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. 19, No. 31
August 24, 1990

NIH GUIDE - Vol. 19, No. 31, August 24, 1990

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

ERRATUM

POLICY NOTICE

NOTE: The NIH Guide for Grants and Contracts will not be published on August 31. The next issue will be September 7.

NOTICES

NIH REGIONAL CONFERENCE IN GRANTS ADMINISTRATION

P.T. 42; K.W. 1014006

National Institutes of Health

A two-day conference on National Institutes of Health grants administration is planned for October 11-12, 1990 at the University of Washington, Seattle, Washington. The conference is hosted by the University of Washington and is targeted for research administrators at institutions in the Pacific Northwest region of the U.S.

Although the focus of the conference is on grants administration, program topics will also be of interest to researchers. On the first day, the morning session concentrates on the peer review process including trends, application development, and electronic grant application development. In the afternoon, discussions feature special interest topics in extramural research such as initiatives for underrepresented minorities and current issues in training programs.

The second day begins with a session on funding issues including a budget case study. In addition, the Federal Demonstration Project will be discussed as well as specific issues relating to grants administration. Program income and lab safety are two topics to be addressed in the afternoon.

Mr. Geoffrey Grant, Grants Policy Officer in the Office of Extramural Research at NIH, representatives from the Division of Research Grants, and grants management and program staff of several awarding components of NIH are featured speakers.

Conference schedule and fee information will be mailed in late August 1990. Mr. Donald Allen, University of Washington, is chairman of the conference. For more information, contact Mr. Allen or Ms. Ginger Draper at (206) 543-4043.

NOTICES OF AVAILABILITY (RFPs AND RFAs)

CLINICAL CENTERS FOR AN ASSESSMENT OF THE EFFICACY OF MINOCYCLINE IN THE TREATMENT OF RHEUMATOID ARTHRITIS

RFP AVAILABLE: RFP-NIH-NIAMS-90-1

P.T. 34; K.W. 0715010, 0755015, 0740025

National Institute of Arthritis and Musculoskeletal and Skin Diseases

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is seeking organizations to serve as the clinical centers for a multicenter, randomized, double-blind, placebo-controlled clinical trial that will assess the efficacy of minocycline hydrochloride in the treatment of rheumatoid arthritis. The clinical centers shall participate with a coordinating center and the NIAMS in all phases of the clinical trial. NIAMS plans to fund one to three centers from this solicitation.

Request for Proposal (RFP) No. NIH-NIAMS-90-1 will be issued on or about August 21, 1990. Proposals will be due on November 20, 1990. To receive a copy of this RFP, please supply this office with two self-addressed mailing labels, and cite the RFP number referenced above. Requests for the RFP must be in writing and addressed to:

Shirley A. Shores
Contracting Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 602
Bethesda, MD 20892

This advertisement does not commit the Government to make an award.

DETAILED DRUG EVALUATION OF ANTI-AIDS AGENTS

RFP AVAILABLE: NCI-CM-17525-27

P.T. 34; K.W. 0715008, 0740018, 0740020

National Cancer Institute

The Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI), is seeking contractors to conduct a number of specialized in vitro and in vivo studies on compounds that are known to inhibit the growth and/or cytopathic effects of human immunodeficiency virus (HIV) and other similar retroviruses. Studies will be conducted to assess the antiviral efficacy of potential anti-HIV agents newly identified by the DTP anti-HIV in vitro screen. Emphasis will be placed on experiments to determine the influence of dose, exposure time, and route of administration on the antiviral activity of new agents in small animal retroviral model(s), and to compare the in vivo effects with the in vitro effects obtained with the same virus. Additional studies may include those to evaluate compound tolerance in small animals, compare efficacies of related compounds, and determine the synergistic potential of compounds in combination. Information gathered by the contract will be used to help in the determination of the most appropriate candidate compound(s) for development and to devise and recommend treatment strategies for clinical trial. In order to protect the laboratory environment and safety of personnel, any offeror proposing to conduct studies using HIV (or other retroviruses with similar pathogenic potential in man), must utilize facilities meeting Biosafety Level 3 criteria. Compounds to be studied will be selected and assigned by the Government. As compounds of a commercially confidential nature (discreet) may be evaluated, pharmaceutical and chemical firms will be excluded from the competition. Also, since structural formulae of discreet materials may be provided by the Government on occasion, the organization must be willing to sign a confidentiality of information statement.

The Principal Investigator (PI) should have: an M.D., D.V.M., or Ph.D. in one of the relevant biological sciences (or equivalent experience). He/She should have managerial experience and experience either in managing an in vivo screening program utilizing small animals or in evaluating the efficacy, toxicity, or mechanism of antiviral agents. The PI should devote approximately 25 percent of his/her time to the project. The NCI expects to award one incrementally funded contract for three (3) years. Each increment will be for one year. The contract will be written on a "level of effort" basis specifying that the contractor is to furnish approximately 31,500 direct labor hours over three years (10,500 labor hours per year).

RFP No. NCI-CM-17525-27 will be available on or about September 13, 1990. Responses will be due November 2, 1990. Copies of the RFP may be obtained by sending a written request to:

Mr. Johnny Jordan
Contract Specialist
Treatment Contracts Section
Research Contracts Branch, OAM
National Cancer Institute
Bethesda, MD 20892

This project is a recompetition of the work being done under contract number N01-CM-87274 Southern Research Institute, Alabama. No collect calls will be accepted.

INVESTIGATIONAL NEW DRUG TOXICOLOGY FOR DRUGS TO TREAT AIDS AND OPPORTUNISTIC INFECTION ASSOCIATED WITH AIDS

RFP AVAILABLE: NIH-NIAID-DAIDS-91-11

P.T. 34; K.W. 0715008, 0740020, 1007009, 0715125

National Institute of Allergy and Infectious Diseases

The Developmental Therapeutics Branch (DTB) of the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), NIH, is seeking contractors with expertise in providing for preclinical toxicology studies in rodents and large-animal models (dogs). The resources to be obtained will complement the National Cooperative Drug Discovery Group effort, contract screening programs for opportunistic infections (OI) within NIAID, and other drug development resources already in place within the Division of AIDS and will complete the basic drug development capability needed by the Institute.

These resources will facilitate the development of promising OI therapies and encourage the pharmaceutical sector to assume the sponsorship of these agents as rapidly as possible. The studies MUST be conducted under Good Laboratory Practice (GLP) conditions as mandated by the Food and Drug Administration (FDA) and will include: range finding studies; single and multiple dose toxicology studies; pharmacokinetics in both rodents and large animals; and immunotoxicity studies in rodents. Offerors must have GLP certification from the FDA at the time of proposal. Sample protocols previously approved by FDA and used for this kind of testing (and indicative of the kind of protocol that may be required), will be provided with the RFP.

This announcement is a new solicitation. The proposed project would be a completion-type, cost-reimbursable contract (one award expected) for a period of five years, to begin approximately April 15, 1991. Copies of RFP-NIH-NIAID-DAIDS-91-11 will be available on or about August 28, 1990, with offers due approximately October 16, 1990.

To receive a copy of the RFP, please supply this office with a written request and two self-addressed mailing labels:

Mr. Bruce E. Anderson, Contract Specialist
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Contract Management Branch
AIDS Preclinical Contracts Section
6003 Executive Blvd., Rm 222P
Bethesda, MD 20892
Telephone: (301) 496-8371

All responsible sources may submit a proposal which will be considered.

This advertisement does not commit the Government to make an award.

RESYNTHESIS OF COMPOUNDS FOR SCREENING

RFPs AVAILABLE: NCI-CM-17528-19 and NCI-CM-17517-19

P.T. 34; K.W. 0740020, 1003006, 1003012

National Cancer Institute

The Drug Synthesis and Chemistry Branch of the Developmental Therapeutics Program, Division of Cancer Treatment, National Cancer Institute (NCI), is seeking contractors with established expertise in the field of synthesis of organic and inorganic compounds to prepare those compounds deemed of interest to the program for evaluation as antitumor and AIDS antiviral agents. Compounds chosen for synthesis will include: known compounds chosen from literature on the basis of biological activity or structural interest; samples required for follow-up testing and which are no longer available from the original source; and small series of compounds, which are closely related structurally to an active lead. Compounds assigned for synthesis will include: carbocycles; heterocycles typically containing nitrogen, oxygen, and sulfur; carbohydrates; nucleosides; and metal coordination complexes. As many as 200 compounds may be assigned over the life of this project. Amounts of compounds to be synthesized will vary widely but will usually be in the range from 100 mg to 5 grams.

The Contractor's Principal Investigator should be trained in synthetic organic chemistry at the Ph.D. level and have experience in the design and efficient synthesis of complex molecules which possess multiple chiral centers.

The NCI signs legally binding agreements with some suppliers (often pharmaceutical or chemical companies) that state that all information on compounds donated by those suppliers will be held confidential. The successful offeror may be assigned a confidential compound as a synthesis or modification target. A chemical or pharmaceutical company could gain valuable data on confidential new lead compounds. The NCI believes that, in order to honor the confidentiality agreement with suppliers and in order to avoid any chance of transmitting privileged data to a competitor, pharmaceutical and chemical companies are excluded from this procurement. For the purpose of the solicitation, a pharmaceutical/chemical company is defined as an organization which manufactures and/or sells drugs and/or chemicals.

Two related RFP's for the "Resynthesis of Compounds for Screening" are currently available. RFP No. NCI-CM-17528-19 is an open competition and RFP No. NCI-CM-17517-19 is a 100 percent Small Business Set-Aside. Offerors who qualify as a small business are encouraged to submit proposals under both

RFP's, however, not more than one award of the total available two to three awards (under both RFPs) will be made to any single offering organization.

RFP Nos. NCI-CM-17528-19 and NCI-CM-17517-19 will be issued upon written request to Zetherine Gore, Contract Specialist, on or about August 20, 1990. Proposals will be due approximately seven weeks thereafter. The contract period is to be three years, beginning approximately September 1991. The incumbent Contractors are New Mexico State University, Las Cruces, New Mexico; Southern Research Institute, Birmingham Alabama; and Starks Associates, Inc., Buffalo, New York.

Copies of the RFP may be obtained by sending a written request to:

Ms. Zetherine Gore, Contract Specialist
National Institutes of Health
National Cancer Institute
Research Contracts Branch,TCS
Executive Plaza South, Room 603
9000 Rockville Pike
Bethesda, MD 20892

COMPREHENSIVE SICKLE CELL CENTER PROGRAM

RFA AVAILABLE: HL-90-15-B

P.T. 04; K.W. 0715032, 0745020, 0745027, 0745070, 0403004

National Heart, Lung, and Blood Institute

Application Date: September 16, 1991

The Division of Blood Diseases and Resources of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health, announces the availability of a Request for Application (RFA) for the Comprehensive Sickle Cell Center Program. New applications and applications for renewal of existing programs are invited. Copies of the RFA and Instructions for the Preparation of Applications are currently available from NHLBI staff.

The major objective of this program is to provide an environment in which resources, facilities, and manpower can be coordinated to expedite the development and application of new knowledge for improved diagnosis, treatment, and prevention of complications related to sickle cell disease. These Centers bring together research (basic, clinical, clinical application) and demonstrations programs in education, counseling, and diagnosis designed to bridge the gap between scientific inquiry and service and reduce the morbidity and mortality from sickle cell disease.

In proposed studies involving humans, females should be included in the study population, otherwise a clear rationale for their exclusion must be provided in the application.

The requirements and format for application submitted in response to the announcement and copies of the RFA may be obtained from:

Charles A. Wells, Ph.D.
Health Scientist Administrator
Sickle Cell Disease Branch
National Heart, Lung, and Blood Institute
Federal Building, Room 508
Bethesda, MD 20892
Telephone: (301) 496-6931

MOLECULAR BIOLOGICAL TECHNIQUES FOR STUDYING CLASS I AND II HLA ANTIGENS

RFA AVAILABLE: HL-90-14-B

P.T. 34; K.W. 1002008, 0710070, 0745065

National Heart, Lung, and Blood Institute

Application Receipt Date: November 29, 1990

The Division of Blood Diseases and Resources (DBDR), National Heart, Lung, and Blood Institute (NHLBI), invites grant applications for a single competition to support research and development to: (1) apply molecular biological techniques to the determination of HLA class I and class II alleles; (2)

compare these type designations with the currently used serological results; and (3) emphasize especially the application of these procedures to the HLA class I and II typing of minority population groups.

The NHLBI has assumed responsibility for the National Marrow Donor Program (NMDP), which has as a major goal the provision of carefully HLA-matched, unrelated bone marrow donors for patients in need of a transplant, but without related donors. As part of this responsibility, the NHLBI would like to encourage the application of molecularly-based HLA class I and II typing of patients and donors. It is particularly important to define various alleles at the molecular level, comparing these findings with those obtained by serological techniques and determining the importance to bone marrow transplantation of the degree and characteristics of molecular matching. For appropriate projects and under appropriate circumstances, cultured cells from donor-recipient pairs (now greater than 315) in the NMDP repository may be made available to qualified investigators. The outcome of the marrow transplant is known for each of these pairs.

Women and minority individuals should be included in the study population, otherwise a clear rationale for their exclusion must be provided in the application. Minority institutions are encouraged to apply and other institutions should attempt to establish collaborative arrangements with minority institutions.

The requirements and format for applications submitted in response to this announcement, and copies of the RFA, may be obtained from:

Paul R. McCurdy, M.D.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 516
Bethesda, MD 20892
Telephone: (301) 496-8387

Luiz H. Barbosa, D.V.M.
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute
National Institutes of Health
Federal Building, Room 504
Bethesda, MD 20892
Telephone: (301) 496-1537

ANIMAL FACILITY IMPROVEMENTS FOR SMALL RESEARCH PROGRAMS

RFA AVAILABLE: RR-90-03

P.T. 34; K.W. 1002002

National Center for Research Resources

Application Receipt Date: December 3, 1990

BACKGROUND

The National Center for Research Resources (NCRR) is announcing a competitive grant program to assist institutions with small biomedical research programs using animals to upgrade and develop their animal facilities. The NCRR anticipates that $1.5 million may be available to support approximately 15 animal facility improvement grants in Fiscal Year 1991.

RESEARCH GOALS AND SCOPE

Institutional animal resource improvement grants are awarded to assist biomedical research and educational institutions in upgrading their animal facilities and developing a centralized animal care program. A major objective is to enable institutions to comply with the USDA Animal Welfare Act and DHHS policies on the care and use of animals. These awards are limited to Alterations and Renovations (A&R) to improve laboratory animal facilities, and related major resource equipment, such as animal cages and cage washers. It is not the purpose of the improvement grant to provide general operating costs for the resource.

To gain approval and support, both the need for resource improvement as well as a sound plan to meet the requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals must be presented and described

in the context of the biomedical research and research training program of the institution.

ELIGIBILITY AND REVIEW

Any domestic public, or private institution, organization or association receiving less than $500,000 (direct costs) in the institution's current fiscal year, for one or more research projects supported by agencies of the Public Health Service and involving the use of animals, is eligible to apply. Institutions are expected to develop a single proposal for campus-wide service.

Applications will be received by the Division of Research Grants. Applicants must use Form PHS 398 (Revised 10/88), "Application for Public Health Service Grant." There will be a single receipt date of December 3, 1990. Applications received after this date will be returned. The Request for Applications (RFA) label available in the Application Form PHS 398 (Revised 10/88) must be affixed to the bottom of the face page. All applications submitted in response to this RFA will be reviewed by Special Review Committees managed by NCRR for scientific merit, and the National Advisory Research Resources Council for program considerations. Earliest possible funding will be July 1991.

MECHANISM OF SUPPORT

Awards will be made as competitive resource grants for a project period of one year. It is expected that approximately 15 awards will be made in Fiscal Year 1991. The number of grants and the specific amount of the awards will depend on the merit and scope of the applications received, as well as the availability of funds. All policies and requirements which govern the grant programs of the PHS apply.

TERMS OF AWARD

Institutions may request major equipment items for their animal resources as well as funds for A&R. Support for new construction is not authorized. The award is limited to $100,000 for A&R and $150,000 for equipment. Matching funds are not required.

INQUIRIES

A copy of the complete RFA, which describes the research goals and scope, terms and conditions, review procedures and criteria, and method of applying, may be obtained by contacting the Animal Resources Program at the following address:

Director
Laboratory Animal Sciences Program
Animal Resources Program
National Center for Research Resources
5333 Westbard Avenue, Room 857
Bethesda, MD 20892
Telephone: (301) 496-5175

This program is described in the Catalog of Federal Domestic Assistance No. 13.306, Laboratory Animal Sciences Primate 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 of Executive Order 12372 or Health Systems Agency review.

RECOGNITION AND MANAGEMENT OF PERILYMPHATIC FISTULA

RFA AVAILABLE: DC-90-02

P.T. 34; K.W. 0715050, 0745070

National Institute on Deafness and Other Communication Disorders

Letter of Intent Receipt Date: October 8, 1990
Application Receipt Date: November 16, 1990

The National Institute on Deafness and Other Communication Disorders (NIDCD) invites applications for assistance awards to support two-phase studies leading first to the development and validation of a marker to be used for the

intraoperative diagnosis of perilymphatic fistula (PLF), and subsequently, to studies of the clinical diagnosis and treatment efficacy of PLF.

Perilymphatic fistulae are abnormal communications between the fluid surrounding the membranous labyrinth of the inner ear and the normally air-filled middle ear space, causing a constellation of symptoms including sudden or progressive hearing loss and dizziness or vertigo. The diagnosis and management of PLF has become one of the most controversial issues in clinical otolaryngology. At the present time there is no generally accepted radiologic, laboratory, or electrophysiologic test that provides objective, unequivocal evidence of the defect; there is no pathologic specimen that can be subjected to laboratory analysis; and photographic documentation techniques have been inadequate. Currently, surgical exploration of the middle ear is the only means by which the presence of PLF can be verified, but the indications for surgical exploration are not uniform and, once the middle ear is exposed, perilymph cannot be distinguished visually from other adventitious fluids. As a result, estimates of the incidence and prevalence of PLF vary widely, although it is possible that it is a significant and often unrecognized factor in the sudden onset or progression of hearing loss and of idiopathic, nonspecific dizziness in adults and children.

The goals of this Request for Applications (RFA) are threefold, encompassed within a two-phase program. Phase 1 is intended to assist groups of investigators in their attempts to develop and validate a marker substance or procedure to identify and differentiate perilymph in the middle ear. The goals for Phase 1 must be met before proceeding to Phase 2 studies. Phase 2 has two goals: first, to conduct clinical studies on objective diagnostic tests for perilymphatic fistula, leading to the establishment of clinical criteria for middle ear exploration; and second, to evaluate the relative efficacy of surgical and non-surgical treatments in alleviating symptoms. All applicant groups are expected to participate fully in both phases of the project.

Awards will be made as cooperative agreements which create an assistance relationship with substantial involvement of NIDCD staff during the performance of the project, as outlined in this RFA. This mechanism is used when the NIDCD wishes to stimulate investigator interest and proposes to advise or assist in an important and opportune area of research. The NIDCD anticipates making 3-5 awards for project periods of five years. Although this project is provided for in the financial plans of the NIDCD, the award of cooperative agreements pursuant to the RFA is contingent on the availability of funds appropriated in fiscal year 1991.

Inclusion of women and minorities as investigators and/or members of study populations is encouraged. If they are excluded, reasons for this exclusion must be specified in the application.

This RFA is a one-time solicitation with a specified deadline of November 16, 1990, for receipt of applications.

The RFA label available in the 10/88 revision of Application Form PHS 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review. In addition, the RFA number and title should be typed on line 2 of the face page of the application form.

A copy of the complete RFA describing eligibility criteria, the research goals and scope, the cooperative agreement mechanism, the review criteria, and the method of applying should be obtained before beginning the application process. Copies of the complete RFA can be obtained from:

Maureen Hannley, Ph.D.
Program Administrator
Division of Communicative Sciences and Disorders
National Institute on Deafness and Other Communication Disorders
Federal Building, Room 1C-04
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-5061

Inquiries concerning this RFA are encouraged and should be directed to Dr. Hannley at the address or telephone number listed above.

Awards will be made under the authority of the Public Health Service Act, Section 301 (42 USC241), and administered under PHS grant policies and Federal Regulation 42 CFR Part 52, and 45 CFR Part 74. This program is not subject to review by a Health Systems Agency or to the intergovernmental review requirements of Executive Order 12372.

ALCOHOL-RELATED TRAUMA: RESEARCH ON REFERRAL AND TREATMENT

PA: PA-90-26

P.T. 34; K.W. 0404003, 0715210, 0745070

National Institute on Alcohol Abuse and Alcoholism

PURPOSE

Given the severity and extent of alcohol-related trauma and the current level of understanding of related state-of-practice issues, additional research is sought toward developing effective mechanisms for detection, appropriate referral, and treatment of patients with trauma related to alcohol consumption.

RESEARCH OBJECTIVES

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) invites studies that examine the trauma setting as a promising but under-utilized arena for facilitating entry into alcoholism treatment by alcohol-abusing and alcoholic trauma victims.

In this regard, NIAAA encourages systematic investigations of: (1) methods for utilizing screening procedures, blood alcohol, urine, and other body fluid tests and the trauma-related medical history, as well as other laboratory procedures in the trauma setting for detecting alcoholism, i.e., what methods (alone and in combination) are found to be the most effective in detecting alcoholism in the emergency care setting; (2) early management of patients with alcohol-related trauma in terms of withdrawal considerations and their effect on the likelihood of entering alcoholism treatment; (3) various factors that may influence emergency staff referral behavior; and (4) current techniques for exploiting the trauma event as an opportunity for initiating treatment for suspected alcohol abuse and dependence in the injured patient.

INCLUSION OF MINORITIES IN STUDY POPULATIONS

Applicants are encouraged to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in a given study, a clear rationale for their exclusion should be provided.

INCLUSION OF WOMEN IN STUDY POPULATIONS

Applicants are encouraged to consider the inclusion of women in the study populations for all clinical research efforts. Exceptions would be studies of diseases that exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If women are not to be included, a clear rationale should be provided for their exclusion. In order to provide more precise information to the treatment community, it is recommended that publications resulting from research in which the study population was limited to one sex for any reason other than the disease or condition studied exclusively affects that sex, should state, in the abstract summary, the gender of the population studied, e.g., "male patients," "male volunteers," "female patients," or "female volunteers."

MECHANISMS OF SUPPORT

Research grant support may be requested for a period of up to 5 years (renewable for subsequent periods). Annaul awards will be made subject to continued availablity of funds and progress achieved. Grant funds may be used for expenses clearly related and necessary to carry out research projects, including both direct costs, which can be specifically identified with the project, and allowable indirect costs of the institution. Funds may not be used to establish; add a component to; or operate a treatment, rehabilitation, or prevention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for those particular costs and for that period of time required by the research. These costs must be justified in terms of research objectives, methods, and designs which promise to yield important generalizable knowledge and/or to make a contribution to theoretical concepts.

ELIGIBILITY

Applications for alcohol research grants may be made by public or private non-profit or profit-making organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minorities are encouraged to apply.

APPLICATION PROCEDURES

Applicants should use the standard research grant application form PHS 398 (rev. 10/88). The title of this announcement, ALCOHOL-RELATED TRAUMA: RESEARCH ON REFERRAL AND TREATMENT, PA-90-26, should be typed in item number 2 on the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions (PHS 398) may be obtained from institutional business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. Application kits may also be obtained from the:

National Clearinghouse for Alcohol and Drug Information
P.O. Box 2345
Rockville, MD 20852
Telephone: (301) 468-2600

The signed original and six permanent, legible copies of the complete application should be submitted to:

Division of Research Grants, NIH
Westwood Building, Room 240
Bethesda, MD 20892**

REVIEW PROCESS

The Division of Research Grants, NIH, serves as the central point for receipt of applications under this announcement. Applications received will be assigned to an Initial Review Group (IRG) in accordance with established Public Health Service Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the application for scientific and technical merit. Notification of the review recommendations will be sent to the Principal Investigator after the initial review. Applications will receive a second-level review by the relevant National Advisory Council, whose review may be based on policy as well as scientific considerations. Only applications recommended for approval by Council may be considered for funding.

REVIEW CRITERIA

Criteria to be used in the merit review of alcohol research grant applications will include the following:

1. The overall scientific and technical merit of the proposal.

2. The adequacy of the methodology to carry out the proposed research including the adequacy of the design for collection and analysis of data.

3. The adequacy of qualifications (including level of education and training) and the research experience of the Principal Investigator and key personnel.

4. Availability of adequate facilities, general environment for the conduct of the proposed research, other resources, and collaborative arrangements necessary for the research.

5. Appropriateness of budget estimates for the proposed research activities.

6. Where applicable, adequacy of procedures to protect or minimize effects on human subjects.

AWARD CRITERIA AND AVAILABILITY OF FUNDS

Applications recommended for approval will be considered for funding on the basis of overall scientific and technical merit of the proposal as determined by peer review, program needs and balance, and availability of funds.

No funds have been set aside specifically for this purpose. Applications received under this announcement will compete for general FY 1991 funds. The amount of funding available will depend on appropriated funds and program priorities at the time of award.

INQUIRIES

Direct inquiries may be addressed to the following NIAAA program staff at 5600 Fishers Lane, Rockville, Maryland 20857:

Fulton Caldwell, Ph.D., C.A.C.
Treatment Research Branch
Division of Clinical and Prevention Research
Room 16C-03
Telephone: (301) 443-0796

John Allen, Ph.D., M.P.A.
Chief, Treatment Research Branch
Division of Clinical and Prevention Research
Room 16C-03
Telephone: (301) 443-0796

This program is described in the Catalog of Federal Domestic Assistance, No. 13.273. Grants will be awarded under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb) and administered in accordance with the PHS Grants Policy Statement and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74.

Applications submitted in response to this announcement are not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through Department of Health and Human Service (HHS) regulations at 45 CFR Part 100 and are not subject to Health Systems Agency review.

APPLIED RESEARCH INTO THE PROCESS OF ALCOHOLISM TREATMENT

PA: PA-90-27

P.T. 34; K.W. 0404003, 0745070

National Institute on Alcohol Abuse and Alcoholism

PURPOSE

In the field of alcoholism most of the interest in treatment has focused on patient outcomes, especially drinking status. Near- exclusive emphasis on assessing outcome at the expense of assessing process may however, impede our understanding of the nature of effective alcoholism treatment. Furthermore, studying the process of treatment in its own right may explain why a particular treatment is or is not effective. While there is some research on the impact of alcoholism program strategies, little has been done on what may be key variables, such as therapist/patient interactions, therapist characteristics, or "extra-treatment" factors in the lives of patients undergoing treatment. Therefore, the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is soliciting applications for grants for applied research designed to investigate the process of alcoholism treatment.

RESEARCH OBJECTIVES

The following are examples of possible areas of study. Applicants should keep in mind that this list is not intended to be exhaustive and that other areas of study that relate to the process of alcoholism treatment are encouraged:

- To improve the degree of treatment participation, information is sought to identify barriers to entering and remaining in treatment.
- To improve treatment planning, under what conditions and at what point in the treatment process should psychological tests or other patient informational inventories be administered?
- Studies are encouraged that examine the role that "milieu" (i.e., the ethos of treatment as experienced by the patient) plays in the treatment of alcoholism.
- What type of alcoholism therapist characteristics are most associated with patient cooperation and treatment completion, as well as what counselor characteristics are associated with the patient learning treatment.

- How do certain elements of the treatment process differentially influence outcomes for racial and ethnic minorities.

- Studies are encouraged which address the issue of patient satisfaction (i.e., the degree to which patients perceive that they are receiving the kind of treatment they expect or deserve to receive).

- Studies are sought that evaluate various methods of assuring and enhancing treatment compliance on the part of individuals undergoing treatment for alcohol abuse and alcoholism.

- Studies are sought that investigate the reasons alcoholic patients completing an inpatient or highly intensive phase of treatment enter or decline to enter the aftercare phase of treatment.

- Because of it's influential status in recovery from alcoholism, and despite the methodological challenges inherent to it's informal membership structure and it's tradition of anonymity, investigators are invited to conduct studies on Alcoholics Anonymous (AA) and other mutual help groups.

INCLUSION OF MINORITIES IN STUDY POPULATIONS

Applicants are encouraged to give added attention (where feasible and appropriate) to the inclusion of minorities in study populations for research into the etiology of diseases, research in behavioral and social sciences, clinical studies of treatment and treatment outcomes, research on the dynamics of health care and its impact on disease, and appropriate interventions for disease prevention and health promotion. If minorities are not included in a given study, a clear rationale for their exclusion should be provided.

INCLUSION OF WOMEN IN STUDY POPULATIONS

Applicants are encouraged to consider the inclusion of women in the study populations for all clinical research efforts. Exceptions would be studies of diseases that exclusively affect males or where involvement of pregnant women may expose the fetus to undue risks. Gender differences should be noted and evaluated. If women are not to be included, a clear rationale should be provided for their exclusion. In order to provide more precise information to the treatment community, it is recommended that publications resulting from research in which the study population was limited to one sex for any reason other than the disease or condition studied exclusively affects that sex, should state, in the abstract summary, the gender of the population studied, e.g., "male patients," "male volunteers," "female patients," or "female volunteers."

MECHANISMS OF SUPPORT

Research grant support may be requested for a period of up to 5 years (renewable for subsequent periods). Annual awards will be made subject to continued availablity of funds and progress achieved. Grant funds may be used for expenses clearly related and necessary to carry out research projects, including both direct costs, which can be specifically identified with the project, and allowable indirect costs of the institution. Funds may not be used to establish; add a component to; or operate a treatment, rehabilitation, or prevention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for those particular costs and for that period of time required by the research. These costs must be justified in terms of research objectives, methods, and designs which promise to yield important generalizable knowledge and/or to make a contribution to theoretical concepts.

ELIGIBILITY

Applications for alcohol research grants may be made by public or private non-profit or profit-making organizations such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minorities are encouraged to apply.

APPLICATION PROCEDURES

Applicants should use the standard research grant application form PHS 398 (rev. 10/88). The title of this announcement, APPLIED RESEARCH INTO THE PROCESS OF ALCOHOLISM TREATMENT, PA-90-27, should be typed in item number 2 on the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions (PHS 398) may be obtained from institutional business offices or offices of sponsored research of most universities, colleges, medical schools, and at other major research facilities. Application kits may also be obtained from the:

National Clearinghouse for Alcohol and Drug Information
P.O. Box 2345
Rockville, MD 20852
Telephone: (301) 468-2600

The signed original and six permanent, legible copies of the complete application should be submitted to:

Division of Research Grants, NIH
Westwood Building
Room 240
Bethesda, MD 20892**

REVIEW PROCESS

The Division of Research Grants, NIH, serves as the central point for receipt of applications under this announcement. Applications received will be assigned to an Initial Review Group (IRG) in accordance with established Public Health Service Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the application for scientific and technical merit. Notification of the review recommendations will be sent to the Principal Investigator after the initial review. Applications will receive a second-level review by the relevant National Advisory Council, whose review may be based on policy as well as scientific considerations. Only applications recommended for approval by Council may be considered for funding.

REVIEW CRITERIA

Criteria to be used in the merit review of alcohol research grant applications will include the following:

1. The overall scientific and technical merit of the proposal.

2. The adequacy of the methodology to carry out the proposed research including the adequacy of the design for collection and analysis of data.

3. The adequacy of qualifications (including level of education and training) and the research experience of the Principal Investigator and key personnel.

4. Availability of adequate facilities, general environment for the conduct of the proposed research, other resources, and collaborative arrangements necessary for the research.

5. Appropriateness of budget estimates for the proposed research activities.

6. Where applicable, adequacy of procedures to protect or minimize effects on human subjects.

AWARD CRITERIA AND AVAILABILITY OF FUNDS

Applications recommended for approval by the appropriate National Advisory Council will be considered for funding on the basis of overall scientific and technical merit of the proposal as determined by peer review, program needs and balance, and availability of funds.

No funds have been set aside specifically for this purpose. Applications received under this announcement will compete for general FY 1991 funds. The amount of funding available will depend on appropriated funds and program priorities at the time of award.

INQUIRIES

Direct inquiries may be addressed to the following NIAAA program staff at 5600 Fishers Lane, Rockville, Maryland 20857:

Fulton Caldwell, Ph.D., C.A.C.
Treatment Research Branch
Division of Clinical and Prevention Research
Room 16C-03
Telephone: (301) 443-0796

John Allen, Ph.D., M.P.A.
Chief, Treatment Research Branch
Division of Clinical and Prevention Research
Room 16C-03
Telephone: (301) 443-0796

This program is described in the Catalog of Federal Domestic Assistance, No. 13.273. Grants will be awarded under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb) and administered in accordance with the PHS Grants Policy Statement and Federal Regulations at 42 CFR Part 52 and 45 CFR Part 74.

Applications submitted in response to this announcement are not subject to the intergovernmental review requirements of Executive Order 12372, as implemented through Department of Health and Human Service (HHS) regulations at 45 CFR Part 100 and are not subject to Health Systems Agency review.

SMALL GRANTS FOR INNOVATIVE TECHNOLOGY

PA: PA-90-28

P.T. 34; K.W. 0706000, 0790000

National Center for Research Resources

Application Receipt Dates: February 1, October 1

The Biomedical Research Technology (BRT) Program identifies and develops advanced technologies needed in biomedical research. Through grants and contracts, it supports an extremely broad and innovative array of technologies. Areas of emphasis in the Program are biomedical computing, biomedical engineering, and technologies for the study of biomolecular and cellular structure and function. To further its mission, the BRT Program supports a small grant award for pilot studies in relevant biomedical technologies.

DESCRIPTION OF THE AWARD

This is a one-year, non-renewable award for a pilot project in a high technology area in engineering, instrumentation, physics, or computer science related to biomedical research. The project should involve a feasibility study of an innovative or hig- risk idea in a high technology. Innovative is considered to be an unusually imaginative or a drastically different approach to a problem. High risk is having uncertain chances for success because no historical base exists for the proposed technological approach. High technology is defined here as working at the frontier (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 relevant technology.

The purposes of the small grants program are to:

1. Provide an opportunity to test new ideas in a high technology that would lead to an expanded research project or implementation of the technology in a working environment; or

2. Develop significant changes in an existing high technology important to biomedical research; or

3. Translate scientific notions into a basis for a future technology.

The award may not be used to supplement support for an ongoing project. Because of the high-risk, feasibility-testing nature of the proposals, support of salaries for student employees working on a dissertation is discouraged.

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 research area.

APPLICATION AND REVIEW PROCEDURE

Applications should be submitted on Form PHS 398 (Rev. 10/88), available at most institutional business offices or from the Division of Research Grants, NIH. Because the format for preparing the small grant application is different from that used for regular research grants, additional information and instructions must be obtained from the BRT Program office listed below. Applications must adhere to this format to be responsive. Unresponsive applications will be returned to the applicant without review.

The review schedule is:

Receipt Date Annually	NCRR Committee Review	Council Review	Earliest Date for Funding
February 1	April	June	July
October 1	November	February	April

REVIEW CRITERIA

Applications will be evaluated using the following criteria: adequacy of scientific merit; characterization as an innovative or high-risk pilot project in a high technology area in engineering, instrumentation, physics, or computer science related to biomedical research; probability the study will provide a basis for more extended research in the relevant technology; adequacy of proposed experimental methods, equipment, or materials; adequacy of the investigator's background and training; adequacy of the available and requested facilities; and appropriateness of budget justifications.

Investigators should be aware that NIH urges applicants to give added attention, where feasible and appropriate, to the inclusion of minorities and women in study populations. If minorities and/or women are not included in a given study involving human subjects, a clear rationale for their exclusion should be provided.

Those criteria which are emphasized in the review of small grant applications are:

- o adequacy of scientific merit,
- o degree of innovation evident in the proposed approach, and
- o degree of risk or uncertain chance of success because no historical base exists for the proposed technological approach.

FUNDING CRITERIA

Applications will compete in accordance with the purposes of the small grant program. Approximately 10 to 20 awards are made per year, contingent on receipt of meritorious applications and appropriated funds.

TERMS OF THE AWARD

The award will provide a maximum of $35,000 (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.

INSTRUCTIONS FOR APPLICANTS

Additional instructions are needed to prepare a small grant application. These are supplementary to those given with PHS 398 (Rev. 10/88). To receive these instructions, please contact:

Biomedical Research Technology Program
National Center for Research Resources
National Institutes of Health
5333 Westbard Avenue, Room 8A11
Bethesda, MD 20892**
Telephone: (301) 496-5411

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 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

MINORITY CLINICAL ASSOCIATE PHYSICIAN SUPPLEMENTS TO GENERAL CLINICAL RESEARCH CENTER GRANTS

PA: PA-90-29

P.T. 04, FF; K.W. 0785035

National Center for Research Resources

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

INTRODUCTION

The National Center for Research Resources (NCRR) hereby notifies physicians and dentists of a new NCRR career development program that is to be funded as a competing supplement to a currently funded General Clinical Research Center (GCRC). This new program is the Minority Clinical Associate Physician (MCAP) Program.

PURPOSE

The purpose of the MCAP Program is to provide up to three years of support to minority physicians or dentists to promote their development towards becoming independent clinical investigators under the direction of senior clinical scientist sponsors.

BACKGROUND

The 1989 NIH Task Force on Physician Scientist Training expressed concern that inadequate numbers of individuals with M.D.s or the other professional doctorates are entering into research careers and that, overall, M.D.s have low NIH grant application and award rates. The MCAP Program provides the opportunity for physicians and dentists to develop clinical research skills and knowledge by conducting scientifically meritorious research projects under the guidance of qualified sponsors. The impetus for establishing the MCAP Program is the recognition of the urgent need to increase the number of underrepresented minority scientists participating in biomedical research as a means of addressing the national problem of a declining scientific pool. Moreover, underrepresented minorities constitute only about 3% of the faculty at U.S. medical schools; thus, relatively small numbers are exposed to the conduct of clinical research in the traditional setting. The eligibility criteria, eligible costs, and application and review procedures for the MCAP Program are discussed below.

ELIGIBILITY

The MCAP applicant must have earned the M.D. or D.D.S. degree or equivalent and completed a residency. Completion of subspecialty (fellowship) training for two years is preferred but not required. The applicant must be a U.S. citizen or hold a permanent immigration visa and should be a member of an underrepresented minority group. The applicant may not hold independent peer-reviewed grant support, as the principal investigator, prior to or concurrently with funding of the MCAP application. An underrepresented minority group is one that has been determined by the grantee institution to be underrepresented in biomedical or behavioral research. In making awards, NIH will give priority to applicants who are Black, Hispanic, Native American, Pacific Islanders, or other ethnic or racial group members who have been found to be underrepresented in biomedical research nationally.

ELIGIBLE COSTS

MCAP applicants who have completed subspecialty (fellowship) training, can request a maximum salary of $42,500 plus fringe benefits for the first year of the award and salary increments of $1,000 for each of the second and third years of the award. MCAP applicants with no subspecialty training can request a maximum salary of $40,000 plus fringe benefits for the first year of the award and salary increment of $1,000 for each of the second and third years of the award. In each case, at least 80 percent time and effort is required for participation in the program. The salary request must be commensurate with institutional salary policies for individuals with comparable experience. Funds for small scientific equipment, supplies, and domestic travel to scientific meetings may be requested up to a maximum of $5,000 per year (domestic travel portion not to exceed $1,000).

REVIEW PROCEDURE AND CRITERIA

Primary review of applications will be by the NCRR General Clinical Research Centers Committee. It will be based on the scientific merit of the proposal,

the qualifications of the applicant, expertise to be gained by the applicant, suitability of the sponsor, and the likelihood that the applicant will become an independent investigator capable of successfully competing for independent peer-reviewed grant support. Secondary review will be by the National Advisory Research Resources Council. Applicants should note that NIH urges the inclusion of minorities and women in study populations. If minorities and women are not included in a protocol, a clear rationale for their exclusion should be provided.

METHOD OF APPLYING

The initial application for MCAP support must be submitted by the Principal Investigator of a funded GCRC (M01) grant as a competing supplement to that grant, using Form PHS 398 (Rev. 10/88) and supplemental GCRC instructions. Three deadlines exist for filing this application: October 1, February 1, and June 1. Applications filed by those dates have the corresponding earliest beginning dates of July 1, December 1, and April 1. In each review cycle, each GCRC may submit either one Clinical Associate Physician application, one MCAP application, or one of each (for two different individuals).

INQUIRIES

Requests for supplemental instructions, information about currently funded GCRCs, and further information on the MCAP Program, including potential sponsors, should be directed to:

Harriet Gordon, M.D.
Medical Officer
General Clinical Research Centers Program
National Center for Research Resources
Westwood Building, Room 10A03
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-6595

CLINICAL ASSOCIATE PHYSICIAN SUPPLEMENTS TO GENERAL CLINICAL RESEARCH CENTER GRANTS

PA: PA-90-30

P.T. 04; K.W. 0785035

National Center for Research Resources

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

INTRODUCTION

The National Center for Research Resources (NCRR) hereby notifies physicians and dentists of an ongoing NCRR career development program which is funded as a competing supplement to a currently funded General Clinical Research Center (GCRC). This ongoing program is the Clinical Associate Physician (CAP) Program.

PURPOSE

The purpose of the CAP Program is to provide up to three years of support to physicians or dentists to promote their development towards becoming independent clinical investigators, under the direction of senior clinical scientist sponsors.

BACKGROUND

The 1989 NIH Task Force on Physician Scientist Training expressed concern that inadequate numbers of individuals with M.D.s or the other professional doctorates are entering into research careers and that, overall, M.D.s have low NIH grant application and award rates. The CAP Program provides the opportunity for physicians and dentists to develop clinical research skills and knowledge by conducting scientifically meritorious research projects under the guidance of qualified sponsors. The eligibility criteria, eligible costs, and application and review procedures for the CAP Program are discussed below.

ELIGIBILITY

The CAP applicant must have earned the M.D. or D.D.S. degree or equivalent and completed residency and at least two years of subspecialty (fellowship) training. The applicant must be a U.S. citizen or hold a permanent

immigration visa. The applicant may not hold independent peer-reviewed grant support, as the principal investigator, prior to or concurrently with funding of the CAP application.

ELIGIBLE COSTS

The CAP Program requires at least 80 percent of time and effort and allows for a maximum salary of $42,500 plus fringe benefits for the first year of the award; salary increases of $1000 for each of the second and third years of the CAP award can be requested. The salary request must be commensurate with institutional salary policies for individuals with comparable experience. Funds for small scientific equipment, supplies, and domestic travel to scientific meetings may be requested up to a maximum of $5,000 per year (domestic travel portion not to exceed $1,000).

REVIEW PROCEDURE AND CRITERIA

Primary review of applications will be by the NCRR General Clinical Research Centers Committee. It will be based on the scientific merit of the proposal, the qualifications of the applicant, expertise to be gained by the applicant, suitability of the sponsor and the likelihood that the applicant will become an independent investigator capable of successfully competing for independent peer-reviewed grant support. Secondary review will be by the National Advisory Research Resources Council.

METHOD OF APPLYING

The initial application for CAP support must be submitted by the Principal Investigator of a funded GCRC (M01) grant as a competing supplement to that grant, using Form PHS 398 (Rev. 10/88) and supplemental GCRC instructions. Three deadlines exist for filing this application: October 1, February 1, and June 1. Applications filed by those dates have the corresponding earliest beginning dates of July 1, December 1, and April 1. In each review cycle, each GCRC may submit either one CAP application, one MCAP application, or one of each (for two different individuals). Applicants should note that NIH urges the inclusion of minorities and women in study populations. If minorities and women are not included in a protocol, a clear rationale for their exclusion should be provided.

INQUIRIES

Requests for supplemental instructions, information about currently funded GCRCs, and further information on the CAP Program should be directed to:

Bernard Talbot, M.D., Ph.D.
Medical Officer
General Clinical Research Centers Program
National Center for Research Resources
Westwood Building, Room 10A03
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-6595

ERRATUM

NATIONAL RESEARCH SERVICE AWARD-INSTITUTIONAL GRANTS

RFA: HS-90-01

P.T. 44; K.W. 0720005, 0730050

Agency for Health Care Policy and Research

This announcement was published in the NIH Guide for Grants and Contracts on August 17, 1990, Vol. 19, No. 30, and contained an incorrect application receipt date. The correct receipt date is October 15, 1990.

**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

NIH/ADAMHA POLICY CONCERNING INCLUSION OF WOMEN IN STUDY POPULATIONS

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

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

The National Institutes of Health (NIH) and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) recognize that most researchers adequately and appropriately consider gender representation in clinical research design. Nevertheless, the following statement is published as a reiteration and further interpretation of the existing NIH/ADAMHA policy concerning inclusion of women in study populations. Clinical research findings should be of benefit to all persons at risk of the disease, regardless of gender. This policy was previously published in the NIH Guide for Grants and Contracts on October 24, 1986; January 23, 1987; March 27, 1987; January 15, 1988; and June 16, 1989. For the purpose of this policy, clinical research includes human studies of etiology, treatment, diagnosis, prevention, and epidemiology of disease, including but not limited to clinical trials. While this policy statement refers to inclusion of women, applicants are strongly reminded that a similar policy exists regarding the inclusion of minorities (NIH Guide for Grants and Contracts - September 25, 1987; January 15, 1988; and June 16, 1989). Both policies must be considered when preparing clinical research applications/proposals for submission to the NIH/ADAMHA.

Public concern requires that clinical studies include both genders in such a way that results are applicable to the general population; exceptions would be those diseases or conditions that occur only in one gender. Therefore, applications/proposals for NIH/ADAMHA support of clinical research should employ a study design with gender representation appropriate to the known incidence/prevalence of the disease or condition being studied. If inclusion of women is impossible or inappropriate with respect to the purpose of the research, the health of the subjects, or other reasons, or if in the only study population available there is a disproportionate representation of one gender, these reasons for excluding women or men must be well explained and justified by the applicant. Similar justification is required if women will not be included in numbers appropriate to the incidence/prevalence of the disease.

In conducting peer review for scientific and technical merit, members of Initial Review Groups (IRGs)/Technical Evaluation Groups (TEGs) will be instructed to evaluate the proposed gender composition of the study population.

1) If there is an inadequate number of women in a study design AND this affects the potential to answer the scientific question(s) addressed, that will be considered a weakness or deficiency in the study design and should be reflected in the assigned score given to the application/proposal, and in the summary statement of the review.

2) If an applicant proposes that there is justification for conducting a study in men only, or in a study population in which the proportion of women does not reflect the gender prevalence of the disease or condition under study, a strong scientific rationale, an explanation of the need to protect the health of the subjects, or other well-supported justification must be provided. The IRG/TEG will be instructed to evaluate the merit of such justifications. Appropriate justification will not adversely affect the assigned score. The NIH/ADAMHA will not fund such applications/proposals unless the justification provided is compelling.

3) If the gender composition of the study population is not described, BUT the study otherwise has the potential to answer the scientific question(s) posed and translate the findings to all persons at risk of the disease, the omission will be documented by the Executive Secretary of the IRG/TEG in an administrative note, and will not adversely affect the scientific assessment and the assigned score. If there is inadequate information on the study population to allow evaluation of the scientific question(s), the review may be deferred. The NIH/ADAMHA funding components will not fund/award grants or contracts until the applicant provides sufficient information on the study population to assure compliance with the NIH/ADAMHA policy on inclusion of women in study populations.

Since the need to modify sample design could delay award and affect the costs of the study, applicants are strongly advised to address this issue in the initial submission. If costs or study designs are significantly affected by such modification, submission of an amended application/proposal for IRG/TEG review and/or reconsideration by the appropriate National Advisory Council or Board may be necessary.

Whenever there are scientific reasons to anticipate differences between men and women with regard to the hypothesis under investigation, applicants should consider the inclusion of an evaluation of gender differences in the proposed study. However, if men and women are enrolled in numbers that reflect the gender proportion of the disease under study, it is not an automatic requirement for the study design to include statistical power for men and women separately.

It is important to note that regardless of the program relevance of the proposed research, the NIH/ADAMHA funding components will not fund/award grants or contracts that do not comply with this policy.

*U.S.GOVERNMENT PRINTING OFFICE:1990-261-138:20011