and conditions, review procedures and criteria, and method of applying, may be obtained by contacting the Animal Resources Program, DRR:

Dr. William I. Gay or Dr. John E. Holman
Animal Resources Program
Division of Research Resources
Building 31 - Room 5B59
National Institutes of Health
Bethesda, Maryland 20892
Telephone: 301-496-5175

This program is described in the Catalog of Federal Domestic Assistance No. 13.306, Laboratory Animal Sciences and Primate Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS: (RFA) 86-CA-14

COMMUNITY CLINICAL ONCOLOGY PROGRAM

P.T. 34; K.W. 0715035, 0785140, 0785035, 0745055, 0415000, 0403004

NATIONAL CANCER INSTITUTE

Application receipt date: October 23, 1986

The Division of Cancer Prevention and Control (DCPC), National Cancer Institute (NCI), invites applications for cooperative agreements to continue its Community Clinical Oncology Program (CCOP). Applications to participate in the program may be submitted by community groups and eligible research bases. New applicants and currently funded programs are invited to respond to this RFA.

This second issuance of the CCOP RFA seeks to strengthen the cancer control focus by expanding the program to require that other cancer control research be conducted in

addition to treatment clinical research. Thus, the research initiative now includes: (1) support for cancer control research in the community; (2) provision of an operational base for the extension of cancer control efforts in early detection, prevention, screening, pretreatment evaluation, treatment, continuing care and rehabilitation; (3) involvement of primary care providers and other specialists in cancer control studies early in the course of clinical treatment; (4) increased involvement of minority and underserved populations in clinical research; and (5) evaluation of CCOP performance and its impact in the community setting.

BACKGROUND

Over 80 percent of patients with cancer are treated in the community. NCI's first CCOP initiative was designed to bring the benefits of clinical research to cancer patients in their own communities by providing support for physicians to enter patients on treatment research protocols. In response to the RFA issued in July 1982, 191 applications were received and 62 CCOPs were funded. Evaluation results to date show that the CCOP has been very effective in accruing patients to clinical research protocols. In the second year of this special program, 4772 patients were entered on study. Across cooperative groups, the CCOP contributed approximately one-fifth of all patients accrued. There has been a notable increase in the number of community physicians and hospitals participating in clinical research (i.e., use of research protocols) since the inception of the CCOP. In general, data from CCOP participants have met the quality control standards of the cooperative groups. As an additional benefit, though many cancer patients may not be eligible for entry on a research protocol, the knowledge gained by physicians from protocol participation should be transferred to the treatment of patients not on protocol.

OBJECTIVES AND SCOPE

The CCOP initiative is designed to:

- o Bring advantages of treatment and other cancer control research to individuals in their own communities by having practicing physicians and their patients participate in clinical treatment and other cancer control research protocols.
- o Provide a basis for involving a wider segment of the community in cancer control research and investigate the impact of cancer therapy and control advances in community medical practices.
- o Increase the involvement of primary health care providers and other specialists (e.g., surgeons, urologists, gynecologists) with the CCOP investigators in treatment and other cancer control research, providing an opportunity for education and interchange of information.
- o Facilitate wider community participation (including minority groups and underserved populations) in future treatment and other cancer control research approved by NCI.
- o Reduce cancer mortality by accelerating the transfer of newly developed cancer prevention, detection, treatment, and continuing care technology to widespread community application.

MECHANISM OF SUPPORT

The CCOP and Research Base awards will be made as cooperative agreements. These are assistance relationships involving cooperation by NCI staff as outlined in the RFA. NCI anticipates making multiple awards under this request. Awards will be for periods of three years. Depending on individual costs and available funds there will be up to 80 awards, with total funding not expected to exceed 10 million dollars per year.

STAFF CONTACT

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

Robert W. Frelick, M.D.
Community Oncology and Rehabilitation Branch
Division of Cancer Prevention and Control, NCI
Blair Building, Room 7A05
Bethesda, Maryland 20892-4200
Telephone: (301) 427-8708

This program is described in the Catalog of Federal Domestic Assistance No. 13.999, Cancer Control. Awards will be made under the authority of the Public Health Service Act, Title IV, Section 403 (Public Law 78-410, as amended; 42 USC 284) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

ONGOING PROGRAM ANNOUNCEMENTS

ADAMHA SMALL GRANT PROGRAM

P.T. 34; K.W. 0710030, 0404000, 0404001, 0404003, 0404009, 0715095

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

The Alcohol, Drug Abuse, and Mental Health Administration announces a revised announcement of its Small Grant Program. There has been a change in the review schedule. Applications will be assigned for review for scientific merit by the Small Grant Review Committee which will meet four times each year (March, June, September, December); review by an Institute Advisory Council has been eliminated. Small grant applications may now be submitted at any time. Approximately 5-6 months should be allowed between submission of the application and the desired starting date of the grant.

According to the revised announcement, the narrative portion of the small grant application may not exceed 10 pages of standard-size type (not including budget, curriculum vitae, and listing of literature cited).

The revised announcement, including review criteria, is available upon request from:

National Institute on Alcoholism and Alcohol Abuse

Helen Chao, Ph.D.
Chief, Biomedical Research Branch
Division of Extramural Research, NIAAA
Room 14C-17
Telephone: (301) 443-4223

National Institute on Drug Abuse

Desmond McLearn
Chief, Grants Management Branch
Office of the Administrator, NIDA
Room 10-25
Telephone: (301) 443-6710

National Institute of Mental Health

Anne Cooley
Division of Extramural Activities, NIMH
Room 9-95
Telephone: (301) 443-4673

The address for all of the above is:

Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857