NIH GUIDE

For Grants and Contracts

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The NIH Guide announces scientific initiatives and provides policy and administrative information to individuals and organizations who need to be kept informed of opportunities, requirements, and changes in extramural programs administered by the National Institutes of Health.

Vol. 20, No. 12
March 22, 1991

NOTICES

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ONGOING PROGRAM ANNOUNCEMENTS

ERRATA

NOTICES

REVIEW PROCEDURES FOR NEW COMPETITIVE PROGRAM PROJECT GRANT APPLICATIONS SUBMITTED JUNE 1, 1991 AND OCTOBER 1, 1991

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

National Heart, Lung, and Blood Institute

Effective with the receipt of applications due June 1, 1991 and October 1, 1991, new and amended new competitive program project grant applications assigned to the National Heart, Lung, and Blood Institute (NHLBI) will be reviewed on a schedule longer than has been the custom in the past. This is necessary in order to carry out the usual NHLBI peer review process for program project grant applications at a time when the number of applications

has greatly increased. These applications will be reviewed by the NHLBI review branch in as timely a manner as is practicable.

The submission of many program project grant applications in excess of the usual workload has already necessitated the delay in review of many applications and has placed a significant burden on review staff, reviewers, and scheduling. The increased percentage of amended applications has contributed to this problem.

The nature of the program project grant has evolved greatly since its inception in the early 1960s. Because of the recent circumstances, the NHLBI is taking the opportunity in the next 9 months to examine the program project grant mechanism. To this end, two NHLBI staff committees are being established to revise program project guidelines and review procedures. The National Heart, Lung, and Blood Advisory Council and extramural scientists will be part of this process. It is currently expected that new program guidelines and review procedures will be presented to the Council in October 1991 with implementation for the February 1, 1992 deadline.

For these reasons, new (Type 1 and amended Type 1) program project grant applications will experience delays in the review cycle. Competing renewal and amended renewal applications will be reviewed under previous schedules in order to avoid gaps in funding and to lessen any problems associated with phasing out of ongoing research efforts and to maintain, where possible, personnel and institutional commitments of currently funded programs.

Questions about this announcement should be directed to:

Ronald G. Geller, Ph.D.
Director, Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 7A/17
Bethesda, MD 20892
Telephone: (301) 496-7416

NIH REGIONAL SEMINAR IN GRANTS ADMINISTRATION

P.T. 42; K.W. 1014006

National Institutes of Health

The Grants Policy Office of the National Institutes of Health (NIH) is sponsoring a two-day seminar on program funding and grants administration. The seminar covers topics of interest to both academic researchers and grants administrators and will be held on May 20-21, 1991, at Indiana University School of Medicine, Indianapolis.

The conference is targeted for an audience of researchers and research administrators at institutions in the Midwest region of the country. Those interested from other states are also invited. Investigators and staff from small and minority colleges, for-profit research organizations, hospitals, universities, and research institutes are encouraged to attend.

Discussions of current issues that affect NIH funding and grants administration are included to give conference participants a comprehensive, up-to-date view of NIH-sponsored research. The first day of the conference focuses on current areas of interest to the research programs of the various awarding components that comprise the NIH. Preparation of an NIH application/proposal and the NIH review process are included as agenda topics. In addition, a panel of Principal Investigators from Indiana University School of Medicine will give their perspective and advice on writing successful applications/proposals.

The program for the second day covers topics associated with pre-award and post-award administration of NIH grants and contracts. Policy and procedural issues affecting NIH grants administration form the basis of the program. General discussions on current issues and the changes they precipitate are integrated with more specific discussions regarding special career development programs, conflict of interest guidelines, and electronic grant application development.

Mr. Geoffrey Grant, Grants Policy Officer in the Office of Extramural Research at NIH and program and grants management staff from several NIH institutes and centers as well as representatives from the Division of Research Grants are featured speakers. Time will be available each day for conference participants to meet informally with the NIH representatives to discuss topics of special interest.

conference agenda and fee information are available. For more information, contact Ms. Jan Walther, Indiana University School of Medicine, at (317) 274-7127.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

A RANDOMIZED, PLACEBO-CONTROLLED TRIAL IN FIRST SEIZURE PATIENTS

REQUEST FOR INFORMATION SYNOPSIS NO.: NIH-NINDS-91-001

P.T. 34; K.W. 0715060, 0755015, 0745005

National Institute of Neurological Disorders and Stroke

Whether early treatment of non-febrile seizures can alter the likelihood of the development of chronic epilepsy is a question yet unresolved. The National Institute of Neurological Disorders and Stroke (NINDS), NIH, is interested in identifying organizations that are potential sources of non-adult patients with first non-febrile seizures for a randomized, double-blind, placebo-controlled trial of the treatment of first seizures. The NINDS is interested in comparing two randomly assigned groups of patients, those assigned to receive an anti-epileptic drug (AED) after the first seizure and those assigned to receive a placebo. The primary comparison will be the proportion of patients with recurrent seizures in each group after treatment and follow-up (up to two years). The NINDS is seeking to determine whether appropriate populations exist for such a clinical trial.

Specifically, information is requested to assess availability of the following:

1. The number of patients diagnosed with first seizure each month in your institution for the past three (3) years, according to decades of age. There must be documented availability of approximately 150 non-adult (6 months to 19 years of age) patients in the first year of enrollment. Patients must be without prior non-febrile seizures, with a maximum of one week of AED treatment for the presenting seizure, and who could be entered into a trial within one week of their first seizure. Immediacy of screening to permit randomization prior to recurrent seizure is a high priority criterion.

2. The current practice in your institution for treating patients with first seizures, including first AED choices, methods for identifying a seizure, a non-febrile seizure, and a first non-febrile seizure.

3. The clinical staff and routine resources available to diagnose, treat, and follow this type of patients. Provide names and professional qualifications and specific experience of clinical personnel who have been involved with trials of a similar nature.

4. Summary of baseline data currently collected on first seizure patients, summary of follow-up data currently and routinely collected, e.g., current frequency of CT scans and/or EEG's. Median duration of patient contacts over the past three (3) years.

5. Identification of the support staff and experience in data entry and data management for clinical trials.

Responses to this request are not mandatory and are solicited on a voluntary basis. A statement of capabilities and qualifications should not exceed 15 typed pages. This announcement does not commit the Government to make an award nor to pay for the preparation of any information submitted. This is not a Request for Proposals. Acknowledgement of receipt of responses will not be made, nor will respondents be notified of the Government's evaluation of the information received.

Responses should be identified with NIH-NINDS RFI Synopsis No. 91-001, and are due 30 days after the publication date of this synopsis. Three (3) copies of your response must be delivered/mailed to:

Mr. Kirkland L. Davis
Contracting Officer
National Institute of Neurological Disorders and Stroke
NIH
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892

FACILITIES CONSTRUCTION PROJECTS TO SUPPORT CENTERS FOR SUBSTANCE ABUSE RESEARCH

RFA AVAILABLE: DA-91-06

P.T. 03; K.W. 0404003, 0404009, 0785035

National Institute on Drug Abuse

Letter of Intent Receipt Date: May 15, 1991
Application Receipt Date: June 24, 1991

Purpose: The Fiscal Year 1991 HHS/Labor appropriation bill (PL 101-517) authorized the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to award competitive grants for the construction and renovation of research facilities. This authorization was based on Congress' belief that there is a need for substance abuse research centers that combine substance abuse treatment programs in the same physical location with inpatient and outpatient clinical research programs and related basic science laboratories.

Support may be requested for the costs of constructing or renovating non-Federal facilities to meet the needs of an integrated research facility, to include clinical and basic research activities on drug and/or alcohol abuse and associated substance abuse treatment activities.

The overall objective of this Request for Applications (RFA) is the creation of facilities that will provide an enhanced environment for the development of basic and clinical research findings on substance abuse and for the rapid transfer of research findings to the clinical care of patients suffering from substance abuse. In addition, the Centers will facilitate improved diagnostic capabilities by treatment providers, physicians, investigators, clinicians and rotating interns, as well as stimulate interest/commitment in substance abuse research.

Award Mechanism: The award mechanism will be the construction grant award (C06).

Eligibility: Any domestic, non-Federal, profit or nonprofit institution, or public organization, or association is eligible to apply. However, to assure that the completed facility will be used in accord with the objectives and scope of this RFA, applicants must be conducting basic and/or clinical research on substance abuse and be engaged in the treatment of substance abuse. Applicants may include universities, colleges, hospitals, public agencies, research institutions, and similar organizations, profit or nonprofit. ADAMHA staff will verify application and award eligibility. Applications judged to be ineligible will be returned to the applicant.

Funding: This one-time solicitation, based on Fiscal Year 1991 appropriations, will make available approximately $4,900,000 to cover allowable costs of approximately 2 construction/renovation projects. Allowable costs under Federal regulations may be less than total construction costs to the institution. ADAMHA encourages but does not require the applicant to arrange additional funding from non-Federal sources for at least 25 percent of the total costs. In any case, prior to the grant award, the applicant must provide an assurance that sufficient funds have been secured from non-federal sources to meet any projected costs in excess of the award amount. All awards under this RFA will be one-time awards that will cover the federal participation for the entire construction/renovation project. No continuation costs and no indirect costs will be awarded.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDIES. For projects involving clinical research, ADAMHA requires applicants to give special attention to the inclusion of women and minorities in study groups. If women and minorities are not included in the populations for clinical studies, a special justification for this exclusion must be provided. Applications without this justification will not be accepted for review.

Letter of Intent: Prospective applicants are asked to submit by May 15, 1991, a short letter of intent to the individual noted below. The RFA describes procedures for submitting this letter.

Application Process: Applicants must use Standard Form 424, "Application for Federal Assistance." For additional information, a copy of the RFA, the Standard Form 424 application, and additional special instructions and guidelines, please contact:

John J. Boren, Ph.D.
Chief, Clinical and Behavioral Pharmacology Branch
Division of Clinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-46
Rockville, MD 20857
Telephone: (301) 443-1263

For fiscal and administrative matters, contact:

Ms. Shirley McKinney
Grants Management Officer
National Institute of Drug Abuse
5600 Fishers Lane, Room 8A-54
Rockville, MD 20879
Telephone: (301) 443-6021

PRE-APPLICATION INSTRUCTIONS: Intergovernmental Review-Executive Order 12372 (rev. 3/1/91)

The intergovernmental review requirements of Executive Order 12372, as implemented through DHHS regulations at 45 CFR Part 100, are applicable to this program. E.O. 12372 sets up a system for State and local government review of proposed Federal assistance applications. Applicants (other than Federally recognized Indian tribal governments) should contact the State Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and to receive any necessary instructions on the State process. A current listing of SPOCs is included in the application kit.

GENE THERAPY STRATEGIES FOR TREATMENT OF COOLEY'S ANEMIA

RFA AVAILABLE: HL-91-04-B

P.T. 34; K.W. 0745032, 0715032

National Heart, Lung, and Blood Institute

Application Receipt Date: July 15, 1991

The Cellular Hematology Branch of the Division of Blood Diseases and Resources, National Heart, Lung, and Blood Institute, announces the availability of a Request for Applications (RFA) on the above subject. Awards will be made to foreign institutions only for research of very unusual merit, need, and promise.

This special program will support research on the development of techniques and strategies for the high-efficiency transfer and long-term expression of normal human beta-globin genes into hematopoietic stem cells in culture and in animals as a first step in the development of a protocol for treating patients with Cooley's anemia.

The support mechanism for this FIVE-year program will be the traditional individual research grant (R01). Although approximately $1,000,000 (for direct plus indirect costs) for this program is included in the financial plans for fiscal year 1992, award of grants pursuant to this Request for Applications (RFA) is contingent upon receipt of funds for this purpose. The specific number of awards to be funded depends on the merit and scope of the applications received and the availability of funds. It is anticipated that approximately five awards will be made.

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

For projects involving clinical research, NIH requires applicants to give special attention to the inclusion of women and minorities in study populations. If women or minorities are not included in the study populations for clinical studies, a specific justification for this exclusion must be

provided. Applications without such documentation will not be accepted for review.

Requests for copies of the RFA may be addressed to:

Helena O. Mishoe, Ph.D.
Health Scientist Administrator
Cellular Hematology Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 5A12
Bethesda, MD 20892
Telephone: (301) 496-5911
FAX: (301) 496-9940

For fiscal and administrative matters, contact:

Ms. Jane Davis
Grants Management
National Heart, Lung, and Blood Institute
Westwood Building, Room 4A15
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7257

ONGOING PROGRAM ANNOUNCEMENTS

TRANSGENIC, CHIMERIC, AND IN VITRO MODELS OF KIDNEY DISEASES

PA: PA-91-35

P.T. 34; K.W. 0755020, 0785095, 0785220, 1002004, 1002002, 0780015

National Institute of Diabetes and Digestive and Kidney Diseases

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

The Division of Kidney, Urologic and Hematologic Diseases (DKUHD) of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) announces a continuing interest in receiving research project applications on the above subject.

BACKGROUND

The need for this initiative was recognized, in part, as a result of a 40th Anniversary Symposium held at NIH in March 1990, organized and sponsored by the DKUHD, titled "Gene Regulation and Cellular Signaling in the Kidney and Urothelium." There have been marked successes in identifying genetic defects involved in diseases of other organs and systems, such as the blood. The power of molecular and cellular techniques in determining the structure of genes and in obtaining information about their regulation has been amply demonstrated in these other systems. As summarized in the symposium, recent investigations of the kidney and urothelial system, particularly with growth factors and their signal transduction systems and with transporter proteins and their genes, indicate that the diseases of the kidney, such as polycystic kidney disease and Alport Syndrome, also can be attacked productively through molecular and cellular approaches.

There is a need for expansion of model systems for use in studying kidney and urological diseases to complement the rapidly expanding arsenal of molecular and cellular techniques. Some valuable approaches that have been identified for modeling other human diseases are beginning to be applied to kidney problems, e.g., transgenic mice have been made that carry various growth factor genes, chimeric mouse kidneys derived from two species have been constructed in vivo at embryonic stages, and in vitro culture techniques are being used that involve co-culture of two or more kidney-derived cell lines. Development of additional transgenic animals that mimic human kidney disorders would be valuable, as would other in vivo and in vitro approaches along the lines briefly summarized here.

The kidney programs of this division have a long and well-documented history of support for investigations into the physiology and cell biology of the kidney (e.g., transport systems) and kidney morphogenesis and growth, all of which support this natural progression into the molecular arena and the need for complementary model systems as described above.

RESEARCH GOALS AND SCOPE

The purpose of this initiative is to stimulate research into the molecular and cellular basis of kidney diseases, with an emphasis on approaches using transgenic animals, chimeric kidneys, and in vitro models. To that end, the following are some of the objectives of this solicitation that are being encouraged:

- Development of transgenic mouse lines carrying various growth factor genes. Transgenic mice carrying numbers of copies of the human growth hormone gene have been created and examined with respect to kidney size and growth parameters. Development of transgenics expressing genes for other growth factors that affect kidney development and regeneration is encouraged.

- Development of chimeric kidneys in vivo, beginning at the embryonic stages as has been done between different strains of mice, might be extended to other rodent species that serve as models for diseases such as polycystic kidney disease (PKD). The role of different cell types in normal development and in the disease process can be explored by using cell types with different genetic markers from different strains or species.

- Development of new kidney-derived cell lines and co-culture of cell lines to further define cellular interactions involved in disease processes and in kidney morphogenesis and regeneration.

- Development of renal epithelial cell lines stably transfected with inducible genes involved in (a) signal transduction, (b) growth and development, and (c) ion channel regulation.

- Development of in vitro models to facilitate studies of kidney cell biology and/or interactions between the kidney and the immune system. Examples are models for studying (a) polar targeting of membrane proteins, (b) vesicular trafficking in physiological and pathophysiological processes, and/or (c) kidney antigen processing and trafficking in cells of the immune system, i.e., in lymphocytes and macrophages.

The above are examples only and should not be viewed as all inclusive.

MECHANISMS OF SUPPORT

Support for this program will be through the grant-in-aid and will be governed by the current policies of grant programs of the National Institutes of Health. New applications may be submitted for the traditional, investigator-initiated research project grant (R01) and First Independent Research Support and Transition (FIRST) Awards (R29). Under these mechanisms, the applicants will plan, direct, and conduct the research programs. The project periods during which the research will be conducted should adequately reflect the time required to accomplish the stated goals and be consistent with the policy for grant support. Support will be provided for up to 5 years (renewable for subsequent periods) subject to the availability of funds and progress achieved.

Research grant applications may be submitted by both nonprofit and profit-making organizations and institutions, state and local governments and their agencies, and eligible agencies of the Federal government.

APPLICATION AND REVIEW PROCEDURES

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications in response to this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRGs, consisting primarily of non-federal scientific and technical experts, will provide the peer review for scientific merit of the proposed research, potential significance of the research findings, adequacy of methodology, availability of necessary facilities, and the qualifications of the research team. A secondary review for policy and program relevance to the research needs and mission of the assigned Institute will be provided by its Advisory Council.

Applications must be submitted using form PHS 398 (rev. 10/88), "Application for Public Health Service Grant," available in the business or grants office of most academic or research institutions and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Westwood Building, Room 449, Bethesda, MD 20892. In order to

ensure proper identification of the application, line 2 of the application form must state "Kidney Diseases Program Announcement, PA-91-35" and check the "YES" box.

The first receipt date for applications will be June 1, 1991, that will receive IRG review in October-November 1991 and Advisory Council review in January-February 1992. The earliest requested start date should be April 1, 1992. Thereafter, the regular NIH receipt dates for grant applications will pertain: October 1, February 1, and June 1 of each year.

The original and six copies of the application are to be sent to:

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

Applicants are encouraged to contact Dr. Scherbenske at the address below prior to submitting applications:

M. James Scherbenske, Ph.D.
Renal Physiology/Cell Biology Program Director
DKUHD/NIDDK
Westwood Building, Room 621
Bethesda, MD 20892
Telephone: (301) 496-7458
FAX: (301) 496-9721

For fiscal and administrative matters, contact:

Linda Stecklein
Grants Management Specialist
National Institute of Diabetes and Digestive and Kidney Diseases
Westwood Building, Room 639
Bethesda, MD 20892
Telephone: (301) 496-7467

This program is described in the Catalog of Federal Domestic Assistance No. 93.849, Kidney, Urologic, and Hematologic Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

SMALL GRANT PROGRAM

PA: PA-91-36

P.T. 34; K.W. 0715148, 0785055, 0755030, 0745027, 0745010, 0715020, 0710030

National Institute of Dental Research

Application Receipt Dates: December 3, April 3, August 3

PURPOSE

The Small Grant Program of the National Institute of Dental Research (NIDR) provides awards of up to $50,000 each in direct costs over a two-year period to support pilot projects conducted by new and minority investigators, and other scientists, who would benefit from assistance to position themselves to compete successfully for research project grant support. The grants also may be used to support high-risk venture research and other small projects that do not lend themselves to support by the research project grant mechanism.

OBJECTIVES AND ELIGIBILITY

The NIDR supports research on the causes, epidemiology, prevention, diagnoses, and treatment of dental caries, periodontal and soft tissue diseases, craniofacial anomalies, and orofacial pain. This includes normal and abnormal craniofacial development; the structure and function of the teeth, jaws, oral mucosa, bone, connective tissue, salivary glands, and other organs and tissues of the craniofacial complex; trigeminal neurobiology; the relationship of behavioral, social, economic, and cultural factors to oral diseases and conditions; dental biomaterials; and the role of fluoride and nutrition in oral health and disease. The NIDR emphasizes the need for research on older

Americans, minority groups, and individuals with medical and handicapping conditions or who are otherwise at high risk for oral health problems.

The primary objective of the NIDR Small Grant Program is to provide career development opportunities for new and minority investigators that will enable them to compete successfully for research support as independent investigators. This support may be research project grants (R01), FIRST awards (R29), or grants from other governmental agencies, non-governmental foundations or other organizations in the private sector.

Small Grants will permit recipients to obtain preliminary data from which hypotheses can be developed, to test the feasibility of an approach or experimental design, to gain experience with new or unfamiliar methods, to initiate collaborative studies, and to demonstrate research competence. These are important for submitting competitive research project grant applications, especially for first time applicants.

Because of the broadening scope of oral health research, this award may be appropriate for experienced investigators planning to explore new areas of research and for investigators working on topics not included in traditional dental research.

Other objectives of the Small Grant Program are to encourage venture research with high risk and possibly high pay-off; support development of new techniques; support small clinical projects; and address hypotheses by analysis of existing data.

The simplified application procedures, the reviewers' awareness of the special objectives of this grant mechanism and the rapid review and funding process work to the advantage of applicants.

SPECIAL TERMS OF THE AWARD

Applicants may request up to $50,000 in direct costs that may be used for up to a 24-month period; however, no more than $35,000 may be awarded for any one year. The grant is not renewable; however, grantees are encouraged to apply for a research project grant or other support to maintain continuity in their studies.

The aims of the proposed project must be distinctly different from those of pending grant applications or funded research projects. The request may not be used to supplement currently supported projects or to provide interim support for projects under review by the Public Health Service.

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study group must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan and summarized in Section 2, E, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, the NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United states racial/ethnic minority populations (i.e., Native Americans, Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive

strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of the research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained in the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to the scientific question(s) addressed and the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

REVIEW AND AWARD PROCEDURES

Applications will be reviewed for scientific merit by the NIDR Special Grants Review Committee. Major factors to be considered in the evaluation of an application include: its significance, originality, feasibility and experimental design; the qualifications of the investigator; the adequacy of the facilities; the appropriateness of the budget; if clinical studies are proposed, the availability and appropriateness of study populations and the utilization of minorities and women as study subjects; and the provisions for the protection of human subjects and for the humane treatment of animals.

The extent to which applications meet the objectives of the Small Grant Program, as outlined above, will be evaluated.

Applications will receive an expedited second level review and be considered for funding on an accelerated schedule.

APPLICATION PROCEDURES

Investigators are urged to communicate with NIDR staff when planning to submit an application. Advice and suggestions by staff may materially assist applicants to ensure that the objectives and format are acceptable.

APPLICATION RECEIPT DATE	REVIEW COMMITTEE MEETING	SECONDARY REVIEW	EARLIEST POSSIBLE BEGIN DATE
December 3	Feb/March	May/June	July 1
April 3	June/July	Oct/Nov	December 1
August 3	Oct/Nov	Jan/Feb	March 1

Applications must be prepared on form PHS 398 (rev. 10/88) and is available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441.

To identify the application as a response to this Program Announcement, check "YES" on Item 2 of page 1 of the application and enter the PA number and the title "Small Grant Program."

The instructions accompanying form PHS 398 must be followed as far as possible but some modifications will be necessary. The entire application may not exceed 25 pages and no appendix may be submitted. Do not include reprints or manuscripts. Applications not conforming with this instruction will be returned to the applicant without review.

On page 1, item 6 - the maximum project period is two years; item 8 - the maximum direct costs is $50,000 and the total costs include direct plus indirect costs.

Page Four - No more than $35,000 may be requested for any one year, with a maximum direct cost of $50,000 for the two-year project period. The budget should be limited to the following categories: personnel, small equipment, supplies, and travel. Requests for other expenditures, for the salary of the Principal Investigator, or equipment over $1,000, will be honored only in unusual circumstances; they should be specifically justified.

The original and four copies of the application must be sent to:

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

At the time of submission two copies of the application must also be sent to:

Scientific Review Branch
National Institute of Dental Research
Westwood Building, Room 519
Bethesda, MD 20892-4500

Requests for additional information must be addressed to:

Director, Extramural Program
National Institute of Dental Research
Westwood Building, Room 503
Bethesda, MD 20892-4500
Telephone: (301) 496-7723

This program is described in the Catalog of Federal Domestic Assistance No. 93.122. 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.

ERRATA

CORRECTION: SUPERFUND HAZARDOUS SUBSTANCES BASIC RESEARCH PROGRAM

RFA: ES-91-02

P.T. 34; K.W. 1007003, 1007009, 1002016, 0760003, 0755020, 0710030

National Institute of Environmental Health Sciences

This Request for Applications was published in the NIH Guide for Grants and Contracts on March 15, 1991, Vol. 20, No. 11, and contained an error in the MECHANISM OF SUPPORT section. The anticipated number of awards was incorrectly stated at 40; the corrected sentence should read: "It is anticipated that approximately 6-13 awards will be made contingent upon the availability of funds."

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

5333 Westbard Avenue
Bethesda, Maryland 20816

*U.S.G.P.O.:1991-281-826:20038