

NIH GUIDE

**For Grants
and
Contracts**

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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.

Vol. 20, No. 5
February 1, 1991

SUZANNE FISHER

1206 PRINCETON PL
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NOTICES

TYPE SIZE IN PHS 398 APPLICATIONS

P.T. 34; K.W. 1014006

Division of Research Grants

In an effort to clarify the current guidelines and in response to some excellent suggestions, we have modified the current guidelines regarding the type size in the PHS 398 application kit. The following revised guidelines replace the paragraph under Specific Instructions - Section, (page 12, PHS 398, Rev. 10/88). They are effective with the February 1, 1991 application receipt deadline.

"It is also essential that type size limitations be observed throughout the application, or the application will be returned without review. For the first (face) page, the type density must be 10 characters per inch (cpi). This limit is to assure that all data typed on this page can be captured for computer processing without truncation. For the rest of the application, the type must be standard size, which is 10 to 12 points (approximately 1/8 inch in height for capital letters). If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of 15 cpi. Finally, there must be no more than six lines of text within a vertical inch. Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be clear and readily legible. Applications not meeting these requirements will be returned without review, or may be subject to deferral."

If you have any questions, contact:

The Referral Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 248
Bethesda, MD 20892
Telephone: (301) 496-7447

STUDY OF GRANT APPLICATION TEXTS IN ELECTRONIC FORM

P.T. 34; K.W. 1014002, 1004008

Division of Research Grants

The Division of Research Grants (DRG), as part of its ongoing efforts to improve the efficiency of its review and data management functions, is studying the feasibility of computer-assisted indexing of grant applications. To conduct this special study, DRG needs a large data base, in electronic form, of the textual portions of applications. The application sections of interest are the 1) Abstract, 2) Specific Aims, 3) Background and Significance, and 4) Literature Cited (Section 2-I).

Therefore, DRG is asking investigators who already have submitted a competing application for individual research grant support (R01) and who have the textual portions of their applications available in an electronic medium (i.e., stored in a computer or on a floppy disk) to send only these portions of their applications to:

Dr. John B. Mathis
Division of Research Grants
National Institutes of Health
Westwood Building, Room 2A-05
Bethesda, MD 20892
Telephone: (301) 402-1464

The application sections listed above should be copied as separate files to a floppy disk (5 1/4" or 3 1/2"). It is most desirable that each file be converted to its ASCII ("DOS File") equivalent before copying. If this is not possible, please indicate on the disk label what word processing program was used to prepare the file.

All data received will be handled as privileged communications and stored in controlled-access files in the NIH mainframe computer. No applicant names will be associated with any computer-based files (except as they may appear in the files themselves). The files will be identified and retrieved by their

code designations only. The DRG will take precautions to maintain the confidentiality of the information submitted.

Please send only files from applications that have been submitted between August 1, 1989 and July 31, 1990. Indicate on the disk label 1) the application's title and 2) the study section and the Institute, Center or Division to which it was assigned.

Note that this request for application information is entirely independent of the current review and award processes of any of the Institutes, Centers or Divisions of the Public Health Service, including DRG. Your response to this announcement should be considered entirely voluntary. Information received as a result of this announcement will not affect the review or funding of any grant application in any way. All information received will be used solely for the study of information management by DRG. All disks received will be returned to the sender if a return address is enclosed.

NATIONAL WORKSHOPS ON "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 the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

I. WEST COAST WORKSHOP

DATES: February 4-5, 1991

WORKSHOP SITE:
Meridien Hotel
50 Third Street
San Francisco, CA 94103

SPONSOR:
University of California at San Francisco
Box 0400
San Francisco, CA 94143

REGISTRATION CONTACT:
Ms. Phyllis Colbert
Workshop Contact Person
University of California at San Francisco
Box 0400
San Francisco, CA 94143
Telephone: (415) 476-1881

TOPIC: "The Use of Human Subjects in Research: AIDS as a Model of Complexity"

II. MIDEAST WORKSHOP

DATES: March 4-5, 1991

WORKSHOP SITE:
Friday Center
Laurel Hill Parkway
Chapel Hill, NC 27599-1020

SPONSORS:
University of North Carolina at Chapel Hill
300 Bynum Hall
Chapel Hill, NC 27599-4100

Shaw University
118 E. South Street
Raleigh, NC 27611

REGISTRATION CONTACT:

Mr. Al Dawson
Director
Friday Center
Laurel Hill Parkway
C. B. 1020
Chapel Hill, NC 27599-1020
Telephone: (919) 962-1106

TOPIC: "Interpreting the Federal Code for the Protection of Human Subjects"

III. MIDWEST WORKSHOP

DATES: April 11-12, 1991

WORKSHOP SITE:

Ramada Inn, Lakeshore
4900 South Lake Shore Drive
Chicago, IL 60615

SPONSORS:

University of Chicago
970 East 58th Street
Chicago, IL 60637

Chicago State University
95th Street at King Drive
Chicago, IL 60628

REGISTRATION CONTACT:

Mr. Arnold L. Aronoff
Associate Director
Faculty and Administrative Services
University Research Administration
University of Chicago
970 East 58th Street
Chicago, IL 60637
Telephone: (312) 702-8669

TOPIC: "Cultural Diversity, Ethics, and Research: A Workshop on Human Subject Protection"

NIH/FDA have planned national human subject protections workshops in other parts of the United States. For further information regarding these workshops contact:

Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES PROGRAM
PROJECT GUIDELINES

P.T. 34; K.W. 0715010, 0715185, 0705050, 1014006

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) announces the availability of revised guidelines for program project applications that are assigned to NIAMS by the Division of Research Grants (DRG). The limitation on direct costs requested will remain at \$5 million over 5 years. These guidelines will be used as the basis for the review of applications received as of June 1, 1991, and thereafter.

The following individual may be contacted for the guidelines and for specific questions related to such applications:

Dr. Michael Lockshin
Director, Extramural Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
9000 Rockville Pike
Building 31, Room 4C32
Bethesda, MD 20892
Telephone: (301) 496-0802

ANNOUNCEMENT OF HHS GRANTS AND CONTRACTS TRAINING COURSE

P.T. 34; K.W. 1014002, 1014006

Public Health Service

COURSE TITLE: Orientation to U.S. Department of Health and Human Services Grants and Contracts Activities for Applicants and Recipients of Awards

COURSE DESCRIPTION: This two-day course has been designed to provide applicants for and recipients of HHS grants and contracts with a better understanding of the procedures that are to be followed and what is expected of them in applying for and in the accounting and stewardship of Federal funds. The first day of the course concentrates on the grants process; the second day is devoted to contracting. Students will be provided with a broad overview of how to conduct contract and grant business with HHS including: how the Department is organized, how the HHS contracts and grants processes are structured, how to identify grant and contract funding opportunities, how to submit effective applications and proposals and what to watch out for once a contract or grant has been awarded by HHS.

TARGET POPULATION: Grant and contract staff of organizations that are presently doing business with HHS as grantees or contractors, and those that plan to submit applications for grants or proposals for contracts. The course is intended for new staff or staff inexperienced with HHS grant and contract activities.

DATES AND LOCATIONS

April 2-3, 1991, 8:30 am - 5:00 pm; Rockville, MD
June 10-11, 1991; 8:30 am - 5:00 pm; Atlanta, GA (historically black colleges and universities only)
August 19-20, 1991; 8:30 am - 5:00 pm; Boston, MA

COURSE OUTLINE

- o Introduction to HHS Assistance (grants/cooperative agreements) and Acquisition (contracts): HHS Mission and Organizational Structure; Assistance vs. Acquisition (The Federal Grant and Cooperative Agreement Act); HHS Grant and Contract Expenditures and Recipients; Introduction to Types and Purposes of HHS Grants; Roles of HHS Grants and Program Management Staffs.
- o Seeking and Applying for HHS Grants/Cooperative Agreements: Sources of Information; Understanding Program Announcements; The application Package; The Complete, Effective Application; Competition and Objective Review.
- o Negotiation and Award Process for Grants/Cooperative Agreements: Cost Analysis and Pre-Award Review; Negotiating-- Clarifying and Revising Proposed Activities; Contents of a Grant Award Document; Funding Outcomes; General and Special Conditions.
- o Grant/Cooperative Agreement Post-Award Issues and Concerns: Monitoring; Audit; Appeals; Progress Reports; Drawdowns; Financial Status Reports; Grant Budget Control; Cost Principles and Unallowable Costs; Purchasing; Property Management.
- o Seeking HHS Contracts: Identifying HHS Contracting Opportunities; The Legal Framework of HHS Contracting; Small Business Contracting Programs; Roles of HHS Contracting and Project Staffs.
- o Responding to Contract Solicitations: Small Purchases--\$25,000 or less; Purchases Greater Than \$25,000; Preparing the Technical Proposal; Preparing the Business Proposal.
- o Proposal Submittal, Contract Negotiation, and Award: Proposal Submission and Evaluation; Negotiation and Award.

- o Contract Administration: Initial Contract Administration Steps; Significant Contract Administration Concerns.

CLASS SIZE: Limited to 25 participants per session to maximize interaction.

ATTENDANCE: Those accepted will be expected to attend the entire session, both full days of the course.

COST: There will be no charge for this course. Travel and accommodations will be the responsibility of participants. Details on exact location of courses and suggested accommodations will be provided to those persons selected.

TO APPLY: On employing organization's letterhead, submit a letter that provides the following information:

Name of applicant
Employing organization: name, address, and telephone number
Position of applicant
Years of experience in grants, contracts, or both
Principal area of interest (grants, contracts, or both)
Reason for wanting to take this course (100 words or less)
Course session desired

APPLICATION DEADLINES

Selection will be made on a first-come, first-served basis. Only one nominee will be selected per institution, per session, unless vacancies occur.

SEND APPLICATION TO

Training Coordinator
Grants Policy Branch
Division of Grants and Contracts
Office of the Assistant Secretary for Health
Parklawn Building, 5600 Fishers Lane, Room 17A45
Rockville, MD 20857

Applicants will be notified as to their acceptance or nonacceptance for this course.

SALARY LIMITATION ON GRANTS AND CONTRACTS

P.T. 34; K.W. 1014006

National Institutes of Health
Alcohol, Drug Abuse, and Mental Health Administration

The purpose of this notice is to inform grant applicants and contract offerors of the Congressionally-mandated salary limitation provision for the second consecutive year.

Section 213 of the Appropriations Act of the Department of Health and Human Services for fiscal year (FY) 1991 (October 1, 1990-September 30, 1991) (Public Law 101-517) restricts the amount of direct salary of an individual under a grant or contract award issued by the National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to a RATE of \$120,000 per year. This requirement is the same as it was for FY 1990. (See NIH GUIDE FOR GRANTS AND CONTRACTS, Vol. 19, No. 3, January 19, 1990.)

NIH and ADAMHA will apply the restriction to all grant and contract awards and to all funding amendments to existing grants and contracts made during FY 1991 and with FY 1991 funds. The salary limitation applies to amounts permitted to be INCLUDED in grant and contract awards as well as amounts allowed to be CHARGED to those awards.

However, an individual's institutional salary, per se, is NOT constrained by this legislative provision.

NIH and ADAMHA grant and contract awards that indicate direct salaries of individuals in excess of a RATE of \$120,000 per year will include an appropriate notification, such as:

According to the Appropriations Act, "None of the funds appropriated in this title for the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration shall

be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of \$120,000 per year." The application/proposal for this project proposed a salary at a rate greater than \$120,000 per year. This award has been reduced accordingly.

Grant applications and contract proposals submitted to the NIH and ADAMHA should continue to request funding at the regular rates of pay of all individuals for whom reimbursement is requested. NIH and ADAMHA will make downward adjustments of direct salary amounts in excess of the ceiling rate and fringe benefits based upon the budget approved as part of the original award. Corresponding indirect costs will also be adjusted.

Following is an EXAMPLE of this process:

Individual's institutional base salary per year	\$150,000
Research effort requested on grant application or contract proposal	50%
Direct salary requested	\$ 75,000
Fringe benefits requested (25% of salary)	\$ 18,750
Applicant organization's indirect costs rate	47%
Amount requested - salary plus fringe benefits plus associated indirect costs	\$137,813

If a grant/contract is to be awarded, the amount included in the award for the above individual will be calculated as follows:

Direct salary - restricted to RATE of \$120,000 times effort (50%) to be devoted to project	\$ 60,000
Fringe benefits (25% of allowable salary)	15,000
Subtotal	\$ 75,000
Associated indirect costs at 47% of subtotal	35,250
Total amount included due to salary limitation	\$110,250
Amount of reduction due to salary limitation (\$137,813 requested minus \$110,250 awarded)	\$ 27,563

Grantee and contractor organizations are reminded of these important points:

- o The salary limitation provision does NOT apply to payments made to consultants under an NIH or ADAMHA grant or contract (however, as with all costs, such payments must continue to meet the test of reasonableness).
- o The salary limitation provision DOES apply to those subawards/subcontracts for substantive work under an NIH or ADAMHA grant or contract.
- o Unobligated funds from a prior grant/contract period "carried over" INTO a FY 1991 award period ARE subject to the salary limitation provision.
- o In a noncompeting continuation application (type 5) setting, a grantee organization is NOT permitted to either (1) redistribute an amount of "excess" salary among other budget categories nor (2) increase the Principal Investigator's effort on the project, in an attempt to apply for the full level of funding as previously recommended by the peer review process.

PUBLIC HEALTH SERVICE POLICY RELATING TO DISTRIBUTION OF UNIQUE RESEARCH RESOURCES PRODUCED WITH PHS FUNDING

P.T. 36; K.W. 0780010

Public Health Service

This announcement is a revision of the one last appearing in the NIH Guide for Grants and Contracts on September 16, 1988, Vol. 17, No. 29, pages 1 and 2. This revised notice contains a number of changes in policy that the agencies of the Public Health Service (PHS) have determined should be implemented.

Investigators conducting biomedical research frequently develop unique research resources. Categories of these resources include: synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Some specific examples are: specialized and/or genetically defined cell lines, including normal and diseased human cells;

monoclonal antibodies; hybridoma cell lines; microbial cells and products; viruses and viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and protein sequences; certain types of animals such as transgenic mice; and intellectual property such as computer programs. The PHS provides the following statement of policy concerning unique research resources developed through PHS awards.

A. Policy on Distribution of Research Resources.

The policy of the PHS is to make available to the public the results and accomplishments of the activities that it funds. Restricted availability of unique resources upon which further studies are dependent can impede the advancement of research and the delivery of medical care. Therefore, when these resources are developed with PHS funds and the associated research findings have been published or after they have been provided to the agencies under contract, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. This policy applies to PHS intramural investigators as well as extramural scientists funded by PHS grants, cooperative agreements, and contracts.

Because of concern that some crystallographers are not making their coordinates available promptly (see Science, Vol. 245, p. 1179), one of the national advisory councils of the NIH and the executive committee of another institute recently adopted resolutions affirming the policy of the International Union of Crystallographers (IUCr) (Acta Cryst., A45: 658, 1989). The PHS has now adopted the IUCr policy that includes data from publications based on spectroscopic data such as nuclear magnetic resonance as well as crystallographic coordinates.

The PHS encourages investigators who have such resources to consult the appropriate Program Administrators who may be of assistance in determining a suitable distribution mechanism. Such a mechanism should take into consideration all applicable Federal regulations including, but not limited to: those regarding human subjects, animal welfare, and use and handling of hazardous materials, where applicable. Investigators requesting materials should provide evidence of having the proper training, experience, and facilities to make use of the items they request. Program staff of the agencies will be available to assist in verification of credentials of requesters where such concern exists on the part of suppliers.

Investigators who believe that they will be unable to implement this policy should promptly contact the appropriate PHS Program Administrator to discuss the circumstances, obtain information that might facilitate compliance with the policy, and reach an understanding in advance of the subsequent award. For research and development contracts, approval should be obtained from the PHS Contracting Officer before distribution of unique resources, unless the terms of the contract permit distribution without prior clearance of the Contracting Officer. In order to facilitate the availability of unique or novel biological materials and resources developed with PHS funds, investigators may distribute the materials through their own laboratory or institution or submit them, if appropriate, to entities such as the American Type Culture Collection or other repositories. In the case of unique biological information, such as DNA sequences or crystallographic coordinates, investigators are expected to submit them to the appropriate data banks because they otherwise are not truly accessible to the scientific community. When distributing unique resources, investigators are to include pertinent information on the nature, quality, or characterization of the materials.

Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify original donors or subjects, directly or through identifiers, such as codes linked to the donors or subjects.

The goals of some programs, e.g., the Human Genome Program, are such that applicants for certain projects may be required to provide plans for the sharing of data and materials. These plans will undergo review by program staff and the national advisory council prior to award.

B. Distribution Costs

Institutions and investigators may charge the requester, if necessary, for the reasonable cost of production of unique biological materials, and for packaging and shipping. Such costs may include labor, supplies, and other directly related expenses. Investigators should note, however, that such a charge accrues as general program income. This should not be an impediment to the distribution of materials, but investigators and institutions are advised that:

- a) for grants, the income is governed by 45 CFR Part 74 and it must be reported on the Financial Status Report. Questions regarding these policies and the treatment of income should be directed to the Grants Management Officer.
- b) for contracts, the income is governed by Federal Acquisition Regulations (FAR) 45.610-3. Contracting Officers must be contacted before generating any revenues from the distribution of materials. Any contract under which research resources would be sold require specific contract instructions. Existing contracts may require an amendment and specific approval of the Contracting Officer to render them allowable.

C. Inventions and Commercialization

Federal policy encourages the commercialization of the products of research developed as a consequence of Federal funding; therefore, the intent of this policy is to not discourage, impede, or prohibit the organization that develops unique research resources or intellectual property from commercializing the products. Investigators may make their materials available to others for commercial purposes with appropriate restrictions and licensing terms as they and their institution deem necessary.

Institutions are reminded that some of these products may be inventions subject to the various laws and regulations applicable to patents and must be reported to the Extramural Inventions Reports Office of the NIH. The terms for licensing of unpatented research products, such as cell lines, monoclonal antibodies, and other materials and products, should generally be no more restrictive than would have been the case had they been patented -- for example, only if there is full public disclosure of the invention/discovery, availability through a repository, and written agreement to end all fees and constraints after 17 years. When reporting is required, it should occur at the earliest possible time. (See 37 CFR 401 and NIH Guide for Grants and Contracts, Vol. 19, No. 6, February 9, 1990, page 2).

NOTICES OF AVAILABILITY (RFPs AND RFAs)

EVALUATION OF VACCINE PROPHYLAXIS AGAINST INFECTIOUS DISEASES IN CHILDREN

RFP AVAILABLE: NIH-NIAID-DMID-91-33

P.T. 34; K.W. 0740075, 0715125, 0770005

National Institute of Allergy and Infectious Diseases

The Respiratory Diseases Branch, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases (NIAID), requires a dedicated Pediatric Vaccine Prophylaxis against Infectious Diseases in Children. The Institute has supported efforts to evaluate control measures for infectious diseases during the past decade and supports Vaccine and Treatment Evaluation Units (VTEUs) to facilitate these efforts. These VTEUs have undertaken Phase I and Phase II clinical trials of bacterial and viral vaccines, other biologicals, and drugs as preventative and therapeutic measures against infectious diseases in people of all ages. With the accelerated development of new vaccines, particularly bacterial vaccines, against infectious diseases in children, the Institute wants to support a dedicated Pediatric Vaccine Evaluation Unit (PVEU). The major emphasis of the PVEU will be Phase I and Phase II evaluation of candidate bacterial vaccines in infants and children. The Contractor must have demonstrated experience in the clinical evaluation of vaccines and have demonstrated capacity to organize and administer a clinical study.

This NIAID-sponsored project will take approximately five (5) years to complete. A Cost Reimbursement Level of Effort contract is anticipated and one award will be made. This is an announcement for an anticipated Request for Proposals (RFP). RFP-NIH-NIAID-DMID-91-33 shall be issued on or about February 4, 1991, with a closing date tentatively set for March 29, 1991.

Requests for the RFP must be directed in writing to:

Paul D. McFarlane
Contract Management Branch
National Institute of Allergy and Infectious Diseases, NIH
Control Data Building, Room 326P
6003 Executive Boulevard
Rockville, MD 20852

To receive a copy of the RFP, please supply this office with two self-addressed mailing labels. All responsible sources may submit a proposal that will be considered. All requests must be in writing. This advertisement does not commit the Government to award a contract.

EVALUATION OF CONTROL MEASURES AGAINST INFECTIOUS DISEASES OTHER THAN AIDS

RFP AVAILABLE: NIH-NIAID-DMID-92-1

P.T. 34; K.W. 0795003, 0715125

National Institute of Allergy and Infectious Diseases

The Enteric Diseases Branch, Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, has a requirement for a Vaccine and Treatment Evaluation Unit (VTEU). This VTEU will conduct Phase I and Phase II Clinical Trials to evaluate candidate vaccines and other prophylactic/therapeutic measures for infectious diseases other than AIDS. A VTEU provides volunteer populations, staff, facilities, and expertise to carry out such work that includes follow-up and focused surveillance. A variety of vaccine types (live, attenuated, inactivated, subunit, conjugated) for prevention of viral and bacterial illnesses are expected.

This announcement is for recompetition of contract No. N01-AI-72629 currently held by the Baylor College of Medicine. The issuance of the Request for Proposals (RFP) will be on or about February 6, 1991, and proposals will be due by the close of business on April 3, 1991. One (1) award is anticipated, and it is expected that the resultant contract will be funded over a period of five years. Any responsible offeror may submit a proposal that will be considered by the Government.

To receive a copy of RFP-NIH-NIAID-DMID-92-1, please supply this office with a written request, citing the RFP number together with two self-addressed mailing labels addressed to:

Mr. Thomas C. Porter
Contracting Officer
National Institute of Allergy and Infectious Diseases
Contract Management Branch
Control Data Building, Room 326P
6003 Executive Boulevard
Bethesda, MD 20892

This advertisement does not commit the Government to make an award.

MATERNAL IMMUNIZATION FOR THE PREVENTION OF INFECTIOUS DISEASES IN NEONATES AND INFANTS

RFP AVAILABLE: NIH-NIAID-DMID-91-32

P.T. 34; K.W. 0740075, 0775020, 0745027, 0715125, 0403020

National Institute of Allergy and Infectious Diseases

The National Institute of Allergy and Infectious Diseases (NIAID) has a requirement to evaluate maternal immunization for prophylaxis against infectious diseases in neonates and infants.

This NIAID-sponsored project will take approximately five (5) years to complete. A cost-reimbursement contract is anticipated. It is anticipated that one to two awards will be made.

This is an announcement for an anticipated Request for Proposal (RFP). RFP-NIH-DMID-91-32 shall be issued on or about February 1, 1991, with a closing date tentatively set for April 1, 1991.

Requests for the RFP shall be directed in writing to:

John M. O'Brien
Contract Management Branch
6003 Executive Boulevard
Control Data Building, Room 326P
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-0195

To receive a copy of this RFP, please supply this office with two (2) self-addressed labels. All responsible sources may submit a proposal that will be considered.

This advertisement does not commit the Government to award.

DEVELOPMENT OF MODELS FOR PEDIATRIC AIDS

RFA AVAILABLE: AI-91-04

P.T. 34; K.W. 0715008, 0755020, 0770005

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: March 11, 1991

Application Receipt Date: April 22, 1991

The National Institute of Allergy and Infectious Diseases (NIAID) is playing a central role in the investigation of methods to treat the Acquired Immunodeficiency Syndrome (AIDS). The disease that occurs in the pediatric population infected with the human immunodeficiency virus (HIV) is different from that occurring in adults. Animal models of fetal and neonatal infection with lentiviruses related to HIV are needed to study aspects of HIV infection and therapeutic approaches unique to the pediatric population.

OBJECTIVES AND SCOPE

NIAID invites applications for individual research project (R01) grants to develop animal models and in vitro models for pediatric HIV infection and disease. Research considered responsive to this Request for Applications (RFA) will develop and use (i) an in vitro model of infection of placenta with HIV suitable for examining the regulation and pathogenesis of HIV and for identifying unique targets for new therapies; and/or (ii) an animal model of transmission of virus, studying transplacental transport of virus or infected cells, the mechanisms of infection and targets for therapies; and/or (iii) an animal model of lentivirus infection of fetal or neonatal animals for studying the pathogenesis of the virus, development of disease, and the action of therapies; and/or (iv) an animal model, using a lentivirus or relevant retrovirus, to define the viral and/or cellular factors that effect transplacental infection and that represent potential targets for new therapies. Investigators should plan to apply the models described above to the design and evaluation of anti-HIV therapies to prevent or interrupt the transmission of HIV from mother to offspring. In addition, use of HIV or a lentivirus such as the simian immunodeficiency virus is preferred. Use of other retroviruses may be considered responsive IF there is evidence presented that it models HIV disease closely. Research plans to (i) solely evaluate various compounds for their ability to cross the placenta in an animal model, (ii) evaluate vaccine-related therapies or immune responses, (iii) develop or use models using MuLV retroviruses, or (iv) develop or use transgenic models or models in which virus is injected directly into the fetus as a model of transmission are not considered responsive to this announcement.

MECHANISM OF SUPPORT

This RFA will use the R01 grant mechanism. The NIAID has allocated \$1,000,000 (total costs) for the initial year of funding applications received in response to this RFA. It is anticipated that three to five applications will be funded. The award of grants pursuant to this RFA is contingent upon the continuing availability of funds for this purpose and upon receipt of a sufficient number of applications of high scientific merit.

This RFA is a one-time solicitation. Generally, future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed by a Division of Research Grants study section. However, if the NIAID determines that there is a sufficient continuing program need, the NIAID may announce a request for renewal applications.

APPLICATION SUBMISSION

Eligibility: Any domestic or foreign institution, university, medical college, hospital, and laboratory or other public, private, or for-profit institution is eligible.

Letter of Intent: Prospective applicants are asked to submit by March 11, 1991, a letter of intent that includes a descriptive title and a description (not to exceed one page) of the proposed research.

Submission: The regular research grant application form PHS-398 (rev. 10/88) must be used in applying. To identify responses to this announcement, check "yes" and type the RFA number and title [RFA AI-91-04, DEVELOPMENT OF MODELS FOR PEDIATRIC AIDS] in item 2 on page 1 of the grant application. The RFA label provided with the instructions must be affixed to the bottom of the face page. 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 completed original application and twenty three (23) copies must be mailed to:

Division of Research Grants
National Institute of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications must be received by April 22, 1991. Awards will be based on scientific merit and the uniqueness of the proposed project. Funding around September 30, 1991, is anticipated.

INQUIRIES

A more detailed RFA may be obtained from:

Polly R. Sager, Ph.D
Developmental Therapeutics Branch
Division of AIDS, NIAID, NIH
6003 Executive Boulevard, Room 244P
Bethesda, MD 20892
Telephone: (301) 496-0636
FAX: (301) 480-5703

DEVELOPMENT OF MODELS FOR PLACENTAL AND PEDIATRIC METABOLISM, TOXICITY, AND TRANSPORT OF anti-HIV DRUGS

RFA AVAILABLE: AI-91-05

P.T. 34; K.W. 0785170, 0715008, 0740012, 1007009, 0755025

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: March 11, 1991
Application Receipt Date: April 22, 1991

The National Institute of Allergy and Infectious Diseases (NIAID) is playing a central role in the investigation of methods to treat the Acquired Immunodeficiency Syndrome (AIDS). Children born to HIV-positive mothers and HIV-infected women are now the fastest growing populations of AIDS patients. Traditionally, new therapies were available to children and pregnant women only after extensive clinical experience in other adult populations. Because of the magnitude and severity of the AIDS epidemic, therapies are now being tested in children and pregnant women early in clinical development. Animal and in vitro models are needed to assess the metabolism and transport of AIDS therapies in the placenta, fetus, and neonate. In addition, the mechanisms of toxicity of therapeutics to the placenta, fetus, and neonate must be examined. This information is critical to facilitate the design of clinical evaluations in HIV-positive pregnant women and their children.

OBJECTIVES AND SCOPE

NIAID invites applications for individual research project (R01) grants to develop and use: (i) in vitro models to assess the metabolism, transport, and mechanisms of toxicity of anti-AIDS therapies in the placenta; (ii) animal models to assess the transplacental transport of AIDS therapies and to determine pharmacokinetics parameters to serve as the basis for clinical trials in humans; (iii) animal models to assess the metabolism and distribution of AIDS therapies in the fetus and neonatal animals to serve as the basis for clinical trials in humans; (iv) animal models to assess mechanisms of toxicity relevant to use of drugs in pregnant women and very young infants. The emphasis should be on issues of pharmacology and toxicity that are specific to the use of AIDS therapies in pregnant women and children born to HIV-positive women. Animal models should be those where placental function or structure or developmental patterns most closely model humans. The Developmental Therapeutics Branch of the Division of AIDS will assist in identifying and providing therapeutic agents to be studied and, where possible, analytical methods for detection of drugs. Research plans to

evaluate standard teratology, reproductive toxicology, or pharmacokinetics in rodents are not considered responsive to this announcement.

MECHANISM OF SUPPORT

This Request for Applications (RFA) will use the R01 grant mechanism. The NIAID has allocated \$1,000,000 (total costs) for the initial year of funding applications received in response to this RFA. It is anticipated that three to five applications will be funded. The award of grants pursuant to this RFA is contingent upon the continuing availability of funds for this purpose and upon receipt of a sufficient number of applications of high scientific merit.

This RFA is a one-time solicitation. Generally, future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed by a DRG study section. However, should the NIAID determine that there is a sufficient continuing program need, the NIAID may announce a request for renewal applications.

APPLICATION SUBMISSION

Eligibility: Any domestic or foreign institution, university, medical college, hospital, and laboratory or other public, private or for-profit institution is eligible.

Letter of Intent: Prospective applicants are asked to submit, by March 11, 1991, a letter of intent that includes a descriptive title and a description (not to exceed one page) of the proposed research.

Submission: The research grant application form PHS-398 (rev. 10/88) must be used in applying. To identify responses to this announcement, check "yes" and type the RFA number and title [RFA AI-91-05, DEVELOPMENT OF MODELS FOR PLACENTAL AND PEDIATRIC METABOLISM, TOXICITY, AND TRANSPORT OF anti-HIV DRUGS in item 2 on page 1 of the grant application. The RFA label provided with the instructions must be affixed to the bottom of the face page. 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 completed original application and twenty three (23) copies must be mailed to:

Application Receipt Office
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

Applications must be received by April 22, 1991. Awards will be based on scientific merit and the uniqueness of the proposed project. Funding around September 30, 1991, is anticipated.

INQUIRIES

A more detailed RFA may be obtained from:

Polly R. Sager, Ph.D
Developmental Therapeutics Branch
Division of AIDS, NIAID, NIH
6003 Executive Boulevard
Bethesda, MD 20892
Telephone: (301) 496-0636
FAX: (301) 480-5703

The full RFA is also available in the electronic version of the NIH Guide for Grants and Contracts, the E-Guide.

HIV IN MOTHERS AND INFANTS: IMMUNITY AND EARLY DIAGNOSIS

RFA AVAILABLE: AI-91-06

P.T. 34; K.W. 0715008, 0775020, 0403020, 0710070

National Institute of Allergy and Infectious Diseases

Letter of Intent Receipt Date: March 15, 1991
Application Receipt Date: May 7, 1991

PURPOSE: Transmission of the acquired immunodeficiency syndrome (AIDS) virus to infants occurs in about 20-35 percent of children born of human immunodeficiency virus-1 (HIV-1) infected mothers. Recent studies suggest that protective immunity may exist in some mothers that can interrupt viral transmission to the infant. In addition, preliminary data suggest that there may be cell-mediated immunity against HIV in infants of infected mothers. There is a pressing need to determine if an immune response on the part of either mother or infant can protect the infant from intrauterine or perinatal infection and/or predict which babies are infected.

RESEARCH OBJECTIVES: Applications are invited that seek to develop innovative techniques for diagnosis prior to eight weeks of age and/or to determine the factors that influence perinatal transmission in order to design potential vaccines and immune-based therapy of infected mothers and/or their infants. Approaches to this question may include, but are not limited to, the following:

- o Identify in pregnant women the correlates of immunity that appear to be protective for their infants, particularly in relationship to the quantity and quality of virus infecting the mother, including humoral and cell-mediated immune responses.
- o Compare immune reactions to HIV-1 of infected and uninfected infants (less than eight weeks of age) born of HIV-infected mothers, including, but not limited to, humoral immunity, cell-mediated immunity, and identification and assessment of maternally derived cells in infants.
- o Develop and evaluate novel methods for early diagnosis during gestation and in infants less than eight weeks of age by means including, but not limited to, reliable and practical immunologic, virologic, and molecular-biologic techniques, safe and reliable methods for prenatal diagnosis of HIV infection, and evaluation of the timing and frequency of HIV transmission from mother to offspring during gestation and the intrapartum period.

Collaboration between scientists and/or institutions is encouraged but not required for response to this announcement. Access to a patient population and, if appropriate, a pre-existing sample collection that is sufficient to allow evaluation of hypotheses must be demonstrated. The use of funds from these grants to support the actual conduct of clinical trials will be judged nonresponsive, but plans for immunologic and virologic assessment of samples from women and infants enrolled in epidemiology or therapy trials that are supported by other funds are encouraged.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

The following is a brief statement of the NIH and ADAMHA policy regarding the inclusion of women and minorities in study populations. Applications that are responsive to this RFA will, by definition, meet the requirement for inclusion of women. The inclusion of minorities must be addressed in application submitted responding to this RFA.

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

This RFA will use the R01 mechanism. The NIAID has allocated \$3,000,000 (total costs) for the initial year of funding applications received in response to this RFA, with the relative level of support between epidemiologic and immunologic studies to be determined by Program Staff. The number of awards to be made is dependent upon receipt of a sufficient number of applications of high scientific merit and upon the availability of funds. The earliest possible award date is September 27, 1991. If NIAID determines that there is a sufficient continuing program need, this RFA will be reissued.

APPLICATION SUBMISSION

Eligibility: Any domestic or foreign institution, university, medical college, hospital, laboratory or other public, private or for-profit institution is eligible.

Letter of Intent: Prospective applicants are asked to submit, by March 15, 1991, a letter of intent that includes a descriptive title and a description (not to exceed one page) of the proposed research. Since applications that do not address areas of program relevance will be considered nonresponsive, potential applicants are strongly encouraged to discuss their research plans with program staff before completing their applications.

Submission: The regular research grant application form PHS-398 (rev. 10/88) must be used in applying. These forms are available at most institutional business offices and from the Division of Research Grants, NIH, 9000 Rockville Pike, Westwood Building, Room 449, Bethesda, Maryland 20892. To identify responses to this announcement, check "yes" and put "HIV IN MOTHERS AND INFANTS: IMMUNITY AND EARLY DIAGNOSIS (RFA AI-91-06)" under item 2 on page 1 of the grant application. The RFA label provided with the instructions must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application so that it may not reach the review committee in time for review.

The completed original application and twenty three (23) copies must be mailed to:

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

INQUIRIES: A more detailed RFA may be obtained from:

Patricia E. Fast, M.D., Ph.D. OR Vaccine R. and D. Branch Division of AIDS, NIAID, NIH 6003 Executive Blvd., Rm. 203E Bethesda, MD 20892 Telephone: (301) 496-8200	Rodney Hoff, M.D., M.P.H. Epidemiology Branch DAIDS, NIAID, NIH 6003 Executive Blvd., Rm. 241P Bethesda, MD 20892 Telephone: (301) 496-6177
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ANIMAL MODELS FOR SUDDEN INFANT DEATH SYNDROME

RFA AVAILABLE: HD-91-05

P.T. 34; K.W. 0755020, 0715205

National Institute of Child Health and Human Development

Application Receipt Date: May 15, 1991

PURPOSE

The National Institute of Child Health and Human Development (NICHD) is interested in expanding the scope of research conducted into the causes and pathologic mechanisms of Sudden Infant Death Syndrome (SIDS). In this solicitation, the NICHD invites applications for studies using fetal and/or young developing animals to elucidate environmental factors and developmental mechanisms during pregnancy and early postnatal life that predispose the young animal to a SIDS-like event, (i.e., sudden death during a sleep period), or the inability to recover from hypoxic or other life-threatening stresses. Information derived from these animal studies is expected to elucidate potential mechanisms of SIDS under experimental conditions unavailable in human infants and lead to the development of diagnostic and preventive strategies.

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity. This Request for Applications (RFA), "Animal Models for SIDS", is related to the priority area of "Maternal and Infant Health".

RESEARCH OBJECTIVES

The primary goals of this RFA are to support research investigations in intact animals or reduced preparations to examine the effects of relevant prenatal insults on the development and function of state-dependent regulatory and life-sustaining systems in infancy; to examine the effects of postnatal environmental challenges, i.e., insults or new stimuli; and/or to investigate animal model systems of developmental disorders/susceptibilities that mimic some aspects of the SIDS phenotype. In the context of these investigations, parallel studies of unperturbed development and function may be proposed. The extent of the normative studies should depend on the existing knowledge base.

Developmental studies that span the fetal and early postnatal period are encouraged.

MECHANISM OF SUPPORT

This program will be funded through the traditional individual research grant award program of NICHD. Grant applications will be reviewed at a single competition by an initial review group convened by NICHD. It is anticipated that eight (8) grants will be awarded under this program, contingent upon receipt of a sufficient number of meritorious applications and the availability of funds.

APPLICATION PROCEDURES

Applications must be submitted on Form PHS 398 (revised 10/88), available in business or grants offices at most academic research institutions and from the Division of Research Grants, NIH. The RFA label available in the 10/88 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 your application such that it may not reach the review committee in time for review. The phrase "ANIMAL MODELS SIDS APPLICATIONS, RFA HD-91-05" must be typed in item 2 of the face page of the application.

INQUIRIES

Applicants may request a copy of the full RFA from:

Marian Willinger, Ph.D.
Health Scientist Administrator
Pregnancy and Perinatology Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Executive Plaza North, Room 643
Bethesda, MD 20892
Telephone: (301) 496-5575

The full RFA is also available on the electronic version of the NIH Guide, the E-Guide.

Inquiries regarding grants management and administrative policy may be directed to:

Douglas Shawver
Supervisory Grants Management Specialist
Grants Management Branch
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 505
Bethesda, MD 20892
Telephone: (301) 496-1303

INTERVENTIONS TO PROMOTE APPLICATION OF STATE-OF-THE-ART CANCER MANAGEMENT IN RURAL AREAS

RFA AVAILABLE: CA-91-05

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

National Cancer Institute

Letter of Intent Receipt Date: March 20, 1991
Application Receipt Date: May 20, 1991

INTRODUCTION

The National Cancer Institute (NCI) invites applications for research projects aimed at strengthening the application of state-of-the-art cancer diagnosis and management practices in rural areas by enhancing links between rural health care providers and regional cancer specialists. The researchers are to test methods that enhance the utilization of existing cancer expertise and resources by rural providers. The development and evaluation of interventions that are sensitive to the cancer problems in a selected rural area and are supported by rural practitioners are important. Researchers are encouraged to be innovative in the development of interventions. Outcomes should be designed to capture changes in cancer diagnosis and management.

BACKGROUND AND PURPOSE

To date, the treatment programs of the NCI have been designed to conduct state-of-the-art cancer treatment research through a network of cancer specialists in university centers and community programs. With this initiative, the NCI strives to reach practitioners who provide care in rural communities and link them with cancer specialists. Such ties are critical to assuring that patients in rural and remote areas have access to the full range of state-of-the-art cancer care.

RESEARCH GOALS AND SCOPE

The purpose of the project is to test ways of enhancing links between rural health care providers and cancer specialists. The NCI expects the interventions to be designed to strengthen associations between the rural generalist providers and regional cancer specialists, and may include targeted training, visiting specialists, and/or clinical trials participation. Evaluation should address indicators of changes in cancer diagnosis and management practices and efficiency of the intervention.

Based on the characteristics of the health care providers and the patients in the rural area in which the research is to be conducted, the researchers are to test approaches to link rural providers and cancer specialists to enhance state-of-the-art cancer management practices of physicians and nurses in the selected rural area. The interventions should incorporate, as appropriate, established resources of the NCI, specifically the Cancer Information Service (CIS) or the Physicians' Data Query (PDQ) or Cancer FAX. Examples of possible interventions include:

- o review of screening and/or biopsy specimens;
- o computer-assisted diagnosis and/or management algorithms;
- o free telephone consultation between cancer specialist and generalist provider;
- o PDQ protocols for patient management with specialist consultation available; and
- o telephone hot-line service for consultation.

The research design should consider both process and health outcome measures as appropriate. The researchers are to focus the intervention on aspects of current cancer patient management that are well described in the baseline data. For example, a pattern of head and neck cancer diagnosis at stages III and IV or the lack of appropriate adjuvant chemotherapy for breast cancer could be the focus.

While mortality rate changes may be sought, NCI realizes that the research design may not have the power to discern such changes. An outcome of interest is the stage of cancer at diagnosis and the proportion of patients who receive state-of-the-art cancer management in the target rural area. Changes in practice are extremely important to document, as well as evaluation of the implementation techniques. Numerous direct and indirect indicators are possible.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 20, 1991, a letter of intent that includes a descriptive title of the proposed research, the name and address of the Principal Investigator, the names of other key personnel, the participating institutions, and the number and the title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, it is requested in order to provide an indication of the number and scope of applications to be reviewed.

The letter of intent should be sent to:

Anne R. Bavier, M.N., F.A.A.N.
Program Director, CORB, EDCOP, DCPC
National Cancer Institute
Executive Plaza North, Room 300-E
Bethesda, MD 20892
Telephone: (301) 496-8541

INQUIRIES

Written or telephone inquiries concerning the objectives and scope of this RFA or inquiries about whether or not specific proposed research would be responsive are encouraged and should be directed to the program director named above. The program director welcomes the opportunity to clarify any issues or questions from potential applicants.

KIDNEY AND UROLOGY RESEARCH CENTERS

RFA AVAILABLE: DK-91-03

P.T. 04; K.W. 0785095, 0785220, 0785055, 0785035, 0710030, 0745027, 0745070

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: March 15, 1991
Application Receipt Date: July 16, 1991

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for research center grants (P50) to be awarded in fiscal year 1992. NIDDK anticipates the award of up to six competitive center grants in fiscal year 1992.

BACKGROUND

Kidney and urologic diseases account for substantial and increasing morbidity and financial burden in the United States. They threaten the health, well-being, and longevity of over 13 million Americans and accounted for an estimated cost of at least \$50 billion in 1990. Although considerable progress has been made in understanding the basic physiology and patho-physiology of the normal renal and urologic systems, there has been only limited progress in unraveling the mechanisms of those disease processes that lead to progressive deterioration in the function of these systems. Nevertheless, major progress has been made in the management of their clinical consequences. For example, renal dialysis and transplantation are life-saving procedures and the clinical management of benign prostatic hyperplasia has improved over the past several years. Unfortunately, these scientific advances have not led to the means to prevent or reverse these diseases, and their incidence is steadily increasing. The proposed multidisciplinary research centers, the George M. O'Brien Kidney and Urologic Diseases Research Centers, should provide the necessary and appropriate expertise to investigate topical areas of research related to the pathogenesis of kidney and urologic diseases such as: immunologically mediated diseases; diabetes mellitus and other endocrine and metabolic disorders; primary renal hypertension; genetic abnormalities; bladder physiology and pathophysiology; developmental and obstructive disorders; and nephrotoxins and toxic cell injury.

OBJECTIVES AND SCOPE

The emphases of this initiative are threefold: (1) to attract new scientific expertise into the study of the basic mechanisms of kidney and urological diseases; (2) to encourage interdisciplinary research; and (3) to extend these basic investigations into innovative clinical and epidemiologic studies of the causes, therapy, and prevention of kidney and urologic diseases and disorders. In approaching the study of these disease processes, it is anticipated that extensive collaboration will be required between individuals in the basic sciences, including cell biology, molecular biology, immunology, genetics, epidemiology, biochemistry, physiology, and pathology with clinical sciences. It is the expressed intent of the announcement to attract into the study of kidney and urologic disorders new investigators not currently active in this field and to explore new basic areas that may have clinical research application. Individual institutions with both basic and clinical research capabilities are eligible to apply. Inter-institutional collaborative research arrangements are also appropriate and are encouraged.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

NIDDK expects to award up to six center grants (P50) in fiscal year 1992 on a competitive basis. The receipt of up to six competitive continuation applications from those centers who are current awardees is anticipated. These applications will compete for awards along with other applications received in response to this announcement. Foreign institutions are not eligible to apply. The anticipated awards are for five years and are contingent upon the availability of appropriated funds. The total amount of available funds to support this program (including both direct and indirect costs) is anticipated to be no more than \$4.2 million per year. No applicant may request more than \$750,000 in total costs (both direct and indirect costs) in the initial budget period.

The complete Request for Applications (RFA) and consultation may be obtained from:

Dr. Ralph L. Bain
Kidney and Urology Research Centers Program Director
DKUHD/NIDDK
Federal Building, Room 102
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-8218

REVIEW PROCEDURES

Applications for an award of a research center grant will be evaluated in a national competition by the NIH peer review process. Applications will be reviewed initially by a special review committee convened by the NIDDK and subsequently by the National Diabetes and Digestive and Kidney Diseases Advisory Council.

METHOD OF APPLYING

Potential applicants are urged to submit a letter of intent to the Program Director by March 15, 1991, regarding their application. The letter of intent is nonbinding and is not a precondition for an award. The letter of intent should include the name(s) of the Principal Investigator(s), principal collaborators, a descriptive title of the proposed research center, and the organization(s) involved. Applications must be submitted using PHS Form 398 (Rev. 10/88). The RFA label contained in the application kit must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing and review of the application. Complete line 2 of the application face page by inserting the title and number of this RFA and checking the YES box.

Mail the completed application (original and four copies) to:

Application Receipt Office
Division of Research Grants
Westwood Building, Room 240
National Institutes of Health
Bethesda, MD 20892**

Simultaneously submit two copies to:

Review Branch, NIDDK
5333 Westbard Avenue
Westwood Building, Room 406
Bethesda, MD 20892

The special single receipt date for submissions in response to this announcement is July 16, 1991, with earliest funding August 1, 1992.

This program is described in the Catalog of Federal Domestic Assistance No. 93.849, Kidney, Urologic, and Hematologic Diseases 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.

SCIENCE EDUCATION PARTNERSHIP AWARD

RFA AVAILABLE: ADAMHA AD-91-01
NIH OD-91-01

P.T. 44; K.W. 0720000, 0710000

Alcohol, Drug Abuse, and Mental Health Administration
National Institutes of Health

Letter of Intent Receipt Date: March 15, 1991
Application Receipt Date: April 25, 1991

BACKGROUND INFORMATION

The President and the Nation's Governors have declared six "National Education Goals," one of which is that by the year 2000, students in the United States will be the world leaders in science and mathematics achievement. Further, unless there are adequate numbers of students entering and remaining in the mathematics and scientific fields of education, the United States will not have a sufficient supply of scientists, engineers, and technicians to meet the Nation's future workforce needs. There is also the need for a scientifically literate society that understands the role of science, biology, and technology. There is a lack of public understanding of behaviors that increase the risk for disease, the use of animals in behavioral and biomedical research, and the necessity for basic research to make progress toward improving health. To help address these issues, the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) and the National Institutes of Health (NIH) are initiating in Fiscal Year 1991 the Science Education Partnership Award (SEPA) Program. To meet their respective missions, the ADAMHA and the NIH are issuing this joint Request for Applications (RFA) for SEPA proposals. Applicants may submit multiple different applications under this RFA; however, substantially similar proposals may not be submitted to the two agencies.

PROGRAM DESCRIPTION

The SEPA Program will support grants designed to encourage scientists to work with educators and community organizations to improve student and public understanding of science, and increase interest of young people in scientific careers. The focus of student activities is to be at the kindergarten through twelfth grade (K-12) level. The scientists who study disease and illness and those who carry out basic research relating to these disorders, have a major contribution to make by conveying their knowledge and also the excitement in doing research. However, it is also essential that scientists work with educators, school administrators, community leaders, the media, and others in order to make effective contributions to improving science education and improving public understanding of both the process and accomplishments of science.

ADAMHA will support partnership projects that focus on any scientific area relevant to the ADAMHA mission. Hence, the focus of this award is on building partnership programs. ADAMHA is especially interested in projects that focus on scientific knowledge about the brain and behavior and their relation to the addictive and mental disorders. This includes the basic sciences underlying these disorders, such as the neurosciences, psychology, pharmacology, genetics, and other relevant sciences.

The NIH SEPA Program will support the development of model programs that join working scientists and educators in enhancing the precollege science education and public understanding in such biomedical science areas as molecular biology, molecular genetics, immunology, neuroscience, and bioinformatics, as well as ethical issues, the benefits and risks of genetic engineering, and the role of environmental health.

ADAMHA and NIH will consider cofunding of projects focussing on general aspects of health science (e.g., the responsible use of animals in biomedical and behavioral science or biotechnology) or scientific areas that cut across the mission of both agencies (e.g., neurosciences, genetics, and health and behavior). A single application should be submitted for such projects.

The ADAMHA and the NIH encourage and support the initiation of cooperative efforts among diverse elements in the scientific and education community,

including university scientists, elementary and secondary schools, foundations, private industry, the media, and museums, to develop model programs for increasing scientific literacy. The ADAMHA/NIH SEPA Program seeks to focus on the improvement of science education through partnerships between public and private sector organizations and the working scientists. Carefully crafted partnerships can create channels for transferring information about new scientific discoveries, improve curricula, and develop textbooks and other materials that increase and impart to students, teachers, and the general public the utility of biomedical/behavioral research. The essential feature of the program is the active participation of scientists with the scientific and technical knowledge and resources with the knowledge and pedagogical expertise of educators. Research institutions are encouraged to provide, from non-Federal sources, incentives for their scientists to participate in the SEPA Program. These incentives may include the awarding of sabbaticals, time released from other duties, or special institutional recognition to individuals, to permit them to participate in the program. Such applicants are also encouraged to use institutional funds released as a result of the SEPA award (e.g., investigators' salaries) for purposes consistent with this award.

ADAMHA and NIH seek the development of model projects and, therefore, priority will be given to applications with the potential for widespread use and replication.

MECHANISM OF SUPPORT/AVAILABILITY OF FUNDS

This RFA will use the grant-in-aid for education projects (R25). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement.

This RFA is a one-time solicitation. The ADAMHA and the NIH expect that \$2 million will be available to each agency (a total of \$4 million) during FY 1991 to support this initiative. Subject to the availability of funds and receipt of a sufficient number of meritorious applications, it is anticipated that approximately ten to twenty projects will be supported.

Applicants may request support for up to three years. Annual direct cost requests for the proposed activities are expected to range from approximately \$100,000 to \$250,000. Indirect costs will be provided. The anticipated award date is September 30, 1991.

REVIEW PROCEDURES

Applications that are complete and responsive will be evaluated for educational and scientific/technical merit by an appropriate peer review group convened by ADAMHA and NIH. Applications may be subjected to triage by a peer review group to determine their educational and scientific merit relative to other applications received in response to this RFA. Those applications judged to be competitive will undergo further merit review. The second level of review will be provided by the National Advisory Mental Health Council and/or the National Advisory Research Resources Council.

METHOD OF APPLYING AND LETTER OF INTENT

The Application for Public Health Service Grant Form PHS-398 (revised 10/88) must be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, NIH, 5333 Westbard Avenue, Bethesda, Maryland 20892, (301) 496-7441. Prospective applicants must request a copy of the complete RFA, which includes supplemental instructions for completion of the Form PHS-398, from the staff identified below (see INQUIRIES).

Prospective applicants are asked to submit, by March 15, 1991, a letter of intent that includes a descriptive title of the proposed project; the name, address, and telephone number of the Principal Investigator; the names of other key personnel, the participating institutions; and the number and title of the RFA in response to which the application is being submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains is extremely helpful in planning for the review of applications. It allows staff to estimate the potential review workload and to avoid possible conflict of interest in the review.

The ADAMHA letter of intent should be sent to the Deputy Director, Division of Extramural Activities, National Institute of Mental Health, Parklawn Building

Room 9-105, 5600 Fishers Avenue, Rockville, MD 20857. The NIH letter of intent should be sent to Dr. Marjorie A. Tingle (see address below). A copy of the letter of intent should be addressed to:

Anthony Demsey, Ph.D.
Associate Director for Referral and Review
Division of Research Grants
National Institutes of Health
Westwood Building, Room 338
5333 Westbard Avenue
Bethesda, MD 20892**

INQUIRIES

Written or telephone inquiries regarding this RFA, and requests for the complete RFA may be directed to either:

Dr. Joel W. Goldstein
ADAMHA SEPA Program
Room 13-103
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-9674

or

Marjorie A. Tingle, Ph.D.
NIH SEPA Program
National Center for Research Resources
Westwood Building, Room 10A11
5333 Westbard Avenue
Bethesda, MD 20892**
Telephone: (301) 496-6743

ADAMHA awards are under the authority of Section 301 of the Public Health Service Act, as amended, (42 U.S.C. 241). NIH awards are under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285). All awards will be administered under PHS grant policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MULTICENTER COOPERATIVE AGREEMENT FOR STUDYING NEURAL TUBE DEFECTS IN MUTANT MICE

RFA AVAILABLE: HD-91-01

P.T. 34; K.W. 0710030, 1002004, 1002019, 1002059, 0755030

National Institute of Child Health and Human Development

Application Receipt Date: April 22, 1991

OVERVIEW

Neural tube defects (NTDs) are among the most common congenital defects, occurring at a rate of 1-2/1000 live births. Despite their frequency the causes of NTDs are still not understood. The National Institute of Child Health and Human Development (NICHD) invites research applications from investigators willing to participate with NICHD assistance under cooperative agreements in a multicenter cooperative program designed to investigate the etiology of neural tube defects. The objective of the study is to bring together a multidisciplinary group of investigators to characterize mammalian neurulation in a mouse genetic model for spina bifida, the curly tail mouse, developed under NICHD contract. Particular emphasis will be given to individual studies examining the molecular, cellular, biophysical, and morphological mechanisms involved in neural tube formation. The cooperative agreement mechanism has been chosen to facilitate identification of the etiology of spina bifida by coordinating research among the individual sites within the program. Analyses of the various aspects of NTD formation will be coordinated among the investigators, and it is anticipated that there will be substantial evolution of the program as new findings are obtained and shared. The benefit of such a cooperative venture will be to better define the mechanisms by which normal neurulation occurs and to characterize the processes leading to NTDs in a well defined mammalian model with an applicability to the human condition.

MECHANISM OF SUPPORT

Support will be available through the cooperative agreement mechanism (U01) between individual investigators and the NICHD. The major difference between a cooperative agreement and a research grant is that there will be substantial programmatic involvement of NICHD staff above and beyond the levels required for traditional program management of grants.

It is anticipated that four awards totaling \$800,000 (direct costs) for the first year will be made with an award period of five years.

REVIEW PROCEDURES

Applications will be reviewed by the NICHD staff for responsiveness to the Request for Applications (RFA) and may receive a triage review for relative scientific merit by a peer review group. Scientific and technical merit will be evaluated by a special review committee convened specifically for this purpose by the Division of Scientific Review, NICHD. A second-level review will be done by the National Advisory Child Health and Human Development Council.

APPLICATION PROCEDURE

Applications must be submitted on form PHS 398, Revised 10/88.

ADDITIONAL INFORMATION

Potential applicants are encouraged to request the detailed RFA by telephoning:

Delbert Dayton, M.D.
Genetics and Teratology Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Executive Plaza North, Room 643
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-5541

The full RFA is also available on the electronic version of the NIH Guide for Grants and Contracts, the E-Guide.

ERRATUM

ADDENDUM: NATIONAL INSTITUTE ON DRUG ABUSE - ANNOUNCEMENT AND GUIDELINES - AUGUST 1990

PA: PA-90-31

P.T. 34; K.W. 0404009, 1014006

National Institute on Drug Abuse

As an addendum to the National Institute on Drug Abuse (NIDA) Research Grants Program Announcement and Guidelines, PA-90-31 (published in the NIH Guide for Grants and Contracts, Vol. 19, No. 32, September 7, 1990, NIDA wishes to include as part of Research Support Mechanisms the following: (7) Program Project Grants (P01). Although the P01 mechanism was included in the September 7, 1990, NIH Guide notice, the complete, printed copy of the announcement inadvertently omitted it as one of the possible support mechanism acceptable under this announcement. Today's notice is to confirm that the P01 support mechanism is acceptable under announcement PA-90-31. All other aspects of the announcement remain unchanged.

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS OR CONTACTING PROGRAM STAFF IN THE WESTWOOD BUILDING IS THE CENTRAL MAILING ADDRESS FOR THE NATIONAL INSTITUTES OF HEALTH. APPLICANTS WHO USE EXPRESS MAIL OR A COURIER SERVICE ARE ADVISED TO FOLLOW THE CARRIER'S REQUIREMENTS FOR SHOWING A STREET ADDRESS. THE ADDRESS FOR THE WESTWOOD BUILDING IS:

5333 Westbard Avenue
Bethesda, Maryland 20816