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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.

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September 20, 1991

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

NOTICES OF AVAILABILITY (RFPs AND RFAs)

CAENORHABDITIS GENETICS CENTER

RFP AVAILABLE: NIH-RR-91-17

P.T. 34; K.W. 0780000, 1002019

National Center for Research Resources

The National Center for Research Resources, National Institutes of Health, requires the services of a contractor for acquisition, storage, characterization, and distribution of wild-type and mutant nematodes, primarily of the species Caenorhabditis elegans. In addition, the contractor shall provide services of maintaining and distributing the genetic map of C. elegans, relevant publications, and the development and communication of uniform genetic terminology for this species. A five-year, cost-reimbursement type contract is anticipated. The solicitation is scheduled for release on or about September 20, 1991 and proposals will be due on or about November 5, 1991. All responsible sources may submit a proposal that will be considered.

Requests for the Request for Proposal (RFP) must be directed to:

John P. DeCenzo
Research Contracts Branch
Division of Contracts and Grants
Office of the Director
National Institutes of Health
Building 31, Room 1B44
9000 Rockville Pike
Bethesda, MD 20892

STUDIES ON THE FEASIBILITY OF A CENTRAL NERVOUS SYSTEM AUDITORY PROSTHESIS

RFP AVAILABLE: NIH-NIDCD-91-03

P.T. 34; K.W. 0705055, 0715050, 0740030

National Institute on Deafness and Other Communication Disorders

The National Institute of Deafness and Other Communication Disorders (NIDCD), NIH, announces the availability of a Request for Proposals (RFP) for a study of the feasibility of a central nervous system auditory prosthesis based on microstimulation of the cochlear nucleus. The cochlear implant is not a viable option for providing auditory information to patients with severe sensorineural hearing loss due to poor eighth nerve survival. Instead, investigators have implanted electrodes on the surface of the cochlear nucleus in over 20 patients with bilateral acoustic neuromas. In these patients the electrodes were connected to speech processors similar to those used in cochlear implants. Most of the patients found that the cochlear nucleus implants provided essentially the same limited information that single channel cochlear implants provide patients with good auditory nerve survival.

Using speech processors custom designed for cochlear nucleus implants, rather than for cochlear implants, deaf subjects have demonstrated substantial improvement in auditory recognition test scores and usefulness of their devices for speech recognition. However, the benefits are still considerably less than those received by many multichannel cochlear implant users.

The NIDCD has been supporting, under contract, a study of the feasibility of a multichannel auditory prosthesis based on microstimulation of the ventral cochlear nucleus with penetrating microelectrodes. The results to date have indicated that practical surgical approaches exist and that microelectrodes can be placed and maintained in the cochlear nucleus without excessive neural damage. There is preliminary evidence that the cochlear nucleus can tolerate chronic electrical stimulation through these microelectrodes. However, questions still exist about whether or not multiple microelectrodes can be accurately placed into the ventral cochlear nucleus, how closely they can be spaced without producing excessive tissue damage, and the long-term positional stability of an array of such electrodes. These questions must be answered in animals before feasibility studies are expanded to human testing.

This requirement represents a recompetition of work currently being performed under a contract at the Huntington Medical Research Institutes, Contract No. NO1-DC-9-2402. It is expected that the incumbent contractor will recompete.

A single award will be made for a performance period of no more than three years.

The contractor will be required to come to Bethesda yearly to present progress on their work at the Neural Prosthesis Workshop sponsored by the Neural Prosthesis Program.

This is not a Request for Proposals (RFP). RFP No. NIH-NIDCD- 91-03 will be issued on or about October 1, 1991, with responses due on or about December 2, 1991. To receive a copy of the RFP, submit a written request to the following address, and supply two self-addressed mailing labels:

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

Attention: RFP No. NIH-NIDCD-91-03

All responsible sources may submit a proposal that will be considered by the Government.

FEASIBILITY GRANTS FOR BRAIN-TUMOR RESEARCH CENTERS

RFA AVAILABLE: NS-92-01

P.T. 34; K.W. 0705010, 0715035, 1002030, 0710085, 0785120, 0745020

National Institute of Neurological Disorders and Stroke

Letter of Intent Receipt Date: November 15, 1991
Application Receipt Date: January 15, 1992

PURPOSE

The National Institute of Neurological Disorders and Stroke (NINDS) announces the availability of a Request for Applications (RFA) for feasibility (exploratory) grants for the development of new brain-tumor research centers. The major purpose of the RFA is to develop additional research capabilities that will lead to improved diagnosis and management of patients with brain tumors and to foster an environment that would enhance the research skills of investigators in specialized methods relevant to the study of brain tumors.

EXPERTISE AND ELIGIBILITY

The Center Director or Principal Investigator must be active in a discipline related to the study and (or) treatment of brain tumors, such as neuro-oncology, neurosurgery, neurology, neurobiology, tumor-cell biology, immunology, neurophysiology, neuroanatomy, neuroradiology, radiation oncology, or neuropharmacology, and have demonstrated the potential for developing and directing a research program. Interrelated biomedical research projects included in the interdisciplinary research centers should be conducted by scientists who represent a variety of disciplines within basic, applied, and clinical science and who will communicate with each other so that new scientific leads may be readily developed and effectively utilized by others. For purposes of planning, it is important to recognize that the content of the individual components of a research center is critical. The research center program must be organized around a central research theme and must encompass a sufficient number of scientifically meritorious research activities (from a minimum of three to five or more) to permit an effective collaborative effort among the participating investigators.

To be eligible for competition under this RFA, applicants must document the existence of, or potential for, ongoing basic, applied, and clinical research related to brain tumors; research resources in the encompassing fields of neuro-oncology and the neurological sciences; clinical facilities that receive and track adequate numbers and types of patients who have brain tumors; cooperation among investigators within the represented disciplines so that scientific leads may be effectively implemented; and a plan for the further development of individual investigators, fellows, or clinicians in specialized techniques or procedures relevant to research on brain tumors.

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.

MECHANISM OF SUPPORT

The support mechanism for this program will be the exploratory (feasibility) grant (P20). These feasibility grants will be awarded for up to three years (not renewable) and may not exceed annual direct costs of $250,000 for each of three years. The NINDS expects to make up to eight awards for exploratory grants depending upon availability of funds.

NOTE: This RFA specifically invites applications for feasibility grants only. Applicants who are beyond the feasibility stage, eligible for center status, for clinical research centers are welcome to apply by submitting an application for any of the three annual receipt dates (February 1, June 1, and October 1). Such applications must conform to the application format as described in the NINDS pamphlet, "Application Guidelines: Program Project and Clinical Research Center Grants" (revised October 1989), that may be obtained from the individual to whom inquiries and letters of intent are directed (address below).

REVIEW PROCEDURES

Upon receipt and referral by the Division of Research Grants (DRG), applications will be reviewed by NINDS staff to determine programmatic responsiveness to this RFA. Applications judged unresponsive will be returned to the applicant. All applications that are complete and responsive may be subjected to a triage by an NINDS review group to determine relative scientific merit among the applications. The NINDS will administratively withdraw those applications judged to be noncompetitive for award. Those applications judged to be competitive for award will be further reviewed for scientific and technical merit by a peer review group convened by the NINDS. No site visits will be made. A second level of review will be by the National Advisory Neurological Disorders and Stroke Council.

METHOD OF APPLYING

Letter of Intent. The NINDS urges applicants to submit a letter of intent including the name and address of the Principal Investigator, names and addresses of coinvestigators responsible for each project within the center, descriptive titles of individual projects and required components, and identification of collaborating institutions. A letter of intent is not binding, does not enter into the review of a subsequent application, and is not a precondition for an award.

Format of Applications. All applicants must use form PHS 398 (revised 10/88). Applicants must use the format as described in the NINDS brochure "Application Guidelines: Program Project and Clinical Research Center Grants" (revised 10/89), that may be obtained from Dr. George N. Eaves at the address below. All applications must be received by January 15, 1992. An application not received by this date will be ineligible for consideration. Awards will be made on or before August 1, 1992.

INQUIRIES

For a copy of the complete RFA, including review criteria and application instructions, contact:

Dr. George N. Eaves
Deputy Director
Division of Stroke and Trauma
National Institute of Neurological Disorders and Stroke
Federal Building, Room 8A13
Bethesda, MD 20892
Telephone: (301) 496-4226

For fiscal and administrative matters, contact:

King P. Bond, Jr.
Grants Management Specialist
National Institute of Neurological Disorders and Stroke
Federal Building, Room 1004
7550 Wisconsin Avenue
Bethesda, MD 20892
Telephone: (301) 496-9203

AUTHORITY AND REGULATIONS

The program to which the intended grants relate is described in the Catalog of Federal Domestic Assistance, entry numbers 93.853, Clinical Research Related Neurological Disorders and 93.854, Biological Basis Research in the Neurosciences. Grants will be awarded under the authority of the Public Health Service Act, Title IV, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants 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.

ONGOING PROGRAM ANNOUNCEMENTS

INDIVIDUAL NATIONAL RESEARCH SERVICE AWARDS IN ALLERGY, IMMUNOLOGY, TRANSPLANTATION, INFECTIOUS DISEASES AND AIDS

PA: PA-91-95

P.T. 34; K.W. 0715008, 0715110, 0710070, 0715125, 0710125

National Institute of Allergy and Infectious Diseases

BACKGROUND AND SCOPE

The intent of this program announcement is to re-emphasize the commitment of the National Institute of Allergy and Infectious Diseases (NIAID) to provide support via National Research Service Awards (NRSA) to increase the number of biomedical investigators who are conducting high-quality research in the areas of allergy, immunology, transplantation, infectious diseases, and AIDS. The NIAID encourages all individuals, and especially underrepresented minorities and women, to submit applications.

Major advances in basic and clinical science coupled with the advanced state of development of basic technology make it imperative to begin applying this new information to clinically based research. Significant needs exist for individuals, particularly those with advanced clinical degrees, to be trained in specific areas of programmatic importance to scientific divisions within the NIAID: the Division of Acquired Immunodeficiency Syndrome (DAIDS), the Division of Allergy, Immunology and Transplantation (DAIT) and the Division of Microbiology and Infectious Diseases (DMID). It is the specific objective of this Program Announcement to promote clinical and basic research training in selected emphasis areas in infectious diseases, immunology, and AIDS for physicians with appropriate backgrounds and for Ph.D.'s from relevant disciplines who wish to do research in these areas.

Division of Acquired Immunodeficiency Syndrome (DAIDS)

o Retroviral Immunopathology. Although there are skilled physicians working with AIDS patients and experienced molecular biologists performing research with the HIV or related viruses, there is a need for clinical researchers (M.D.'s or Ph.D.'s) to perform research on the immunopathogenesis of the HIV. The emphasis of this initiative is to support investigators who perform laboratory studies at the molecular level on patient samples and basic researchers (retrovirologists) to perform clinical research with the ultimate goal of elucidating the immunopathogenesis of AIDS. Examples of research areas that are encouraged include T cell depletion, viral replication and production, properties of viral latency, immune responses to HIV infection, and genetic variation of HIV within a patient population.

Division of Allergy, Immunology and Transplantation (DAIT)

o Inflammatory Bowel Diseases (IBD). Recent advances in our knowledge of mucosal immunity and IBD have led to the conclusion that immune mechanisms are major components in the pathogenesis and evolution of Crohn's disease and ulcerative colitis. Vigorous research is needed in the characterization of the cellular and molecular components of the immune mediated mechanisms involved in the development of these conditions. Areas of specific interest include the regulation of the responses by immunomodulators, identification of the antigens involved in the initiation and recurrence of IBD, characterization of intra-epithelial T cells and their specificity repertoire, analysis of activation of mucosal immunocytes, and development of animal models of the disease.

o Immunologic Skin Diseases. Autoimmune mechanisms and immuno-inflammatory components appear to play central roles in the development of numerous skin disorders including atopic dermatitis, allergic contact dermatitis and angioedema. The mechanisms underlying the basic immunologic processes and immunopathology of these diseases are incompletely understood, although some advances have been made such as the results that have been recently reported on the striking effects of immuno-suppression in the treatment of psoriasis. Basic training in immunology would allow dermatologists and dermatopathologists to better understand the pathogenesis of many skin diseases, and would facilitate the development of new, improved immuno-modulatory therapies.

o Immunologic Eye Diseases. The eye and its surrounding tissues comprise a complicated organ system in which immunologically mediated diseases that are intrinsic to the eye or are ocular manifestations of systemic disease often occur. Autoimmunity is the main cause of uveoretinitis in this country. Knowledge of the chemistry and

sources of ocular autoantigens is just now emerging. Training of ophthalmologists and other individuals with suitable backgrounds in clinical and basic science in the immunopathology of eye diseases such as uveitis, various forms of keratitis, and conjunctivitis would enable them to develop new approaches to eye disease research, including applications of emerging immunomodulatory therapies to prevent or halt the progress of these diseases.

Division of Microbiology and Infectious Diseases (DMID)

o Sexually transmitted diseases (STDs). In order to meet evolving demands for high quality STD research, there is an urgent need to increase STD research opportunities. Areas of emphasis in STD research include sequelae of STDs in women (e.g., infertility and adverse outcomes of pregnancy); genital ulcer disease (particularly chancroid and syphilis); human papillomavirus infection; and the inter-relationships between HIV infection and other STDs. Because of the interdisciplinary character of these research issues, there is a need to encourage research training to include not only specialists in infectious diseases, but also other clinical investigators (e.g., obstetricians, gynecologists, and pediatricians), behavioral scientists, and basic researchers.

o Tuberculosis. The Department of Health and Human Services (DHHS) Advisory Council for the Elimination of Tuberculosis has listed the training of tuberculosis researchers as a high priority item necessary to achieve tuberculosis control. Additional individuals trained as physician-investigators and basic scientists to initiate high quality research programs on tuberculosis would be highly desirable. Therefore, there is a great need to promote clinical and basic research training in all aspects of tuberculosis control but particularly training in epidemiology, treatment, immunology and molecular biology.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Program Announcement, Individual National Research Service Awards in Allergy, Immunology, Transplantation, Infectious Diseases and AIDS, is related to the priority areas of HIV infection, sexually transmitted diseases, and immunization and infectious diseases. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

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 and cooperative agreements 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 population 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/ offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, 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 (including American Indians or Alaskan Natives), 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 research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within 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 answer 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.

MECHANISMS OF SUPPORT

This announcement is for individual NRSA (F32, F33) applications seeking support for postdoctoral fellows who will advance research in these areas. Such a program must be designed to provide the developing scientist appropriate training to become an independent investigator capable of constructing and executing rigorous research protocols carefully crafted to examine a hypothesis.

The support mechanisms for training are summarized in this announcement. Instruction and application forms for each of the mechanisms may be obtained from the office of sponsored programs at most research institutions and from the Division of Research Grants, NIH, (301) 496-7441. Only U.S. citizens and non-citizen nationals are eligible for support under these programs.

A. INDIVIDUAL NATIONAL RESEARCH SERVICE AWARD (F32)

Individual NRSA awards are given only at the postdoctoral level. The application must describe a specific research project that is guided and sponsored by a preceptor at a particular institution. This support is for full-time research training. Provisions of these awards include:

o Awards for up to 36 months of training (waivers may be granted to M.D.s upon written request for an additional year);

o Stipends based on years of experience from date of degree to issuance of award: stipend range is $18,600 - $32,300 per year;

o Institutional allowance of $3,000 per year ($2,000 per year for fellows at NIH) to help meet expenses;

o All support exceeding 12 months requires either service or financial payback.

B. SENIOR NATIONAL RESEARCH SERVICE AWARD (F33)

Senior fellowships are designed for experienced scientists who wish to make major changes in the direction of their research career, to broaden their research capabilities, or to enlarge their command of an allied research field. Provisions of the award include:

o Awards may be for up to 24 months;

o Candidates must have received a doctoral degree or equivalent and have had at least seven subsequent years of relevant professional or research experience;

o Stipends range up to a maximum of $32,300 per year.

o All support exceeding 12 months requires either service or financial payback.

APPLICATION SUBMISSION AND REVIEW FOR INDIVIDUAL NRSA'S IN NIAID

Application receipt dates for these awards are January 10, May 10, and September 10. Institute assignment decisions will be governed by customary programmatic considerations as specified in the NIH Referral Guidelines. Applicants for the two types of fellowship awards must use the Fellowship Application Kit (PHS 416-1, Revised 4/89). Fellowships will be reviewed through the accelerated NIH peer review system in the Division of Research Grants. Earliest possible start dates will be six months after the receipt dates.

Applications submitted in response to the six emphasis areas described above must be identified by typing "PA-91-95, INDIVIDUAL NRSAs" on line 2 of the face page, below the title of the project. Applications for training in areas other than those emphasized above must leave line 2 blank.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed activity. In such a case, a letter of agreement from either the GCRC program director or Principal Investigator may be included with the application.

For further information about NIAID individual NRSAs, contact the representative from the appropriate NIAID Division:

Nancy R. Brown
Health Specialist
Basic Research and Development Program
Division of AIDS
Control Data Building, Room 208N
Bethesda, MD 20892
Telephone: (301) 402-0755

Leslye D. Johnson, Ph.D.
Chief, Enteric Diseases Branch
Division of Microbiology and Infectious Diseases
Westwood Building, Room 748
Bethesda MD 20892
Telephone: (301) 496-7051

Eugene M. Zimmerman, Ph.D.
Special Assistant to the Director
Division of Allergy, Immunology and Transplantation
Westwood Building, Room 752
Bethesda, MD 20892
Telephone: (301) 496-8973

For inquiries regarding fiscal and business matters, contact:

Ms. Barbara Huffman
Special Assistant for Operations
Office of the Chief, GMB, DEA, NIAID
Westwood Building, Room 718
Bethesda, MD 20892
Telephone: (301) 496-7075

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.855, Immunology, Allergic and Immunologic Diseases Research, and No. 93.856, Microbiology and Infectious 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 grants policies and Federal Regulation 42 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

REDUCTION OF CANCER RISK BEHAVIORS IN HIGH-RISK YOUTH

PA: PA-91-96

P.T. 34; K.W. 0715035, 0411005, 0403001, 0745027

National Cancer Institute

Application Receipt Dates: February 1, 1992, June 1, 1992, and October 1, 1992

PURPOSE

The National Cancer Institute (NCI) invites applications for studies to develop, evaluate, and disseminate effective cancer risk reduction methods and materials, and prevention intervention strategies for populations of high-risk youth, i.e., children or youth aged 10 to 18 years who are living in families or households with incomes below the poverty level.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives for children and adolescents contained in its publication "Healthy People 2000.' This program announcement (PA), Reduction of Cancer Risk Behaviors in High-Risk Youth, specifically targets the nutrition, tobacco, alcohol, HIV infection, and general cancer prevention priority areas. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone 202-783-3238).

RESEARCH OBJECTIVES

It is estimated that 20 percent of all American children under 18 years of age live in poverty. Included in this group are approximately 15 percent of all White children, 40 percent of all Hispanic children, and 45 percent of all Black children. These young people are extremely vulnerable to several unhealthy behaviors. Children of poverty often experiment with or are regular users of tobacco and/or alcohol, are sexually active without the benefits of barrier protection, and have nutritional habits that are unhealthful. Many of these young people live in a world where stable familial relations are the exception, and where the social and institutional environment challenges rather than nurtures development. From a public health perspective the effects of these conditions are at least two-fold: first, they make programmatic efforts especially difficult to implement, frequently causing impoverished youth to become underserved and hard-to-reach; and second, these conditions predispose children to health-compromising behaviors, thus making them 'high-risk.'

This PA has two major research objectives related to the high- risk youth population: (1) Develop and test, through community-level institutions, methods and interventions for the primary prevention of cancers related to poor diet, tobacco use, alcohol use, and early or unprotected sexual activity (applicants must focus interventions on at least two of these four risk factors); and (2) Summarize and publish process and outcome results of these methods and interventions for use by community-level organizations that serve high-risk youth.

Intervention sites may include, but are not limited to: community health centers, the juvenile justice system, community youth organizations, and schools. Two types of evaluation must take place under this PA: (1) outcome evaluation to judge how effectively the intervention has worked, and (2) process evaluation to identify ways of improving the program and to determine how much of the program is being implemented as planned. Investigators will be required to give full details of how they intend to accomplish these types of evaluation, and explain how they will recruit and track what is likely to be a hard-to-reach population. Prevention programs must use a variety of culturally sensitive approaches rather than a single approach, and should be adapted to the special needs of

high-risk youth to provide them with skills to make their own decisions to refrain from unhealthy behaviors in spite of peer, advertising, and other pressures endemic to their social environment.

MECHANISM OF SUPPORT

The mechanisms of support for this announcement are the research project grants (R01) and the First Independent Research Support and Transition (FIRST) award (R29). Except as otherwise stated in this PA, awards will be administered under the PHS grants policy as stated in the PHS Grants Policy Statement.

ELIGIBILITY

Applications may be submitted by non-profit and for-profit organizations, by public and private entities such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal Government. Applications from minority individuals and women are encouraged. Foreign organizations are eligible to apply, and domestic applications may include foreign components.

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

National Institutes of Health (NIH) policy is that applicants for NIH 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 in studies of diseases that 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 and compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial or ethnic group, together with a rationale for its choice. In addition, gender and racial or 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 on grant application form PHS 398 in Sections 2A-D of the Research Plan AND summarized in Section 2E (Human Subjects).

Applicants are urged to carefully assess the feasibility of including the broadest possible representation of minority groups. However, 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 or ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), 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 or 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, applicants must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

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

Peer reviewers will specifically address 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 answer 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 a 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 that do not comply with these policies.

REVIEW PROCEDURES

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit in accordance with the usual NIH peer review procedures. Following study section review, the applications will receive a second-level review by an appropriate national advisory council.

AWARD CRITERIA

Applications will compete for available funds with all other applications for assistance funding by the NIH. The following will be considered in making funding decisions: (1) quality of the proposed project as determined by peer review; (2) availability of funds; and (3) balance and priority of research topics.

METHOD OF APPLYING

Grant application kits (form PHS 398, rev. 10/88) are available at most institutional business and grant or contract offices and may be obtained from the Office of Grant Inquiries, Division of Research Grants, Westwood Building, Room 449, National Institutes of Health, Bethesda, MD 20892, telephone (301) 496-7441. The title and number of this announcement must be typed on Line 2 on the face page of the application. The completed original application and six copies must be sent or delivered to:

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

INQUIRIES

Requests for further information on the research goals of this PA are to be addressed to the Program Director:

D. Michael Anderson, Ph.D., M.P.H.
National Cancer Institute
Division of Cancer Prevention and Control
Executive Plaza North, Room 218
9000 Rockville Pike
Bethesda, MD 20892-4200
Telephone: (301) 496-8577

Requests for information on fiscal policies are to be directed to:

William Wells
National Cancer Institute
Division of Grants Administration
Executive Plaza South, Room 242
9000 Rockville Pike
Bethesda, MD 20892-4200
Telephone: (301) 496-7800 ext. 7800

Written and telephone inquiries concerning the objectives and scope of this PA and inquiries about whether or not specific proposed research would be responsive, clarifying scientific content and objectives of an application, size and focus of a research program, organization of an application, and appropriate use of consultants are strongly encouraged and are to be directed to Dr. D. Michael Anderson at the above address and telephone number. The Program Director welcomes the opportunity to clarify any issues or questions from potential applicants.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Grants will be awarded 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 grants 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.

EXPLORATORY/DEVELOPMENTAL GRANTS FOR RESEARCH ON THE ETIOLOGY OF ALCOHOLISM

PA: PA-91-97

P.T. 34; K.W. 0404003, 0755030

National Institute on Alcohol Abuse and Alcoholism

PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is soliciting applications for exploratory/developmental grants for research on the etiology and treatment of alcoholism. This announcement describes the interest in research on the etiology of alcoholism and accompanies a parallel announcement for research on alcoholism treatment assessment. Exploratory/developmental grants (R21) are intended to develop new research activities that will be building blocks in the development of future, more intensive, and larger research studies. Grants supported under this announcement will be limited to a two-year effort and a maximum of $70,000 in direct costs per year.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement is related to the priority area of alcohol abuse reduction. Potential applicants may obtain free of charge a copy of "Healthy People 2000" (Full Report: Stock No 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-783-3238).

ELIGIBILITY

Applications may be submitted by any nonprofit or for-profit organization, whether public or private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISMS AND PERIOD OF SUPPORT

Research support mechanisms are limited to exploratory/developmental grants (R21) for up to $70,000 in direct costs per year for up to two years. Annual awards will be made subject to continued availability of funds and progress achieved.

AVAILABILITY OF FUNDS

In Fiscal Year 1992, NIAAA estimates that approximately $1 million will be available for approximately 10 to 12 exploratory/developmental awards under this announcement and the related announcement for Exploratory/Developmental Grants (R21) for Alcoholism Treatment Assessment Research. However, the amount of funding will depend on appropriated funds and program priorities at the time of award.

RESEARCH OBJECTIVES

The objectives of the NIAAA exploratory/developmental grants for research on the etiology of alcoholism are to: (1) conduct pilot studies leading to new programs or the enhancement or modification of existing research programs that may improve our understanding of the etiology of alcoholism; (2) improve the methodology for evaluating the vulnerability to alcoholism; and (3) plan and conduct research that may lead to the development of new concepts for clinical treatment of alcoholism. In addition, the NIAAA is interested in projects that focus on etiologic mechanisms of alcoholism that may be unique to special groups such as women, adolescents and youth, the elderly, and minority and ethnic populations.

Applications solicited by this announcement are pertinent to a broad range of measurement and methodological issues, including creating, developing, modifying, and enhancing instruments, techniques, or analytic strategies to assist in research on the etiology and assessment of alcoholism. Basic research projects on etiology should develop new information about how alcohol affects the body and behavior so that more effective strategies can be designed and developed for the successful assessment and treatment of alcoholism. Specific goals may include:

1. Clarifying the basis for alcohol craving so that more effective therapeutics agents, such as dopaminergic agonists and serotonin uptake inhibitors, can be designed and tested.

2. Clarifying the roles of various neurotransmitter receptors, such as those for GABA, NMDA, and adenosine, and of G proteins in the adaptation to the actions of alcohol.

3. Clarifying the etiology of alcohol-induced brain alterations that may increase ethanol intake.

4. Developing approaches to study the evolution of adolescent alcohol abuse during critical stages of maturation. Such research could include the effects of alcohol on the brains of immature animals and the interaction of neurobiological, behavioral, and environmental influences in humans that might have relevance to the possible vulnerability of adolescents to develop alcoholism.

5. Developing and validating new screening instruments or biological and behavioral markers for early identification of individuals at risk for alcohol abuse/alcoholism.

6. Elucidating the mechanistic basis for abnormal vulnerability to alcohol-induced organ and tissue damage (e.g., brain, heart, liver, pancreas, etc.) that needs clinical management during treatment. Studies may include genetic susceptibilities as well as abnormalities in metabolism or calcium and magnesium ion distribution, free radical formation, and hemodynamic/ hypertension changes. Developing and validating new medications for diminishing alcohol induced injury is central to this issue.

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

Applications for ADAMHA grants and cooperative agreements are required to include both women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including either woman or minorities is provided. This requirement is intended to ensure that research findings will be of benefit to all persons at risk of the disease, disorder, or condition under study. For the purpose of these policies, clinical research involves human studies of etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders or conditions, including but not limited to clinical trials; and minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics).

ADAMHA recognizes that it may not be feasible or appropriate in all clinical research projects to include representation of the full array of U.S. racial/ethnic minority populations. However, applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups.

Applications should include a description of the composition of the proposed study population by gender and racial/ethnic group, and the rationale for the numbers and kinds of people selected to participate. 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.

Applications should incorporate in their study design gender and/or minority representation appropriate to the scientific objectives of the work proposed. If representation of women or minorities in sufficient numbers to permit assessment of differential effects is not feasible or is not appropriate, the reasons for this must be explained and justified. The rationale may relate to the purpose of the research, the health of the subjects, or other compelling circumstances (e.g., if in the only study population available, there is a disproportionate representation in terms of age distribution, risk factors, incidence/prevalence, etc., of one gender or minority/majority group).

If the required information is not contained within the application, the review will be deferred until it is complete. Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If gender and/or minority representation/ justification are judged to be inadequate, reviewers will consider this as a deficiency in assigning the priority score to the application.

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

APPLICATION RECEIPT AND REVIEW SCHEDULE

Receipt Dates New/Renewal	Initial Review	Advisory Council Review	Earliest Start Date
Jun 1/Jul 1*	Oct/Nov	Jan/Feb	Apr 1
Oct 1/Nov 1*	Feb/Mar	May/Jun	Jul 1
Feb 1/Mar 1*	May/Jun	Sep/Oct	Dec 1

* Competing continuation, supplemental, and revised applications are to be submitted on these dates.

Consequences of Late Submission

Applications received after the above receipt dates are subject to assignment to the next review cycle.

APPLICATION PROCESS

Applicants must use the grant application form PHS 398 (rev. 10/88). The number and title of this program announcement "PA-91-97, Exploratory/Developmental Grants for Research on the Etiology of Alcoholism" must be typed in item number 2 on the face page of the PHS 398 application form.

Application kits containing the necessary forms and instructions may be obtained from business offices or offices of sponsored research at most universities, colleges, medical schools, and other major research facilities. If such a source is not available, the following office may be contacted for the necessary application material:

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 completed application must be sent to:

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

REVIEW PROCESS

The Division of Research Grants, NIH, serves as a central point for receipt of applications for most discretionary PHS grant programs. Applications received under this announcement will be assigned to an Initial Review Group (IRG) in accordance with established PHS Referral Guidelines. The IRG, consisting primarily of non-Federal scientific and technical experts, will review the applications for scientific and technical merit. Notification of the review recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate national advisory council whose review may be based on policy considerations as well as scientific merit.

REVIEW CRITERIA

Criteria for scientific/technical merit review of applications will include the following:

o The overall significance and scientific and technical merit of the proposed research.

o The appropriateness and adequacy of the experimental design, including the adequacy of the methodology for collection and analysis of data, including research schematics, detailed analytic plans, and proposed instrumentation.

o The adequacy of the qualifications (including level of education and training) and relevant research experience of the principal investigator and key research personnel.

o The availability of adequate facilities, general environment for the conduct of proposed research, other resources, and collaborative arrangements necessary for the research.

o The appropriateness of budget estimates for the proposed research activities.

o If applicable, the adequacy of procedures to protect or minimize possible adverse effects on humans, animals, or the environment.

o Conformance of the application to the policy on the inclusion of women and minorities in study populations.

AWARD CRITERIA

Applications recommended for consideration by the National Advisory Council on Alcohol Abuse and Alcoholism will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, NIAAA program needs and balance, and availability of funds.

TERMS AND CONDITIONS OF SUPPORT

Grant funds may be used for expenses clearly related and necessary to conduct research projects, including direct costs that 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 intervention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for costs required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield generalizable knowledge and/or make a significant contribution to theoretical concepts.

Grants must be administered in accordance with the PHS Grants Policy Statement (Rev. October 1, 1990).

INQUIRIES

Potential applicants are encouraged to seek preapplication consultation and may contact the individuals listed below for consultation in preparing an application under this announcement.

Direct inquiries related to program issues to:

Basic Etiology:

Sam Zakhari, Ph.D. or Walter Hunt, Ph.D.
Division of Basic Research
National Institute on Alcohol Abuse and Alcoholism
Parklawn Bldg., Room 16C-05
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4223

Treatment and Treatment Assessment:

Joanne Fertig, Ph.D.
Treatment Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
Parklawn Bldg., Room 14C-20
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-0796

Direct inquiries related to fiscal matters to:

Elsie Fleming
Grants Management Branch
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 16-86
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4703

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.273. Awards are made under the authority of Sections 301 and 510 of the Public Health Service Act as amended (42 USC 241 and 290bb).

Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards. The program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

EXPLORATORY/DEVELOPMENTAL GRANTS FOR ALCOHOLISM TREATMENT ASSESSMENT RESEARCH

PA-91-98

P.T. 34; K.W. 0404003, 0795005

National Institute on Alcohol Abuse and Alcoholism

PURPOSE

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) is soliciting applications for exploratory/ developmental grants for research on the etiology and treatment of alcoholism. This announcement describes the interest in research on alcoholism treatment assessment and accompanies a parallel announcement for research on the etiology of alcoholism.

Exploratory/developmental grants (R21) are intended to develop new research activities that will be building blocks in the development of future, more intensive, and larger research studies. Grants supported under this announcement will be limited to a two-year effort and a maximum of $70,000 in direct costs per year.

HEALTHY PEOPLE 200

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This program announcement is related to the priority area of alcohol abuse reduction. Potential applicants may obtain free of charge a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-783-3238).

ELIGIBILITY

Applications may be submitted by any nonprofit or for-profit organization, public or private, such as universities, colleges, hospitals, laboratories, units of State or local governments, and eligible agencies of the Federal Government. Women and minority investigators are encouraged to apply.

MECHANISM AND PERIOD OF SUPPORT

Research support mechanisms are limited to exploratory/ developmental grants (R21) for up to $70,000 in direct costs per year for up to two years. Annual awards will be made subject to continued availability of funds and progress achieved.

AVAILABILITY OF FUNDS

In Fiscal Year 1992, NIAAA estimates that approximately $1 million will be available for approximately 10 to 12 exploratory/developmental awards under this announcement and the related announcement for Exploratory/Developmental Grants (R21) for Research on the Etiology of Alcoholism. However, the amount of funding will depend on appropriated funds and program priorities at the time of award.

RESEARCH OBJECTIVES

The objectives of NIAAA exploratory/developmental grants for alcoholism treatment assessment research are to: (1) support promising activities of institutions that wish to build a capacity to do alcoholism treatment assessment research; (2) conduct pilot studies leading to expansion, enhancement, or modification of existing alcoholism treatment research programs; (3) plan and conduct pilot research leading to the possible development of clinical trials in alcoholism treatment assessment research; and to (4) develop instruments and methodologies that can support larger scale studies on alcoholism treatment.

Applications solicited by this announcement are pertinent to a broad range of measurement and methodological issues, including creating, developing, modifying, or enhancing instruments, techniques, or analytic strategies to assist in alcoholism studies. Some specific types of interests include:

o Development of measures of patient variables, including patient classification systems, that may contribute to effective, differential treatment planning.

o Normalization and validation of patient assessment and treatment outcome measures.

o Development of measures of alcoholism program characteristics (e.g., access factors, structure, treatment atmosphere, counselor characteristics, patient satisfaction) that may elucidate their contribution to treatment effectiveness.

o Development of measures of extra-treatment variables, such as social/environmental support, coercion for treatment, and patient motivation, that may be associated with alcoholism recovery.

o Development of procedures to assess and enhance patient compliance with treatment and treatment research protocols.

o Development and evaluation of psychosocial and biochemical measures of alcoholism and alcohol consumption.

o Formulation or extension of experimental methodologies and quantitative techniques to advance alcoholism treatment research.

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

Applications for ADAMHA grants and cooperative agreements are required to include both women and minorities in study populations for clinical research, unless compelling scientific or other justification for not including either woman or minorities is provided. This requirement is intended to ensure that research findings will be of benefit to all persons at risk of the disease, disorder, or condition under study. For the purpose of these policies, clinical research involves human studies of etiology, treatment, diagnosis, prevention, or epidemiology of diseases, disorders or conditions, including but not limited to clinical trials; and minorities include U.S. racial/ethnic minority populations (specifically: American Indians or Alaskan Natives, Asian/Pacific Islanders, Blacks, and Hispanics).

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

APPLICATION RECEIPT AND REVIEW SCHEDULE

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Consequences of Late Submission

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APPLICATION PROCESS

Applicants must use the grant application form PHS 398 (rev. 10/88). The number and title of this program announcement "PA-91-98, Exploratory/ Developmental Grants for Alcoholism Treatment Assessment Research" must be typed in item number 2 on the face page of the PHS 398 application form.

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REVIEW PROCESS

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recommendations will be sent to the applicant after the initial review. Applications will receive a second-level review by an appropriate national advisory council whose review may be based on policy considerations as well as scientific merit.

REVIEW CRITERIA

Criteria for scientific/technical merit review of applications will include the following:

o The overall significance and scientific and technical merit of the proposed research.

o The appropriateness and adequacy of the experimental design, including the adequacy of the methodology proposed for collection and analysis of data, including research schematics, detailed analytic plans, and proposed instrumentation.

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

o The availability of adequate facilities, general environment for the conduct of proposed research, other resources, and collaborative arrangements necessary for the research.

o The appropriateness of budget estimates for the proposed research activities.

o Where applicable, the adequacy of procedures to protect or minimize possible adverse effects on human, animals, or the environment.

o Conformance of the application to the policy on inclusion of women and minorities in study populations.

AWARD CRITERIA

Applications recommended for consideration by the National Advisory Council on Alcohol Abuse and Alcoholism will be considered for funding on the basis of overall scientific and technical merit of the research as determined by peer review, NIAAA program needs and balance, and availability of funds.

TERMS AND CONDITIONS OF SUPPORT

Grant funds may be used for expenses clearly related and necessary to conduct research projects, including both direct costs that 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 intervention service program. Support for research-related treatment, rehabilitation, or prevention services and programs may be requested only for costs required by the research. These costs must be justified in terms of research objectives, methods, and designs that promise to yield generalizable knowledge and/or make a significant contribution to theoretical concepts.

INQUIRIES

Potential applicants are encouraged to seek preapplication consultation and may contact the individuals listed below for consultation in preparing an application under this announcement. Direct inquiries relating to program issues to:

Treatment and Treatment Assessment:

Joanne Fertig, Ph.D.
Treatment Research Branch
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
Parklawn Bldg., Room 14C-20
5600 Fishers Lane
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Basic Etiology:

Sam Zakhari, Ph.D. or Walter Hunt, Ph.D.
Division of Basic Research
National Institute on Alcohol Abuse and Alcoholism
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Direct inquiries regarding fiscal matters to:

Elsie Fleming
Grants Management Branch
Office of Planning and Resource Management
National Institute on Alcohol Abuse and Alcoholism
Parklawn Building, Room 16-86
5600 Fishers Lane
Rockville, MD 20857

Telephone: (301) 443-4703

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.273. Awards are made under the authority of Sections 301 and 510 of the Public Health Service Act, as amended (42 USC 241 and 290bb).

Federal regulations at 42 CFR Part 52, "Grants for Research Projects," and Title 45 CFR Parts 74 and 92, generic requirements concerning the administration of grants, are applicable to these awards. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

STUDIES ON OBESITY

PA: PA-91-99

P.T. 34; K.W. 0715145, 0710095, 0765020

National Institute of Diabetes and Digestive and Kidney Diseases
National Heart, Lung, and Blood Institute
National Institute of Child Health and Human Development
National Cancer Institute
National Institute on Aging
National Center for Nursing Research
National Institute of Neurological Disorders and Stroke
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute on Deafness and Other Communication Disorders
National Institute of Mental Health

BACKGROUND INFORMATION

Research on the biomedical and behavioral aspects of obesity is an important component of the NIH nutrition research program. Obesity is widely prevalent in the United States, affecting both children and adults. Data on body mass index from the second National Health and Nutrition Examination Survey (1976-80) indicated that 24 percent of men and 27 percent of women were overweight (body mass index equal to or greater than 27.8 for men and 27.3 for women). The prevalence of obesity in adults has not declined in the past three decades; some data suggest that its prevalence in children has increased over this time. Obesity is particularly prevalent in minority populations, especially among minority women. Obesity is multifactorial in origin, reflecting inherited, environmental, cultural, and socioeconomic conditions.

Obesity is associated with elevated serum cholesterol levels, elevated blood pressure, and noninsulin-dependent diabetes, and is an independent risk factor for coronary heart disease. It also increases the risk for gallbladder disease and some types of cancer and has been implicated in the development of osteoarthritis of the weight-bearing joints. Obesity acquired during childhood or adolescence often persists into adulthood and increases the risk for some chronic diseases later in life.

The great prevalence of obesity and its physical and mental health consequences make its prevention and treatment a public health priority.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention goals of "Healthy People 2000", a PHS-led national activity for setting priorities. This program announcement is related to the priority areas of nutrition, physical activity and fitness, heart disease and stroke, cancer, diabetes, and chronic disabling conditions. Potential applicants may obtain free of charge a copy of "Healthy People 2000" (Full Report: No. 017-001-474-0, or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone: 202-783-3238).

RESEARCH GOALS AND SCOPE

The emphasis of this program announcement is the support of research on the biomedical and behavioral aspects of exogenous obesity. The goals of this research, which includes basic, clinical, and population research, are to establish a clear understanding of the etiology, prevention, and treatment of this multifaceted condition. For example, the determinants of obesity during the early stages of the life cycle need to be identified in order to prevent the onset of obesity early in life and to identify individuals at high risk of becoming obese later in life. Preventive therapies, as well as successful treatment regimens, need to be designed. In order to accomplish these goals, further research is needed on the behavioral and developmental aspects of obesity in terms of its natural history and determinants in infancy, childhood, and adolescence; on the molecular, metabolic, genetic, and neurological aspects of obesity; on the successful treatment of obesity; and on the effects of obesity on health and longevity. A major question with respect to the health implications of obesity is determining the relative roles of body composition, body fat, and the regional distribution of body fat in the morbidity and mortality attributed to obesity. There is also the need to learn more about adipose tissue morphology as a determinant of the pattern of fat distribution and the impaired health and shortened life span associated with the obese state. Finally, more information is needed to support health-based standards of desirable weight for various age, sex, and ethnic groups.

Examples of research areas in obesity of particular interest include, but are not limited to, the following:

Molecular, Metabolic, and Genetic Factors

o Mechanisms by which obesity contributes to the development of diseases such as diabetes, coronary heart disease, hypertension, and cancer, as well as possible differences in such mechanisms among different ethnic groups.

o The contribution of genetic and metabolic factors to obesity, including the molecular and genetic basis of energy metabolism and the nature of genetic aberrations in human obesity.

o Interactions of genetic and environmental factors, as well as dietary, behavioral, and social factors, in the etiology of obesity and their effects on the ability to lose weight successfully.

o The contribution of muscle metabolism to energy balance.

o Methods for measuring body fat distribution and determining its effects on disease.

o Hypometabolism and factors that influence energy expenditure.

o Influence of gestational diabetes on subsequent weight gain of offspring.

o Role of nutrient composition of the diet in energy balance.

Neurological and Endocrine Factors

o The neurophysiology of ingestive behavior, including an understanding of the mechanisms of anorexia.

o Central nervous system/hypothalamic/autonomic nervous system (including sympathetic nervous system) control of energy intake and expenditure, including the neuroanatomical organizations and pathways that control food intake and the behavioral, hormonal, and metabolic mechanisms by which such pathways influence satiety mechanisms and body weight.

o Role of the brain in mediating acquisition, extinction, and aversion of associations to gustatory, olfactory, and trigeminal stimulation.

o Neuroanatomical pathways connecting the gastrointestinal system to the hypothalamus, and the effect of changes in the gastrointestinal system on the electrophysical activity in the hypothalamus.

o Functional and structural alterations in the brain resulting from changes in food intake in animals, as well as gustatory, olfactory, and trigeminal stimulation.

o Neurological mechanisms of taste, smell, and common chemical reception in a variety of animal models.

Behavioral and Developmental Factors

o Behavioral interventions to prevent and treat obesity at all ages and in various population groups, including minority populations.

o Behavioral change strategies for weight loss and to prevent relapse after weight loss.

o Application of the techniques of behavioral neuroscience to the prevention and treatment of obesity.

o Mechanism of action of reinforcers of food intake and physical activity.

o Sensory-specific studies of habituation phenomena.

o Genetic/environmental/behavioral interactions.

Treatment of Obesity

Due to the serious health implications of obesity, research must continue to find successful measures to treat obesity and to prevent its recurrence. Various treatments that need to be examined include the use of hypocaloric regimens, the effects of exercise alone or in combination with caloric restriction on metabolism and subsequent weight loss, and behavioral therapies. Such treatments need to be examined across the various stages of the life cycle and in different risk groups. Treatment outcomes, including regression of risk factors and effects on other medical disorders, need to be examined, including:

o Treatment models and efficacy in various age groups and in minority populations.

o Influence of duration of obesity on adverse health effects and response to intervention.

o Effects of weight cycling on cardiovascular risk factors, fat patterning, and other physiological measures.

o The effect of mild exercise on appetite and the role of exercise in weight control.

o Mechanism of action and efficacy of pharmacologic agents in energy balance and weight control.

Prevention of Obesity

o Research emphasis on preventing obesity in children, adolescents, and adults and encouraging healthy active lifestyle at all ages.

o Interventions to reduce sedentary behavior.

o Evaluation of prevention strategies targeted at specific racial, ethnic, and socioeconomic high-risk groups.

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

National Institutes of Health (NIH) policy is that applicants for NIH 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 in studies of diseases that 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 and compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial or ethnic group, together with a rationale for its choice. In addition, gender and racial or 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 on grant application form PHS 398 in Sections 2A-D of the Research Plan AND summarized in Section 2E (Human Subjects).

Applicants are urged to carefully assess the feasibility of including the broadest possible representation of minority groups. However, 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 or ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), 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 or 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, applicants must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

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

Peer reviewers will specifically address 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 answer 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 a 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 that do not comply with these policies.

MECHANISM OF SUPPORT

The mechanism of support for this program will be the grant-in-aid (RO1 and R29). The regulations (Code of Federal Regulations, Title 42, Part 52 and Title 45, Part 74) and policies that govern the research grant programs of the Public Health Service will prevail. The award of grants pursuant to this request for grant applications is contingent upon ultimate receipt of appropriated funds for this purpose.

The NIH requires applicants for grants to give added attention (where feasible and appropriate) to the inclusion of minority groups and/or women in the study populations for research. For proposed population-based studies that do not include women and/or minorities, a clear rationale for not including either or both must be provided.

METHOD AND CRITERIA OF REVIEW

Assignment of Application: Applications will be received by the Division of Research Grants (DRG), NIH, referred to an appropriate study section for scientific review, and assigned to individual Institutes for funding consideration. These decisions will be governed by customary programmatic considerations as specified in the DRG Referral Guidelines.

Review Procedures: Applications in response to this announcement will be reviewed in competition with other applications received in the same review cycle, and in accord with the customary NIH peer review procedures. The initial review for scientific and technical merit will be by a review group composed mostly of non-Federal scientific consultants (study section). Following study section review, the application will be evaluated by the appropriate Institute Advisory Council or Board with respect to the adequacy of the technical merit review and the program relevance of the research proposed. The review criteria customarily employed by the NIH PHS for research grant applications will prevail.

Deadlines: Applications will be accepted in accordance with the usual receipt dates for new applications: October 1, February 1, and June 1.

METHOD OF APPLYING

Applications should be submitted on form PHS 398 (rev. 10/88) that is available in the business or grants and contracts office at most academic and research institutions and from the Office of Grants Inquiries, Division of Research Grants, NIH, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. In line 2 on the face page of the application, the phrase, "Studies on Obesity" must be inserted.

For further information, investigators are encouraged to contact one or more of the following individuals:

Van S. Hubbard, M.D., Ph.D.
Director, Obesity, Eating Disorders and Energy Regulation Program
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Westwood Building, Room 3A18B
Bethesda, MD 20892
Telephone: (301) 496-7823

Eva Obarzanek, Ph.D., M.P.H., R.D.
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Division of Epidemiology and Clinical Applications
National Heart, Lung, and Blood Institute
Federal Building, Room 604
Bethesda, MD 20892
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Gilman Grave, M.D.
Endocrinology, Nutrition and Growth Branch
Center for Research for Mothers and Children
National Institute of Child Health and Human Development
Executive Plaza North, Room 637A
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Ann W. Sorenson, Ph.D.
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Biology of Aging Program
National Institute on Aging
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June Lunney, Ph.D., R.N.
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Joan A. McGowan, Ph.D.
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National Institute of Arthritis and Musculoskeletal and Skin Diseases
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Jack Pearl, Ph.D.
Health Scientist Administrator
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Contacts for fiscal and administrative inquiries:

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National Institute of Diabetes and Digestive and Kidney Diseases
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Grants Operations Branch
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Telephone: (301) 496-7536

E. Douglas Shawver
Office of Grants and Contracts
National Institute of Child Health and Human Development
Executive Plaza North, Room 501
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Telephone: (301) 496-1303

Eileen Natoli
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This program announcement replaces a previous one published in the NIH Guide for Grants and Contracts, Vol. 13, No. 4, March 30, 1984.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.848, 93.847, 93.837, 93.865, 93.393, 93.866, 93.854, 93.173, and 93.242. Awards are made under the authorization of the Public Health Service Act, Section 301 (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.