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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. 15
April 12, 1991**

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NOTICES

INSTITUTIONAL TRAINING APPLICATIONS FOR NATIONAL RESEARCH SERVICE AWARDS: APPLICATION RECEIPT DATES

P.T. 44; K.W. 0720005, 0404003, 0414000, 0404009

Alcohol, Drug Abuse, and Mental Health Administration

The Alcohol, Drug Abuse, and Mental Health Administration announces that beginning October 1, 1991, National Research Service Awards for Institutional Training applications (T32) will have only one receipt date, May 10. The applications will receive an October peer review by the appropriate Initial Review Group and be reviewed by the appropriate Advisory Council in early February. Funding decisions will be made in late February. The earlier notification of funding decisions will enable the timely recruitment of trainees. Requests for start dates as early as March 1 will be accepted, but the start date for most training programs will continue to be July 1. This notice applies to all T32 applications submitted to the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health. Training applications received after May 10 will be returned to the training director without review. The receipt and review of short-term training grants (T35s) will not change.

ANIMAL WELFARE EDUCATION PROGRAM

P.T. 34; K.W. 0502000, 0201011

National Institutes of Health

The National Institutes of Health (NIH), Office for Protection from Research Risks (OPRR), Division of Animal Welfare, is cosponsoring with the Washington University School of Medicine and the St. Louis University Medical Center an animal welfare education program entitled, "Recurrent Controversies in Protocol Review." The workshop will be held on May 2-3, 1991, at the Hyatt Regency Hotel at St. Louis Union Station, St. Louis, MO.

The meeting is open to institutional administrators, Institutional Animal Care and Use Committee (IACUC) members, laboratory animal veterinarians, scientific investigators, and other institutional staff who have responsibility for high-quality management of institutional animal care and use programs. The workshop will focus on the many controversial issues in protocol review and the responsibility of the IACUC in the resolution of protocol issues that fall into the gray area of professional judgment and discretion.

For further information, contact:

Office of Continuing Medical Education
Washington University School of Medicine
Telephone: (800) 325-9862 Interstate
(314) 362-6893 in Missouri

NOTICES OF AVAILABILITY (RFPs AND RFAs)

INSTITUTIONAL CLINICAL TRAINING GRANTS: PROFESSIONAL TRAINING ADDRESSING SEVERE MENTAL DISORDERS

RFA AVAILABLE: MH-91-10

P.T. 44; K.W. 0720005, 0715129, 0730050

National Institute of Mental Health

Application Receipt Date: June 12, 1991

PURPOSE

The purpose of the National Institute of Mental Health (NIMH) clinical training program is to enhance the quality and effectiveness of services to persons with major mental disorders. Insufficient numbers of well-trained mental health professionals are available to serve (1) severely and persistently mentally ill adults, e.g., adults with schizophrenic disorders or mood disorders, including homeless persons with these disorders; (2) seriously emotionally disturbed children and adolescents; (3) elderly persons with

mental disorders; (4) individuals with mental disorders in rural areas; (5) racial/ethnic minorities with mental disorders.

This program is designed to recruit and prepare mental health professionals in the core mental health disciplines of social work, psychiatric nursing, psychology, psychiatry, and marriage and family therapy who are well trained and experienced in modern mental health diagnostic, treatment, and rehabilitation techniques, research methodologies and findings, and the delivery of care within community-based systems.

TRAINING ISSUES

Applicants under this Request for Applications (RFA) must focus in depth on one or more of the priority populations described below. Programs must demonstrate that they incorporate the latest diagnostic and treatment procedures, as well as the latest relevant research findings. The priority service populations for this RFA are:

- o Severely and persistently mentally ill adults
- o Children and adolescents with mental disorders
- o Elderly with mental disorders
- o Mentally ill in rural areas
- o Racial/ethnic minorities with mental disorders

Additional cross-cutting priorities are linkages between academic programs and State/community service systems, i.e., public-academic linkages and linkages with clinical researchers and research trainers. All programs must also show evidence that curriculum content and clinical field experiences address ethnic and cultural issues.

ELIGIBILITY

Accredited and/or approved departments/divisions in the mental health disciplines of psychiatric nursing, psychiatry, psychology, social work, and marriage and family therapy in colleges or universities of the United States, including territories and possessions, are eligible to apply. Multidisciplinary applications are encouraged. One clinical training grant may be applied for in each of the core disciplines under this RFA.

APPLICATION CHARACTERISTICS

Applications must include a brief description of the applicant educational institution and, if appropriate, associated service and clinical research settings, including background, history, programmatic focus, organization, resources, personnel, and record of educational/service/research linkage achievements.

TERMS AND CONDITIONS OF SUPPORT

In fiscal year 1991, approximately \$1.2 million will be available to fund approximately 15 to 20 3-year awards under this RFA. The mechanism of support will be the graduate training programs (T01). Awards will be limited to a maximum of \$80,000 (total costs) per year, with the exception of multidisciplinary awards that may be funded up to \$120,000 (total costs) per year.

Payback Provisions

Any trainee who receives a clinical traineeship in psychology, psychiatry, psychiatric nursing, social work, or marriage and family therapy, in an established training program, designed to be for a period of 180 days or more under an NIMH clinical training grant, must pay back a period of obligated service equal to the length of the traineeship.

APPLICATION PROCEDURES

Applications kits (PHS 398, rev. 10/88) containing the necessary forms and Special Instructions must be obtained by contacting the Education and Training Branch staff. Applicants must use the Special Instructions included in the application kit, specifically designed for this NIMH Institutional Clinical Training Grant program.

REVIEW OF APPLICATIONS

A dual review system is used to ensure expert, objective review of the quality of applications. The first step, peer review for educational and technical merit, is by primarily non-Federal experts comprising Initial Review Groups. Notification of the review recommendations will be sent to the applicant after the initial review. The final review is by the National Advisory Mental Health Council. Only applications recommended for approval by the Council may be considered for funding.

RECEIPT AND REVIEW SCHEDULE

Receipt of Application	Initial Review	National Advisory Mental Health Council Review	Earliest Award Date
June 12, 1991	July	September	September 1991

STAFF CONSULTATION

Staff consultation on clinical training grants is available from:

Lemuel B. Clark, M.D., Chief
Education and Training Branch
Division of Clinical Research
National Institute of Mental Health
5600 Fishers Lane, Room 7C02
Rockville, MD 20857
Telephone: (301) 443-5850

Additional information on payback requirements and fiscal and administrative issues is available from:

Mr. Stephen Hudak
Chief, Grants Management Section
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-26
Rockville, MD 20857
Telephone: (301) 443-4456

MENTAL HEALTH CLINICAL TRAINING GRANTS: INDIVIDUAL FACULTY SCHOLAR AWARDS

RFA AVAILABLE: MH-91-14

P.T. 44; K.W. 0720005, 0715129, 0785185, 0414000, 0417000

National Institute of Mental Health

Application Receipt Date: June 12, 1991

PURPOSE

There is a marked disparity between the need for treatment of persons with major mental disorders and the availability of appropriately trained mental health professionals to assess, provide, and supervise the treatment. For this reason, the National Institute of Mental Health (NIMH) supports the Individual Faculty Scholar Awards program to develop a cadre of academically based faculty scholars who will guide the training of professionals in the core mental health disciplines (psychiatry, social work, psychology, psychiatric nursing, and marriage and family therapy) and who will play major leadership roles in the continued development of their professions.

PRIORITIES

Schizophrenic Disorders

The National Institute of Mental Health (NIMH) has designated schizophrenia as one of its foremost research priorities. In so doing, NIMH recognized the enormous public health challenge posed by schizophrenia, acknowledged the immense and chronic burden borne by people with this disorder and by their families, and made a commitment to rapidly advance our state of knowledge and clinical training relative to this major mental illness. Faculty who are expert clinicians and researchers are needed to train additional mental health professionals to provide services for those affected by this illness.

Mood, Anxiety, and Personality Disorders

Mood, anxiety, and personality disorders rank among the most serious and pervasive public health problems in the United States. Depressive disorders affect one in twenty American adults in any one-month period, and the figures for anxiety are even higher. Most persons with depression also have an anxiety disorder. Although effective psychotherapeutic and pharmacological treatments exist, research shows that most depressed and anxious persons are undiagnosed, often untreated, and frequently treated inappropriately. Improved service provider training is needed and possible. Faculty with clinical and research expertise in these disorders are needed to train service providers and researchers.

Severe Mental Disorders of Children and Adolescents

Major efforts are needed to increase understanding of the causes and determinants of child and adolescent psychopathology, determine the effectiveness of biologic, psychotherapeutic, and social treatments, develop more effective service delivery systems, and enlarge the cadre of qualified, committed researchers and clinicians. The critical shortage of mental health professionals trained to diagnose, treat, and rehabilitate children and adolescents with severe mental disorders requires focused clinical and research training programs.

Mental Disorders of the Aging

Risk factors for mental disorders multiply through old age along such dimensions as physical limitation, social disruption, and psychological loss. Many surveys have shown increases in the prevalence of symptoms of depression in Alzheimer's disease and other dementing disorders and in behavioral problems such as sleeplessness, agitation, and confusion that are disruptive to established patterns of family and community life. Faculty leadership to establish research and training programs in geriatric mental health is extremely limited; growth in this area represents a significant priority in NIMH.

In addition to these four priority areas, scholars are encouraged to focus on specific subgroups that continue to be underserved. The problem of co-morbidity (i.e., the mentally disordered who are also substance abusers) is recognized as a challenge since 32 percent of persons with mood disorders and 47 percent of persons with schizophrenia also have an addictive disorder. Other subgroups include minority and rural populations.

Another area of interest is the development of strong ties between academic mental health training institutions and public mental health facilities. These systems offer a rich opportunity for enhanced services in the public sector. Thus, NIMH strongly encourages faculty scholar proposals that demonstrate collaborative linkages between academic centers and those public mental health service settings where the seriously mentally ill receive treatment.

ELIGIBILITY

On behalf of a qualified nominee, applications may be submitted by an academic department or professional school in a U.S. college, university, or nonprofit mental health training institution.

Nominees must be U.S. citizens or have been lawfully admitted to the United States for permanent residence. Nominees must have a full-time academic appointment or be assured of such an appointment upon completion of this award. Women and minority candidates are particularly encouraged to apply.

Payback

Any graduate or postgraduate trainee, including a faculty scholar awardee, in psychology, psychiatry, nursing, social work, or marriage and family therapy who receives support in an established training program designed to be for a period of 180 days or more under an NIMH clinical training grant must pay back through a period of obligated service equal to the length of support. The period of support need not be continuous. Any support received for any period of time under previous NIMH clinical training grants, if the stipend was awarded on or after September 1, 1981, will count toward this total. The conditions of the obligated service requirement are set forth in the 42 Code of Federal Regulations Part 64a.

APPLICATION PROCEDURES

Application kits (PHS 398, rev. 10/88) are available from the Education and Training Branch, Division of Clinical Research, NIMH (see the final section of this announcement). Applications to be considered for fiscal year 1991 funding, with an expected start date of September 1991, must be received (not post-marked) by June 12, 1991.

REVIEW OF APPLICATIONS

A dual review system is used to ensure expert, objective review of the quality of applications. Initial peer review for educational and technical merit is by Initial Review Groups (IRGs) comprised of non-Federal mental health authorities. Final review is by the National Advisory Mental Health Council whose review may be based on policy as well as educational and technical merit.

AWARD CRITERIA

It is anticipated that in fiscal year 1991 up to six new Individual Faculty Scholar Awards (T01) will be made. The maximum total cost per award is estimated to be \$117,000 per year. A disciplinary school or department in a single institution may submit multiple faculty scholar applications as long as each focuses on a different priority area. In considering multiple requests, however, applicants should be aware that NIMH funding decisions are based, at least in part, on disciplinary and geographic distribution considerations. Awards will be limited to one per professional school or academic department for each priority area.

The responsibility for award decisions on applications recommended for approval by the National Advisory Mental Health Council lies solely with authorized NIMH program staff. The following basic criteria will be used in making award decisions:

- o quality of the overall application as determined during the review process
- o quality of public-academic linkages provision
- o where appropriate, balance among disciplines, geographic locations, and priority areas
- o availability of funds

STAFF CONSULTATION

Application kits and staff consultation on all aspects of clinical training in the core mental health disciplines in relation to schizophrenic disorders, mood disorders, and severe mental disorders of children and adolescents, with the exception of specific research issues bearing upon these populations, are available from:

Lemuel B. Clark, M.D., Chief
Education and Training Branch
Division of Clinical Research
National Institute of Mental Health
5600 Fishers Lane, Room 7C02
Rockville, MD 20857
Telephone: (301) 443-5850

Additional information on payback requirements and fiscal and administrative issues is available from:

Mr. Stephen Hudak
Chief, Grants Management Section
Grants Management Branch
National Institute of Mental Health
5600 Fishers Lane, Room 7C-26
Rockville, MD 20857
Telephone: (301) 443-4456

PUBLIC HEALTH APPROACHES TO BREAST AND CERVIX SCREENING

RFA AVAILABLE: CA-91-14

P.T. 34; K.W. 0715035, 0745020, 0745027, 0745035

National Cancer Institute

Letter of Intent Receipt Date: June 7, 1991

Application Receipt Date: August 2, 1991

The Division of Cancer Prevention and Control (DCPC) of the National Cancer Institute (NCI) invites grant applications from a consortium of public health agencies or institutions to develop, implement, and evaluate programs designed to increase breast and cervical cancer screening of older, low income, low education, and minority women. Priority will be given to applications specifically designed to include evaluation of breast and cervical screening utilization of women over the age of 65 and those targeting populations residing in rural areas. Among Hispanic women, priority will be given to applications targeting Puerto Rican and Cuban populations to provide more comprehensive information on Hispanic populations. The NCI currently funds projects targeting Hispanic women of Mexican descent.

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 Request for Applications (RFA) 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).

RESEARCH GOALS AND SCOPE

The goal of this project is to develop, implement, and evaluate programs designed to increase breast and cervical cancer screening of older, low income, low education, and minority women.

The primary objectives of this research are to demonstrate how a consortium of community agencies can:

- 1) Characterize utilization patterns for breast and cervical screening in the target population through baseline surveys. These data will establish frequency of screening, as well as assess barriers to utilization.
- 2) Design and pilot test interventions to recruit women in need of breast and cervical cancer screening regimens that can
 - o be integrated with other health services used by these women
 - o affect the behavior of non-health agency clients.
- 3) Evaluate the effectiveness of specific interventions to reach the target population for breast and cervical cancer screening.
- 4) Ensure compliance with follow-up recommendations for women with anything but completely normal mammograms (i.e., indeterminate or suspicious findings) and smears (i.e., further action recommended).
- 5) Establish a mechanism to describe prospectively the screening behavior of the targeted women in view of current NCI recommendations, i.e., establish whether or not women are coming back at recommended intervals for screening.

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

The following is the NIH and ADAMHA policy regarding the inclusion of women and minorities in study populations. Applications that are responsive to this RFA will, by definition, meet the requirement for inclusion of women. The inclusion of minorities must be addressed in application submitted responding to this announcement.

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.

ELIGIBILITY REQUIREMENTS

Grants-in-aid may be awarded to profit and nonprofit organizations and institutions, and governments and their agencies within the United States. However, it should be noted that this RFA is primarily targeted at demonstrating a consortium approach, involving public agencies or institutions, such as health departments, community and migrant health centers, or public hospitals with established linkages to the target population (e.g., the health department or community health center may have experience with providing or contracting for the health services, a regional agency on aging may have established networks with elderly women, and a voluntary organization may have experience with providing public education campaigns). This approach seeks to address the problem in a coordinated fashion while taking advantage of the public agency's role as noncompetitive collaborator, stimulator, convenor, and facilitator of existing resources to increase mammography and Pap smear utilization in women least likely to be screened. The lead agency must demonstrate experience with disease control but does not necessarily need to be the direct provider of the screening services. In many communities, the lead agency is likely to be a health department, however, other public agencies could fill this role. Among the team of applicants or consortium, one institution must be proposed as the lead institution to serve as the applicant and assume responsibility for the conduct of the award.

MECHANISM OF SUPPORT

Support of this program will be through a National Institutes of Health (NIH) grant-in-aid (R01). Applicants will be responsible for the planning, direction, and execution of the proposed project. Allowable direct costs for the intervention will not include funds to pay for mammograms and Pap smears. However, expenses incurred in developing and promoting the utilization of these services, such as baseline and follow-up surveys, design of materials, and public and professional education are considered allowable costs. Except as otherwise stated in this RFA, awards will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement, DHHS Publication No. (OASH) 90-50,000, revised October 1, 1990.

This RFA is a one-time solicitation. Future unsolicited competing renewal applications will compete with all investigator-initiated applications and be reviewed by the Division of Research Grants (DRG). However, if the NCI determines that there is a sufficient continuing program need, a request for renewal applications will be announced. Only recipients of awards under this RFA will be eligible to apply.

Approximately \$5,400,000 in total costs for four years (\$1,200,000 for year one and for year four, \$1,500,000 for years two and three) will be committed to fund applications submitted in response to this RFA. It is anticipated that three to four awards will be made, depending on the receipt of a sufficient number of applications of high scientific merit. The total project period for applications submitted in response to this RFA must not exceed four years. The earliest feasible start date for the initial awards will be April 1992. Although this program is provided for in the financial plans of the NCI, the award of grants pursuant to this RFA is also contingent upon the availability of funds for this purpose.

INQUIRIES

Copies of the complete RFA and additional information concerning the objectives and scope of this research may be obtained from:

Helen I. Meissner, Sc.M., C.H.E.S.
Program Director
Public Health Applications Research Branch
National Cancer Institute
EPN, Room 239G
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-0273

Grants management inquiries should be directed to:

Marian F. Focke
Grants Management Specialist
Grants Administration Branch
EPS, Room 242
Grants Administration Branch
National Cancer Institute
9000 Rockville Pike
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 46

DIAGNOSIS AND TREATMENT OF LYME DISEASE

RFA AVAILABLE: AR-91-04

P.T. 34; K.W. 0715125, 1002032, 0745020, 0745070

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: May 1, 1991

Application Receipt Date: June 17, 1991

I. PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for grants to conduct research on the diagnosis and treatment of Lyme disease.

II. BACKGROUND

Lyme disease is a spirochetal disease, usually transmitted by the bite of a tick, most often by a nymphal *Ixodes dammini*, when they are prevalent in the Spring. It has become the most common tick-borne illness in the United States, with approximately 8,800 new cases reported in 1990.

Lyme disease remains difficult to diagnose, in part because the causative agent, *Borrelia burgdorferi*, is usually not easily cultured or directly observable from patients' specimens. Currently available standard laboratory tests are not fully satisfactory in that they lack sensitivity and specificity and are not well standardized.

Underdiagnosis has proven to be a problem in parts of the country where it is not endemic or is relatively uncommon. Lyme disease can present with a wide variety of signs and symptoms, making it difficult for physicians with little or no experience with it to make a correct diagnosis. On the other hand, in parts of the country where Lyme disease is well established and where there has been extensive publicity, patients with signs and symptoms suggestive of Lyme disease may be diagnosed inappropriately as having the disease when in fact they have some other disease resembling it.

Both aspects of this problem could be addressed by more sensitive, accurate, and inexpensive diagnostic tests. In general, serologic tests currently available do not detect some cases of early Lyme disease; conversely, in the later stages of the disease, tests are often too sensitive and less specific.

Once diagnosed, the manifestations of Lyme disease appear to be potentially treatable with a variety of antibiotics. The optimal regimen, including choice of drug, dose, route of administration, and length of therapy, has yet to be determined. Further clarification is also needed to determine the best method of treating disease sequelae at both early and late stages of Lyme disease.

RESEARCH GOALS AND SCOPE

The goal of this Request for Applications (RFA) is to stimulate research to effect better diagnosis and treatment of Lyme disease. Applications submitted in response to this RFA are expected: to concentrate upon developing and testing methods of diagnosis that are more reliable, accurate, and sensitive than current techniques to detect Lyme disease in patients; and/or to develop and test improved ways to treat all aspects (arthritic, cardiac, neurologic, and so forth) and stages of the disease.

Specific issues that may be addressed include, but are not limited to:

Diagnosis:

- o Classification and validation of clinical criteria;
- o Proper identification of erythema migrans (in contrast to non-tick insect bites);
- o Whether diagnostic criteria differ in children and adults;
- o Optimal methods for serodiagnosis;
- o The effect of therapy on serodiagnosis;
- o The utility of various biological fluids and tissue for diagnosis;
- o The best and most sensitive methods to detect spirochetal antigens;
- o Differential diagnosis strategies.

Treatment:

- o Drugs to be used in treating erythema migrans;
- o Optimal treatments for arthritis, neurologic, cardiac, and other later manifestations of Lyme disease;
- o Appropriate treatment of Lyme disease in children;
- o Appropriate treatment of Lyme disease in pregnant women;
- o Utility of prophylactic antibiotics in exposed individuals from endemic areas;
- o Appropriate treatment of congenital Lyme disease.

MECHANISM OF SUPPORT

Applications considered appropriate responses to this RFA are the traditional research project grant (R01). Approximately \$1,500,000 in total costs per year for three to five years will be committed by the NIAMS specifically to fund applications submitted in response to this RFA. Approximately seven awards are expected to be made for this RFA.

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 and 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.

REVIEW PROCEDURES AND CRITERIA

Applications will be reviewed initially by the Division of Research grants for completeness and will be assigned to a special NIAMS review group. Evaluation for responsiveness to the RFA is an NIAMS program staff function. Applications that are judged non-responsive will be returned to the applicant but may be submitted as investigator-initiated applications at the next receipt date. Those applications judged to be both responsive and competitive will be evaluated for scientific/technical merit by an appropriate initial review group convened by the NIAMS Review Branch. The second level of review will be conducted by the National Advisory Council of the NIAMS.

APPLICATION PROCEDURES

The research grant application form PHS 398 (revised 10/88) must be used in applying for these grants. These forms are available at most institutional business offices and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892.

Applications must be received by June 17, 1991. If an application is received after that date it will be returned to the applicant. If the application submitted in response to this RFA is substantially similar to a research grant

application already submitted to the NIH for review, but has not yet been reviewed, the applicant will be asked to withdraw either the pending application or the new one. Simultaneous submission of identical applications will not be allowed, nor will essentially identical applications be reviewed by different review committees. Therefore, an application cannot be submitted in response to this RFA that is essentially identical to one that has already been reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

Letter of intent: Prospective applicants are asked to submit a letter of intent by May 1, 1991. This letter should include the name of the institution any other participating institutions, the Principal Investigator and other key investigators, and a descriptive title. Such a letter of intent is not binding and will not enter into the review of any application subsequently submitted, nor is it a necessary requirement for application. Letters of intent are requested solely for review planning purposes. NIAMS staff will not provide responses to such letters. Letters of intent are to be sent to:

Dr. Tommy L. Broadwater
Chief, Grants Review Branch
Extramural Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 5A05A
Bethesda, MD 20892
Telephone: (301) 496-0754

The full RFA may be obtained from:

Dr. Lawrence Petrucelli
Arthritis Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
5333 Westbard Avenue
Westwood Building, Room 405
Bethesda, MD 20892
Telephone: (301) 496-7326

For fiscal and administrative matters, contact:

Diane M. Watson
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 407-A
Bethesda, MD 20892
Telephone: (301) 496-7495

ONGOING PROGRAM ANNOUNCEMENTS

CHILD AND ADOLESCENT MENTAL HEALTH SERVICE SYSTEM RESEARCH DEMONSTRATION PROJECTS

PA: PA-91-40

P.T. 34, AA; K.W. 0715095, 0715129, 0403004

National Institute of Mental Health

PURPOSE

This announcement, based on recommendations in the "National Plan for Research on Child and Adolescent Mental Disorders" and on part of the National Institute of Mental Health (NIMH) Public-Academic Liaison (PAL) initiative, is intended to stimulate investigator-initiated research demonstration projects (R18s) of State and local-level service systems for children and adolescents with, or at risk for, serious emotional or mental disorders. The purpose of this announcement is to advance the development of research that will contribute to the establishment and maintenance of effective mental health service delivery systems for children and adolescents with, or at risk for, serious emotional or mental disorders, especially those systems that include community-based services and interagency coordination.

A number of factors have converged to create a need for a research demonstration program that can enhance service systems developed previously under the Child and Adolescent Service System Program (CASSP). First, States and communities have moved toward the creation of balanced systems of care that encompass a full range of community-based service options for children

and adolescents with severe emotional disturbance and their families. This has created new challenges in understanding how to develop effective service delivery systems to meet the needs of this population. Second, to meet the requirements of P.L. 99-660, States are increasingly interested in improving their systems of care for children and adolescents. And third, there is an increasing interest in the development of interventions to improve outcomes in high-risk children and adolescents (as reflected in P.L. 99-457).

Areas that particularly need to be studied include innovative service system models that follow the CASSP principles of multi-agency, community-based, child and family-centered care. Such models are being developed by State and private service system demonstration efforts (e.g., the Robert Wood Johnson Foundation Child Mental Health Initiative). Also, little is known about youth at risk for severe emotional disturbance. Appropriate, accessible, and comprehensive services for these troubled youth are uncommon, and little systematic research has been conducted to determine the characteristics of this population and the most efficacious way of organizing and providing a system of care for them. Even those service models that successfully manage and coordinate care for this population have not been rigorously studied. The research demonstration mechanism will provide a rigorous approach to study the effectiveness of innovative models of providing, organizing, and/or financing services for children and adolescents with, or at risk for, serious emotional and mental disorders by studying service interventions applied in actual service settings.

Applications for research demonstration projects must be designed to address specific questions and produce data that show the effectiveness of different approaches to service system development. Investigators are especially encouraged to assess the system from the perspective of individual children and families and to include clinical outcome measures as well as assess the broader impact of these new systems on both child and family functioning and quality of life.

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

For projects involving clinical research, ADAMHA requires applicants to give special attention to the inclusion of women and minorities in study populations. If women and 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.

ELIGIBILITY

Only State mental health authorities, other State agencies in which the State-wide responsibility for child mental health resides, or other State child services coordinating organizations as designated by the Governor, are eligible to apply for these grants in coordination with local service agencies, universities, and research organizations. Applications from the latter organizations must be accompanied by a letter from the Governor making such a designation. Entities that have been so designated from a prior CASSP grant need not submit an additional letter of designation. Women and minority investigators are especially encouraged to be included in the application.

Since these grants are for service system development for children and adolescents with, or at risk for, serious emotional or mental disorders at the State and then the community level, it is imperative that the proper State mental health financing and planning authority be the entity from which the grant activities are performed. The degree of coordination across State agencies required to develop the type of systems needed by the target population can best happen at the State level.

APPLICATION PROCEDURES

Applicants must use the current version of form PHS 398 (revised 10/88). PHS 398 application kits are available from most universities and are also available from:

Child and Family Support Branch
Division of Applied and Services Research
National Institute of Mental Health
5600 Fishers Lane, Room 11C-05
Rockville, MD 20857
Telephone: (301) 443-1333

Type the number of this Program Announcement PA-91-40 and the title "Child and Adolescent Mental Health Services Research Demonstration Project" in item 2 of the face page of the application.

The original and six (6) copies of the application must be received (not postmarked) by the close of business on receipt date at the latest; applications received after receipt date will be held for review during the next cycle.

Applications must be sent to:

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

PERIOD OF SUPPORT AND AVAILABILITY OF FUNDS

Applications assigned to NIMH will be considered for a maximum of three years of support to cover both direct and indirect costs. It is recognized that applicants may want to extend the period of support to continue a longitudinal study of subjects. When such a design is anticipated, applicants should outline the full scope of the project and propose to reapply during the third year for competitive continuation funding. In FY 1990, approximately \$1.5 million was available to support four projects.

RECIPT AND REVIEW SCHEDULE

To be considered for FY 1991 funding, applications must be submitted by June 1, 1991.

Applications that are received after the June 1, 1991, receipt date will be reviewed in accordance with the regular 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.

Applicants are encouraged to contact Institute staff before applying for an award:

Ira S. Lourie, M.D.
Chief, Child and Family Support Branch
or Diane L. Sondheimer
Chief, Research Demonstration Program, CFSB
Division of Applied and Services Research
National Institute of Mental Health
Parklawn Building, Room 11C-05
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-1333

For fiscal and administrative matters, contact:

Stephen Hudak
Chief, Grants Management Section
National Institute of Mental Health
Parklawn Building, Room 7C23
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4456

ECONOMICS OF AGING, HEALTH, AND RETIREMENT

PA: PA-91-41

P.T. 34, CC; K.W. 0710010, 0715000, 0408006, 0413001, 0417000

National Institute on Aging

I. BACKGROUND AND GOALS

The National Institute on Aging (NIA) invites qualified researchers to submit applications on the Economics of Aging, Health, and Retirement.

Research in economic and health issues relevant to the older population will be particularly important given continued increases in life expectancy. With these additional years of old age, new patterns of labor force participation and retirement have emerged. For example, in the U.S. older workers, particularly men, are living longer yet retiring earlier. Work behaviors are directly related to the economic status of the elderly population. Many of the oldest elderly women, especially those who are widowed and who did not participate continually in the labor force, have an especially high rate of poverty. As the size of this fast growing subgroup of the older population increases, shifts in the financial well-being of the older population can be expected. In the future, many older persons may have inadequate financial resources to support themselves during lengthy periods of chronic illness or disability. Research that focuses on the current profile of labor force participation and health is needed to identify emerging patterns and trends among the elderly.

Given the impending changes in the size, composition, and characteristics of the elderly population, research on life course transitions of the elderly is necessary to ensure the provision of health and retirement services for tomorrow's elderly. Over the life course, people face a number of economic constraints within which they have to make a series of decisions, for example, how much to save for retirement, when to retire, what types of life, health, and long-term care insurance to carry, how to consume savings, when to sell a house, with whom to live. Functional limitations also play a role in economic decision making of the elderly. For example, an older disabled person may choose to live with a child rather than use community care services. These financial decisions eventually affect the well-being of the older person. Thus, transitions in work, economic well-being, health, and interdependency are all interwoven, and research on life course transitions is needed to better understand such complex relationships.

This announcement reflects the broad responsibilities of the NIA that was established by law in 1974 for the "conduct and support of biomedical, social, and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged." This announcement is coordinated with, but does not replace, other relevant announcements from the Behavioral and Social Research Program, such as Behavioral and Social Research on Aging, the Oldest Old, and Formal Health Care. While this announcement is focused primarily on economic analysis, several of these research issues include demographic, sociological, and psychological approaches, as in these other announcements.

II. SPECIFIC OBJECTIVES

A wide range of studies related to health and retirement economics of the elderly are solicited, including studies of A) the dynamics of life course transitions, B) cross-sectional and trend analyses, and C) methodological analyses.

Longitudinal studies of transitions over the life course, including cross-cultural comparisons, are of particular interest. Cross-sectional studies are also of interest; in some cases cross-sectional studies may be the most appropriate, and in other cases longitudinal data may be unavailable. Appropriate methodological studies are welcome. In addition, applicants may propose experiments and innovations that will lead to the enhanced well-being of older people.

The following is a nonexhaustive listing of major topics of concern; projects that focus on under-researched topics are particularly encouraged.

A. Studies of Life Course Transitions

Aging can be considered a movement through a series of life events. A dynamic approach to the study of life course events recognizes that transitions are not only dependent on factors present at the time of transition, but are also

related to previous transitions. Major life course transitions relate to work and retirement decisions, wealth accumulation and decumulation, health status changes, long-term care, and housing and living arrangements.

1. Labor force participation and retirement

Most analyses of labor force participation and retirement have been static; the few dynamic models have oversimplified the complex processes in work transitions and labor market exits. Behavioral models are needed to explain research questions such as:

- o What are the economic antecedents and consequences of retirement? What are the relative magnitudes of pension and health (or other social) effects on retirement? How do economy-wide, firm-specific, and occupation-specific (e.g., health and scientific personnel, academics, agricultural workers) factors influence full-time to part-time employment transitions? What are the economic, organizational, and perceptual factors related to early retirement plans?
- o How does disease progression interact with the work environment of older workers?
- o What are the economic implications of programs designed to encourage older persons to remain in or re-enter the labor force? How will the American's with Disadvantages Act impact on disabled older workers? What factors encourage employees to retain older disabled workers?

2. Economic well-being

Although the financial status of the older population has improved on average, significant subgroups of this population experience considerable economic hardship and poverty. Little is known about the dynamics of entry into poverty in old age. Our knowledge of the changes over time in consumption of goods and services by the elderly is also limited. Studies should focus on both the causes and effects of changes in economic well-being of older persons, and may include topics such as:

- o What are the effects on income and wealth of events such as widowhood, divorce, remarriage, illness, retirement, and migration? What factors erode or enhance economic well-being of older people and how can these be incorporated in public policy? What are the special factors affecting minority elderly, women or men, living alone, and the oldest old?
- o What are the implications of current and projected patterns of bequests and inheritances?
- o How does financial status affect transitions in the health and well-being of older people?
- o What are the economic aspects of inter-generational exchanges, such as the provision of care in the home by friends and relatives?

3. Health and functioning

Since there have been virtually no data sources that include adequate longitudinal information on health and economic status combined, little is known about the economic causes and consequences of illness and disability. Questions of interest include:

- o How do disease progression and changes in functional status interact with health-care expenses, wealth, and economic well-being of older persons and their spouses and children? How is economic status correlated with health and functional status (including duration of disabling episodes) over the life cycle, and what are the implications of these correlates?
- o What are the costs of chronic diseases of old age such as Alzheimer's, arthritis, heart disease, diabetes, general frailty, and the economic benefits of interventions such as prevention, geriatric assessment, and case management? How should such calculations treat issues such as co-morbidities, competing causes of death, and the direct (monetary) and indirect (e.g., opportunity) costs of caretaking?

- o What is the impact of cognitive impairment on financial well-being and economic decision making?

4. Long-term care

The recent dramatic increases in the costs of care in nursing homes and at home have lent themselves to even more dramatic projections of future costs of long-term care. Research is needed to improve these forecasts and projections, for they serve as the actuarial bases for private and public long-term care insurance plans. Specific research topics include:

- o What is the capacity of individuals to pay for the care that may be needed?
- o How do economic variables affect the demand and use of institutional and paid community care and what role do economic factors play in choosing between various types of care services over the life course?
- o How do patterns of financing affect the mix of impairments within institutions? How does the availability of Medicaid affect decisions to institutionalize older people?

5. Housing and living arrangements

Research on the living arrangements of the elderly has for the most part been confined to cross-sectional analyses and many cross-sectional economic analyses of newly emerging forms of housing and living arrangements remain to be done. A life-course approach to housing and living arrangements might examine the causes of changes in living arrangements or in-home ownership status. Relevant questions include:

- o How do transitions in health status, family composition, and the ability to pay for medical care relate to changes in living arrangements of older persons?
- o How are housing decisions incorporated into the financial planning of older people? What are the implications of projected changes in the value of housing?

6. Comparative analyses

Cross-national and cross-State data are useful in assessing the role of policies and institutions over time on the health and economic well-being of older populations. Questions of interest include:

- o How does the income mix of the elderly vary across countries? How do the various income and retirement policies affect the age and process of retirement? How does the return-to-work phenomena vary across industrialized countries? Who are the poor elderly in other nations? What have been the effects of social experiments such as reverse annuity mortgages in other countries? Are the causes and consequences of retirement similar across industrialized countries?
- o How do different State-level long-term care policies, such as Medicaid and certificate-of-need laws, affect the health and economic well-being of older people?
- o Are health systems of other industrialized nations more cost effective in increasing the life and especially active life expectancy of older people? What is the effect of population aging on the health sector expenditures in developing nations?

This program announcement is oriented towards the industrialized countries; however, NIA is collaborating with the Agency for International Development and the World Health Organization to encourage increased research in less developed countries, including collaborative research projects between U.S. institutions and researchers in other countries. Investigators interested in such studies should contact the Behavioral and Social Research (BSR) Program officer listed below.

B. Cross-sectional and Trend Analyses

While the dynamic life course methodological approach is useful in a variety of research areas, cross-sectional and trend analyses are also important in many under-researched areas. Examples of issues of interest include:

- o How do economic conditions of older people vary across minority groups and how have they changed over time?
- o How do resources versus needs vary by age within the elderly population?
- o What is the extent and mix of private health insurance coverage in the older population, and what are the costs to employers of retiree health benefits?
- o How important are extended kin to household economic well-being, and what are the patterns of resource sharing within families and across households?
- o What are the consumption patterns of older people?

C. Methodological Studies

Appropriate methodological studies are welcome. Improved methods for measuring the costs of illness and disability among older people are needed. Descriptive studies may also be needed, for example, that sharpen and improve the definitions and measurements of initial and subsequent states used in dynamic models. Studies that calibrate and improve various measurements, e.g., equivalence scales, for example of poverty, economic well-being, and health status, are needed, along with new survey instruments that collect valid retrospective data on lifetime financial and labor force history. Econometric innovations that contribute to the analysis in social and biomedical sciences of the complex multivariate dynamic life-course processes are also welcome.

III. CONCEPTUALIZATION AND METHODOLOGY

A wide variety of studies are encouraged including studies that involve primary data collection and studies that analyze and model archived data. Cross-sectional, synthetic cohort, panel, and dynamic analyses of true longitudinal data are all encouraged; the development of models, including micro-simulation models, is welcome; the appropriate methodology should be selected in view of the particular research question. Macro-level analyses where the major focus is on the implications of population aging may be appropriate. International, State-regional perspectives and cross-national studies can often provide powerful insights into circumstances of older people in this nation, and comparative studies are encouraged where relevant. Some problems will require collaboration with scientists from several disciplines; such studies are also encouraged.

IV. DATA RESOURCES

Following the Report of the Ad Hoc Advisory Panel on Extramural Program Priorities for Data Collection in Health and Retirement Economics (copies of which may be obtained from the BSR Program contact listed below), many of the national survey data bases (such as the Health and Retirement Survey, the Consumer Finance Survey, the Survey on Income and Program Participation, the Longitudinal Study on Aging, the National Longitudinal Surveys of Labor Market Experience, the National Long Term Care Survey, the National Nursing Home Followup Survey, and the Panel Study on Income Dynamics) are in the field or are undergoing major enhancements (e.g., new supplements and reinterview waves; linkages to administrative data such as the National Death Index or Medicare Files) that will increase their value for research on aging. Applicants may obtain information from staff or the University of Michigan National Computerized Archive on Data on Aging for these and other databases. Applicants proposing major data collection efforts or enhancements must address in their application the sharing and archiving all such newly created data resources. Where data confidentiality issues present barriers to archiving, as in the case of firm-level proprietary data, or community data and epidemiological studies, applicants should consult BSR staff for advice.

V. INCLUSION OF MINORITIES AND WOMEN

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, together with a rationale for its choice. 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 review will be deferred until the information is provided.

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.

VI. ELIGIBILITY

Applications for research grants may be made by public or private, for-profit or non-profit organizations, such as universities, colleges, hospitals, or laboratories. Women and minority investigators, in particular, are encouraged to apply.

VII. MECHANISMS OF SUPPORT

The primary mechanisms for support of this initiative are the research project grant (R01), program project (P01), FIRST award (R29), institutional training grant (T32), individual fellowships (F32, F33), and research career development awards (K04).

VIII. REVIEW CRITERIA AND APPLICATION PROCEDURES

R01, R29, F32, F33 and K04 applications will be reviewed for scientific and technical merit by an appropriate Initial Review Group of the Division of Research Grants. All other applications will be reviewed by an appropriate Institute review group. Secondary review will be by the corresponding National Advisory Council. Applications compete on the basis of scientific merit.

Although it is not required, potential applicants are encouraged to contact NIA staff in advance of formal submission. This may be accomplished by

calling the program office listed below. Requests for additional information should be addressed to:

Richard Suzman, Ph.D.
Behavioral and Social Research Program
National Institute on Aging
Building 31, Room 5C32
Bethesda, MD 20892
Telephone: (301) 496-3136

For fiscal and administrative matters, contact:

Joe Ellis
Grants and Contracts Management Office
National Institute on Aging
Building 31, Room 5C07
Bethesda, MD 20892
Telephone: (301) 496-1472

Applicants must use the research project application form (PHS 398, revised 10/88, reprinted 9/89) that is available at the applicant's institutional research office and from the Office of Grants Inquiries, Division of Research Grants, NIH (301-496-7441). Individual fellowship applicants must use PHS 416-1 (revised 7/88). In order to expedite the application's routing, please check the box on the application face sheet indicating that your proposal is in response to this announcement and type (next to the box) "Economics of Aging, Health and Retirement, PA-91-41."

The application (with six copies) must be mailed to:

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

If applying for an F32, the application and only two copies need to be sent to the above address.

Receipt dates for Research Project Grant, Career Development Award, and FIRST Award applications are February 1, June 1, and October 1 of each year. Those for the individual fellowships (F32, F33) and institutional training grants (T32) applications are January 10, May 10, and September 10.

This program is described in the Catalog of Federal Domestic Assistance No. 93.866. Agency 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 41 USC 289) and be subject to PHS Grant Policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to Health Systems Agency review.

CLINICAL CANCER THERAPY RESEARCH

PA: PA-91-42

P.T. 34; K.W. 0715035, 0740020, 0745005, 0755025, 0785140

National Cancer Institute

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

I. PURPOSE

The National Cancer Institute (NCI) seeks grant applications to conduct clinical therapeutic studies of neoplastic diseases in human subjects. Clinical research, by definition, involves a clinician/patient-subject interaction with a therapeutic intent. This Program Announcement (PA) encompasses a full range of therapeutic studies and clinical trials employing drugs, biologics, radiation, or surgery. The intent of the announcement is to encourage clinical researchers to translate insights in cancer biology and the development of new agents into innovative cancer therapeutic studies.

This type of grant solicitation (Program Announcement) is utilized when it is desired to encourage investigator-initiated research projects in areas of special importance to the National Cancer Institute. Applicants who will be funded under this PA will be supported through the customary National Institutes of Health (NIH) grant-in-aid (R01, R29).

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 PA, Clinical Cancer Therapy Research, 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).

II. BACKGROUND INFORMATION

In the past several years, the research effort into understanding the basic biology of the cancer cell has been highly productive. Recent discoveries concerning the role of growth factors, genes that promote and suppress neoplasia, mechanisms of treatment sensitivity and resistance, and the biology of the immune systems have provided the basis for the development of novel and improved cancer treatments. The rate of progress in the treatment of cancer will depend upon the translation of these basic and preclinical discoveries into clinical cancer therapies. The NCI supports an extensive network of clinical and laboratory research studies related to cancer therapy through contracts, grants, and cooperative agreements. At present, the traditional research grant mechanism (R01, R29) is underutilized by clinical investigators for the support of clinical research. The Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment, NCI, the program primarily responsible for the promotion and translation of new basic and preclinical research into therapeutic advances, receives relatively few research grant applications. Whereas a Request for Applications (RFA) represents a single solicitation, a PA provides the opportunity for the receipt of new applications on an indefinite basis. NCI encourages clinical investigators to submit clinical therapeutic studies and is committed to moving advances in basic biology and drug development into the clinical setting.

III. RESEARCH GOALS AND SCOPE

The Division of Cancer Treatment (DCT) is requesting qualified investigators to develop research grant applications (R01, R29) involving clinical therapeutic studies of neoplastic diseases. Clinical studies must involve human subjects and be designed to ultimately improve cancer treatment. The applications may include single or multi-institutional (e.g., consortia, cooperative groups) research studies with appropriate biological correlates linked to these studies. New clinical therapeutic studies may employ drugs, biologics, radiation, or surgery used as single agents/modalities or in combination. Biological correlative studies that have clinical relevance to cancer therapies and are aimed at improving cancer treatment are also appropriate.

Some examples of clinical therapeutic studies include: 1) therapies based on novel mechanisms of action; 2) mechanism of action and metabolic studies of antitumor agents; 3) studies of mechanisms of hormone-, drug- or radiation-resistance and reversal; 4) mechanism of action of biological response modifiers in the treatment of cancer, e.g., cancer immunotherapy (monoclonal antibodies, cytokines, antisense, and vaccines) alone or in combination with chemotherapeutic agents; 5) mechanism of action of new growth factor targeted therapies; 6) new radiation therapies or radiation modifiers to enhance cell kill or protect normal tissue; 7) surgical therapies in combination with therapeutic agents.

Some examples of biological correlative studies include: 1) phenotypic or genotypic alterations that appear to correlate with the development of drug-, hormone-, or radiation-resistance; 2) oncogenes, growth factors, and specific antigen expression on tumor cells; 3) pharmacokinetic and pharmacodynamic measurements; 4) biochemical pharmacologic parameters; 5) imaging studies to assess efficacy of treatment.

Investigators are not limited to the above areas of potential studies. Clinical research, by definition, must involve a clinician/patient-subject interaction with a therapeutic intent.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources are requested to identify the GCRC as a resource for conducting the proposed research.

IV. MECHANISM OF SUPPORT

Support of this program will be through the research project (R01 and R29) NIH grant-in-aid. Applicants will be responsible for the planning, direction, and execution of the proposed project. All PHS and NIH grants policies will apply to applications received in response to this announcement. Domestic

applicants may request no more than five years of support, and foreign applicants may request no more than three years. Applications submitted in response to this PA will compete for funds with all other investigator-initiated applications. The award of grants in response to this PA is also contingent upon the availability of funds.

V. 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, clinical cooperative group) if appropriate. Applications from minority individuals and women are encouraged.

VI. REVIEW PROCEDURES AND CRITERIA

A. REVIEW PROCEDURE

Upon receipt, applications will be reviewed initially by the Division of Research Grants (DRG) for completeness. Incomplete applications will be returned to the applicant without further consideration. Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for scientific and technical merit by appropriate peer review groups. Following peer review, the applications will receive a second-level review by the appropriate national advisory council/board.

B. 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, together with a rationale for its choice. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects.

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

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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 review will be deferred until the information is provided.

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.

VII. METHOD OF APPLYING

The research grant application form PHS 398 (revised 10/88) must be used in applying for these grants and will be accepted at the regular application deadlines. These forms are available at most institutional business offices; from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, Room 449, Westwood Building, Bethesda, MD 20892; or from the NCI Program Director named below. The title and number of this announcement must be typed in line 2 on the face page of the application.

The original application and six (6) signed exact photocopies must be submitted or delivered to:

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

IX. INQUIRIES

Written or telephone inquiries concerning the objectives and scope of this PA and inquiries about whether or not specified proposed research would be responsive are encouraged and should be directed to the Program Directors, Ms. Diane Bronzert and Dr. Roy Wu, at the address below. The Program Directors welcome the opportunity to clarify any issues or questions from potential applicants.

For Technical Information:

Ms. Diane A. Bronzert or
Dr. Roy S. Wu
Program Directors
Cancer Therapy Evaluation Program
Division of Cancer Treatment
National Cancer Institute
EPN, Room 734
Bethesda, MD 20892
Telephone: (301) 496-8866
FAX #: (301) 480-4663

For Business Information:

Ms. Donna Shields
Grants Management Specialist
National Cancer Institute
EPS, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800

This program is described in the Catalog of Federal Domestic Assistance No 93.395, Cancer Treatment Research. Awards are made under the authorization of the Public Health Service Act, Sections 301, 410, and 411 (Public Law 78-410, 42 USC 241 as amended, Public Law 99-158, 42 USC 285a) and administered under PHS grant policies and Federal Regulations at 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.

NOTICE OF MEETING

CONFERENCE: FOSTERING SCIENTIFIC INTEGRITY IN BIOMEDICAL RESEARCH

P.T. 42; K.W. 1014004, 1014006

National Institutes of Health

The National Institutes of Health (NIH), the Association of American Medical Colleges, and Washington University School of Medicine are co-sponsoring an interactive conference for biomedical investigators, research administrators, and university attorneys with an interest in fostering the integrity of scientists. The goals of the workshop are to discuss the scope of the problem of scientific misconduct; to identify perceived or real factors contributing to misconduct; to discuss the roles of Congress, NIH, and institutions in managing allegations of scientific misconduct; to examine how well specific institutions have dealt with allegations of fraud, plagiarism or other unacceptable scientific practices; to discuss any special ethical considerations associated with Industry/University ties; and to discuss the responsibilities of authors and collaborators in maintaining scientific integrity in research. Several break-out sessions will address focussed topics of particular concern.

This conference is approved for credit in AMA Category 1.

DATES: April 25-26, 1990

SITE: The Adams Mark Hotel, St. Louis, MO

PROGRAM AND REGISTRATION INFORMATION: Telephone: (800) 325-9862, interstate
(314) 362-6893, in Missouri

**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:

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