

# NIH Guide for Grants and Contracts

Vol. 14, No. 12, November 8, 1985

U.S. DEPARTMENT OF HEALTH  
AND HUMAN SERVICES

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The NIH Guide is published at irregular intervals to announce scientific initiatives and to provide policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in grants and contracts activities administered by the National Institutes of Health.

Two types of supplements are published by the respective awarding units. Those printed on yellow paper concern contracts: solicitations of sources and announcement of availability of requests for proposals. Those printed on blue paper concern invitations for grant applications in well-defined scientific areas to accomplish specific program purposes.

### Have You Moved?

If your present address differs from that shown on the address label, please send your new address to: Grants and Contract Guide Distribution Center, National Institutes of Health, Room B3BN10, Building 31, Bethesda, Maryland 20205, and attach your address label to your letter. Prompt notice of your change of address will prevent your name from being removed from our mailing list.

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NOTICE

Change in Application Receipt Dates

Effective Date: January 1, 1986

P.T. 04, 22, 34, 44; K.W. 0710030, 0404000

The Division of Research Grants (DRG) NIH, receives applications for research and training grants and cooperative agreements for the Public Health Service (PHS). More than 30,000 competing applications are processed and assigned for review and funding each year.

Competing applications are received on a cycle linked to the meeting times of the initial review groups and the National Advisory Councils and Boards that review the applications. One of DRG's major responsibilities is to analyze application trends with a view toward making the best use of limited resources by distributing workloads as evenly as possible within the constraints of a cyclical review process. As a result of this analysis, DRG has established new receipt dates. These dates appear on the following page.

Please note these dates are effective January 1, 1986.

APPLICATION RECEIPT DATES, REVIEW AND AWARD SCHEDULE

Application Receipt Dates				Initial Review Group Dates	National Advisory Council/ Board Dates	Earliest Possible Beginning Date *
Jan. 10 May 10 Sept. 10	Feb. 1 June 1 Oct. 1	Mar. 1 July 1 Nov. 1	Apr. 15 Aug. 15 Dec. 15	May/June Oct./Nov. Feb./Mar.	Sept./Oct. Jan./Feb. May/June	Dec. 1 Apr. 1 July 1
for All individual NRSA applications.* All new and competing continuation Institutional NRSA Training grant applications.	for All new research grant applications, <u>unless specified differently in a Program Announcement or Request for Applications.</u> Career Development awards and Conference grant applications. New and competing continuation Program Project and Center applications.	for Competing continuation & supplemental research grant applications.	for Small Business Innovation (SBIR) Program, both Phases. (Phase II applicants must have completed a federally-funded Phase I project.)			

\* Individual NRSA applications are not reviewed by Council. Their start dates are therefore approximately 4 months earlier than indicated.

All applications must be received by the above dates. If the receipt date falls on a weekend, it will be extended to Monday; if the date falls on a holiday, it will be extended to the following workday. The receipt date will be waived only in extenuating circumstances. To request such a waiver, include an explanatory letter with the signed completed application. No waiver will be granted prior to receipt of the application. It is in an applicant's best interest to submit early and avoid the otherwise unavoidable rush associated with announced receipt dates.

effective January 1, 1986

NOTICE

9TH ANNUAL NIH RESEARCH SAFETY SYMPOSIUM

P.T. 42; K.W. 0725015, 0715175

Radiation Safety Issues in Laboratory and Clinical Research Institutions

What the Non-Expert Needs To Know

December 16-17, 1985  
Washington, D.C.

The Division of Safety, National Institutes of Health (NIH) is pleased to announce the 9th Annual NIH Research Safety Symposium. The symposium this year will focus on radiation safety issues in laboratory and clinical research institutions and, in particular, **what the non-expert needs to know about radiation safety**. Thus, the symposium should be of special interest to research institution administrators, managers, research support personnel, nursing and other patient-care staff, safety personnel, and their technical staffs.

Rather than a highly technical discussion, the symposium is designed to provide a forum for presenting and discussing those radiation safety issues which are important to an institution and to a broad spectrum of an institution's employees. The introductory session will provide an understanding of the uses and benefits of ionizing radiation in biomedical research and an awareness of the key terms and concepts related to radiation and radiation safety.

Radiation safety issues to be addressed include the following:

- o The risk of radiation exposure, including perception of risk, and radiation benefits.
- o The regulatory environment inherent to the use of radiation.
- o Radiation liability and litigation.
- o Strategies for reducing radiation risk.
- o Special concerns related to radiation and pregnancy.
- o Disposal of low-level radioactive waste in 1986.
- o Management of multi-hazard (biological, chemical, and radiological) situations.

**Symposium Location:**

Sheraton Washington Hotel  
Connecticut Avenue at Woodley Road  
Washington, D.C. 20009

Telephone: (202) 328-2000

The hotel is located on the Red Line of the Metro  
Subway, Woodley Park-Zoo stop.

**Accommodations:**

A block of rooms has been reserved at the Sheraton Washington for symposium participants. The room rate is \$55.00 for a single and \$75.00 for a double. In order to be assured of a sleeping room, participants should contact the Sheraton Woodley Park Hotel by November 15, 1985.

**Registration:**

To register for the symposium, please return the registration form found on the last page of this issue no later than November 25, 1985 to:

Mark S. Brown  
9th Annual NIH Research Safety Symposium  
Social and Scientific Systems, Inc.  
7101 Wisconsin Avenue, Suite 610  
Bethesda, Maryland 20814

Telephone: (301) 986-4870

REGISTRATION FORM

9th Annual NIH Research Safety Symposium

Radiation Safety Issues in Laboratory and Clinical Research Institutions

What the Non-Expert Needs to Know

December 16-17, 1985  
Washington, D.C.

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Affiliation: \_\_\_\_\_

Address: \_\_\_\_\_

Please return this form by **November 25, 1985** to:

Mark S. Brown  
9th Annual NIH Research Safety Symposium  
Social and Scientific Systems, Inc.  
7101 Wisconsin Avenue, Suite 610  
Bethesda, Maryland 20814

Telephone: (301) 986-4870



NOTICECLINICAL TRIALS IN VISION RESEARCH

P.T. 34; K.W. 1002046, 0755015

**NATIONAL EYE INSTITUTE**

The National Eye Institute (NEI) is announcing its intention to support future clinical trials generally utilizing the COOPERATIVE AGREEMENT mechanism when an assistance mechanism of research support is deemed appropriate.

NEI clinical trials are research projects directed at improved prevention, diagnosis, prophylaxis, or treatment of human eye conditions. The goal of an NEI clinical trial is to identify risk factors for visual loss and to determine the safety and effectiveness of prophylactic, diagnostic, or treatment procedures in reducing visual loss.

Assistance mechanisms are used in general when the results or outcomes are primarily for the benefit of the scientific or clinical communities. The NEI employs two types of assistance mechanisms: cooperative agreements and research project grants. Cooperative agreements are used to support research when NEI staff are substantially involved in the conduct of the research. Applications for clinical trials may be submitted at the initiative of investigators, or in response to specific NEI Requests for Applications. In either case, potential applicants are strongly encouraged to communicate with NEI staff with respect to the preparation and submission of an application.

The rules and regulations affecting cooperative agreements are the same as those for regular grants. The only difference is that NEI staff are to be involved in the conduct of the trial along with the investigators according to specific terms and conditions which are described in the Request for Applications (RFA) and included in the Notice of Grant Award. In the case of investigator-initiated cooperative agreements, terms and conditions will be similar to those currently in use for institute-initiated clinical trials, but the applicant investigator or NEI staff may propose modifications appropriate to the particular study.

Copies of the Terms of Agreement which specify the areas of NEI staff involvement in current cooperative agreements are available on request. The terms and conditions are not likely to vary significantly from one trial to another, but are adapted for a particular study. Applicants who are considering initiating an application for an NEI-funded clinical trial should consult with the NEI.

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This program is described in the Catalog of Federal Domestic Assistance No. 13.871, Sensory-Motor Disorders and Rehabilitation. 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.

In some instances it may not be practical for NEI staff to participate substantially in the conduct of some trials, for example, a single center trial of very limited scope, or a single center trial at a foreign institution; therefore, the support mechanism in these situations would be the regular research project grant. It is also likely that the National Eye Institute will continue to initiate a few clinical trials that are more directly a continuation of Institute research with the results intended for a direct Institute benefit; in these cases a contract mechanism will be utilized, as appropriate.

For further information or copies of current Terms of Award, please contact:

Dr. Israel Goldberg  
Deputy Associate Director  
Extramural and Collaborative Programs  
National Eye Institute  
Building 31 - Room 6A51  
9000 Wisconsin Avenue  
Bethesda, Maryland 20892

Telephone: 301 - 496-5983

NOTICEAVAILABILITY OF FROZEN SERUM PANELS

P.T. 36; K.W. 0780005, 0715035

**NATIONAL CANCER INSTITUTE**

The National Cancer Institute (NCI) is interested in evaluating serum assays which are potentially useful in cancer diagnosis, prognosis and the monitoring of therapy. Coded panels of frozen sera are available from two banks established by the Diagnosis Program, Division of Cancer Biology and Diagnosis. Sera are carefully collected and maintained in 1 ml glass vials at -70 C.

The Breast Cancer Serum Bank collection contains sera from breast cancer patients, benign disease patients and normal controls.

The Diagnosis Serum Bank collection contains sera from patients with a wide variety of neoplasms, patients with benign diseases and control subjects.

Requestors of test panels must document the discriminatory power of their assays by providing preliminary data, including: a brief description of the assay, results for cancer patients, results for patients with non-malignant disease and results for healthy normal control subjects. Reprints of pertinent publications or pre-publications should be included, when possible. The assays must provide accurate determinations with no more than 1 ml of serum. Requestors must agree to accept specimens under a blind code number and to report the results of their analysis to the NCI. Requestors will receive the panel code once their results have been verified by the NCI. Requests for coded serum panels should be sent to:

Project Officer  
Breast Cancer Serum Bank

or

Project Officer  
Diagnosis Serum Bank

Diagnosis Program  
National Cancer Institute  
National Institutes of Health  
Westwood Building - Room 10A10  
Bethesda, Maryland 20892

REVISED ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

85-OD-02

ACADEMIC RESEARCH ENHANCEMENT AWARD

P.T. 34, 14; K.W. 0710030

NATIONAL INSTITUTES OF HEALTH

Application Receipt Date: January 15, 1986

In its report accompanying the Fiscal Year 1985, appropriation for the National Institutes of Health (NIH) Congress called for an initiative to strengthen the research milieu of non-research-intensive, four-year colleges and universities that provide undergraduate training for a significant number of our nation's research scientists. In FY 85, the NIH made \$5,000,000 available for this purpose and will be able to award over 75 "Academic Research Enhancement Awards" (AREAs). This award is designed to enhance the research environment of educational institutions that have not been traditional recipients of NIH research funds. The award is intended to support new research projects or expand ongoing research activities proposed by faculty members of these institutions in areas related to the health sciences.

The NIH is inviting grant applications for a second round of AREAs to be awarded in FY 86.

Institutions eligible for the AREA Program are defined as those that offer baccalaureate degrees in the sciences related to health, but did not receive an NIH Biomedical Research Support Grant (BRSG) in four out of the five fiscal years from FY 1981 through FY 1985. If in doubt about whether an institution is eligible consult your institution's Office of Sponsored Research. Alternatively, contact either of the following offices at NIH:

Office of the Associate Director  
for Extramural Affairs  
Shannon Building - Room 111  
National Institutes of Health  
Bethesda, Maryland 20892

Telephone: (301) 496-5356

or

Office of Special Programs and Initiatives  
Building 31 - Room 1B54  
National Institutes of Health  
Bethesda, Maryland 20892

Telephone: (301) 496-1968

Investigators eligible for the Program are those who will not have active research grant support (including an AREA) from either NIH or ADAMHA (Alcohol, Drug Abuse, and Mental Health Administration) at the time of award of an AREA grant. Applicants for AREAs may not submit a regular NIH or ADAMHA research grant application for essentially the same project.

Funding decisions will be based on the proposed research project's scientific merit and relevance to NIH programs, and the institution's contribution to the undergraduate preparation of doctoral-level health professionals. Among projects of essentially equivalent scientific merit and program relevance, preference will be given to those submitted by institutions that have granted baccalaureate degrees to 25 or more individuals who, during the period 1977-1984, obtained academic or professional doctoral degrees in the health related sciences.

AREAs are awarded on a competitive basis. Applicants may request support for up to \$50,000 in direct costs (plus applicable indirect costs) for a period not to exceed 24 months. Although this award is non-renewable, it will enable qualified individual scientists within the eligible institutions to receive support for feasibility studies, pilot studies and other, small-scale research projects preparatory to seeking more substantial funding from the regular NIH research grant programs.

Applications for this award will be accepted under the regular application submission procedures of the Division of Research Grants (DRG) of NIH. Grant applications must be prepared and submitted on PHS 398 grant application forms. An abbreviated format and simplified instructions will be provided for use in preparing these applications. The receipt date is January 15, 1986.

Those individuals and institutions meeting eligibility requirements and wishing to receive further information and/or application materials should write to:

AREA  
Office of Grant Inquiries  
Division of Research Grants  
National Institutes of Health  
Westwood Building - Room 449  
Bethesda, Maryland 20892

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-AM-02

ADDITIONAL CLINICAL CENTERS FOR THE DIABETES CONTROL AND  
COMPLICATIONS TRIAL (DCCT)

P.T. 34, 04; K.W. 0715075, 0755015

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY  
DISEASES

Application receipt date: January 21, 1986

The National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK) announces the availability of a Request for Applications (RFA) inviting applications for additional Clinical Centers to participate with the NIADDK in the ongoing Diabetes Control and Complications Trial (DCCT). The DCCT is a multicenter collaborative clinical trial to assess the relationship between metabolic control and development of the early vascular complications of insulin-dependent diabetes mellitus (IDDM). The DCCT was designed to consist of four sequential phases:

Phase	I	--	Planning
Phase	II	--	Feasibility Study
Phase	III	--	Full-Scale Trial
Phase	IV	--	Data Analysis and Reporting

The Protocol for the DCCT was developed during Phase I and tested during Phase II. Based on the results from this feasibility study, the NIADDK has determined that it will proceed with the full-scale clinical trial which is expected to run until June 1993. Four to six additional Clinical Centers will be selected to join with the existing 21 DCCT Clinical Centers (listed below) in the conduct of the full-scale clinical trial (Phase III) and the data analysis and reporting phase (Phase IV).

The main rationale for adding new Clinical Centers at this juncture in the DCCT is to assure that a sufficient sample size of volunteers can be recruited and followed to provide adequate statistical power to answer the major study question. Selection of additional Clinical Centers will also address the problem of poor geographic distribution of the current Clinical Centers; therefore, preference will be given to applicants from institutions in metropolitan areas of the contiguous 48 states of the United States currently unserved by a DCCT Clinical Center.

The assistance mechanism that will be used to support the additional Clinical Centers, the cooperative agreement, is similar in many respects to the traditional NIH research grant; however, it differs from a research grant principally in the extent and nature of the involvement of NIADDK staff. The staff of the NIADDK is substantially involved as an active partner in all aspects of the scientific and technical management of the DCCT above and beyond the levels required for administration of traditional research grants.

An RFA is available which outlines the DCCT in more detail, the requirements for participation as a Clinical Center, and the method of applying. The deadline for receipt of applications for Clinical Centers is January 21, 1986. Applications received after this date will not be considered. Additional information and copies of the RFA and the DCCT Protocol can be obtained from:

Carolyn Siebert, M.P.H.  
 Clinical Trial Coordinator  
 Diabetes, Endocrinology and Metabolic Diseases  
 National Institute of Arthritis, Diabetes, and  
 Digestive and Kidney Diseases, NIH  
 Westwood Building - Room 628  
 Bethesda, Maryland 20892

Telephone: (301) 496-7645

#### DCCT Clinical Centers

Case Western Reserve University, Cleveland	University of Minnesota, Minneapolis
Children's Hospital of Philadelphia	University of Missouri at Columbia
Cornell University, New York City	University of Pittsburgh
Henry Ford Hospital, Detroit	University of Tennessee, Memphis
Joslin Diabetes Center, Inc., Boston	University of Texas, Dallas
Massachusetts General Hospital, Boston	University of Toronto
Mayo Foundation, Rochester	University of Washington, Seattle
Medical University of South Carolina, Charleston	University of Western Ontario, London
Park Nicollet Med. Fdn., Minneapolis	Vanderbilt University, Nashville
University of Iowa, Iowa City	Washington University, St. Louis
	Yale University, New Haven

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR APPLICATIONS: RFA

86-ES-01

NON-MAMMALIAN SPECIES IN TOXICOLOGICAL TESTING

P.T. 34; K.W. 1007001, 1007003, 1007009

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Application Receipt Date: February 15, 1986

I. BACKGROUND INFORMATION

The National Institute of Environmental Health Sciences (NIEHS) is the principal Federal agency in support of research and training related to understanding of the biological effects of substances found in the environment on human health. The Institute is seeking research applications to develop and compare non-mammalian methods of animal testing of biologically active environmental substances with traditional animal methods. Historically, the Institute has supported Marine and Freshwater Biomedical Centers which provide core support to facilitate multidisciplinary research on marine and freshwater organisms as model systems for elucidating mechanisms of toxicity of environmental agents. Other center and project grants supported by the NIEHS focus their research on the development of in vitro systems to supplement or reduce in vivo studies for the evaluation of chemicals of environmental concern. The Institute also pursues this objective through the contract mechanism.

II. GOALS AND SCOPE

The NIEHS requests research applications directed toward development, validation and use of non-mammalian methods of animal testing which can be employed to study the biological effects of environmental agents. The Institute will favor applications that aim to study the similarities and differences between biological effects in mammalian and non-mammalian species and how these findings might bear upon interpretation of possible effects in humans.

- A. It is expected that non-mammalian species may be employed for the following applications.

This program is described in the Catalog of Federal Domestic Assistance, No. 13.112, Characterization of Environmental Health Hazards; 13.113, Biological Response to Environmental Health Hazards; 13.114, Applied Toxicological Research and Testing; 13.115, Biometry and Risk Estimation. 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.



1. Screening tests: The development, validation and testing of methods to screen xenobiotics for biologic effects.
2. Detection of exposure: Develop methods which will facilitate the early detection of exposure to xenobiotics and serve as sentinels of ecological damage.
3. Species substitution: Develop the use of non-mammalian species for toxicological testing to provide information of the quality and kind now obtained through the use of traditional animal modes.

### III. METHOD OF APPLYING

Applications should be submitted on form PHS 398, the application form for the traditional research grant. Application kits containing this form and the necessary instructions are available in most institutional business offices or from the Division of Research Grants, NIH. The original and six copies of the application must be received by February 15, 1986. Applications must be sent to:

Division of Research Grants  
National Institutes of Health  
Westwood Building - Room 240  
5333 Westbard Avenue  
Bethesda, Maryland 20892

The face page of the application should be labeled **"In response to RFA 86-ES-01."**

### IV. STAFF CONTACT

Questions relating to this announcement should be directed to:

Dr. Edward Gardner, Jr.  
Program Director, RGP, EP  
National Institute of Environmental  
Health Sciences  
P O. Box 12233  
Research Triangle Park, NC 27709

Telephone: 919-541-7724

ANNOUNCEMENT

AVAILABILITY OF REQUEST FOR COOPERATIVE AGREEMENT APPLICATIONS

86-NS-01

CLINICAL EVALUATION OF COPOLYMER I FOR EXACERBATING-REMITTING

MULTIPLE SCLEROSIS - A MULTI-INSTITUTIONAL CLINICAL TRIAL

P.T. 34; K.W. 0715140, 0755015

NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND  
STROKE

Application Receipt Date: January 21, 1986

The National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) invites applications for a cooperative agreement to support a multi-institutional clinical trial of copolymer I for exacerbating-relmitting multiple sclerosis (ER MS).

I. BACKGROUND

The prophylactic and therapeutic effects of the synthetic polypeptide copolymer I have been demonstrated in a variety of animals with experimental autoimmune encephalomyelitis. The safety of copolymer I in man has also been demonstrated in a small number of MS patients. In a recent small pilot study in patients with ER MS copolymer I was reported to reduce the number and frequency of relapses and to modify the degree of disability assessed at two years after initiation of therapy.

Although the etiology and pathogenesis of MS are unknown, the search for a therapeutic modality that will retard or arrest the ingravescent course of MS is pressing. Preliminary studies suggest that copolymer I may offer promise of such efficacy. The precise mechanism of action of copolymer I remains to be established, but the favorable results of pilot studies urge early and comprehensive evaluation of its efficacy and safety. The potential for defining and optimizing the putative beneficial effect of copolymer I only can be realized by a carefully designed multi-institutional collaborative clinical trial. The execution of such a trial requires a major commitment of time and resources by clinician scientists. Program planning is desirable in the effort to demonstrate the effect of copolymer I before it is introduced into general use.

This program is described in the Catalog of Federal Domestic Assistance No. 13.853. Awards will be made under the authority of Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended; 42 USC 282) 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.

## II. RESEARCH GOALS AND SCOPE

A collaborative, multi-institutional, randomized, placebo-controlled trial would be proposed for evaluating the effectiveness and safety of copolymer I in modifying the clinical course of exacerbating-remitting multiple sclerosis. The proposed trial should allow for the confident:

- A. Determination of the safety of copolymer I in humans in a large population of MS patients.
- B. Identification of the co-existing conditions that contraindicate the use of copolymer I.
- C. Confirmation and validation of the effect, or lack of effect, of copolymer I in reducing the frequency of attacks in ER MS patients.
- D. Determination of whether copolymer I significantly modifies the long-term disability of ER MS patients.

The NINCDS staff will participate with the awardee primarily through the Multiple Sclerosis Clinical Trial Monitoring Committee (MS-CTMC), in the conduct of the study, e.g., in the decisions to proceed from one step of the study to the next, such as refinement of the protocol and procedural manual, patient recruitment, treatment and follow-up, termination of recruitment, and data analysis. Staff will assist in the modification, if necessary, and implementation of criteria for excluding from the study those patients who may experience untoward reactions, and of interim data analyses for safety and efficacy. Full details of NINCDS's involvement are outlined under "Terms of the Award" in the complete RFA.

## III. MECHANISM OF SUPPORT

The award will be made as a cooperative agreement. A cooperative agreement is an assistance instrument with substantive participation of NINCDS staff during performance of the project. The terms of NINCDS staff participation, which the awardee institution and principal investigator must accept, are included in the complete RFA.

The NINCDS anticipates making a single award as a result of this request. It is anticipated that \$1 million will be available to fund the initial year's award. The award will be made for a period of up to five years. The starting date for the initial annual period will be on or around July 1, 1986.

All policies and requirements that govern the grant programs of the U.S. Public Health Service apply, including the requirement for cost sharing. Although this program is provided for in the financial plans of the NINCDS, the award of a cooperative agreement pursuant to this RFA is also contingent upon the continuing availability of appropriated funds for this purpose.

IV. STAFF CONTACT

A copy of the complete RFA describing the research goals and scope, the nature of NINCDS staff participation, the review criteria and method of applying can be obtained by contacting:

Emanuel M. Stadlan, M.D.  
Deputy Director  
Demyelinating, Atrophic, and Dementing  
Disorders Program  
National Institute of Neurological  
and Communicative Disorders and Stroke  
Federal Building - Room 700  
7550 Wisconsin Avenue  
Bethesda, Maryland 20892

Telephone: (301) 496-2313

ANNOUNCEMENT

BIOMEDICAL RESEARCH SUPPORT SHARED INSTRUMENTATION GRANTS

P.T. 36; K.W. 0735015, 1002024, 1014001

**DIVISION OF RESEARCH RESOURCES**

Application Receipt Date: February 15, 1986

I. BACKGROUND

The Division of Research Resources (DRR) is continuing its competitive Biomedical Research Support (BRS) Shared Instrumentation Grant Program initiated in Fiscal Year 1982. The program was established in recognition of the long-standing need in the biomedical research community to cope with rapid technological advances in instrumentation and the rapid rate of obsolescence of existing equipment. The objective of the program is to make available, to institutions with a high concentration of PHS-supported biomedical investigators, research instruments which can only be justified on a shared-use basis and for which meritorious research projects are described.

Eligible institutions may submit more than one application for different instrumentation in the Fiscal Year 1987 review cycle.

II. RESEARCH GOALS AND SCOPE

This program is designed to meet the special problem of acquisition and updating of expensive shared-use instruments which are not generally available through other PHS mechanisms, such as the regular research, program project and center grant programs, or the Biomedical Research Support (BRS) Grant Program. Proposals for the development of new instrumentation will not be considered.

III. ELIGIBILITY

The BRS Shared Instrumentation Grant Program is a subprogram of the BRS Grant Program of DRR. Awards are made under the authority of the BRS program and are made to institutions only, not to individuals. Therefore, eligibility is limited to institutions which receive a BRS grant award. Awards are contingent on the availability of funds.

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This program is described in the Catalog of Federal Domestic Assistance No. 13.337, Biomedical Research Support. 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.

#### IV. MECHANISM OF SUPPORT

BRS Shared Instrumentation Grants provide support for expensive state-of-the-art instruments utilized in both basic and clinical research. Applications are limited to instruments that cost at least \$100,000 per instrument or system. Types of instrumentation supported include, but are not limited to, nuclear magnetic resonance systems, electron microscopes, mass spectrometers, protein sequencer/amino acid analyzers and cell sorters. Support will not be provided for general purpose equipment or purely instructional equipment. Proposals for "stand alone" computer systems will only be considered if the instrument is solely dedicated to the research needs of a broad community of PHS-supported investigators. Awards will be made for the direct costs of acquisition of new, or the updating of existing, research instruments. The institution must meet those costs (not covered in the normal purchase price) required to place the instrumentation in operational order as well as the maintenance, support personnel and service costs associated with maximum utilization of the instrument. There is no upper limit on the cost of the instrument, but the maximum award is \$300,000. Grants will be awarded for a period of one year and are not renewable. Supplemental applications will not be accepted. The program does not provide indirect costs or support for construction or alterations and renovations. Cost sharing is not required. If the amount of funds requested does not cover the total cost of the instrument, an award will not be made unless the remainder of the funding is assured. Description of the proposed co-funding must be presented with the application. Assurance of co-funding, signed by an appropriate institutional official, must be presented to DRR prior to the issuance of an award.

A major user group of three or more investigators should be identified. Each major user must have PHS peer-reviewed research support at the time of the award. The application must show a clear need for the instrumentation by projects supported by multiple PHS research awards and demonstrate that these projects will require at least 75% of the total usage of the instrument. Major users can be individual researchers, or a group of investigators within the same department or from several departments at the applicant institution. PHS extramural awardees from other institutions may also be included.

If the major user group does not require total usage of the instrument, access to the instrument can be made available to other users upon the advice of the advisory committee. These users need not be PHS awardees but priority should be given to PHS supported scientists engaged in biomedical research.

A progress report will be required which describes the use of the instrument, listing all users, and indicating the value of the instrumentation to the research of the major users and to the institution as a whole.

#### V. ADMINISTRATIVE ARRANGEMENTS

Each applicant institution must propose a Principal Investigator who can assume administrative/scientific oversight responsibility for the instrumentation requested. An internal advisory committee to assist in this responsibility should also be utilized. The Principal Investigator and the advisory group are responsible for the development of guidelines for shared use of the instrument, for preparation of all reports required by the NIH, for relocation of the instrument within the

grantee institution if the major user group is significantly altered and for continued support for the maximum utilization and maintenance of the instrument in the post award period.

A plan should be proposed for the day-to-day management of the instrument including designation of a qualified individual to supervise the operation of the instrument and to provide technical expertise to the users. Specific plans for sharing arrangements and for monitoring the use of the instrument should be described.

## VI. REVIEW PROCEDURES AND CRITERIA

Applications are reviewed by specially convened initial review groups of the Division of Research Grants (DRG) for scientific and technical merit and by the National Advisory Research Resources Council of the DRR for program considerations. Funding decisions are the responsibility of the DRR and will not be made prior to November 15, 1986.

Criteria for review of applications include the following:

- A. The extent to which an award for the specific instrument would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited.
- B. The availability and commitment of the appropriate technical expertise within the major user group or the institution for use of the instrumentation.
- C. The adequacy of the organizational plan and the internal advisory committee for administration of the grant including sharing arrangements for use of the instrument.
- D. The institution's commitment for continued support of the utilization and maintenance of the instrument.
- E. The benefit of the proposed instrument to the overall research community it will serve.

## VII. METHOD OF APPLYING

Copies of a more detailed announcement are being mailed to Program Directors of BRS grants and to sponsored program offices at all institutions currently receiving BRS grants. Interested investigators should obtain the complete announcement prior to preparing an application.

Applications must be received by February 15, 1986. Applications received after this date will not be accepted for review in this competition. The original and four copies should be sent to:

Application Receipt Office  
Division of Research Grants  
National Institutes of Health  
5333 Westbard Avenue  
Bethesda, Maryland 20892

Inquiries and two copies of the application should be submitted to:

Biomedical Research Support Program  
Division of Research Resources  
National Institutes of Health  
Building 31 - Room 5B23  
9000 Rockville Pike  
Bethesda, Maryland 20205

Telephone: (301) 496-6743



**ANNOUNCEMENT****DEMONSTRATION AND EDUCATION RESEARCH IN CYSTIC FIBROSIS****P.T. 34; K.W. 0715135, 0715165, 0403004, 0502017, 0414000****NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

Application Receipt Dates: February 1, June 1 and October 1

Cystic fibrosis is the most frequent lethal genetic disease of white Americans, affecting about 30,000 people in the United States. Although in the past cystic fibrosis patients have died at a very early age, today the average age for survival is more than 20 years. The disease may affect several body organs, including the lungs, pancreas, intestines, liver, gallbladder, and reproductive system, but the pulmonary aspects are the most pervasive and life threatening.

Treatment of cystic fibrosis is a complicated process of dealing with the symptoms present in the several organ systems involved and necessitates patient and family cooperation to maintain a continuing treatment regimen. Patients must adhere to a medication schedule, exercise, eat an adequate diet with supplementary digestive enzymes, and perform postural drainage. Moreover, patients must adjust to a chronic disease which will be fatal at a relatively young age. Depression, anger, and family tension are frequently seen in cystic fibrosis, often hindering the medical management and self-management of the disease. Compliance with treatment may be sporadic. In adolescence, especially, compliance often decreases and the normal struggles for independence are exacerbated by the continuing dependence on parental and medical involvement and economic dependence on parents. Moreover, cystic fibrosis patients often do not have normal social relationships.

Given this complicated medical picture, education of CF patients and their families is essential. Cystic fibrosis centers around the country consider education an important part of the medical management, but education of CF patients has not yet emerged as an area of research.

The intent of this announcement is to emphasize the importance of the problem and to invite the cooperation of investigators to address and offer solutions to this multi-faceted problem. It is expected that applications will be submitted by multidisciplinary teams that may include, but will not be limited to, pulmonary physicians, nurses, behavioral scientists, and educators.

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This program is described in the Catalog of Federal Domestic Assistance number 13.838, Lung Diseases. 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.

Applications may deal with newly and/or previously diagnosed CF patients and their families. Adolescent CF patients could be studied as a special group. Emphasis should be on programs designed to encourage adherence to treatment plans, to reduce hospitalization, and to promote psychosocial adjustment. Evaluation of behavior change should be a major component.

#### APPLICATION SUBMISSION AND REVIEW

Application receipt dates for new applications are the regular application receipt dates of February 1, June 1, and October 1. The earliest possible award date is approximately nine months after the receipt date. Applicants should use the regular research grant application Form PHS 398, which is available at most institutional business offices or from the Division of Research Grants (DRG), NIH.

To identify responses to this announcement, check "yes" and write "**Demonstration and Education Research in Cystic Fibrosis**" under item 2 of page 1 of the application. The completed application should be mailed to the following:

Division of Research Grants  
National Institutes of Health  
Westwood Building - Room 240  
5333 Westbard Avenue  
Bethesda, Maryland 20892

The DRG will assign applications for review according to the NIH process for regular research grant applications. Additional information may be obtained by contacting:

Joan M. Wolle, Ph.D., M.P.H.  
Prevention, Education, and  
Research Training Branch  
Division of Lung Diseases  
National Institutes of Health  
Westwood Building - Room 640  
5333 Westbard Avenue  
Bethesda, Maryland 20892

Telephone: (301) 496-7668

ANNOUNCEMENT

SMALL GRANTS PROGRAM FOR EPIDEMIOLOGY

P.T. 34; K.W. 0715035, 0785055

DIVISION OF CANCER ETIOLOGY

NATIONAL CANCER INSTITUTE

Application Receipt Dates: February 1, June 1, October 1

The Division of Cancer Etiology, National Cancer Institute (NCI) invites Small Grant applications relating to cancer epidemiology beginning with the February 1 receipt date in 1986.

I. PURPOSE OF THE AWARD

This is a short-term award, not to exceed two years, intended to provide support for pilot projects, testing of new techniques, or innovative or high-risk projects which could provide a basis for more extended research.

II. ELIGIBLE APPLICANTS

Investigators are eligible to apply for a Small Grant to support research on a topic relevant to cancer etiology if they are interested in:

- A. Planning a complex epidemiologic investigation.
- B. Developing or validating a laboratory procedure for the ultimate purpose of applying it in cancer epidemiologic research.
- C. Carrying out an innovative epidemiologic research project not related to ongoing supported research, for which rapid funding is justified (the availability of special personnel for limited time periods is considered to be an important factor in evaluating the need for rapid funding).

If the research will constitute a doctoral dissertation, a written statement from the applicant's dissertation chairperson or equivalent academic

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This program is described in the Catalog of Federal Domestic Assistance No. 13.393, Cancer Cause and Prevention Research. Awards are under authorization of the Public Health Service Act, Section 301(c) and Section 402 (Public Law 78-410, as amended; 42 USC 241, 42 USC 282) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

supervisor that the project proposal has his/her approval must accompany the application; if the study is selected for support under this program, a statement of approval of the full dissertation committee is required before funding will be made.

### III. TERMS OF THE AWARD

The award will provide a maximum of \$25,000 in direct costs. These funds may be used for technical assistance, supplies, small equipment, and travel required by the project. Salary support for the principal investigator will not be allowed. The normal duration of support is one year but applications may be made for longer periods (up to two years) if the limit on total funding noted above is not exceeded. The NCI expects to make approximately 8 awards from each review cycle. Unless specifically stated to the contrary herein, all policies and requirements which normally govern the grants programs of the PHS apply.

### IV. REVIEW PROCEDURES AND CRITERIA

Applications will be reviewed for scientific and technical merit by a committee convened by NCI and consisting primarily of non-Federal scientists. All applications will be evaluated with respect to the following:

- A. The significance and scientific merit of the proposed project.
- B. The methodology, including information to be derived.
- C. The investigator's background and training for carrying out the project.
- D. Adequacy of the available and requested facilities.
- E. The adequacy of justification presented for budget requests.

In addition to these general criteria, the following specific ones will apply as appropriate:

1. For pilot projects, the appropriateness of the exploratory activities and the likelihood that their completion will provide the basis for a definitive protocol.
2. For high-risk, innovative research, the extent to which completion of the proposed activities is likely to yield insight into the need for additional research.
3. For dissertation research, the quality of the education environment and the supervision to be provided the candidate.

Applications not meeting one of the three criteria stated above under "Eligible Applicants", or failing to meet the page limitations specified in this announcement, will be returned to the proposed Principal Investigator without undergoing committee review.

## V. METHOD OF APPLYING

Applications shall be submitted on Form PHS 398, available at most institutional business offices or from the Division of Research Grants, NIH. Because the guidelines for preparing this application are different from those used for regular research grants, the instructions given below must be followed in preparing and submitting an application.

An accelerated review is planned as follows:

<u>Receipt Date</u>	<u>Committee Review</u>	<u>Earliest Possible Review Funding Date</u>
October 1	November	January
February 1	March	May
June 1	July	September

In order to expedite the review of your application, you are asked to submit two sets of copies of the application. The copies you send to the Referral Office of the NCI are of great practical importance to you, because they can be sent to members of the review group with a minimum of delay. The two groups of copies are as follows:

Send or deliver the original (typewritten and signed) and FOUR signed exact photocopies in one package to the Division of Research Grants using the mailing label enclosed in the application kit, as specified in the general instructions. Clearly label the outside of the package: **PROGRAM ANNOUNCEMENT RESPONSE: SMALL GRANTS PROGRAM FOR EPIDEMIOLOGY, DCE, NCI.** Enclose in that package the self-addressed three-part postcard, form PHS-3830.

**IN ADDITION**, in a separate package, mail or deliver 2 additional exact photocopies of the signed application to:

Referral Officer  
Grants Review Branch  
National Cancer Institute  
Westwood Building - Room 820  
5333 Westbard Avenue  
Bethesda, Maryland 20892

Telephone: (301) 496-3428

Prospective applicants are encouraged to contact:

Dr. Genrose Copley  
Landow Building - Room 8C16  
7910 Woodmont Avenue  
Bethesda, Maryland 20892

Telephone: (301) 496-9601

## VI. REPORTING REQUIREMENTS

If an award is made in response to a Small Grants Application, a Final Progress Report and an Invention Statement must be submitted within ninety days after the termination of the award. This final reporting requirement is the same as that for other types of research grants and is in accord with 45 CFR 74.82. The information will be especially helpful to the NCI in evaluating the usefulness of the Small Grant Award Mechanism.

## VII. SUPPLEMENTARY INSTRUCTIONS FOR APPLICANT-INVESTIGATORS, SMALL GRANTS PROGRAM FOR EPIDEMIOLOGY

Applications are to be submitted on the standard PHS research grant application form (PHS-398, Rev. 5/80), following the instructions supplied with those forms EXCEPT for the following (see pages 8-15, Instruction Sheet for PHS-398):

- A. Face Page of Application Item 2: DCE Small Grants Program for Epidemiology. Item 6: Ordinarily, only one year of support is provided; within the limits on total funding, however, applicants may apply for up to two years of support. Item 10: Not applicable; mark NA.
- B. Application page 4: Detailed Budget for First 12-Month Period. Funds should be limited to the following categories: personnel (including technicians), supplies, travel and small equipment items. All requests for expenditures must be strongly and SPECIFICALLY justified. The total request may not exceed \$25,000 in direct costs. (Use a separate page for this explanation of the need for proposed expenditures.)
- C. Application page 5: Budget Estimates for All Years. Applicants requesting one year's support should not submit this. (In that case, this page may be used to justify budget requests for the one-year project period.)
- D. Biographic data: Do not exceed one page except in the case of dissertation research. It is expected that the doctoral candidate's dissertation adviser will be the P. I. and thereby signifies approval of the protocol. Additional documentation which permits evaluation of the educational environment and supervision to be provided this research should be included together with pertinent information about the candidate.
- E. Section 2 of application: (follows page describing Resources and Environment)
  1. Specific Aims: Not to exceed one page.
  2. Significance: Not to exceed one page.
  3. Progress Report/Preliminary Studies: If applicable, not to exceed two pages.
  4. Experimental Design and Methods: Not to exceed ten pages.
  5. Human Subjects through Literature Cited: Not to exceed four pages.

These page limitations and others in the PHS-398 Application Instructions must be observed or the application will not be accepted. If an exception to this requirement is necessary, discussion with Program staff and a brief written explanation is necessary prior to submission.

#### VIII. SUGGESTIONS FOR PERSONS PREPARING APPLICATIONS FOR THE DCE SMALL GRANTS PROGRAM

As applicant-investigator, you are responsible for preparing an application which conveys the maximum information to reviewers, in the clearest possible form, and with the minimum of verbiage.

The DCE Small Grants Program is intended to offer rapid review of applications requesting limited support of certain budget categories (technicians, supplies and equipment). Please note that all expenditures included in the budget plan require explicit and strong justification. Some suggestions follow, to help you in demonstrating how your project meets program goals.

- A. Be sure you specify which of the target groups of investigators you represent (planning an epidemiologic study, developing a test for future epidemiologic use, innovative or high-risk studies, dissertation research.)
- B. Make it clear why pilot data are needed, or how the proposed research is innovative.
- C. It is important that the specified page limitations for each section of the text be strictly observed. Note, for example, that the section describing methods may not exceed 10 pages. This abbreviated format means that you must present your case with special clarity.
- D. Be sure to list your most important positions and publications relevant to this project in your biographic data.

ANNOUNCEMENT

SMALL GRANTS PROGRAM FOR PILOT PROJECTS

P.T. 34; K.W. 0706000, 1002024, 1014001, 0790000, 1004000

BIOMEDICAL RESEARCH TECHNOLOGY PROGRAM

DIVISION OF RESEARCH RESOURCES

Application Receipt Dates: February 1, June 1, October 1

The Biomedical Research Technology Program was established in 1962 to provide biomedical research scientists with complex technological capabilities required to solve biomedical and clinical research problems. This is primarily done by funding regional resources for the application of advanced technologies to biomedical research problems and the development of new instrumental and methodological approaches to such problems. At present the Program focuses on knowledge engineering, information technology, digital technology, biomedical engineering, and technologies for the study of biomolecular and cellular structure and function. To further this mission, the BRT Program supports a small grant award for support of pilot studies. Approximately ten to twenty awards per year are made, contingent on receipt of meritorious applications and appropriated funds.

I. PURPOSE OF THE AWARD

This is a one-year, non-renewable award for pilot projects in a high technology in engineering, instrumentation, physics or computer science related to biomedical research. The projects should involve feasibility studies of innovative ideas in a high technology. High technology is defined here as working at the limits of understanding of a technology. The project should be oriented towards new instrumental or methodological approaches and provide a basis for more extended research in the project's technology.

This program is described in the Catalog of Federal Domestic Assistance No. 13.371, Biotechnology 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 42 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency reviews.



The purpose of the small grants program is to:

- A. Provide an opportunity to test new ideas in a high technology that will lead to a larger research project or implementation of the technology in a working environment such as a BRT resource.
- B. Develop significant changes in an existing high technology important to biomedical research.
- C. Translate scientific notions into a basis for a future technology.

## II. ELIGIBLE APPLICANTS

This program is open to both non-profit and for profit organizations and is designed to support engineers and other scientists for work in high technological projects in the biomedical area. (The BRT Program has a New Investigator Research Award program for recently trained or less experienced scientists.)

## III. APPLICATION AND REVIEW PROCEDURE

Applications should be submitted on Form PHS 398, available at most institutional business offices or from the Division of Research Grants, NIH. Because the format for preparing this application is different from that used for regular research grants, additional information and instructions should be obtained from the BRT Program staff contact listed below. Applications must adhere to this format to be responsive. Unresponsive applications will be returned to the applicant without review. An accelerated review will be scheduled as follows:

Receipt Date Annually	Institute Committee Review	Council Review	Earliest Date for Funding
February 1	March-April	May-June	June
June 1	July-September	Sept.-Oct.	November
October 1	November-January	Jan.-Feb.	February

Applications recommended for approval will either be funded or withdrawn immediately after review by the National Advisory Research Resources Council.

## IV. REVIEW CRITERIA

Applications will be evaluated with respect to the following criteria: the significance and scientific merit of the proposed project; its characterization as an innovative pilot project in a high technology in engineering, instrumentation, physics or computer science related to biomedical research; the probability the study will provide a basis for more extended research in the projects technology; the methodology, including choice of experimental methods, equipment or materials; the investigator's background and training for carrying out the project; adequacy of the available and requested facilities; and the adequacy of justifications presented for budget requests.

In the review of these applications the following aspects of the work proposed in the applications are emphasized:

- o scientific merit,
- o innovative approach or drastically different approach, and
- o the risk or uncertain chance of success because no historical base exists.

The award may not be used to supplement support for an ongoing project.

#### V. FUNDING CRITERIA

Applications will compete with each other in accordance with the purposes of the small grant program.

#### VI. TERMS OF THE AWARD

The award will provide a maximum of \$25,000 (direct costs) for personnel, consultants, supplies, small equipment, and travel required by the project. The award will be for one year, and in most cases can be extended for an additional year without additional funds.

#### VII. STAFF CONTACT

For further information prospective applicants are strongly urged to contact:

Dr. Jack Hahn, Ph.D.  
Head, Computer Technology Section  
Biomedical Research Technology Program  
Division of Research Resources  
National Institutes of Health  
Building 31 - Room 5B 43  
9000 Rockville Pike  
Bethesda, Maryland 20892

Telephone: (301) 496-5411

ANNOUNCEMENT

OPPORTUNITIES FOR RESEARCH ON ADOLESCENT FAMILY LIFE

INVESTIGATOR-INITIATED RESEARCH GRANTS AND NEW INVESTIGATOR RESEARCH AWARDS

P.T. 34; K.W. 0775020, 0710005, 0404000, 0730005

OFFICE OF ADOLESCENT PREGNANCY PROGRAMS  
OFFICE OF POPULATION AFFAIRS, PHS

Application Receipt Dates: February 1, June 1, and October 1

I. BACKGROUND

The Adolescent Family Life (AFL) Program was enacted in 1981, to develop and evaluate model demonstration projects to postpone adolescent sexual activity; develop and evaluate model demonstration care projects that provide comprehensive health and social services for pregnant or parenting teens; present adoption as a viable option to parenthood for young, unmarried mothers; and conduct research on related topics. The AFL research component has both basic and applied thrusts in order to provide knowledge needed to support the range of AFL program goals.

II. RESEARCH GOALS AND SCOPE

The following research problem areas have been identified as those most needing attention from the viewpoint of the AFL Program:

A. Influences on Adolescent Premarital Sexual Behavior:

Demographic, economic, social, psychological, and physical characteristics that are related to adolescent premarital sexual activity; the influence of family, peers, the media, and other factors on the initiation of adolescent premarital sexual activity; the adolescent's decision-making process about premarital sexual activity as this is influenced by developmental stage, societal attitudes, ethical values, family/peer relationships, and other factors that enter into the decision-making process. Different patterns of influence for adolescent males and females.

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This program is described in the Catalog of Federal Domestic Assistance No. 13.111, Adolescent Family Life Research Grants. Awards are made under the authority of Title XX of the Public Health Service Act and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review, unless the proposed research would establish a demonstration project for purposes of collecting data.

B. Consequences of Adolescent Premarital Sexual Behavior:

The effects of adolescent premarital sexual behavior on adolescent males and females, particularly with regard to their development (psychological, social, educational, moral, etc.) and physical health; how these consequences differ for major subgroups of the population or other groupings.

C. Consequences of Adolescent Premarital Pregnancy:

Social, psychological, physiological and other consequences of an adolescent premarital pregnancy and the social mechanisms that operate to ameliorate the negative consequences of such a pregnancy; impact on family of origin/extended family of an adolescent premarital pregnancy, family response to various stages of the pregnancy, and how these vary by major population subgroups or other groups.

D. The Adoption Option for the Unmarried Adolescent Mother:

Social, psychological, legal and service dimensions of the pregnant adolescent's adoption decision-making process. Role of the counseling process, social attitudes toward single parenthood, family involvement, the putative father, and the pregnant teen's own characteristics and expectations in the adoption decision-making process.

The effect (social, economic, or psychological) of the adoption decision on the adolescent mother, the child and/or the adoption family. Short and long-term adjustments and use of post-adoption services by an adolescent mother who places a child for adoption.

The differences among and usage of various adoption and care arrangements (formal adoption, informal adoption, temporary foster care, closed adoption and open adoption arrangements) and the differential outcomes for the adolescent mother, the child and/or the adoption family.

E. Parenting by the Unmarried Adolescent Mother:

Factors influencing parenting behavior of the unmarried adolescent mother and consequences of different kinds of parenting behavior for her and her offspring; role of unmarried adolescent mother's family of origin/extended family in adolescent parenting experience, how this differs by major population subgroups or other groupings, and the effect of such differences on the unmarried mother and her offspring; role of the father of the child of the unmarried adolescent mother in the parenting process and the impact of how his role is played on the mother and her child.

F. Adolescent Pregnancy Services:

The scope and impact of public and private sector services and policies directed toward adolescent pregnancy prevention, care, and parenting.

Evaluations of discrete strategies or interventions designed to eliminate adolescent premarital sexual relations and to assist families in effectively communicating their values about sexual matters to their children.

Evaluations of discrete strategies or interventions that might enhance service delivery of care services (e.g., health care, educational and vocational services, family planning services) to pregnant and parenting adolescents and their families.

Applications should include a well-organized statement of the problem to be addressed the research design, the conceptual framework within which the design has been developed, the methodology to be employed, the evidence upon which the analysis will rely, and the manner in which the evidence will be analyzed.

### III. MECHANISMS OF SUPPORT

The support mechanisms for this program will be the individual research project grant award and the New Investigator Research Award (NIRA). Direct costs should not exceed \$100,000 for each year of the project in the former case and \$37,500 in the latter case. Awards can be made for a maximum of three years in both cases, although the Office of Adolescent Pregnancy Programs (OAPP) is particularly interested in shorter-term projects as well as those making use of already existing data. Yearly continuation of a multi-year award is contingent on grantee performance and availability of funds. Competition is open to any corporation, public or private institution or agency, including corporations operated for profit.

In order to make data available to others, copies of data sets and accompanying documentation produced with funds granted through this announcement will be deposited with a public use data archive or with OAPP. The cost of making such data available should be budgeted in the proposal.

This announcement is a standing announcement of opportunities for research on Adolescent Family Life and will prevail until superseded by a subsequent announcement. Funding decisions can be expected within eight months of an application receipt date.

Approximately one million dollars is available annually from OAPP for new awards in the AFL research area, contingent upon the receipt of appropriated funds for this purpose.

### IV. REVIEW PROCEDURES AND CRITERIA

Applications in response to this solicitation will be reviewed on a nationwide basis and in competition with other submitted applications by committees convened by the Division of Research Grants (DRG) NIH, in accord with the usual NIH peer review procedures. Peer review criteria include:

- A. Scientific merit and significance of the project.
- B. Competency of proposed staff in relation to the type of research involved.
- C. Feasibility of the project.
- D. Reasonableness of proposed budget period in relation to the proposed research.
- E. Amount of grant funds necessary for completion, and adequacy of applicant's resources available for project.

- F. Adequacy of methodology proposed to carry out research.
- G. Adequacy of the proposed means for protecting against adverse effects upon humans, animals, or the environment, where an application involves activities which could have such effects.

Applications recommended for approval will be selected for funding by the Deputy Assistant Secretary for Population Affairs, Office of Population Affairs, on the basis of priority score, AFL program relevance, and availability of funds.

#### V. METHOD OF APPLYING

Applications should be prepared on PHS form 398, which is available in the business or grants and contracts office at most academic and research institutions or from:

Office of Grants Inquiries  
Division of Research Grants  
National Institutes of Health  
Westwood Building - Room 449  
5333 Westbard Avenue  
Bethesda, Maryland 20892

Telephone: 301 - 496-7441

Completed applications should be submitted to:

Division of Research Grants  
National Institutes of Health  
Westwood Building - Room 240  
5333 Westbard Avenue  
Bethesda, Maryland 20892

Type across the mailing envelope and item two on the application face page: **"Research on Adolescent Family Life."** In addition, **"New Investigator Research Award"** should be added for proposals falling in this specialized category. Organizations which contemplate submitting a NIRA application should request the pamphlet, "New Investigator Research Awards," from DRG/NIH before developing the application and follow the guidelines contained therein.

#### VI. IDENTIFICATION OF CONTACT POINTS

Staff at the OAPP will assist to the extent possible in matters of scope, relevance, or other questions about review, administration, and funding of applications received in response to this announcement. Investigators are encouraged to contact the following individual:

Eugenia Eckard  
Office Population Affairs, OASH, DHHS  
Hubert H. Humphrey Building - Room 731E  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Telephone: 202 - 245-1181

ANNOUNCEMENTOPPORTUNITIES FOR RESEARCH IN FAMILY PLANNING SERVICE DELIVERY IMPROVEMENTINVESTIGATOR-INITIATED RESEARCH GRANTS AND NEW INVESTIGATOR RESEARCH AWARDS

P.T. 34; K.W. 0730010, 0730050, 0413002

OFFICE OF FAMILY PLANNING, OFFICE OF POPULATION AFFAIRS

PUBLIC HEALTH SERVICE

Application Receipt Dates: February 1, June 1, and October 1

I. BACKGROUND INFORMATION

The Office of Family Planning (OFP) which administers Title X of the Public Health Service Act, the major source of Federal funding for voluntary family planning services in this country, has an applied research program oriented toward the provision of knowledge that will enable the Title X program to improve its delivery of family planning services to low-income women and other clients in need of such services but otherwise unable to afford them. The knowledge sought is that needed by family planning service providers, particularly those at the clinic level, to better understand the service delivery processes with which they are involved and ways to influence these processes in the desired direction. Investigations of a number of topics can help build the needed knowledge.

II. RESEARCH GOALS AND SCOPE

The following research problem areas have been identified as those most needing attention from the viewpoint of family planning services delivery improvement:

- A. Family Planning Client Behavior: Factors influencing who comes to family planning clinics, when they come, their expectations, their satisfaction, effectiveness of their contraceptive behavior, and their pattern of clinic attendance and contraceptive use.

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This program is described in the Catalog of Federal Domestic Assistance No. 13.974, Family Planning--Services Delivery Improvement Research Grants (SDI). Awards are made under the authority of Section 1004(a) of Title X of the Public Health Service Act (42 U.S.C. 300a-2(a)) and administered under PHS grant policies and Federal Regulations, most specifically at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review, unless the proposed research would establish a demonstration project for purposes of collecting data.

- B. Adolescent Family Planning Clients: Analyses of ways to better serve adolescents who are obtaining Title X services.
- C. Male Family Planning Clients: Identification of barriers to and strategies for bringing about effective involvement of males in family planning services; analyses of developmental processes that operate against responsible male sexual and family planning behavior.
- D. Targeting of Family Planning Services: Effectiveness of different kinds of strategies for targeting family planning services to low-income and other special needs clients (e.g., cultural or ethnic minorities, populations in rural or other distinctive geographical settings, unemployed, physically handicapped, mentally ill, or retarded); effectiveness of special approaches to delivery of family planning services for these subgroups.
- E. Clinic Personnel Behavior: Factors influencing the manner in which different types of family planning personnel perform their roles; consequences of such differences for effectiveness of clients' family planning behavior; successfulness of training or other strategies in enhancing personnel role performance; factors in recruiting and retaining competent family planning personnel; impact of clinic personnel characteristics on clinic quality of care and efficiency.
- F. Organization and Management of Family Planning Services: Effects of managerial and organizational factors at the clinic and other levels (e.g., funding arrangements, organization type, staffing patterns, facility/location characteristics) on efficiency and effectiveness of family planning service provision. Analyses of how costs can be contained or reduced while maintaining quality of family planning services provided; evaluations of how integration of family planning services with other services affects the character of family planning service provision.
- G. Role of Private Physician: Factors influencing role of private physician in providing family planning services to low-income women and adolescents.
- H. Natural Family Planning: Factors affecting choice of Natural Family Planning (NFP) as a method of fertility regulation in family planning clinics and other settings; determinants of NFP use-effectiveness; conditions under which NFP is an effective component of infertility services; studies of how to improve provision of NFP in family planning clinic settings.
- I. Infertility Services: Factors influencing the need for and provision of infertility services among low-income women; conditions for successful treatment of low-income women's various infertility problems; studies of how to improve provision of infertility services in Title X programs.
- J. Counseling Services: Evaluations of the role and effectiveness of various kinds of contraceptive education counseling approaches in different kinds of family planning clinic settings; studies of ways to include/improve counseling of pregnant adolescents concerning the adoption option in family planning clinic settings.



Applications should include a well-organized statement of the problem to be addressed, the research design, the conceptual framework within which the design has been developed, the methodology to be employed, the evidence upon which the analysis will rely, and the manner in which the evidence will be analyzed. The question of how findings from the proposed study will have general applicability to concerns of family planning services programs in this country should be addressed.

### III. MECHANISMS OF SUPPORT

The support mechanisms for this program will be the individual research project grant award and the New Investigator Research Award (NIRA). Direct costs should not exceed \$100,000 for each year of the project in the former case and \$37,500 in the latter case. Awards can be made for a maximum of three years in both cases, although OFP is particularly interested in shorter-term projects as well as those making use of already existing data. Yearly continuation of multi-year awards is contingent on grantee performance and availability of funds. Competition is open to any public or private non-profit institution or agency.

In order to make data available to others, copies of data sets and accompanying documentation produced with funds granted through this announcement will be deposited with a public use data archive or with OFP. The cost of making such data available should be budgeted in the proposal.

This announcement is a standing announcement of opportunities for research in family planning service delivery improvement and will prevail until superseded by a subsequent announcement. Funding decisions can be expected within eight months of an application receipt date. Approximately one million dollars is available annually from OFP for new awards in the family planning service delivery improvement research area, contingent upon the receipt of appropriated funds for this purpose.

### IV. REVIEW PROCEDURES AND CRITERIA

Applications in response to this solicitation will be reviewed on a nationwide basis and in competition with other submitted applications, by committees convened by the Division of Research Grants (DRG) NIH in accord with the usual NIH peer review procedures. Peer review criteria include:

- A. Scientific merit and significance of the project.
- B. Competency of proposed staff in relation to the type of research involved.
- C. Feasibility of the project.
- D. Reasonableness of proposed budget period in relation to the proposed research.
- E. Amount of grant funds necessary for completion, and adequacy of applicant's resources available for project.
- F. Adequacy of methodology proposed to carry out research.

- G. Adequacy of the proposed means for protecting against adverse effects upon humans, animals, or the environment, where an application involves activities which could have such effects.

Applications recommended for approval will be selected for funding by the Deputy Assistant Secretary for Population Affairs, Office of Population Affairs, on the basis of priority score, OFP program relevance, and availability of funds.

#### V. METHOD OF APPLYING

Applications should be prepared on PHS form 398, which is available in the business or grants and contracts office at most academic and research institutions or from:

Office of Grants Inquiries  
Division of Research Grants  
National Institutes of Health  
Westwood Building - Room 449  
5333 Westbard Avenue  
Bethesda, Maryland 20892

Telephone: (301) 496-7441

Completed applications should be submitted to:

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

Type across the mailing envelope and item two on the application face page: **"Research in Family Planning Service Delivery Improvement."** In addition, "New Investigator Research Award" should be added for proposals falling in this specialized category. Organizations which contemplate submitting a NIRA application should request the pamphlet, "New Investigator Research Awards," from DRG/NIH before developing the application and follow the guidelines contained therein.

#### VI. IDENTIFICATION OF CONTACT POINTS

Staff at OFP will assist to the extent possible in matters of scope, relevance, or other questions about review, administration, and funding of applications received in response to this announcement. Investigators are encouraged to contact the following individual for further information:

Patricia Thompson, Ph.D.  
Office of Family Planning  
Office of Population Affairs  
Hubert H. Humphrey Building - Room 731E  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Telephone: (202) 245-1181