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For Grants and Contracts

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NOTICES

PHS 398 GRANT APPLICATION, REVISED 9/86, NOW AVAILABLE

P.T. 34; K.W. 0710030, 1014002

National Institutes of Health

The newly revised Public Health Service grant application form (PHS 398) is now available. The new version replaces the form presently in use, dated 5/82.

The new PHS 398 application kit includes instructions for applying for new, competing renewal, and competing supplemental research grant support. In addition, the new version incorporates the National Research Service Award (NRSA) Institutional Training Grant form (formerly the PHS 6025 form) as well as supplemental instructions for applying for a Research Career Development Award (RCDA). The new form should be used by NRSA Institutional Training Grant applicants starting with the September 10, 1987 receipt date, and by research grant and RCDA applicants starting with the October 1, 1987 receipt date.

Applicant organizations should note that a new assurance related to misconduct in science has been added to the application form. This assurance is required under section 493 of the PHS Act as amended by P.L. 99-158, the "Health Research Extension Act". That statute requires the Department of Health and Human Services (DHHS) to issue regulations requiring applicant organizations to establish an administrative process for reviewing reports of scientific fraud and to report to the Secretary any investigation of alleged scientific fraud that appears substantial.

PHS expects to publish a notice of Proposed Rulemaking (NPRM) implementing this requirement in the near future. It is important to note that the legislation does not require, and PHS does not intend to require, agency approval of institutional procedures, nor is it intended that the regulations will spell out in detail the administrative requirements for institutional procedures. Thus it would be quite appropriate for you to check "yes" if your institution has procedures in place now. However, applicants will not be required to provide this certification for the September 10 or October 1 application receipt dates. Future announcements in the GUIDE will note the dates of the proposed and final regulations.

CLARIFICATION OF ELIGIBILITY FOR THE PHYSICIAN SCIENTIST AWARD FOR DENTISTS (K11)

P.T. 34; K.W. 0710030, 0785040, 1014002

National Institute of Dental Research

The announcement describing the Physician Scientist Award for the NIH, which appeared in the "NIH Guide for Grants and Contracts", Volume 15, No. 3, February 28, 1986, included the National Institute of Dental Research accepting applications for this award. To the general NIH announcement, the NIDR added an extra page (#10), specifically directed to the NIDR's "Physician Scientist Award Program for Dentists" (PSA). The NIDR specified that it would accept applications only for the INDIVIDUAL award.

However, we wish to clarify the ambiguity of the following sentence, which appears in the first paragraph of the NIDR page. It now reads:

"The new Physician Scientist Award (PSA), which is restricted to those holding D.D.S., D.M.D., or other health professional degrees in the clinical sciences, is expected to be helpful in accomplishing this specific aim."

This sentence should read as follows:

"The new Physician Scientist Award for Dentists (PSA), which is restricted to those holding the D.D.S., D.M.D., or another equivalent dental degree, is expected to be helpful in accomplishing this specific aim."

The remainder of the text of the original NIDR announcement is unchanged.

DATED ANNOUNCEMENTS (RFPs AND RFAs AVAILABLE)

ESTABLISHMENT OF A SURVEILLANCE SYSTEM OF WOMEN UNDERGOING TREATMENT FOR INFERTILITY WITH IN VITRO FERTILIZATION

RFP AVAILABLE: NICHD-CE-87-06

P.T. 34; K.W. 0413002, 0785055, 1004008

National Institute of Child Health and Human Development

This Procurement is totally set-aside for small business concerns. For purposes of this procurement, a small business concern is a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is proposing on government contracts, and whose average annual receipts for the preceding three fiscal years do not exceed \$3.5 million.

The Contraceptive Evaluation Branch, Center for Population Research, National Institute of Child Health and Human Development, National Institutes of Health is seeking small business organizations capable of establishing a surveillance system of women undergoing treatment for infertility with in vitro fertilization (IVF) in the United States in order to monitor the medical and lifetime fertility sequelae of the procedure. The objectives of this project are two-fold: (1) to mount a centrally coordinated, collaborative effort which will result in a national registry of these patients and (2) to implement the system established above in order to investigate the extent to which the procedure may produce a wide spectrum of adverse health effects.

The first phase of the project will incorporate identification and selection of the participating clinics, development of the data collection instruments, development of patient follow-up strategies and pilot testing of all mechanisms of the system. The implementation phase will include estimation of risk of various endocrinologic conditions, menstrual disorders, reproductive abnormalities, and psychological sequelae in addition to generating and exploring new medical hypotheses. It is anticipated that this will be a five year project and that a single contract award will be made. It is estimated that the project will require the following personnel: a physician at the coordinating center to serve as principal investigator, a systems analyst, a project manager and clerical support. The participating clinical sites will require project managers (nurse/epidemiologists) and the part-time participation (advisory) of the physician(s) performing the procedure.

Organizations responding to this announcement should have demonstrated competency in managing multicenter collaborative research projects and the capability of meeting the following requirements: (1) Familiarity with the technical aspects of in vitro fertilization procedures and ability to identify clinics with this technology available; (2) Experience in reproductive epidemiology; (3) Ability to train and supervise appropriate personnel at the clinical sites; and (4) Database management skills including quality assurance.

RFP-NICHD-CE-87-06 will be issued on or about July 1, 1987. Proposals will be due approximately 60 days thereafter. Copies of the RFP may be obtained by sending written requests to the following address. Please include a self-addressed label.

Paul J. Duska, Contracting Officer
Contracts Management Section, OGC
National Institute of Child Health and Human Development
Landow Building, Room 6C-25
7910 Woodmont Avenue
Bethesda, Maryland 20892

DIABETES CENTERS

RFA AVAILABLE: 87-DK-10

P.T. 04, 34; K.W. 0715075, 0785050, 0710030

National Institute of Diabetes and Digestive and Kidney Diseases

Application Receipt Date: October 13, 1987

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) invites applications for a Center grant to be awarded in Fiscal Year 1988. NIDDK anticipates the competitive award of one Diabetes Endocrinology Research Center (DERC) in Fiscal Year 1988.

BACKGROUND

At the present time, the NIDDK supports six DERCs. These centers are part of an integrated program of diabetes-related research support within the NIDDK. Centers have provided a focus for increasing the efficiency and collaborative effort among groups of successful investigators at institutions with established comprehensive diabetes research bases.

OBJECTIVES AND SCOPE

The objectives of the DERCs are to bring together investigators from relevant disciplines in a manner which will enhance and extend the effectiveness of research being conducted in the field of diabetes and its complications. A Diabetes Center must be an identifiable unit within a single university medical center or a consortium of cooperating institutions, including an affiliated university. The overall goal of the DERC is to bring together on a cooperative basis, clinical and basic science investigators in a manner which will enrich the effectiveness of diabetes research. A program of excellence in biomedical research in the area of diabetes and related metabolic and endocrine disorders in the form of NIH-funded research projects, program projects, or other peer-reviewed research must be 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.

The DERCs are 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 diabetes or diabetes-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 for new investigators or for established investigators in other research disciplines where their expertise may be applied to diabetes research. The Center grant may also include limited funds for program enrichment such as seminars, visiting scientists, consultants, workshops, etc.

MECHANISM OF SUPPORT

NIDDK expects to award one DERC Grant in Fiscal Year 1988 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 RFA (general description and Guidelines for the DERC) and consultation may be obtained from:

Dr. Sanford Garfield
Diabetes Centers Program Director
Diabetes, Endocrinology, and Metabolic Diseases Division
National Institute of Diabetes and
Digestive and Kidney Diseases
Bethesda, Maryland 20892
Telephone: (301) 496-7418

REVIEW PROCEDURES

Applications for a DERC 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

Potential applicants are urged to submit a letter of intent regarding their application. The letter of intent is nonbinding and is not a precondition for an award. The letter of intent should include the name(s) of the principal investigator and principal collaborators, descriptive titles of the core facilities and pilot/feasibility projects, and the organization(s) involved.

Applications must be submitted using Form 398 (Rev. 9/86). The RFA label contained in the application kit must be affixed to the bottom of the face page of the original copy of the application. Failure to use this label could result in delayed processing and review of your application.

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

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

Simultaneously submit two copies to Dr. Sanford Garfield at the address noted above.

The special single receipt date for submissions in response to this announcement is October 13, 1987, with earliest funding July 1, 1988.

ONGOING PROGRAM ANNOUNCEMENTS

SUPPORT FOR SCIENTIFIC MEETINGS - NATIONAL EYE INSTITUTE

P.T. 42; K.W. 1002046, 1014002

National Eye Institute

Progress in vision research is fostered by frequent exchanges of scientific information among investigators in this field and between vision scientists and scientists in other fields. These exchanges occur informally, in collaborations, in publications, and in regular scheduled national and international meetings. The National Eye Institute (NEI) continues to offer support for special, one-time meetings, workshops, and conferences. Preferential consideration is given to applications developed in conjunction with NEI extramural staff which address specific research needs as identified in "Vision Research - A National Plan: 1983-1987" and in more recent NEI program planning evaluations. The focus of supported meetings will generally be on vision research areas in great need of new or multidisciplinary scientific approaches and ideas. Investigators planning to submit applications for the support of scientific meeting are, therefore, strongly encouraged to discuss their applications in advance with appropriate NEI extramural staff. For further information, please contact:

Jack A. McLaughlin, Ph.D.
National Eye Institute
Building 31, Room 6A51
Bethesda, Maryland 20892
Telephone: (301) 496-5983

REVISED ANNOUNCEMENT: THE FIRST INDEPENDENT RESEARCH SUPPORT AND TRANSITION (FIRST) AWARD (R-29)

(This document replaces the previous August 1, 1986 announcement)

P.T. 34; K.W. 0710030, 1014002

National Institutes of Health

The National Institutes of Health (NIH) announces the continuing availability of the FIRST Award (R-29). Based on earlier review experiences the objectives and features of the R-29 mechanism are further defined and clarified.

OBJECTIVE

The objective of the FIRST award is to provide a sufficient period of research support for newly independent biomedical investigators to initiate their own research and demonstrate the merit of their own research ideas. These grants are intended to underwrite the first independent investigative efforts of an individual; to provide a reasonable opportunity to demonstrate creativity,

productivity, and further promise; and to help in the transition to traditional types of NIH research project grants. The award is not intended for persons in mid-career who may be in transition to another endeavor. FIRST awards generally will provide funds for 5 years during which time the newly independent investigator can establish his or her own research program and make significant and innovative contributions to laboratory or clinical science disciplines in biomedical research.

ELIGIBILITY

To be eligible for a FIRST award, the proposed principal investigator (PI) must be genuinely independent of a mentor yet at the same time must be at the beginning stages of his or her research career with, for example, no more than five years research experience since completing postdoctoral research training or its equivalent. If the applicant is in the final stages of training, it is permissible to apply, but no FIRST award will be made to persons in training status. In addition, the proposed PI must otherwise be eligible to serve in the same capacity on a traditional research project grant (R-01) awarded to the applicant institution. The applicant investigator must never have been designated previously as PI on any PHS-supported research project OTHER THAN a PHS small grant (R-03), an Academic Research Enhancement Award (R-15) or certain research career awards (K series) directed principally to physicians, dentists or veterinarians with little research experience. (Current or past Research Career Development Awardees are not eligible.) Subproject leaders on multicomponent awards such as Program Project grants (P-01), Center grants (P-50) or Minority Biomedical Research Support grants (S-06) may also be eligible, however potential applicants in these categories are urged to contact the appropriate person from the awarding unit listed below.

An important principle to remember with regard to eligibility is that the more extensive the prior independent research experiences, regardless of funding sources, the greater likelihood there will be diminished enthusiasm among reviewers for the FIRST award application.

GENERAL FEATURES

PRE-AWARD

- 1 Only domestic organizations and institutions are eligible to receive FIRST awards.
- 2 A FIRST award is for a distinct research endeavor and may not be used merely to supplement or broaden an ongoing project at the applicant institution.
- 3 An individual may submit only one FIRST award application to the Public Health Service (PHS) for any particular receipt date and may not submit any other type of research grant application (including research career applications) to the PHS during that particular review cycle. Applications for other projects may be submitted while the FIRST award is in force provided that the time and effort is less than 100% on the FIRST award.
- 4 FIRST award applications must request 5 years of research support. Applications submitted to the NIH in which the request is for less than 5 years of support will be designated as R01s and so reviewed unless the applicant withdraws the application.
- 5 The PI must make a commitment of no less than 50% effort to the proposed project.

Up to 100% effort may be requested if a greater commitment of the principal investigator is required to do the research. The request for effort of the applicant investigator will be reviewed and reductions may be recommended.

- 6 Application page limitations apply to the Research Plan (Section 2) of the PHS 398 application form. Sections A-D of the Research Plan, as described on page 20 of the instructions for the PHS 398 (Rev. 9/86), are limited to a total of 20 pages including tables, figures and chemical structures. Applications exceeding the 20-page limitation will be returned.

If appendix material is submitted, six collated sets must be included with the application package. Identify each of the six sets with the name of the principal investigator and the project title. This material will not be routinely duplicated and will be used in a limited way by members of the initial review group.

- 7 In very unusual circumstances, FIRST awards may be recommended by the initial review group or the awarding Institute for periods of less than five years.

POST-AWARD

- 1 The total direct cost award for the 5-year period may not exceed \$350,000. The direct cost award in any budget period should not exceed \$100,000. Indirect costs will be paid to the grantee institution in accord with applicable policy of the Department of Health and Human Services (DHHS).

The authority to carry over unobligated direct cost funds from one budget period to the subsequent one under certain conditions will be a feature of this award and may be accomplished at the discretion of the principal investigator and the grantee institution. If funds have been restricted by a specific term or condition on the Notice of Grant Award, they may not be automatically carried over without the prior approval of the awarding unit.

Carryover is effected by notification on the financial status report, which the grantee submits within 90 days of the termination of each budget period. Upon receipt of the notification, the awarding unit will issue a revised Notice of Grant Award, which will reflect the increased authorization of direct costs. Indirect costs will be paid to the awardee institution in accord with applicable DHHS policy.

- 2 FIRST awards are not renewable. The PI on a FIRST award may submit a traditional research project grant (R-01) application to continue and extend the research supported by a FIRST award.
- 3 Grantee Institutions may extend the final budget period of the project one time for a period up to one year beyond the original termination date shown on the Notice of Grant Award. Such an extension may be made only when any one of the following applies:
 - o additional time beyond the established expiration date is required to assure adequate completion of the originally approved project scope or objectives;
 - o continuity of Public Health Service (PHS) grant support is required while a competing application is under review; or
 - o the extension is necessary to permit an orderly phaseout of a project that will not receive continued support.

The fact that funds remain at the expiration of the grant is not in itself sufficient justification for an extension without additional funds.

The grantee institution must notify the awarding unit of the extension prior to the expiration date of the project period. Upon notification, the awarding unit will issue a revised Notice of Grant Award to change the termination date. Grantees may not extend project periods previously extended by the awarding unit.

- 4 Replacement of the PI on a FIRST award will not be approved. Transfer of the FIRST award with the principal investigator to another institution for the remaining performance period may be requested.
- 5 Except as indicated above, all relevant portions of the PHS Grant Policy Statement are applicable to these awards.

ADDITIONAL DOCUMENTATION

The following is to be addressed in a letter or memorandum from a suitable department head or dean and should be included with the application.

- o Eligibility of proposed principal investigator independently to lead a research project at the applicant institution. Is this person otherwise qualified to be the PI on a traditional research project grant (R01)?
- o Details of intended commitment of the institution to the project for the five-year period.

In addition, three letters of reference are needed. At least two must be received a minimum of three weeks before the initial review, or the application will be deferred. Such letters are critically important when the investigator's research originality and potential for independent investigation are not reflected in his/her research experience. For example, when the application is from the institution where the proposed PI received postdoctoral research training, it must be made absolutely clear that the FIRST award would be to support a research endeavor independent of that conducted in the former training environment.

The applicant is responsible for determining that letters be sent to the cognizant Executive Secretary after notification of Study Section assignment is received in the mail.

REVIEW CRITERIA

Review criteria and procedures are those of the regular NIH system of dual peer review: evaluation for scientific and technical merit by an initial review group (study section) taking into consideration the investigator's stage of development and merit of the proposed research, followed by recommendation of the cognizant national advisory council or board. In addition, the PI must demonstrate the potential to carry out independent research and clear evidence of ability to develop a sound research plan. The quality of education, scientific training, research experience, commitment to a research career as well as the institutional commitment will be important in the review process.

IMPLEMENTATION

All awarding units of the NIH are authorized to use this mechanism.

It should be noted that these applications compete for funding with traditional types of NIH research project grants and that the NIH has no special set-aside funds for FIRST awards.

HOW TO APPLY

Applicants must use the PHS-398 (Rev. 9/86) application form and must provide relevant information on eligibility. (See Section II.) The acronym "FIRST" should be typed on line 2 of the application face page.

Applications must be submitted to the Division of Research Grants (DRG) in accordance with regular receipt dates (See below). Assignment to the most appropriate Institute and initial review group will be carried out by the DRG according to established guidelines.

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

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

The following table indicates the review and award cycle:

Application Receipt Dates	Initial Review Group Dates	National Advisory Council/Board Dates	Earliest Possible Beginning Date
February 1, June 1 October 1	June/July October/November February/March	September/October January/February May/June	December 1 April 1 July 1

PARTICIPATING BUREAUS, INSTITUTES, DIVISIONS AND CENTERS OF THE NATIONAL INSTITUTES OF HEALTH

Additional information may be obtained by contacting:

National Institute on Aging

Dr. Miriam Kelty, Associate Director
Office of Extramural Affairs
National Institute on Aging
Building 31, Room 5C05
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-9374

National Institute of Allergy and Infectious Diseases (NIAID)

Dr. Luz A. Froehlich, Deputy Director
Extramural Activities Program
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Westwood Building, Room 703
Bethesda, Maryland 20892
Telephone: (301) 496-7688

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Dr. Steven J. Hausman, Deputy Director
Extramural Activities Program
Westwood Building, Room 403
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7495

National Cancer Institute (NCI)

Mr. Hernon Fox, Referral Officer
National Cancer Institute
Westwood Building, Room 828
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-3428

National Institute of Child Health and Human Development (NICHD)

Mrs. Hildegard Topper,
Special Assistant to the Director
National Institute of Child Health and Human Development
Building 31, Room 2A03
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-1848

National Institute of Dental Research (NIDR)

Dr. Marie U. Nylen, Director
Extramural Programs
National Institute of Dental Research
Westwood Building, Room 503
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7723

National Institute of Diabetes, and Digestive and Kidney Diseases (NIDDK)

Dr. Walter S. Stolz, Director
Division of Extramural Activities
National Institute of Diabetes, and Digestive and Kidney Diseases
Westwood Building, Room 657
National Institutes of Health
Bethesda, Maryland 20982
Telephone: (301) 496-7277

National Institute of Environmental Health Sciences (NIEHS)

Dr. Edward Gardner, Science Administrator
Extramural Programs, NIEHS
P.O. Box 12233
Research Triangle Park, North Carolina 27709
Telephone: (919) 541-7724

National Eye Institute (NEI)

Dr. Jack A. McLaughlin, Acting Associate Director
National Eye Institute
Building 31, Room 6A51
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-5983

National Institute of General Medical Sciences (NIGMS)

Dr. David Wolff, Deputy Associate Director
Office of Program Activities
National Institute of General Medical Sciences
Westwood Building, Room 955
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-7063

National Heart, Lung, and Blood Institute (NHLBI)

Dr. Henry G. Roscoe, Deputy Director
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 7A17
Bethesda, Maryland 20892
Telephone: (301) 496-7225

National Library of Medicine (NLM)

Mr. Peter A. Clepper, Program Officer
Biomedical Information Support Branch
Extramural Programs
Building 38A, Room 5S-518
National Library of Medicine
Bethesda, Maryland 20894
Telephone: (301) 496-4221

National Institute of Neurological and Communicative Disorders and Stroke (NINCDS)

Mr. Edward Donohue, Deputy Director
Division of Extramural Activities
National Institute of Neurological and Communicative Disorders and Stroke
Federal Building, Room 1016
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-4188

National Center for Nursing Research (NCNR)

Dr. Doris Bloch, Acting Director
Division of Extramural Programs
National Center for Nursing Research
Building 38A, Room B2E17
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-0526

Division of Research Resources (DRR)

Dr. James F. O'Donnell, Deputy Director
Division of Research Resources
Building 31, Room 5B03
National Institutes of Health
Bethesda, Maryland 20892
Telephone: (301) 496-6023

**THE MAILING ADDRESS GIVEN FOR SENDING APPLICATIONS TO THE DIVISION OF RESEARCH GRANTS 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