NIH GUIDE

For Grants and Contracts

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

Vol. 20, No. 20
May 24, 1991

NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

ONGOING PROGRAM ANNOUNCEMENTS

NUCLEIC ACID AND PROTEIN SEQUENCE ANALYSIS WORKSHOP FOR BIOMEDICAL RESEARCHERS

P.T. 42; K.W. 0760053, 0755045, 0780018

National Center for Research Resources

The Pittsburgh Supercomputing Center (PSC) is conducting a five-day workshop on "Nucleic Acid and Protein Sequence Analysis," August 5-9, 1991. This workshop is funded by a grant from the National Center for Human Genome Research of the National Institutes of Health.

The workshop will familiarize biomedical researchers with computational methods and provide practice in applying supercomputing resources to problems of concern in macromolecular sequence analysis. The workshop will emphasize alignment of and pattern extraction from multiple sequences. Participants will gain practical experience on Pittsburgh Supercomputing Center's Cray Y-MP/832 in (1) comparing and aligning sequences, (2) identifying informative patterns in a set of sequences, and (3) using extracted informative patterns to identify related sequences. Participants will gain experience with rigorous dynamic programming approaches to multiple sequence alignment as well as with consensus word approaches; they will also learn how to use profile analysis effectively on their own problems. Participants are encouraged to bring sequence analysis problems from their current research.

Workshop Leaders: Stephen Altschul and Greg Schuler from the National Library of Medicine and Michael Gribskov from the Frederick Cancer Research Facility of the National Cancer Institute.

This five-day workshop will introduce participants to VAX VMS and Unicos, the Cray version of the AT&T System V Unix operating system. No prior computing experience is required.

A limited number of grants to cover travel and hotel accommodations are available for U.S. academic participants. A few openings for industry-based biomedical researchers may be available for a fee of $1000. Enrollment is limited to 20 participants. The deadline for the submission of applications is June 14, 1991.

Grants of supercomputing time to allow biomedical researchers to explore the appropriateness of supercomputing for their computational problems are available through a program funded by the Biomedical Research Technology Program, National Center for Research Resources, National Institutes of Health.

For application forms and further information, call or write:

Nancy Kiser
Biomedical Coordinator
Pittsburgh Supercomputing Center
4400 Fifth Avenue
Pittsburgh, PA 15213
Telephone: (412) 268-5206 or 1-800-222-9310 (PA)
1-800-221-1641 (outside PA)
E-mail: kiser@a.psc.edu or kiser@cpwpsca.bitnet

AVAILABILITY OF RESOURCE FOR DIETARY INTAKE AND NUTRITION RESEARCH

P.T. 34; K.W. 0710095, 0780000

National Heart, Lung, and Blood Institute

The Nutrition Coordinating Center (NCC) at the University of Minnesota is a unique national resource available for dietary data collection and nutrient calculation for epidemiological studies, clinical trials, and other medical research studies. The center provides standardized procedures for collecting food intake data and calculating nutrient intakes at the high level of specificity needed for investigations of the relationship between diet and disease.

Investigators can use the services of the NCC in two ways. First, they can license use of the Minnesota Nutrition Data System (NDS). NDS is a microcomputer-based software package for interactive dietary data collection and nutrient calculation. NDS prompts the user to describe food intake at the level of detail required for dietary research and calculates the nutrient

content of the intake. Then NDS presents the data on the screen, in printed reports, or in ASCII files that can be merged with other study data or with statistical analysis software. The NDS database allows the user to describe over 150,000 foods and 6,000 brand name products. The database contains values for 93 nutrients, including soluble and insoluble fiber fractions, 23 individual fatty acids, and 18 amino acids. NDS can be used to guide 24-hour dietary recall interviews or to process food intake records. NDS can also be used to collect and analyze diet histories and to calculate the nutrient content of recipes. A customized version of NDS is being used in the National Health and Nutrition Examination Survey (NHANES III) to collect dietary data from more than 30,000 Americans.

Alternatively, investigators can send dietary intake records to NCC for processing. Data collection and processing procedures can be customized to meet the needs of specific studies. Investigators may reanalyze data collected in the past to take advantage of improved analytical data and new nutrients added to the database. Over the past 17 years, NCC has processed more than 250,000 records.

NCC also provides a two-day training program for dietary interviewers. For investigators who send dietary intake records to NCC for processing, the training ensures the use of standardized data collection procedures tailored to the research protocol. Interviewers are certified following satisfactory completion of the training. For investigators using the NDS directly, the training is designed to enhance use of the software to meet research protocol requirements. Over the past 17 years, NCC has trained and certified more than 600 dietary interviewers.

NCC receives its major support from the National Heart, Lung, and Blood Institute, the National Cancer Institute, and the National Center for Health Statistics. NCC services and software are used by investigators in academia, government, non-profit organizations, and industry. Users are required to pay a fee to cover part of the operational costs.

For information and fee schedules, contact:

Marilyn Buzzard, PhD
Director
Coordinating Center
2221 University Avenue, SE
Suite 310
Minneapolis, MN 55414
Telephone: (612) 627-4869
FAX: (612) 626-9054

CURRENTLY ACTIVE NATIONAL CANCER INSTITUTE PROGRAM ANNOUNCEMENTS

P.T. 22, 34; K.W. 0715035, 0710030, 0720005

National Cancer Institute

In addition to unsolicited grant applications and grant applications in response to other Program Announcements, the National Cancer Institute is current accepting applications in response to the following Program Announcements, which appeared in the NIH Guide for Grants and Contracts on the dates indicated. Also, refer to the the publication, "NIH Extramural Programs, available from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892.

- Individual Postdoctoral National Service Award Fellowships in Radiological Sciences Related To Cancer (Vol. 20, No. 17, April 26, 1991)
- Clinical Cancer Therapy Research (Vol. 20, No. 15, April 12, 1991)
- The NCI Outstanding Investigator Grant (Vol. 20, No. 9, March 1, 1991)
- Surgical Oncology (Vol. 19, No. 46, December 28, 1990)
- Multidisciplinary Research on Solid Tumors (Vol. 19, No. 23, June 22, 1990)
- Obesity, Endocrine and Fat Metabolism and Cancer Risk (Vol. 19, No. 19, May 18, 1990)

- Domestic Animal Models of Retroviral Associated Malignancies (Vol. 19, No. 19, May 18, 1990)
- Epidemiologic Studies of Cancer and Human Retroviruses (Vol. 19, No. 18, May 4, 1990)
- Underlying Molecular, Cellular and Immunological Factors in Age-Related Cancers (Vol. 19, No. 16, April 20, 1990)
- NCI/MARC Summer Training Supplement (Vol. 18, No. 43, December 1, 1989)
- Studies on Cancer Etiology in Finfish and Shellfish (Vol. 18, No. 33, September 22, 1989)
- Specific Cancer Cell Targeting Using Molecular Genetic Technology (Vol. 18, No. 6, February 24, 1989)
- Regulation of Prostatic Involution as Related to Prostatic Cancer (Vol. 18, No. 6, February 24, 1989)
- Small Grants Program for Epidemiology (Vol. 17, No. 25, August 5, 1988)
- The Role of Growth Regulatory Factors in Normal and Neoplastic Prostate (Vol. 16, No. 42, December 25, 1987)

Copies and information related to the background of the above Program Announcements are available by contacting:

Vincent T. Oliverio, Ph.D.
Associate Director
Division of Extramural Activities
National Cancer Institute
National Institutes of Health
Building 31, Room 10A05
Bethesda, MD 20892
Telephone: (301) 496-9138
FAX: (301) 402-0062

NOTICES OF AVAILABILITY (RFPs AND RFAs)

MICROSTIMULATORS AND MICROTRANSDUCERS FOR FUNCTIONAL NEUROMUSCULAR STIMULATION

RFP AVAILABLE: NIH-NINDS-91-12

P.T. 34; K.W. 0740050, 0745047, 0715140

National Institute of Neurological Disorders and Stroke

The Neural Prosthesis Program (NPP) of the National Institute of Neurological Disorders and Stroke, NIH, is developing safe, reliable, and effective systems for functional neuromuscular stimulation (FNS) in spinal cord injured individuals. Such systems require the integration of both motor and sensory function into a paralyzed limb. A contract to develop an implantable microstimulator was begun two years ago and considerable progress has been made. In this requested research effort, the development of the microstimulator will be continued and the development of a microtransducer to sense joint angle will be initiated. The Contractor will be required to exert its best efforts to develop implantable, microsized receiver-stimulators and transducer-telemeters for functional neuromuscular stimulation (FNS). It is anticipated that one award will be made for a period of three years in January 1992.

This is not a Request for Proposals (RFP). To receive a copy of the RFP, please submit a written request to the following address, and supply this office with two self-addressed mailing labels. All responsible sources shall be considered by the agency. The RFP will be issued on or about May 29, 1991, with proposals due on July 29, 1991.

Contracting Officer
Contracts Management Branch, DEA
National Institute of Neurological Disorders and Stroke, NIH
Federal Building, Room 901
7550 Wisconsin Avenue
Bethesda, MD 20892
Attention: RFP No. NIH-NINDS-91-12

NEW THERAPEUTIC APPROACHES TO THE TREATMENT OF PROSTATE CANCER

RFA AVAILABLE: CA-91-16

P.T. 34; K.W. 0715035, 0705075, 0745070, 0755015, 0760020, 0760025

National Cancer Institute

Letter of Intent Receipt Date: July 22, 1991
Application Receipt Date: October 15, 1991

PURPOSE

The Division of Cancer Treatment (DCT) of the National Cancer Institute (NCI) invites research grant applications (R01) from interested investigators to perform clinical studies in prostate cancer to improve treatment results and clinical outcome. Investigators are encouraged to utilize laboratory advances in understanding tumor growth and hormonal control in prostate cancer to develop an integrated research program of laboratory experimentation and concurrent clinical studies. New and experienced investigators in relevant fields and disciplines may apply to fund therapeutic clinical studies.

The 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 RFA, New Therapeutic Approaches to the Treatment of Prostate Cancer, is related to the priority area of cancer. 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).

BACKGROUND INFORMATION

The incidence of prostate cancer continues to increase each year and has now surpassed lung cancer to become the most common carcinoma in males. It is estimated that approximately 122,000 new cases will be diagnosed in 1991 accounting for 19 percent of all male cancers. Black men in the United States have the highest rate of prostate cancer in the world. At the time of presentation, more than 50 percent of newly diagnosed patients will have either locally advanced or metastatic disease. Prostate cancer is the second leading cause of death from neoplasia among men, with more than 32,000 deaths estimated for 1990. It is an important cause of morbidity and mortality in the elderly. These upward trends are expected to continue as the male population ages.

When prostate cancer is diagnosed early while still confined to the prostate, the disease is curable with radical prostatectomy or radiation therapy. For patients with more advanced stages, initial treatment is based on prostatic cancer cell growth's presumed hormonal dependence and includes surgical castration and diethylstilbestrol. In recent years, new methods of hormone treatment utilize pharmacologic agents capable of reducing or blocking the action of testosterone, the major circulating androgenic hormone, by interrupting the complex interactions between the hypothalamus, pituitary, testis, and adrenal glands. However, these new therapeutic agents do not prevent the emergence of hormone-resistant cells. Advanced prostate cancers ultimately fail to respond to androgen deprivation. The mechanisms involved in the development of androgen resistance are not understood. There is no alternative therapy that can be offered at present to these patients that consistently results in reduction in tumor mass or palliation of symptoms.

In recent years, basic researchers have made promising new advances in understanding the mechanisms of growth control in the human prostate cell. The growth and differentiation of benign and malignant prostatic epithelial cells are regulated by androgens which in turn are modulated by growth factors and other hormones. Clinical trials utilizing suramin, which interferes with heparin-binding growth factors, have recently shown responses in advanced prostate cancer. The mechanism of action of suramin is still not completely understood and ancillary laboratory studies are needed. In addition, biological response modifiers in combination with chemotherapy have achieved

promising results in other tumor models but have not been adequately explored in prostate cancer. Recent advances in understanding the molecular and cellular mechanisms operative in resistance to chemotherapy have led to the design of new therapeutic strategies to overcome drug resistance in other tumors. Many opportunities exist to develop new treatment strategies in prostate cancer utilizing laboratory advances in understanding tumor growth and hormonal control.

RESEARCH GOALS AND SCOPE

The major goal of this Request for Applications (RFA) is to foster interactions between basic science laboratories and clinicians performing clinical trials for patients with prostate cancer. Investigators are encouraged to propose pilot therapeutic clinical studies or new clinical trials (Phase I, II, or III) designed to improve therapy in prostate cancer patients. The application may include ancillary laboratory studies linked to the clinical trial. Applications must be focused on integrating clinical goals with laboratory research areas.

This RFA envisions funding therapeutic clinical studies that test and exploit basic findings concerning cellular targets of treatment or response to drug or hormone therapies. Clinical studies should involve human subjects and be designed to improve cancer treatment. Examples of clinical studies include: (1) growth factor or hormone therapies utilizing new agents; (2) treatment therapies for overcoming hormone, drug, or radiation resistance; (3) treatment therapies based on novel mechanisms of action; (4) biologics in combination with drug or radiation regimens; (5) new therapies combining endocrine manipulations with chemotherapeutic agents; and (6) radiation modifiers to enhance cell kill or protect normal tissue.

Laboratory research studies that are relevant to the therapeutic clinical studies may be included. Investigators already participating in relevant ongoing clinical trials are encouraged to develop related complementary laboratory studies. Laboratory experimentation may be designed to examine mechanism of action, mechanism of resistance, or conduct pharmacological analysis of the antitumor agents utilized in the patient studies. Laboratory studies designed to improve diagnosis or studies examining benign prostate disease are not applicable.

MECHANISM OF SUPPORT

Support of the program will be through the National Institutes of Health (NIH) grant-in-aid (R01). Applicants will be responsible for the planning, direction, and execution of the proposed project. Approximately $750,000 in total costs per year for three years will be committed specifically to fund applications submitted in response to this RFA. It is anticipated that three to four awards will be made. Applications with requested budgets greatly exceeding these general parameters may be at a disadvantage with respect to final funding decisions. This funding level is dependent on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to the present RFA should not exceed three years. The earliest feasible start date for the initial award will be July 1, 1992.

ELIGIBILITY REQUIREMENTS

Non-profit organizations and institutions, governments and their agencies, and occasionally individuals are eligible to apply. For-profit organizations are also eligible unless specifically excluded by legislation. Both domestic and foreign applicants may apply. Applications may be submitted from a single institution or may include arrangements with multiple institutions (e.g., consortia and Clinical Trials Cooperative Group) where appropriate.

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. The inclusion of women is standard terminology for all grants and contracts; however, due to the specific cancer subject of this RFA (Prostate), it is not applicable under this RFA.

INQUIRIES

This is an abbreviated version of the RFA. Copies of the complete RFA and additional information concerning the objectives and scope of this research may be obtained from:

Ms. Diane Bronzert
Program Director
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
Executive Plaza North, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX: (301) 480-4663

Written or telephone inquires of a budgetary, administrative, and/or policy nature should be directed to:

Ms. Carolyn Mason
Grants Management Specialist
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 243
6120 Executive Blvd.
Bethesda, MD 20892
Telephone: (301) 496-7800, extension 59
FAX: (301) 496-8601

ONGOING PROGRAM ANNOUNCEMENTS

COMBINED PSYCHOSOCIAL AND PHARMACOLOGIC TREATMENTS RESEARCH

PA: PA-91-54

P.T. 34; K.W. 0414000, 0710100, 0715129, 0715177

National Institute of Mental Health

The National Institute of Mental Health (NIMH) seeks applications from investigators to study the efficacy of combined psychosocial and pharmacologic treatment of specific mental disorders. Disorders of interest include schizophrenia, mood disorders, anxiety, somatoform, personality disorders, eating disorders, childhood and adolescent disorders, and mental disorders of the aging. NIMH is particularly interested in research on the relative efficacy of combined treatment compared with psychosocial or pharmacologic treatments administered singly in any of the above-mentioned disorders. Research investigations on acute, longer term, and maintenance phases of treatment are welcome. NIMH is also interested in the development of new empirical models for testing the efficacy of combined pharmacologic and psychosocial treatments.

ELIGIBILITY

These grants are available to any public, private, profit, or nonprofit institution such as a university, college, hospital, or community agency, and units of State or local governments and authorized units of the Federal government.

MECHANISMS OF SUPPORT

Research support may be requested through applications for the full range of research grant mechanisms, including but not limited to a regular research grant (R01), small grant (R03), First Independent Research Support and Transition (FIRST) award (R29), program project (P01), and Clinical Research Centers Program (P30). Applications must be prepared on the current version of the Public Health Service Form 398 (revised 10/88).

Support may be requested for a period of 5 years for individual research project grants (R01), program projects (P01), Clinical Research Centers (P30), and FIRST awards (R29), and up to 2 years for small grants (R03). FIRST and small grants are not renewable. Competing continuation applications may be submitted for R01s, P01s, and P30s for projects that plan to build on the findings of the previously supported research. A competing supplemental

application may be submitted for R01s and P01s during an approved period of support to expand the scope or protocol of a project.

Applications for all mechanisms under this program announcement will compete with other investigator-initiated applications. In fiscal year 1992, subject to availability of funds, it is estimated that approximately $500,000 will be made available to support three or four new regular research grants under this announcement at an average annual award amount of $150,000 - $200,000 in direct costs. Applications submitted in future years will compete with others submitted for funding.

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.

Investigators are encouraged to pay attention to certain methodological issues on the preparation of their applications. For example, the design should permit comparison of the combined treatment with one or both of its components and at lest one control condition. The investigator may consider a parallel

group design in which all treatments are initiated concurrently or a sequencing or constructive design in which psychotherapy is substituted for or added to a pharmacotherapeutic regimen or vice versa. There should be randomization or some form of systematic assignment to treatment and control groups that does not bias outcome in favor of one class of treatment.

Patient samples should meet DSM-III-R criteria for the disorder under study. The research protocol should include appropriate inclusion and exclusion criteria as well as information regarding how patients and control or comparison subjects will be recruited, assessed, and diagnosed. The type and format of psychosocial therapy must be specified, and in manual form. The pharmacologic treatment should also be specified with a well-defined dosage schedule and procedures for administration and management of the medication. It is desirable that no combination of treatment be studied unless evidence exists from controlled investigations of the efficacy of the individual modalities being combined for the specific disorder under study.

Outcome measures should be appropriate for the therapies being evaluated. Also, it is important to consider the patterns of effects, such as additive effects, interactive effects, facilitating, potentiating effects, negative effects, and effects over time. Investigators should give attention to possible bias in the research setting, and the data analysis plan should be appropriate to the research questions posed. This plan should be capable of providing statistical analysis of the interactive effects of treatment.

REVIEW PROCEDURES

Applications in response to this announcement will be reviewed on a nationwide basis in accordance with the usual Public Health Service peer review procedures for research grant applications. Applications will be accepted in accordance with the usual receipt dates for new applications. Award criteria include the quality of the application as determined by the initial review group and the appropriate Advisory Council, program relevance, and availability of funds.

For further information on programmatic issues and to request a copy of the full announcement, contact:

Barry E. Wolfe, Ph.D.
Mood, Anxiety and Personality Disorders Research Branch
Division of Clinical Research
Room 10C-24
Telephone: (301) 443-3568

H. Alice Lowery
Schizophrenia Research Branch
Division of Clinical Research
Room 10C-06
Telephone: (301) 443-3524

George T. Niederehe, Ph.D.
Mental Disorders of the Aging Branch
Division of Clinical Research
Room 7-105
Telephone: (301) 443-1185

Peter S. Jensen, M.D.
Chief, Child and Adolescent Disorders Research Branch
Division of Clinical Research
Room 10-104
Telephone: (301) 443-5944

Robert F. Prien, Ph.D.
Associate Director for Clinical Psychopharmacology
Division of Clinical Research
Room 10C-26
Telephone: (301) 443-4527

For further information on grants management issues, contact:

Stephen J. Hudak
Grants Management Section
Grants Management Branch
Room 7-23
Telephone: (301) 443-4456

The mailing address for all of the above is:

National Institute of Mental Health
5600 Fishers Lane
Rockville, MD 20857

This program is described in the Catalog of Federal Domestic Assistance No. 93.242, Mental Health Research Grants. Under the authority of Section 301 of the Public Health Service Act, P.L. 78-410, as amended, 42 U.S.C. 241, and subject to availability of funds, NIMH will accept grant applications in response to this announcement.

NEUROPEPTIDE MODULATION OF SALIVARY IMMUNITY

PA: PA-91-55

P.T. 34; K.W. 0710070, 0715148, 0760060, 0760075

National Institute of Dental Research

PURPOSE

The National Institute of Dental Research (NIDR) supports studies to improve knowledge of the development, structure, function, and diseases of the salivary glands and to determine the influence of salivary constituents on oral health. Toward this end, the NIDR seeks to stimulate basic and clinical research, research training, and manpower development in the broad area of neuropeptide modulation of the salivary immune system.

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 (PA), Neuropeptide Modulation of Salivary Immunity, is related to the priority area of Oral Health. 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).

BACKGROUND

The ability of the host to resist infection or to modify the colonization patterns of microorganisms that enter the oral cavity is, in part, dependent upon the presence of a fully functional mucosal immune system. In immunologically sufficient adults, secretory IgA is the major immunoglobulin species detected in salivary secretions and thus is considered to be the principal mediator of salivary immunity. Although antibody induction and cell migration studies have provided evidence supporting a linkage of salivary glands to the mucosal immune network, detailed investigations on the mechanism by which IgA committed B cells from gut-associated lymphoid tissue (GALT) "home" to the individual salivary glands, and studies on cell traffic between salivary glands have not yet been performed.

Two subclasses (IgA1 and IgA2) of IgA exist in serum and secretions of adults. In secretions, including saliva, as much as half of the IgA may be IgA2. The functional significance of these two subclasses is as yet unresolved. However, the IgA1 subclass proteins are cleaved by a group of bacterial proteases that do not affect the IgA2 subclass. These proteases, which are produced by several pathogenic species including suspected periodontal pathogens, may thus interfere with IgA-mediated immunity.

IgM, with a secretory component non-covalently attached, also can be detected in major salivary gland secretions of many adults. In conditions of IgA deficiency, this pentameric immunoglobulin often can be found to replace the absent IgA in saliva, thus providing a compensatory mucosal defense mechanism. IgG is only marginally detected in major salivary gland saliva, but is present in detectable and often significant amounts in saliva from minor salivary glands.

Increasing attention is being paid to the effect of the nervous system on immune function. Stress and mental illnesses are known to affect immune responses. The results of studies over the last decade indicate that the immune and neuroendocrine tissues produce, communicate, and regulate with a battery of similar, if not identical, informational molecules. Cells of these two systems produce molecules that were previously thought to be unique. It has been hypothesized for many years and now well documented that this communication is bidirectional with products of the neuroendocrine system

affecting the biological behavior of cells of the immune system and vice versa. Recent studies have demonstrated that neuropeptides, such as vasoactive intestinal peptide, substance P, and somatostatin, can differentially affect lymphocyte proliferation, immunoglobulin synthesis, and lymphokine production. Moreover, it has been established that lymphocytes can produce neuropeptides, such as endorphins and corticotropin hormone, and that lymphoid tissues are extensively innervated by adrenergic and peptidergic nerves. It is almost certain that these nerves release neuropeptides locally in lymphoid organs. Taken together with the fact that lymphocytes express specific receptors for various neuropeptides and that the concentration of neuropeptides in the mucosa is much higher than in the blood, these data implicate neuropeptides in the control of the mucosal immune system. This may be of importance for future clinical studies because neuropeptide regulation of salivary immunity could modulate inflammatory salivary diseases, dental caries, and periodontal disease or may influence colonization of the oral mucosa by opportunistic microflora. Furthermore, the development of pharmacologic agents to modulate the effects of neuropeptides on the salivary immune system will be of interest as the mechanisms by which neuropeptides modulate salivary immune or inflammatory processes are delineated.

OBJECTIVES AND SCOPE

Based on a recommendation by the Dental Research Programs Advisory Committee at its April 25-26, 1989 meeting, applications are invited for research project grants (including minority research supplements), program project grants, First Independent Research Support and Transition (FIRST) awards, small grants, career development awards, and postdoctoral fellowships in the broad area of neuropeptide modulation of the salivary immune system, including secretory immunity. Some examples of important aspects of salivary immunity for consideration in this connection might include, but should not be limited to:

- The migration of lymphocytes from gut-associated lymphoid tissue to and within salivary glands.
- The up/down regulation of cytokine receptors expressed by salivary lymphocytes and the role of cytokines in inducing B cell switches and terminal differentiation to immunoglobulin-producing plasma cells within specific gland types.
- The role of lymphocyte subset distribution in "unimmunized" and antigen-perturbed salivary glands in the regulation of immunoglobulin and antibody production.
- The cytokine induction of salivary gland epithelial cell differentiation with emphasis on enhanced secretory component production and polymeric IgA transport.
- The isotype, subclass, and molecular form (monomeric, polymeric, or secretory) distribution of immunoglobulins in salivas from neonatal and adult glands.
- The enhancement of immune response upon immunization via various routes (e.g., active stimulation of GALT and local antigen delivery) for the prevention of oral diseases.
- The potentially progressive lymphocytic infiltration that is a common feature of all organs (including salivary glands) affected by Sjogren's syndrome.

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

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The composition of the proposed study population must be described in terms of gender and racial/ethnic group, together with a rationale for its choice. In addition, gender and racial/ethic issues should be addressed in developing a

research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, 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

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

Applications considered appropriate responses to this announcement include the traditional research project grant (R01), the program project grant (P01), the First Independent Research Support and Transition (FIRST) award (R29), the small grant (R03), the postdoctoral individual fellowship (F32) and senior fellowship (F33) awards, and the following career development awards: the Modified Research Career Development Award (K04), the Physician Scientist for Dentists Award (K11), and the Individual Dentist Scientist Award (K15). The specific application forms and kits required in this connection are available in the business or grants and contracts offices of most academic and research institutions and may be obtained from:

Office of Grant Inquiries
Division of Research Grants
Westwood Building, Room 449
National Institutes of Health
Bethesda, MD 20892-4500
Telephone: (301) 496-7441

Applicants are encouraged to seek support from other public sources and private sector sources, including foundations and industrial concerns, for studies that will complement and expand the research supported by the NIDR. A summary of the objectives and financial support for such studies must be included in the application.

APPLICATION AND REVIEW PROCEDURES

Applications will be accepted on an indefinite basis in accordance with the receipt dates specified in the pertinent application kits.

Applications in response to this announcement will be reviewed in competition with other applications and in accordance with the usual National Institutes

of Health peer review procedures. The initial review for scientific and technical merit will be by an appropriate study section. Secondary review will be by an appropriate advisory council. The review criteria will be those customary for the support mechanism selected. Funding decisions will be based upon relative scientific merit, program relevance, and the availability of appropriated funds.

On the face page, item 2, of the application form PHS 398 (rev. 10/88), the word "Yes" must be checked and the phrase "Neuropeptide Modulation of Salivary Immunity, PA-91-55" must be typed in the space provided. In the case of fellowship applications, the same phrase must be typed on line 3 of the face page of form PHS 416-1 (rev. 7/88). The original and six copies of the application must be sent or delivered to:

Grant Application Receipt Office
Division of Research Grants
National Institute of Health
Westwood Building, Room 240
Bethesda, MD 20892-4500**

For further information concerning this announcement and the available mechanisms of support, applicants are encouraged to contact:

G.G. Roussos, Ph.D.
Chief, Caries, Restorative Materials, and Salivary Research Branch
National Institute of Dental Research
Westwood Building, Room 505
Bethesda, MD 20892-4500
Telephone: (301) 496-7884

For fiscal and administrative matters, contact:

Ms. Theresa Ringler
Grants Management Officer
National Institute of Dental Research
Westwood Building, Room 518
Bethesda, MD 20892
Telephone: (301) 496-7437

This program is described in the Catalog of Federal Domestic Assistance No. 93.122. Awards will be made under authorization 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.

CLINICAL INVESTIGATOR AWARD - NURSING

PA: PA-91-56

P.T. 34; K.W. 0785130, 0785035, 0710030

National Center for Nursing Research

PURPOSE

The Clinical Investigator Award (CIA) (K08) is designed to be a mid-career development award. The candidate is expected to conduct a research project in an area related to nursing systems, the promotion of health, prevention of disease, and mitigation of acute and chronic illnesses or disabilities.

OBJECTIVES AND ELIGIBILITY CRITERIA

The objective of this program is to enhance the development of clinically trained individuals into independent clinical investigators. The program enables candidates to investigate a well-defined problem under a sponsor competent to provide guidance in the chosen area of research at an NIH-supported center program, such as the specialized centers supported by the National Center for Nursing Research, the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute of Diabetes and Digestive and Kidney Diseases, or one of the General Clinical Research Centers supported by the National Center for Research Resources.

The candidate must:

- Be a U.S. citizen, a noncitizen national of the U.S., or have been lawfully admitted to the U.S. for permanent residence.
- Be a registered nurse.
- Hold a doctorate or equivalent degree.
- Show evidence of scholarly achievements (e.g., articles and books).
- Have sufficient research experience and background (generally 4-8 years beyond the doctorate) so that time devoted to research would ensure the development of a highly qualified nurse investigator. The candidate may not be a current Principal Investigator of a research grant (R01, R29, R15) nor have been a Principal Investigator in the past.
- Describe in detail the clinically oriented research project that is to be conducted under this support. Identify plans for a research development program designed to enhance the candidate's research skills (e.g., course work; clinical, laboratory, and statistical techniques; and application and usage of equipment). Clinically oriented research projects focusing on basic, biological, and/or behavioral research topics are appropriate and encouraged.
- Describe in detail the training component of the application. Provide a clear discussion of how the training component complements the research project to be conducted.
- Identify a sponsor (and a cosponsor if desired) who is working at an NIH-supported research center or a General Clinical Research Center. The sponsor (and cosponsor) must be recognized as an accomplished investigator in the research area proposed, have experience in training independent investigators, and be willing to provide the guidance for the awardee's development and research plan. The sponsor or the cosponsor must be committed to continue this involvement through the individual's total period of development under this award.
- Have the approval and a letter of support from the Center Director to allow him/her to pursue the research and share in the center's resources, if neither the sponsor nor the cosponsor is the director of the center where the candidate desires to conduct the research.
- Provide in the application letters of support from the sponsor and the cosponsor delineating the match with the applicant's research plans and their willingness to provide the necessary assistance for the candidate. Letters of support from the sponsor and the cosponsor must list the research fellows they have and will be monitoring during the period of this application.
- Provide a letter with strong justification for describing why the sponsor and the cosponsor were selected. The letters must detail the expertise of the sponsor and the cosponsor, the environment and resources, and level of commitment available to the candidate from the sponsor and the cosponsor, and the benefits the candidate will gain from the experience.
- Commit 75-100 percent effort to the proposed research and research-related activities.
- Document that the grantee institution is a domestic university, nursing school, or comparable institution with strong, well-established research and training programs in the chosen area and/or strong ties to the institution housing the Research Center Program that is to support the CIA candidate. The Center Director must have the interest, capability, and commitment to provide the environment to support clinically trained individuals in the development of independent research.

CONDITIONS OF THE AWARD

- Awards may be made for a period of 3 years and are not renewable.
- Allowable direct costs will not exceed $70,000 a year. The salary requested must be consistent with the established salary structure of the grantee institution for persons of equivalent

qualifications, experience, and rank up to a maximum of $50,000 per year plus related fringe benefits. Supplementation of salary from non-Federal sources is allowable. Requested effort must be at least 75 percent, but may range up to 100 percent for research and research-related activities. Salary and fringe benefits will be awarded accordingly (i.e., 75 percent of the candidate's full-time base salary up to a maximum of $50,000 plus associated fringe benefits for a guaranteed protection of 75 percent effort committed to research and research-related activities). In addition, Other Research Support costs (personnel other than the awardee, equipment, supplies, and travel) may be requested up to $20,000. In no case, however, will the total direct costs exceed $70,000.

- Indirect costs will not exceed 8 percent of the direct costs, exclusive of tuition and fees and equipment expenditures.

- The release or retention of salary and fringe benefit grant funds for the awardee on other PHS-supported research grants will be reviewed on a case-by-case basis. For example, such funds may be approved for retention if the effort is justified as above and beyond the total commitment to research funded in the NCNR CIA. Funds budgeted in a PHS-supported research or training grant for an individual's salary and applicable fringe benefits, but freed as a result of funding a career award for that individual, may not be used for any other purpose except when the individual no longer participates in the grant-supported activity and another individual replaces him or her and requires comparable remuneration.

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.

REVIEW CRITERIA

The following characteristics will be considered:

- Background and high potential of the candidate for a research career as a clinical investigator.
- Sponsor and cosponsor must have an active and productive program of research in the area of the candidate's research interests.
- Appropriate consultants for the concepts and methods used with the research proposal (e.g., theorists, methodologists, and statisticians).
- The scientific merit of the research project. The soundness of the plan for research development and training.
- The plan detailing the protection of the 75-100 percent of the candidate's time to be spent in research and research-related activities.
- Appropriateness of the availability of the environment and resources necessary to implement the proposal's program of research and development.
- Plan of the Center's support of the candidate during the period of the award.

REVIEW PROCESS AND METHOD OF APPLYING

Applications will receive initial scientific and technical review by the Nursing Science Review Committee (NRRC). Second level review will be by the National Advisory Council on Nursing Research.

Applications will be reviewed three times a year according to the following schedule:

Applications Received by	NRRC	Council Review	Earliest Starting Date
October 1	Feb/March	May/June	July 1
February 1	June/July	September/October	Dec 1
June 1	Oct/Nov	Jan/Feb	April 1

Applications must be submitted on the research grant application form PHS 398 (rev. 10/88). If not available at the institution's office of sponsored programs, it may be requested from:

Office of Grants Inquiries
Division of Research Grants
Westwood Building, Room 449
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7441

Completion of the application includes following the general instructions from the PHS 398 application form and incorporating the following additional information:

- Complete item 2 on the face page by typing in "NCNR K08 Clinical Investigator Award, PA-91-56."
- Utilize the Research Career Development Award (RCDA) Table of Contents, but relabel the page "Clinical Investigator Award."

- Complete a biographical sketch for the candidate, the sponsor, and the cosponsor.

- Provide information on "Other Support" and plans for the candidate, the sponsor, and the cosponsor.

- Utilize the Research Career Development Award Reference Guidelines, but relabel the page "Clinical Investigator Award Reference Guidelines." Submit four letters of reference documenting the candidate's research skills and experience.

NCNR CONTACTS FOR SPECIFIC RESEARCH AREAS OF EMPHASIS

Acute and Chronic Illness - Dr. Mary Lucas, Dr. Laura James
Health Promotion and Disease Prevention - Dr. Sharlene Weiss, Dr. June Lunney
Nursing Systems - Dr. Patricia Moritz, Dr. Barbara Pillar

National Center for Nursing Research
Building 31, Room 5B03
Bethesda, MD 20892
Telephone: (301) 496-0523

NCNR CONTACT FOR BUDGET AND ADMINISTRATIVE MATTERS

Ms. Sally Nichols
Grants Management Office
National Center for Nursing Research
Building 31, Room 5B06
Bethesda, MD 20892
Telephone: (301) 496-0237

This program is described in the Catalog of Federal Domestic Assistance No. 93.336, Nursing Research, and No. 93.866. Awards are under authorization of the Public Health Service Act, Title IV, Part A (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 Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review, April 6, 1988.

ACADEMIC INVESTIGATOR AWARD - NURSING

PA: PA-91-57

P.T. 34; K.W. 0785130, 0710030

National Center for Nursing Research

PURPOSE

The Academic Investigator Award (K07) is designed to be a mid-career development award. The candidate is expected to conduct a research project in an area related to nursing systems, the promotion of health, prevention of disease, and mitigation of acute and chronic illnesses or disabilities.

OBJECTIVES AND ELIGIBILITY CRITERIA

The objectives of this program are to enhance the development of research faculty in, and the research activities related to, nursing science, thus strengthening the research capabilities of individuals under the mentorship of their sponsors. The goal of this grant mechanism is to strengthen faculty expertise by enhancing knowledge and skills in a specialized focus area of nursing science.

The candidate must:

- Be a U.S. citizen, a noncitizen national of the U.S., or have been lawfully admitted to the U.S. for permanent residence.

- Be a registered nurse.

- Hold a doctorate or equivalent degree.

- Have an academic appointment at the sponsoring institution.

- Show evidence of scholarly achievements (e.g., articles and books).

- Have sufficient research experience and background (usually four to eight years beyond the doctorate) so that time released from teaching and administrative duties and devoted to research would ensure the development of a highly qualified nurse investigator. The candidate may be a current Principal Investigator on a research grant (R01, R15) or have been a Principal Investigator in the past (R01, R29, R15).

- Describe in detail the research project to be conducted under this support. Identify plans for a research development program designed to enhance the candidate's research skills (e.g., course work; clinical, laboratory, and statistical techniques; application and use of equipment).

- Describe in detail the career development plan of the application. Provide a clear discussion of how the career development plan complements the research project to be conducted.

- Identify a sponsor (and a cosponsor if desired) who is recognized as an accomplished investigator in the research area proposed, who has experience in training independent investigators and who will provide the guidance for the awardee's development and research plan. The sponsor or the cosponsor is not required to be a faculty member of the candidate's sponsoring institution, but must be committed to continue this involvement through the individual's total period of development under this award. If the sponsor or the cosponsor is geographically distant from the candidate, detailed rationale must be provided to document the sponsor-candidate relationship and level of commitment for the successful implementation and completion of the research proposed (e.g., travel plans, telephone conferences, and computer linkages). Letters of support from the sponsor and the cosponsor delineating the match with the applicant's research plans and willingness to provide the necessary assistance must be included in the application. Letters of support from the sponsor and the cosponsor must list the research fellows they have and will be monitoring during the period of this award.

- Provide a letter with strong justification for why the sponsor and the cosponsor were selected. The letter must detail the expertise of the sponsor and the cosponsor, the environment and resources, the level of commitment available to the candidate from the sponsor and the cosponsor, and the benefits the candidate will gain from the experience.

- Commit 75-100 percent effort to the proposed research and research-related activities.

The dean of the school must:

- Present in writing a detailed plan to protect 75-100 percent of the candidate's time to be spent in research and research-related activities.

- Identify and demonstrate availability of the environment and resources (populations of patients, manpower, materials, equipment, laboratory facilities of the sponsor and cosponsor) necessary to implement the proposed program of research and development.

CONDITIONS OF THE AWARD

- Awards may be made for a period of three years and are not renewable.

- Allowable direct costs may not exceed $70,000 a year. The salary requested must be consistent with the established salary structure of the grantee institution for persons of equivalent qualifications, experience, and rank up to a maximum of $50,000 per year plus related fringe benefits. Supplementation of salary from non-Federal sources is allowable. Requested effort must be at least 75 percent, but may range up to 100 percent for research and research-related activities. Salary and fringe benefits will be awarded accordingly (i.e., 75 percent of the candidate's full-time base salary up to a maximum of $50,000 plus associated fringe benefits for a guaranteed protection of 75 percent effort committed to research and research-related activities). In addition, Other Research Support costs (personnel other than the awardee,

equipment, supplies, and travel) may be requested up to $20,000. In no case, however, will the total direct costs exceed $70,000.

- Indirect costs will not exceed 8 percent of the direct costs, exclusive of tuition and fees and equipment expenditures.

- The release or retention of salary and fringe benefit grant funds for the awardee on other PHS-supported research grants will be reviewed on a case-by-case basis. For example, such funds may be approved for retention if the effort is justified as above and beyond the total commitment to research funded in the NCNR Academic Investigator Award. Funds budgeted in a PHS-supported research or training grant for an individual's salary and applicable fringe benefits, but freed as a result of funding a career award for that individual, may not be used for any other purpose. However, if the K07 awardee no longer participates in the grant-supported activity and another individual replaces him or her and requires comparable remuneration, the salary and fringe benefit funds may be used for the replacement.

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.

REVIEW CRITERIA

The following characteristics will be considered:

- Background and high potential of the candidate for a research career as an academic investigator.
- Sponsor and cosponsor must have an active and productive program of research in the area of the candidate's research interests.
- Appropriate consultants for the concepts and methods used with the research proposal (e.g., theorists, methodologists, and statisticians).
- The scientific merit of the research project. The soundness of the plan for research development and training.
- The plan detailing the protection of the 75-100 percent of the candidate's time to be spent in research and research-related activities.
- Appropriateness of the availability of the environment and resources necessary to implement the proposal's program of research and development.

REVIEW PROCESS AND METHOD OF APPLYING

Applications will receive initial scientific and technical review by the Nursing Science Review Committee (NRRC). Second level review will be by the National Advisory Council for Nursing Research.

Applications will be reviewed three times a year according to the following schedule:

Applications Received by	NRRC	Council Review	Earliest Starting Date
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February 1	June/July	Sep/Oct	Dec 1
June 1	Oct/Nov	Jan/Feb	April 1

Applications must be submitted on the research grant application form PHS 398 (rev. 10/88). If not available at the institution's office of sponsored programs, it may be requested from:

Office of Grants Inquiries
Division of Research Grants
Westwood Building, Room 449
5333 Westbard Avenue
Bethesda, MD 20892
Telephone: (301) 496-7441

Completion of the application includes following the general instructions from the PHS 398 application form and incorporating the following additional information:

- Complete item 2 on the face page by typing in "NCNR K07 Academic Investigator Award, PA-91-57."
- Utilize the Research Career Development Award (RCDA) Table of Contents, but relabel the page "Academic Investigator Award."
- Complete a biographical sketch for the candidate, the sponsor, and the cosponsor.
- Provide information on "Other Support" and plans for the candidate, the sponsor, and the cosponsor.
- Utilize the Research Career Development Award Reference Guidelines, but relabel the page "Academic Investigator Award Reference Guidelines." Submit four letters of reference documenting the candidate's research skills and experience.

NCNR CONTACTS FOR SPECIFIC RESEARCH AREAS OF EMPHASIS

Acute and Chronic Illness - Dr. Mary Lucas, Dr. Laura James
Health Promotion and Disease Prevention - Dr. Sharlene Weiss, Dr. June Lunney
Nursing Systems - Dr. Patricia Moritz, Dr. Barbara Pillar

National Center for Nursing Research
Building 31, Room 5B03
Bethesda, MD 20892
Telephone: (301) 496-0523

NCNR CONTACT FOR BUDGETARY AND ADMINISTRATIVE MATTERS

Ms. Sally Nichols
National Center for Nursing Research
Grants Management Officer
Building 31, Room 5B06
Bethesda, MD 20892
Telephone: (301) 496-0237

This program is described in the Catalog of Federal Domestic Assistance No. 93.336, Nursing Research, and No. 93.866. Awards are under authorization of the Public Health Service Act, Title IV, Part A (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 Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review, April 6, 1988.

RESEARCH ON HOSPITALIZATION OF ADOLESCENTS FOR MENTAL DISORDERS

PA: PA-91-58

P.T. 34; K.W. 0715129, 0770015, 0403001, 0745020

National Institute of Mental Health

PURPOSE

The National Institute of Mental Health (NIMH) seeks applications for the support of research on adolescents with mental disorders in both inpatient and residential treatment settings. This announcement will also support objective 6.3 of "Healthy People 2000: National Health Promotion and Disease Prevention Objectives." 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

Research issues of interest include: severity of illness, diagnoses, and characteristics of hospitalized adolescents; the types, intensities, and/or duration of treatment received by adolescents across treatment settings; development and testing of improved assessment criteria for hospitalization of adolescents; assessment of quality of care provided to adolescents in the inpatient setting; behavioral and social outcomes of inpatient treatment for adolescents with mental disorders; effects of payment mechanisms on access to hospital treatment, quality, and availability of treatment services and length of stay for various adolescent populations; role of juvenile justice system, social service system, and/or school system and their interface with hospitalized adolescents; alternate forms of treatment for adolescents with mental disorders; and effectiveness of hospital treatment for adolescents with mental disorders and co-occurring alcohol and/or drug abuse.

ELIGIBILITY

Applications may be submitted by any nonprofit or for-profit organization, including units of State and local governments.

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.

SUPPORT MECHANISMS

Research support may be requested through applications for an individual research grant (R01), the First Independent Research and Transition (FIRST) award (R29), and a small grant (R03).

PERIOD OF SUPPORT

Applicants may request support for up to five years for research projects. Small grants are limited to two years and may not be renewed. FIRST awards may be made for up to five years and are not renewable. Annual awards will be made, subject to continued availability of funds and progress achieved. During Fiscal Year 1990 the Services Research Branch of the NIMH Division of Applied and Services Research funded approximately $5 million in child and adolescent research.

APPLICATION PROCEDURES

Applicants must use the form PHS 398 (revised 10/88). The program announcement number and the short version of the title for this program announcement must be typed in item number 2 on the face page of the application form; also check "yes" on item 2.

The signed original and six 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 PROCEDURES

Applications will be reviewed in accordance with the regular PHS review schedule:

Receipt Dates New/Renewal	Initial Review	Advisory Council Review	Earliest Start Date
June 1/July 1*	Oct./Nov.	Jan./Feb.	Apr. 1
Oct. 1/Nov. 1*	Feb./Mar.	May/June	July 1
Feb. 1/Mar. 1*	May/June	Sept./Oct.	Dec. 1

*Amended applications (new or renewal) are to be submitted on the latter dates.

FURTHER INFORMATION

For further programmatic information, prospective applicants should contact:

Ann Hohmann, Ph.D., M.P.H. or Junius Gonzales, M.D.
Services Research Branch
Division of Applied and Services Research
National Institute of Mental Health
Room 18C-14
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-3364

For further information of a grants management nature, prospective applicants should contact:

Stephen J. Hudak, Chief
Grants Management Section
National Institute of Mental Health
Room 7C-23
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4456

This program is described in the Catalog of Federal Domestic Assistance, Nos. 93.242, 93.281, and 93.282). 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 and 92, the National Institute of Mental Health will accept applications in response to this announcement.

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

5333 Westbard Avenue
Bethesda, Maryland 20816

* U.S. G.P.O.:1991-281-826:20046