

# NIH GUIDE

## For Grants and Contracts

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## NOTICES

### IMPLEMENTATION OF NEW RESTRICTIONS ON LOBBYING REGARDING GRANTS AND COOPERATIVE AGREEMENTS

P.T. 34; K.W. 1014004, 1014006

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

The purpose of this notice is to update the information on this subject published in the December 15, 1989 edition of the NIH GUIDE FOR GRANTS AND CONTRACTS (Vol. 18, No. 44).

#### BACKGROUND

Section 319 of Public Law 101-121, which was signed October 23, 1989 by the President, amends Title 31, United States Code, by adding a new Section 1352, entitled "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions."

Section 1352 generally prohibits recipients of Federal grants, cooperative agreements, contracts, and loans from using Federal (appropriated) funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a SPECIFIC grant, cooperative agreement, contract, or loan. Section 1352 also requires that each person who requests or receives a Federal grant, cooperative agreement, contract, or loan must disclose lobbying undertaken with non-Federal (non-appropriated) funds. These requirements apply to (1) grants, cooperative agreements, and contracts EXCEEDING \$100,000 (total costs), and (2) a loan, or a Federal commitment to insure or guarantee a loan, exceeding \$150,000.

The information furnished in this notice relates SOLELY to grants and cooperative agreements. The requirements for contracts have been made part of the contractual document itself.

#### IMPLEMENTATION OF REQUIREMENTS

On December 20, 1989, the Office of Management and Budget (OMB) issued "interim final guidance" in the FEDERAL REGISTER (Vol. 54, No. 243) for governmentwide implementation of, and compliance with, the requirements of Section 1352. A few of the major points in the OMB guidance are:

- o The guidance is effective December 23, 1989.
- o The requirements apply to ALL "Persons" (foreign and domestic) defined as "an individual, corporation, company, association, authority, firm, partnership, society, State, and local government, regardless of whether such entity is operated for profit or not for profit." An Indian tribe or other Indian organization is EXCLUDED from this term.
- o Although "lobbying" is NOT defined, the term "influencing or attempting to influence" means "making, with the intent to influence, any communication to or appearance before an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any covered Federal action" (grant, cooperative agreement, contract, loan and "the extension, continuation, renewal, amendment, or modification" thereto).
- o There are two types of requirements in connection with a particular grant or cooperative agreement:
  1. Prohibited is (a) use of APPROPRIATED funds to pay lobbyists; and (b) use of APPROPRIATED funds by grantees to INFLUENCE the awarding of a specific grant or cooperative agreement.
  2. Disclosure concerning payments to lobbyists with NON-APPROPRIATED funds.
- o The prohibition on the use of appropriated funds DOES NOT APPLY TO:
  1. Reasonable compensation to an applicant's EMPLOYEE for "agency and legislative liaison activities" NOT DIRECTLY RELATED to a specific grant or cooperative agreement.

2. Reasonable payment to an applicant's EMPLOYEE or OTHER INDIVIDUAL for "professional or technical services" rendered DIRECTLY in the preparation, submission, or negotiation of an application for a grant or cooperative agreement, or for meeting requirements imposed by law.

Traditional interaction of investigators and other grantee organization personnel with NIH and ADAMHA program officials and grants management staff continue to be ALLOWABLE communications. Some EXAMPLES of such interaction are: technical discussions concerning the investigator's particular science area(s); reporting of scientific progress on existing awards; information or scientific discoveries germane to continuation of such awards; and inquiry concerning the "peer review" and/or "funding" status of grant or cooperative agreement applications.

UNALLOWABLE communications include those, when supported by FEDERAL funds, that argue for approval or advocate funding of the grant or cooperative agreement application. Disclosure of payments to lobbyists supported by NON-FEDERAL funds are to be reported on Standard Form LLL, "Disclosure of Lobbying Activities," as described below.

#### ISSUANCE OF GRANTS AND COOPERATIVE AGREEMENTS

The current application forms PHS 398 and 2590 (Revised 10/88, Reprinted 9/89) will undergo a general revision prior to their current expiration date of 3/31/91. In addition, application form PHS 5161-1 (Revised 3/89) will undergo a general revision prior to its current expiration date of 9/30/91. The new restrictions on lobbying will be part of the forms revision. However, until that occurs, following are INTERIM procedures addressing the lobbying assurance.

Beginning December 23, 1989, the CERTIFICATION REGARDING LOBBYING must be completed and returned to the National Institutes of Health (NIH) or the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) awarding component before a grant or cooperative agreement award EXCEEDING \$100,000 (total costs) may be issued. Standard Form LLL, "Disclosure Form to Report Lobbying," IF REQUIRED, must be filed according to its instructions.

Applicant organizations submitting grant and cooperative agreement applications to the NIH and ADAMHA should submit the CERTIFICATION REGARDING LOBBYING and Standard Form LLL, "Disclosure Form to Report Lobbying," IF REQUIRED, with ALL applications. Both the CERTIFICATION REGARDING LOBBYING and DISCLOSURE FORM are found at the end of this edition of the NIH GUIDE FOR GRANTS AND CONTRACTS.

For grant and cooperative agreement application purposes, PLEASE REPRODUCE THE CERTIFICATION and attach it, COMPLETED AND SIGNED, to the application as follows:

- o Behind the CHECKLIST page, for competing applications (Form PHS 398);
- o Behind the APPLICATION FACE page, for noncompeting continuation applications (Form PHS 2590);
- o Behind the Assurances-Non-Construction Programs page, Standard Form 424B, for both competing and noncompeting continuation applications (Form 5161-1).

For grant and cooperative agreement application purposes, PLEASE REPRODUCE THE DISCLOSURE FORM, and attach it, COMPLETED AND SIGNED, IF REQUIRED, to the application in the same manner as immediately above.

The following procedure applies ONLY to those applications that have been submitted prior to this notice:

Upon being informed by the NIH or ADAMHA awarding component that a grant or cooperative agreement award IS LIKELY TO BE ISSUED, grantee organizations may send the CERTIFICATION and DISCLOSURE FORM, IF REQUIRED, to that awarding component.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

HUMAN X CHROMOSOME COSMID MAPPING

REQUEST FOR STATEMENT OF CAPABILITIES: NIH-NINDS-90-001

P.T. 34; K.W. 1002058, 1002008

National Institute of Neurological Disorders and Stroke

The Section of Receptor Biochemistry and Molecular Biology, Laboratory of Molecular and Cellular Neurobiology, National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), is seeking to identify organizations capable of providing support for a large-scale DNA sequencing project. The overall goal of the project is to determine the sequence of a set of overlapping cosmid clones comprising the human chromosome region Xq27.3-Xq28. Please note that the goal of any proposed contract will not be to develop a contiguous sequence for the region. Specific support needed will be in the area of cosmid cloning and mapping. The offeror is required to demonstrate the ownership of a preexisting set of cosmids which comprise a 3-4 fold coverage of the Xq27.3-Xq28 region and can provide a single set of ordered, minimally overlapping cosmids of the Xq27.3-Xq28 region. The Government will provide overlapping yeast artificial chromosome (YAC) clones mapped to the region to facilitate cosmid contig development. Additional restriction mapping of the cosmid DNA will be required. Offerors must demonstrate expertise in molecular genetics and X chromosome cosmid cloning by submitting reprints/preprints of prior work in this field.

THIS IS NOT A REQUEST FOR PROPOSALS (RFP). The Government does not intend to award a contract on the basis of responses to this announcement nor to make payment for preparation of any information which may be submitted. Upon receipt of qualified responses to this request, the NINDS plans to announce and issue an RFP and qualified sources will be furnished a copy. If qualified responses are not received, no RFP will be issued. Acknowledgement will not be made by the Government of receipt of responses, nor will respondents be notified of the Government's evaluation of information submitted.

Capability statements which address the aforementioned requirements should be identified with NIH-NINDS-90-001 and must be received by no later than 3:30 p.m. local time on March 27, 1990. Five copies of your response are to be submitted to:

Eileen D. Webster  
Contracts Management Branch  
National Institute of Neurological Disorders and Stroke, NIH  
Federal Building, Room 901  
7550 Wisconsin Avenue  
Bethesda, MD 20892

HUMAN X CHROMOSOME MAPPING WITH YEAST ARTIFICIAL CHROMOSOMES

REQUEST FOR STATEMENT OF CAPABILITIES: NIH-NINDS-90-002

P.T. 34; K.W. 1002058, 1002008

National Institute of Neurological Disorders and Stroke

The Section of Receptor Biochemistry and Molecular Biology, Laboratory of Molecular and Cellular Neurobiology, National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), is seeking to identify organizations capable of providing support for a large-scale DNA sequencing project. The overall goal of the project is to determine the sequence of a set of overlapping cosmid clones comprising the human chromosome region Xq27.3-Xq28. Please note that the goal of any proposed contract will not be to determine the sequence of Yeast Artificial Chromosome (YAC) clones. Specific support needed will be in the area of YAC cloning and mapping. An ordered library of YAC clones are needed to meet the objective of sequencing this region. The YAC library will be used to help assemble an ordered set of cosmids for the specified region. The offeror is required to demonstrate the possession of preexisting YAC clones from the Xq27.3-Xq28 region that provide partial or full coverage of the region and can demonstrate the ability to complete a library of ordered YAC clones that form a contig for the Xq27.3-Xq28 region. Offerors must demonstrate expertise in molecular genetics and X chromosome YAC cloning by submitting reprints/preprints of prior work in this field.

THIS IS NOT A REQUEST FOR PROPOSALS (RFP). The Government does not intend to award a contract on the basis of responses to this announcement nor to make payment for preparation of any information which may be submitted. Upon receipt of qualified responses to this request, the NINDS plans to announce and issue an RFP and qualified sources will be furnished a copy. If qualified responses are not received, no RFP will be issued. Acknowledgement will not be made by the Government of receipt of responses, nor will respondents be notified of the Government's evaluation of information submitted.

Capability statements which address the aforementioned requirements should be identified with NIH-NINDS-90-002 and must be received by no later than 3:30 p.m. local time on March 27, 1990. Five copies of your response are to be submitted to:

Eileen D. Webster  
Contracts Management Branch  
National Institute of Neurological Disorders and Stroke, NIH  
Federal Building, Room 901  
7550 Wisconsin Avenue  
Bethesda, MD 20892

MICROMACHINED INTRACORTICAL RECORDING ELECTRODE ARRAYS

RFP AVAILABLE: NIH-NINDS-90-11

P.T. 34; K.W. 0706010, 0706000

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke, NIH, has a requirement for the design, fabrication and testing of multiple-electrode intracortical recording probes and related structures. Probes that contain integrated circuit electronics to amplify and multiplex the spike waveforms from different microelectrode recording sites must be fabricated and tested. Protection of the probe electronics in a saltwater environment must be demonstrated in vitro using functioning (electrically stressed) active probes. Test probes to evaluate long-term insulation stability at the probe-cable interface and electrode systems with ribbon cables must be developed, fabricated, and made available to other researchers for evaluation and experimentation.

It is anticipated that one award will be made for a period of three years.

This is not a Request for Proposals (RFP). RFP No. NIH-NINDS-90-11 will be available after March 15, 1990. Responses will be due by close of business May 14, 1990. To receive a copy of the RFP, please submit a written request to the following address, and supply this office with two self-addressed mailing labels. All responsible sources shall be considered by the agency.

Contracting Officer  
Contracts Management Branch, DEA  
National Institute of Neurological Disorders and Stroke, NIH  
Federal Building, Room 901  
7550 Wisconsin Avenue  
Bethesda, MD 20892

Attention: RFP No. NIH-NINDS-90-11

BIOMATERIALS FOR INSULATION OF IMPLANTABLE, MICROMACHINED, ELECTRONICALLY ACTIVE ELECTRODES

RFP AVAILABLE: NIH-NINDS-90-10

P.T. 34; K.W. 0750005, 0706000, 0740050

National Institute of Neurological Disorders and Stroke

The National Institute of Neurological Disorders and Stroke, NIH, has a requirement for development and evaluation of insulating, thin-film coating systems for neural prosthetic implants that will be implanted in the central nervous system. This will involve the development and evaluation of methods and materials to insulate two conductors that will form a connecting cable to a microprobe and the insulation of the interface area between this connecting cable and the probe.

It is anticipated that one award will be made for a period of three years.

This is not a Request for Proposals (RFP). RFP No. NIH-NINDS-90-10 will be available after March 15, 1990. Responses will be due by close of business May 14, 1990. To receive a copy of the RFP, please submit a written request and two self-addressed mailing labels to the following address. All responsible sources shall be considered by the agency.

Contracting Officer  
Contracts Management Branch, DEA  
National Institute of Neurological Disorders and Stroke, NIH  
Federal Building, Room 901  
7550 Wisconsin Avenue  
Bethesda, MD 20892

Attention: RFP No. NIH-NINDS-90-10

EFFICACY TRIAL OF AN ACELLULAR PERTUSSIS

RFP AVAILABLE: RFP-NIH-NIAID-DMID-90-30

P.T. 34; K.W. 0740075, 0755015

National Institute of Allergy and Infectious Diseases

The solicitation is divided into two parts. Part 1 is a request for a proposal for a feasibility statement and a developmental plan which, in six months time, would allow the successful offerors to submit a detailed proposal for a clinical trial to demonstrate the safety and efficacy of acellular pertussis vaccines. Part 1 addresses the basic, but essential criteria and qualifications needed to properly conduct a Phase III efficacy trial to compare one or more acellular pertussis vaccines to a whole cell product. Part 2 of the solicitation is a request for a proposal that details the conduct of a clinical trial of candidate acellular pertussis vaccines. It is important to note that at this time, each offeror only needs to respond to Part 1. The U.S. Government recognizes that information gathered under Part 1 may be required to implement an optimal response to Part 2. However, in responding to Part 1 the offeror should take into consideration the requirements specified in Part 2. Successful offerors will be given 6 months to obtain information for the development of a proposal for Part 2. Only those successful Part 1 offerors will be eligible to submit a proposal for Part 2. Substantial assistance from representatives of the U.S. Public Health Service to help design an optimal study for performing a Phase III randomized, double-blind efficacy trial in infants will be available to all successful Part 1 offerors. Six months post award, the successful Part 1 offerors will have the option of submitting a proposal in response to Part 2. Both Part 1 and Part 2 proposals will be reviewed by a panel of experts. Multiple awards may be issued for Part 1 and Part 2. The Institute expects to make three awards for Part 1.

The issuance of the RFP will be on or about March 2, 1990, and responses will be due by the close of business on May 4, 1990.

Any responsible offeror may submit a proposal for Part 1 will be considered by the Government.

Request for the RFP should be directed to:

Ms. Rosemary McCabe Hamill  
Contracting Officer  
Contract Management Branch  
National Institute of Allergy and Infectious Diseases, NIH  
Westwood Building, Room 707  
Bethesda, MD 20892

Please provide this office with two self-addressed mailing labels.

ANIMAL MODELS OF HUMAN VIRAL INFECTIONS FOR EVALUATION OF EXPERIMENTAL THERAPEUTICS

RFP AVAILABLE: RFP-NIH-NIAID-DMID-91-2

P.T. 34; K.W. 0755020, 0715125, 0710075

National Institute of Allergy and Infectious Diseases

The Antiviral Research Branch of the Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases has a

requirement to obtain animal model systems to evaluate the clinical potential of experimental therapeutic agents for the treatment of human viral infectious diseases and to facilitate the entry of these drugs into clinical trials.

The Contractor should demonstrate the capability to provide a model system(s) which has features similar to the corresponding infection in humans. The successful offeror should demonstrate the pathologic and immunologic aspects of the model in association with virus infection, and the utility of this model to evaluate clinical effectiveness of experimental therapeutics.

The issuance of the RFP will be on March 1, 1990. Responses are due by close of business on June 8, 1990. It is expected that the contract will be awarded for five years. Approximately six awards are anticipated.

Requests for this RFP should be directed to:

Ms. Ann Linkins  
Contract Specialist  
National Institute of Allergy and Infectious Diseases  
Contract Management Branch  
Westwood Building/Room 707  
5333 Westbard Avenue  
Bethesda, Maryland 20892

To receive a copy of this RFP, please supply this office with two (2) self-addressed labels. Please reference RFP-NIH-NIAID-DMID-91-2.

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

RESEARCH DEMONSTRATION ON COMMUNITY-BASED RURAL HEALTH CARE MODELS FOR MINORITY POPULATIONS

RFA AVAILABLE: 90-NR-01

P.T. 34, FF; K.W. 0730050, 0403004

National Center for Nursing Research  
Agency for Health Care Policy and Research  
Health Resources and Services Administration

Application Receipt Date: June 15, 1990

**PURPOSE AND OBJECTIVES**

The purpose of this initiative is to refine, implement, and study replicable community-based nursing practice models for providing health care to minority persons living in rural areas. These models will examine factors which influence the quality of patient care, patient outcomes, and access to care and take into consideration associated cost and benefits. Each model will include one or more nursing interventions which could be tested and validated as a part of this project. Populations targeted for this effort are limited to one or more of the following: persons 65 years or older, childbearing women, adolescents at risk for early pregnancy, children and infants. Specific objectives of this initiative are to:

- o Implement an empirically derived community-based nursing practice model with specified nursing interventions in such a manner that the quality of patient care delivered, patient outcomes, the degree of cost effectiveness and its impact on patient outcomes can be determined.
- o Determine how nursing interventions, as components of the community-based model, influence the quality, outcomes, and costs of care.
- o Demonstrate improved methods for expanding access to health care services for the targeted populations.
- o Assure the use of relevant research in the refinement of the design, implementation and examination of the effect of the community-based nursing practice model(s).
- o Facilitate the replicability of the model(s) in other community settings through documentation of the process of model development and implementation and the dissemination of project outcomes.
- o Target minority rural-based populations for the provision of health care. These populations are limited to one or more of the following: persons 65



years of age or older, childbearing women, adolescents at risk for early pregnancy, children and infants.

#### ELIGIBILITY

Applicants may be nonprofit organizations and institutions that have demonstrated expertise in nursing practice and research; that have demonstrated ability to conduct community-based clinical research projects; and that have demonstrated capability in developing and managing research and demonstration projects. Eligibility is restricted to U.S. institutions. A combination of clinical, research, and administrative expertise and commitment will be necessary at the grantee institution and at the rural study site(s).

#### LENGTH OF SUPPORT

It is anticipated that the proposed projects will be five years in length. The initial year will be devoted to refining the model based on the presentation in the application and to the collection of base line data. The model will be implemented not later than one year after grant award. Although this activity is provided for in the financial plans of the National Center for the Division of Nursing, Health Resources and Services Administration Nursing Research (NCNR), Agency for Health Care Policy and Research (AHCPR) and the Division of Nursing (DN), Agency for Health Care Policy and Research (AHCPR), funding beyond the first year will be contingent on satisfactory progress and availability of funds for this purpose.

#### MECHANISM OF SUPPORT

Each award for the community-based nursing practice models for minority persons in rural areas will be made as a research and demonstration grant. The start date for funded projects will be approximately September 30, 1990. A total of \$1,500,000 (\$600,000 by NCNR, \$600,000 by AHCPR, \$300,000 by DN) of Federal funds (for both direct and indirect costs) will be allocated to support the initial year's awards. The total number of awards will depend on quality, scope, and cost of approved applications.

#### APPLICATION PROCEDURES

Applicants must address all requirements as presented in this Request for Applications (RFA).

Applications must be received by June 15, 1990.

Use application form PHS 398 (rev. 10/88). This may be secured from the Office of Grants Inquiries, Division of Research Grants, NIH, Bethesda, Maryland 20892 (telephone 301-496-7441) or from institutional grants and contract offices.

Type in bold letters on line 2 of the face page of the application and the words "RFA 90-NR-01: NCNR/AHCPR/DN Nursing Rural Model." The RFA label contained in the PHS 398 packet must be attached to the bottom of the face page of the original application.

#### INQUIRIES

For further information, guidelines and consultation on program requirements contact:

Dr. Patricia Moritz  
Chief, Nursing Systems Branch  
National Center for Nursing Research  
National Institutes of Health  
Building 31, Room 5B09  
Bethesda, MD 20892  
Telephone: (301) 496-0523

Dr. Mary S. Hill  
Chief, Nursing Education Practice Resources Branch  
Division of Nursing, BHP, HRSA  
5600 Fishers Lane, Room 5C14  
Rockville, MD 20857  
Telephone: (301) 443-6193

Dr. Jerry L. Weston  
Agency for Health Policy and Research  
5600 Fishers Lane, Room 18A19  
Rockville, MD 20857  
Telephone: (301) 443-2716

For information regarding budgetary/administrative issues contact:

Mrs. Sally A. Nichols  
National Center for Nursing Research  
National Institutes of Health  
Building 31, Room 5B06  
Bethesda, MD 20892  
Telephone: (301) 496-0237

These programs are described in the Catalogue of Federal Domestic Assistance No. 13.361: Nursing Research; No. 13.226: Health Services Research and Development Grants; and No. 13,359 Nursing Special Project Grants. Awards will be made under the authority of the Public Health Service Act, Sections 301 and 483, as amended by Public Law 99-158; Section 299a as amended by Public Law 101-239; and Section 820 as amended by Public Law 100-607. Awards will be administered under PHS grant policies and Federal Regulations - 42 CFR Part 52, 45 CFR Part 74 and 42 CFR Part 57, Subpart T. These programs are not subject to the intergovernmental review requirements of Executive Order 12372, or to Health System Agency review.

FUNCTIONAL TESTS OF NUTRITIONAL STATUS IN PREGNANT WOMEN, INFANTS, AND CHILDREN

RFA AVAILABLE: 90-HD-06

P.T. 34, AA, II; K.W. 0710095, 0775020, 0765020, 1003002

National Institute of Child Health and Human Development

Application Receipt Date: June 13, 1990

The Endocrinology, Nutrition and Growth Branch of the Center for Research for Mothers and Children of the National Institute of Child Health and Human Development (NICHD) invites research grant applications for studies of functional tests of nutritional status in pregnant women, infants, and children. Methods are needed for determining, by minimally invasive means, the adequacy of nutritional status in relation to nutrient requirements by measuring biochemical processes in vivo. By issuing this request for applications (RFA) the Institute seeks to stimulate investigators' interest in an area of research important to the Institute's mission.

**BACKGROUND**

Frank nutritional deficiencies producing overt clinical disease are no longer a major public health problem in the United States. The suboptimal availability of nutrients, however, can produce a slowing or disruption of normal growth and development before or after birth. Most current approaches to estimating nutrient status are inadequate for the discrimination of subclinical states of nutrient deprivation. Blood levels of nutrients such as trace elements or vitamins may not be sensitive to changes in whole body content or may not reflect nutrient availability in specific tissues or particular subcellular sites. Direct determinations of tissue levels are likely to require undesirable invasive procedures. Functional studies, on the other hand, which measure nutrient-dependent metabolic processes, can indicate the adequacy of nutrient supply in specific tissues or at specific subcellular sites.

**OBJECTIVES AND SCOPE**

The purpose of this RFA is to stimulate the development of methods for evaluating the availability of critical nutrients in pregnant women, infants, and children, by evaluating metabolic processes or reactions which are dependent on those nutrients. Methods are sought which would be minimally invasive, so that they could be used repeatedly for assessment of nutrient status. Accurate techniques for use in careful clinical studies and simple methods appropriate for population screening are needed. For some nutrients, animal model studies may be an appropriate first step in method development. Applications are not limited to studies of micronutrients; for example, research on methods for determining the adequacy of protein intake as it affects the accretion of lean body mass in low-birth-weight infants would be useful, as would tests for the adequacy of assimilation of calcium, phosphorous, and iron.

Investigators are encouraged to include minority groups in their study populations.

## MECHANISMS OF SUPPORT

Applications in response to this RFA will be funded through the traditional individual research grant (R01) award program of the NICHD. It is anticipated that four awards will be made under this RFA.

## APPLICATION PROCEDURE

Applications must be submitted on form PHS-398 (rev. 10/88). Detailed instructions for application are available as additional information.

## ADDITIONAL INFORMATION

The complete RFA is available from:

Ephraim Y. Levin, M.D.  
Medical Officer  
Endocrinology, Nutrition and Growth Branch  
Center for Research for Mothers and Children  
National Institute of Child Health and Human Development  
Room 637, Executive Plaza North  
Bethesda, MD 20892  
Telephone: (301) 496-5593

This program is described in the catalog of Federal Domestic Assistance No. 13.865, Research for Mothers and Children. Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241), and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency.

## CYSTIC FIBROSIS CORE CENTER GRANT

RFA AVAILABLE: 90-DK-07

P.T. 04; K.W. 0715165, 0710030

National Institute of Diabetes and Digestive and Kidney Diseases

Letter of Intent Receipt Date: May 15, 1990  
Application Receipt Date: July 16, 1990

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for a Core Center Grant (P30) in Cystic Fibrosis, to be awarded in Fiscal Year 1991.

## BACKGROUND

The NIDDK-supported Cystic Fibrosis Research Centers (CFRC) are part of an integrated program of cystic fibrosis-related research support provided by NIDDK. These centers have provided a focus for increasing collaboration and cost effectiveness among groups of successful investigators at institutions with established comprehensive cystic fibrosis research bases. NIDDK supports four Specialized Centers of Research (P50) and one Core Center Grant (P30) in Cystic Fibrosis. NIDDK anticipates receipt of a competing continuation application from the existing Core Center, and invites other competing applications for a single Core Center grant to be awarded in Fiscal Year 1991.

## OBJECTIVES AND SCOPE

The objectives of the CFRCs are to bring together investigators from relevant disciplines in a manner that will enhance and extend the effectiveness of research related to cystic fibrosis and its complications. A cystic fibrosis center must be an identifiable unit within a single university medical center or a consortium of cooperative institutions, including an affiliated university. The overall goal of the CFRC is to bring together on a cooperative basis clinical and basic science investigators in a manner that will foster multi-disciplinary research on a central theme related to cystic fibrosis. An existing program of excellence in biomedical research in the area of cystic fibrosis and related metabolic disorders is required. This research should be in the form of NIH-funded research projects, program projects, or other peer-reviewed research that is in existence at the time of submission of a center application. Close cooperation, communication, and collaboration among all involved personnel of all professional disciplines are ultimate objectives. Applicants should consult with NIDDK staff concerning plans for the development of the center.

A P30 CFRC is based on the core concept. Cores are defined as shared resources that enhance productivity or in other ways benefit a group of investigators working in cystic fibrosis or cystic fibrosis-related areas to accomplish the stated goals of the center. Two other types of activities may also be supported with center funding--a pilot and feasibility program and an enrichment program. The pilot and feasibility program provides modest support for new initiatives or feasibility research studies. This program is directed at new or established investigators in other research disciplines where their expertise may be applied by cystic fibrosis research. The center grant may also include limited funds for program enrichment such as seminars, visiting scientists, consultants, workshops, etc.

Investigators should be aware that NIH urges applicants to give added attention, where feasible and appropriate, to the inclusion of minorities and women in study populations. If minorities and/or women are not included in a given study, a clear rationale for their exclusion should be provided. Merely including an arbitrary number of minority group and women participants in a given study is insufficient to guarantee generalization of results. An attempt should be made to obtain the same proportionality as occurs nationally.

#### MECHANISM OF SUPPORT

NIDDK expects to award one P30 CFRC Grant in Fiscal Year 1991 on a competitive basis. The receipt of one competitive continuation application is anticipated, and it will be in competition for the award together with other applications received in response to this announcement. Foreign institutions are not eligible to apply. The anticipated award will be for five years and is contingent upon the availability of appropriated funds. The annual direct costs requested may not exceed \$750,000. NIDDK anticipates that up to \$1.12 million may be available for total costs of this award in FY 1991.

#### REVIEW PROCEDURES

Applications for a CFRC grant will be evaluated in national competition by the NIH grant 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

##### NIDDK Core Center Guidelines:

Applicants should request NIDDK Administrative and Review Guidelines for Core Center Grant Applications. These guidelines contain important additional information on the format of applications and review criteria.

##### Letter of Intent:

Prospective applicants are encouraged to contact one of the program administrators indicated below. A letter of intent is not mandatory and does not influence the review or funding decisions, but it will enable the NIDDK to plan the review. It will also ensure that each potential applicant receives important supplemental information prior to expending considerable effort in application preparation. The letter of intent should include the name(s) of the principal investigator and principal collaborators, descriptive titles of the core facilities and pilot/feasibility projects, and the organization(s) involved.

##### Format for Application:

Applications must be submitted using PHS Form 398 (Rev. 10/88) available at most institutional business offices or from the Division of Research Grants, NIH, 301/496-7441. On item 2 of the face page of the application, applicants should enter: RFA: Cystic Fibrosis Core Center Grant, RFA number, 90-DK-07. 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 the application to the extent that it may not reach the review committee in time for review.

##### Application Procedure:

Applications must be received by July 16, 1990; the original and four copies of the application should be sent or delivered to:

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

Two additional copies of the application should be sent to:

Review Branch  
National Institute of Diabetes and Digestive and Kidney Diseases  
Westwood Building, Room 406  
Bethesda, MD 20892

**Timetable:**

A letter of intent should be submitted no later than May 15, 1990.  
Applications must be received by July 16, 1990. Any applications received  
after this date will be considered ineligible for this special solicitation.

APPLICATION RECEIPT DATE	INITIAL REVIEW	COUNCIL REVIEW	EARLIEST START DATE
July 16, 1990	Nov/Dec 1990	February 1991	April 1991

**Inquiries:**

Inquiries regarding this announcement, the guidelines for structuring a Core  
Center Grant project application and method of applying should be directed to  
the program administrator:

Nancy Lamontagne, Ph.D.  
Director, Cystic Fibrosis Program  
NIDDK  
Westwood Building, Room 607  
Bethesda, MD 20892  
Telephone: (301) 496-4980

\*\*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

U. S. Department of Health and Human Services

**Certification Regarding Lobbying**

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Award No.	Organizational Entity
Name and Title of Official Signing for Organizational Entity	Telephone No. of Signing Official (       )
Signature of Above Official	Date Signed



## INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.  
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.



**DISCLOSURE OF LOBBYING ACTIVITIES  
CONTINUATION SHEET**

Approved by OMB  
5010-1046

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