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For Grants
and
Contracts

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Vol. 17, No. 32
October 7, 1988

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NOTICES

NOTICE: FEDERAL RIGHTS TO INVENTIONS UNDER FELLOWSHIPS AND TRAINING GRANTS

P.T. 22, 44; K.W. 1014002

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

The Federal Government's rights to inventions under fellowship and training grants are defined in 35 U.S.C. 212 as follows:

"No scholarship, fellowship, training grant, or other funding agreement made by a Federal agency primarily to an awardee for educational purposes will contain any provision giving the Federal agency any rights to inventions made by the awardee."

Current Public Health Service (PHS) fellowship and training grant applications request information regarding inventions, which is inconsistent with the statute. In fact, as identified in the PHS GRANTS POLICY STATEMENT, inventions information and reporting requirements pertain solely to research grants.

Accordingly, applicants for an individual National Research Service Award (NRSA) should disregard all information and requests for information concerning inventions in the application package for new and competing continuation individual NRSA's (Form PHS 416-1 (Rev. 6/85)) and the application package for noncompeting continuation individual NRSA's (Form PHS 416-9 (Rev. 6/85)).

Applicants for an institutional NRSA should disregard all information and requests for information concerning inventions in the application package for new and competing continuation institutional NRSA's (Form PHS 398 (Rev. 9/86)) and the application package for noncompeting continuation institutional NRSA's (Form PHS 2590 (Rev. 9/86)).

In view of 35 U.S.C. 212 above, Final Invention Statement and Certification, Form HHS 568 (Rev. 8/87), is not applicable to fellowships and training grants.

SOURCES SOUGHT

A RANDOMIZED TRIAL OF UMBILICAL ARTERY CATHETER PLACEMENT: ASSOCIATION OF HIGH LEVEL CATHETERS WITH INTRAVENTRICULAR HEMORRHAGE

Sources Sought Announcement: NICU Study

P.T. 34; K.W. 0755015, 0403020, 0785135

National Institute of Child Health and Human Development

The National Institute of Child Health is seeking sources capable of performing a study involving the placement of umbilical artery catheters in a high or low position in inborn very low birth weight infants. The purpose of the study is to determine if high level umbilical artery catheters are associated with a higher incidence of intraventricular hemorrhage than are low level catheters.

The requirements of the study will be:

1. To have available a level 3 neonatal intensive care unit (NICU) capable of mechanically ventilating infants with a minimum annual admission rate of 300 infants per year and a minimum annual birth rate of 3,000. The unit must be willing to enter a minimum of 50 very low birth weight infants (less than 1500 grams) into the study per year.
2. Each NICU will be responsible for obtaining approval from their Institutional Review Board of the proposed protocol.
3. Assignment of the infant to receive either a high or low umbilical artery catheter will be communicated to the NICU by a Data Coordinating Center. The NICU will be responsible for enrolling the infant into the study and obtaining parental consent for the infant's participation. The NICU will then be responsible for inserting the umbilical artery catheter (3.5 Fr. for < 1200

gram infants; 5.0 Fr. for 1200 gram and over infants) and verifying the catheter's assigned position.

4. The NICU will be responsible for abstracting the information requested on an abstract form provided by the Data Coordinating Center. This information will come from the first 5 days of life and will include such variables as mean daily fluid intake, respirator settings, exposure to certain drugs, demographic information and birth information.

5. On day 5 to 7 the NICU will be expected to have an ultrasound of the infant's head performed as part of routine care. The reading of the ultrasound by the radiologist at the hospital, of which the NICU is a part, should be reported according to the classification scheme of Papile and recorded on the data abstract form.

6. Upon receipt of the data abstract form by the Data Coordinating Center the NICU will be reimbursed a fixed fee for the enrollment of the infant.

Centers that believe they possess the necessary capabilities to perform the tasks specified above must supply the following required information:

1. Evidence documenting the available population of newborns meeting the criteria stated above. MINIMUM SUBMISSION REQUIREMENT: Provide annual numbers of births in your hospital and the number of inborn and outborn infants admitted to your NICU for the two most recent years available.

2. Evidence documenting the number of umbilical artery catheters placed annually and the usual level of placement. MINIMUM SUBMISSION REQUIREMENT: As stated.

3. Evidence documenting the usual time for head ultrasounds for very low birth weight infants and your institutional radiologist's experience in reading ultrasounds. Also supply the type of ultrasound equipment available. MINIMUM SUBMISSION REQUIREMENT: The number of head ultrasounds done in a year and the age at which the ultrasound was done. If annual figures are not available, supply the number and timing of ultrasounds performed in a consecutive series of recent very low birth weight infants that have been discharged. Also include the incidence of intraventricular hemorrhage over the past year.

4. Evidence documenting the routine collection of information requested on the data form. MINIMUM SUBMISSION REQUIREMENT: Nursing flow sheet for recording of infants vital signs and respirator settings.

5. Evidence documenting the capacity of the responding physician's ability to carry out a research protocol and a description of the role that the responding physician has played in previous research protocols. MINIMUM SUBMISSION REQUIREMENT: A protocol from a previous study carried out in the NICU.

6. Evidence documenting staff qualifications and experience in the areas of neonatology and NICU nursing and a description of the nursery layout. MINIMUM SUBMISSION REQUIREMENT: Provide the curriculum vitae for key personnel and the usual staffing pattern of the NICU by attending physicians, housestaff and nurses. Also supply the number of beds assigned to various levels of care and the occupancy rate.

THIS IS NOT A REQUEST FOR PROPOSAL. Responses should not include cost or pricing information. Concise responses addressing the above requirements are requested. Ten copies of the requested information shall be due no later than the close of business (4:00 pm, E.S.T.) on November 15, 1988.

All responses should reference "NICU STUDY" and be submitted to :

Mr. Harvey Shifrin
Contracting Officer
Contracts Management Section, OGC
National Institute of Child Health
and Human Development
Executive Plaza North, Room 515
Bethesda, Maryland 20892

DATED ANNOUNCEMENTS (RFPs AND RFAs)

ALZHEIMER'S DISEASE RESEARCH CENTERS

RFA AVAILABLE: 89-AG-01

P.T. 04; K.W. 0715180, 0710030

National Institute on Aging

Application Receipt Date: January 18, 1989

Letter of Intent Receipt Date: November 4, 1988

BACKGROUND

The National Institute on Aging (NIA) is inviting grant applications from interested institutions to establish centers of excellence devoted to the study of Alzheimer's disease and related dementing disorders of the aged. This solicitation is to increase the number of existing centers authorized under the Public Health Service Act, (Section 445). An ADRC will be expected to foster the following related functions: conducting multidisciplinary research, training scientists and clinicians, and teaching and/or transferring new information concerning Alzheimer's disease and related disorders.

ELIGIBILITY

Institutions eligible for Specialized Center Grants are those at which there are at least three principal investigators with any PHS agency or comparable peer reviewed research project (R01) grants, each with at least two years of committed support remaining at the time of application or one or more program project (P01) grants, which also have at least two years of committed support remaining. Institutions that can demonstrate the ability to launch such a research effort are also eligible.

MECHANISM OF SUPPORT

The support mechanism for this program will be the traditional NIH grant-in-aid. The award of grants is contingent upon the availability of funds for this purpose. The intent is to fund up to three ADRC grants.

REVIEW PROCEDURES AND CRITERIA

Applications received in response to the RFA will be reviewed for scientific and technical merit by an NIA initial review group. Proposals may first receive a preliminary review by a subcommittee of the review panel to establish those applications deemed to be competitive. Proposals judged to be non-competitive or non-responsive will be administratively withdrawn and returned to the applicant with an abbreviated summary noting the major areas of concern. Applications judged to be competitive will be given full review. Following review by the initial review group the applications will be evaluated by the National Advisory Council.

METHOD OF APPLYING

The application must be submitted on the 9/86 revision of form PHS 398. The RFA label available in the 9/86 revision of Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. Although not mandatory, potential applicants are encouraged to submit to the address indicated below, a non-binding letter of intent to apply by November 4, 1988. Applications must be received by January 18, 1989, for earliest start date of September 30, 1989. If received late, the application will be returned without review.

Applicants should write or phone to obtain the complete RFA, the guidelines for preparing an application properly and to discuss their plans with and direct any other inquiries to:

Associate Director, NNA, NIA, NIH
Building 31, Room 5C35
9000 Rockville Pike
Bethesda, Maryland 20892
Telephone: (301) 496-9350

CENTERS FOR AIDS RESEARCH

RFA AVAILABLE: 88-AI-15

P.T. 04; K.W. 0715120, 0710030, 0785035, 1014001

National Institute of Allergy and Infectious Diseases

Letter of Intent Date: December 1, 1988

Application Receipt Date: January 5, 1989

Background Information

The NIAID is reannouncing a Request for Applications (RFA) for its "Centers for AIDS Research" (CFAR) program, and invites applications for a limited number of awards in FY89 for Centers for AIDS Research. The purpose of the CFAR is to facilitate the development of new knowledge from various relevant biomedical sciences and/or the application of such knowledge to clinical investigations with the ultimate goal of achieving improved diagnosis, treatment, and prevention of AIDS and its sequelae.

RESEARCH GOALS AND SCOPE

The AIDS Research Center Core Support Grant is intended to enhance and extend the effectiveness of groups of related research projects and investigators already funded through other peer-reviewed support mechanisms such as Research Grants, Cooperative Agreements or Research Contracts. The eligible Centers must have an established base of research excellence and the Center Core Support Grant is designed to support those activities that will consolidate and focus AIDS and AIDS-related research efforts in a coordinated administrative and scientific programmatic structure. The Center Core Support Grant is intended to contribute to the stability and further development of ongoing AIDS research activities, promote further collaboration and interaction between participating investigators, and provide support for administration and research resources, and leadership for Center activities.

MECHANISM OF SUPPORT

Specifically, the Center Core Support Grant initiative will provide funding for: 1) shared equipment, space, and facilities; 2) facilitating the integration of basic with clinical and applied research on AIDS and its sequelae; 3) discretionary or development funding required to support efforts of new investigators until independent funding is secured; 4) the administrative activities of the Center; 5) senior leadership personnel who have the responsibility for overall direction of the Center; 6) leaders of each proposed core component or shared resource; 7) alteration and renovation of existing structures to provide suitable facilities for AIDS or AIDS-related research; and 8) the costs of planning and evaluation of the Center.

Approximately \$3.0 million dollars is included in the NIAID financial plans for Fiscal Year 1989 for grants awarded in response to this solicitation. NIAID anticipates the award of two to three AIDS research center grants in fiscal year 1989. Grants will be funded for up to five years starting in July, 1989.

ELIGIBILITY

Applications from domestic academic, non-profit or for-profit research institutions are eligible for awards. Only one application may be submitted from a given institution. Support of all Center activities will be coordinated through a Central Operations Office located within the Center Director's institution.

Each applicant must have at least \$750,000 (Direct Costs) per year of current NIH support for ongoing research projects in AIDS or AIDS-related research. This may include research grants, contracts and/or Cooperative Agreements. An applicant may be a single institution or a consortium. Eligible current support must have been obtained through the NIH peer review mechanism. At least two of the component-funded projects or one multidisciplinary program (e.g., a P01) must be NIAID-supported. Only domestic institutions are eligible to apply. Applicants may request funding for up to five years.

INQUIRIES

Additional information and a copy of the full RFA may be obtained from:

Dr. William J. Gartland
AIDS Program
NIAID, NIH
6003 Executive Blvd
Room 247P
Bethesda, Maryland 20892
Telephone: (301) 496-0545

Special instructions and format examples for preparation of these applications have been developed, and should be requested from Dr. Gartland or from:

Dr. Hortencia Hornbeak
Acting Chief, AIDS Review Section
Program and Project Review Branch
NIAID
Westwood Building, Room 3A-05
5333 Westbard Avenue
Bethesda, Maryland 20892
Telephone: (301) 496-0123

RADIOLABELED IMMUNOCONJUGATE DOSIMETRY

RFA AVAILABLE: 89-CA-04

P.T. 34; K.W. 0785190, 1013026, 0710070

National Cancer Institute

Application Receipt Date: January 6, 1989

The Radiation Research Program (RRP), Division of Cancer Treatment (DCT), of the National Cancer Institute (NCI), announces the availability of a Request For Applications (RFA) for the above program. The main objective is to develop and validate techniques to estimate radiation dose to neoplastic and normal cells and tissues from the in-vivo administration of antibodies and antibody fragments labeled with radioactive nuclides. Alpha, beta and photon emitters have been proposed as potential labels and, therefore, proposals are invited that develop dosimetry for any or all of the proposed radionuclides.

Radiolabeled immunoconjugates directed against tumor cell-surface antigens have shown promise as both diagnostic and therapeutic agents in-vitro and in human tumor implants in animals. The prospect of an agent directed specifically against neoplastic cells has led to clinical trials in humans. While calculating the dose delivered by the low activity used in diagnosis is desirable, it is mandatory in therapy when a large activity of radiolabeled immunoconjugate must be delivered to the neoplastic tissue in order to achieve the desired improvement in patient survival. Being able to calculate dose requires that one can determine the distribution within the body, for both normal and neoplastic tissue, through measurement or through the extrapolation of experimental or theoretical data. Recent measurement by microdosimeters and observations from autoradiography have shown the distribution in tumors to be much more inhomogeneous than could be appreciated by available nuclear medicine imaging, including SPECT. Dosimetry, to date, has not accounted well for this aspect or for irregularly shaped tumors. The use of an extended MIRD-type calculation has been proposed, but MIRD's major assumption is homogeneous distribution of radionuclide. Present methods provide an estimate of dose, but clearly some modification of "normal" methods or new development must be made. The dosimetry may even have to be modified for each antibody, radionuclide (alpha, beta, or gamma emitter) and/or target. Thorough evaluation of cancer therapy using radiolabeled immunoconjugates requires the best calculation of dose that can be performed.

It is anticipated that approximately three of possibly four scientifically meritorious applications can be funded.

Request for copies of the complete RFA should be addressed to:

Robert J. Morton, M.S.
Program Director
Radiotherapy Development Branch
Radiation Research Program
Division of Cancer Treatment
National Cancer Institute
National Institutes of Health
9000 Rockville Pike, EPN Room 800
Bethesda, Maryland 20892
Telephone: (301) 496-9360

DIGESTIVE DISEASES CORE CENTERS

RFA AVAILABLE: 89-DK-01

P.T. 04; K.W. 0715085, 0715135, 0785035, 0765035, 0710030

National Institute of Diabetes and Digestive and Kidney Diseases

Application Receipt Date: February 15, 1989

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for Digestive Diseases Core Center Grants to be awarded in Fiscal Year 1990.

The objectives of the Core Center are to bring together, on a cooperative basis, clinical and basic science investigators in a manner which will enhance and extend the effectiveness of research being conducted in the field of digestive diseases. Within the research activities of the Center should be research that is relevant to the underlying cause(s), mechanism(s), diagnosis, early detection, prevention, control and treatment of digestive diseases and related physiological, pathophysiological, congenital or metabolic disorders resulting from such diseases. The focus of the research program in the center can be a disease such as pancreatitis, functional bowel disease, chronic hepatitis; an organ such as liver, esophagus, large bowel; a process such as absorption, secretion, motility or an appropriate combination thereof which may also include areas of relevant technology.

Institutions that have the necessary foundation of multidisciplinary digestive diseases-related research are encouraged to apply for a Digestive Diseases Core Center Grant. Each applicant must show that at least fifty percent of the fiscal support for the ongoing research projects in areas relevant to digestive diseases is from the NIDDK and that the remainder of the research projects to be included in the center research base are relevant to the goals of the research Core Center. Foreign institutions are not eligible to apply.

NIDDK expects to award up to four Digestive Diseases Core Center Grants in Fiscal Year 1990 on a competitive basis. The receipt of four competitive continuation applications is anticipated and they will be in competition for an award together with other applications received in response to this announcement. The NIDDK anticipates that the next announcement (RFA) for Digestive Diseases Core Center applications will be in September 1989.

The complete RFA, Core Center Grant Guidelines as well as consultation may be obtained from:

Dr. Ralph L. Bain
Digestive Diseases and Nutrition
Centers Program
National Institute of Diabetes
and Digestive and Kidney Diseases
Bethesda, Maryland 20892
Westwood Building, Room 3A15
Telephone: (301) 496-6045

Potential applicants are urged to submit a letter of intent by December 16, 1988 regarding their application.

The RFA label (found in the 9/86 revision of application form PHS 398) 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 of an application such that it may not reach the review committee in time for a review.