NIH GUIDE

For Grants and Contracts

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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NOTICES

NOTICES OF AVAILABILITY (RFPs AND RFAs)

NATIONAL WORKSHOPS ON "PROTECTION OF HUMAN SUBJECTS"

P.T. 42; K.W. 0783005

National Institutes of Health
Food and Drug Administration

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) are continuing to sponsor a series of workshops on the responsibilities of researchers, Institutional Review Boards (IRBs), and institutional officials for the protection of human subjects in research. The workshops are open to everyone with an interest in research involving human subjects. The meetings should be of special interest to those persons currently serving or about to begin serving as a member of an IRB. Issues discussed at these workshops are relevant to all other Public Health Service agencies. The current schedule includes the following:

I. WEST COAST WORKSHOP

DATES: February 4-5, 1991

WORKSHOP SITE:
Meridien Hotel
50 Third Street
San Francisco, CA 94103

SPONSOR:
University of California at San Francisco
Box 0400
San Francisco, CA 94143

REGISTRATION CONTACT:
Ms. Phyllis Colbert
Workshop Contact Person
University of California at San Francisco
Box 0400
San Francisco, CA 94143
Telephone: (415) 476-1881

TOPIC: "The Use of Human Subjects in Research: AIDS as a Model of Complexity"

II. MIDEAST WORKSHOP

DATES: March 4-5, 1991

WORKSHOP SITE:
Friday Center
Laurel Hill Parkway
Chapel Hill, NC 27599-1020

SPONSORS:
University of North Carolina at Chapel Hill
300 Bynum Hall
Chapel Hill, NC 27599-4100

Shaw University
118 E. South Street
Raleigh, NC 27611

REGISTRATION CONTACT:
Mr. Al Dawson
Director
Friday Center
Laurel Hill Parkway
C. B. 1020
Chapel Hill, NC 27599-1020
Telephone: (919) 962-1106

TOPIC: "Interpreting the Federal Code for the Protection of Human Subjects"

III. MIDWEST WORKSHOP

DATES: April 11-12, 1991

WORKSHOP SITE:
Ramada Inn, Lakeshore
4900 South Lake Shore Drive
Chicago, IL 60615

SPONSORS:
University of Chicago
970 East 58th Street
Chicago, IL 60637

Chicago State University
95th Street at King Drive
Chicago, IL 60628

REGISTRATION CONTACT:
Mr. Arnold L. Aronoff
Associate Director
Faculty and Administrative Services
University Research Administration
University of Chicago
970 East 58th Street
Chicago, IL 60637
Telephone: (312) 702-8669

TOPIC: "Cultural Diversity, Ethics, and Research: A Workshop on Human Subject Protection"

NIH/FDA have planned national human subject protections workshops in other parts of the United States. For further information regarding these workshops contact:

Darlene Marie Ross
Executive Assistant for Education
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
9000 Rockville Pike
Building 31, Room 5B59
Bethesda, MD 20892
Telephone: (301) 496-8101

SMALL GRANTS PROGRAM - REVISED GUIDELINES

P.T. 34; K.W. 1014006

National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) announces the availability of revised guidelines for the NHLBI Small Grants Program originally announced in the NIH Guide for Grants and Contracts, Vol. 19, No. 7, February 16, 1990. Copies are available from:

Director
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
Westwood Building, Room 7A17
Bethesda, MD 20892
Telephone: (301) 496-7416

ALZHEIMER'S DISEASE AND RELATED CEREBRAL DEGENERATIVE DISORDERS

RFA AVAILABLE: NS/AG-91-03

P.T. 34; K.W. 0715180, 0705010, 0710010, 1002030, 0755030, 0765033

National Institute of Neurological Disorders and Stroke
National Institute on Aging

Letter of Intent Receipt Date: April 1, 1991
Application Receipt Date: May 6, 1991

Background

The Division of Demyelinating, Atrophic, and Dementing Disorders of the National Institute of Neurological Disorders and Stroke (NINDS) and the Neuroscience and Neuropsychology of Aging Program of the National Institute on Aging (NIA) jointly announce the availability of a Request for Applications (RFA) on Alzheimer's Disease and Related Cerebral Degenerative Disorders. The NINDS and NIA are interested in enhancing the support of innovative research projects designed to elucidate the etiology or pathogenesis of cerebral degenerative disorders such as Alzheimer's disease, to improve diagnosis, and eventually to provide sound bases for effective therapy. Topics of interest include studies in genetics, mechanisms of cell death, nerve growth factors, animal modeling, neuroimaging, and various aspects of differential diagnosis. Applications on related topics or other problem areas are also encouraged.

Mechanism of Support

The support mechanism for this program will be the regular research grant (R01). The Institutes expect to make at least 20 awards.

Review Procedures

All applications should be submitted on form PHS 398 (10/88 revision). Applications judged by staff to be nonresponsive to the RFA will be administratively withdrawn and returned to the applicant. All applications that are complete and responsive to this RFA will be evaluated by an NINDS peer review group. Applications judged competitive for award will be subsequently reviewed by the National Advisory Neurological Disorders and Stroke Council and the National Advisory Council on Aging.

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.

Method of Application

Applications must be received by May 6, 1991. The review for scientific and technical merit of applications judged responsive to the RFA will take place in June/July 1991 and Council review will be in September 1991. Awards will begin prior to October 1, 1991.

Potential applicants may receive the full RFA by E-Guide or on request from:

Eugene J. Oliver, Ph.D.
Health Scientist Administrator
Division of Demyelinating, Atrophic, and Dementing Disorders
National Institute of Neurological Disorders and Stroke
National Institutes of Health
Federal Building, Room 806
Bethesda, MD 20892
Telephone: (301) 496-1431

or

Carl D. B. Banner, Ph.D.
Program Director, Etiology of Alzheimer's Disease
Dementias of Aging Branch, NNA
National Institute on Aging
National Institutes of Health
Building 31, Room 5C35
Bethesda, MD 20892
Telephone: (301) 496-9350

MANAGEMENT OF ALZHEIMER'S DISEASE SYMPTOMS

RFA AVAILABLE: NR/AG-91-01

P.T. 34; K.W. 0715180, 0785035, 0404000

National Center for Nursing Research
National Institute on Aging

Letter of Intent Receipt Date: April 8, 1991
Application Receipt Date: May 20, 1991

The National Center for Nursing Research (NCNR) and the National Institute on Aging (NIA) invite applications for R01 research proposals for preliminary investigations that will lead to large-scale clinical studies on the assessment and nonpharmacological management of secondary symptoms exhibited by patients with Alzheimer's disease and related disorders (AD). The Alzheimer's Association is cooperating with NCNR and NIA in this Request for Applications (RFA).

Estimates indicate that 4 million Americans presently suffer from Alzheimer's disease or related dementias. The impact of AD on patients, families, and society is severe and is anticipated to grow as older persons, the group most at risk for AD, continue to increase in number. Although it may not yet be possible to prevent, treat, or permanently alter the course of the underlying disease, interventions can be developed and systematically tested that reduce the patient's secondary symptoms and preserve function. In addition to cognitive symptoms, non-cognitive secondary symptoms, which are frequently seen across the course of Alzheimer's disease and present significant management problems, are of special concern. These may include, but are not limited to, wandering, disturbed sleep, pacing, agitation, feeding and dressing difficulties, incontinence and toileting difficulties, screaming and other vocalizations, aggression and violence, and inappropriate sexual behavior. These symptoms not only contribute to decisions to institutionalize affected individuals, but also lead to the use of chemical and physical restraints.

While there exists a great deal of clinical and anecdotal information about methods that can effectively deal with individual symptoms, little data exist that have been obtained with the rigor of design and procedures of the controlled clinical trial. Therefore, applications are solicited for preliminary investigations and feasibility studies that will lay the groundwork for the development of rigorously controlled clinical trials to test interventions for the management of the secondary symptoms. Applications are invited for support of projects to address issues including, but not limited to:

- the identification of underlying factors in research subjects that result in behavioral symptoms and methods to address these factors.
- the development of preliminary work and early investigations that will lead to the nonpharmacologic management and treatment of the secondary symptoms exhibited by patients with Alzheimer's disease and related disorders.
- provision of a rigorous scientific base that will lead to controlled clinical trials in institutional or noninstitutional settings by delineating approaches for the management of symptoms, the duration of change, and the procedures required to maintain the change, if possible.
- development of instruments to assess behavioral problems and monitor changes.
- careful scientific observations of the natural history/ clinical course of the behavioral changes that occur during the progression of Alzheimer's disease.

MECHANISM OF SUPPORT

NCNR and NIA are allocating up to $75,000 in direct costs for each award for each funding year, not to exceed three years. The intent is to fund ten to fifteen R01 grants by September 30, 1991.

Following the standard NIH peer review process, Principal Investigators may submit their applications and summary statements to the Alzheimer's Association for funding consideration. The Alzheimer's Association may fund selected grants at a maximum level of $45,000 total costs each year with a 10 percent ceiling on indirect costs, for a maximum of three years. The Alzheimer's Association project start dates for funding may not coincide with the NCNR or NIA award dates. Applicants may not receive funding from both NIH and the Alzheimer's Association for the same application.

SPECIAL INSTRUCTIONS FOR INCLUSION OF WOMEN AND MINORITIES IN CLINCAL 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 or represented in the study populations for clinical studies, a special justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

REVIEW PROCEDURES AND CRITERIA

The individual research grant application form PHS-398 (revised 10/88 or 9/89) must be used to apply for these grants. Upon receipt, applications will be reviewed by NIH staff for completeness and responsiveness. Incomplete applications will be returned to the applicant without further consideration. Applications not responsive to the scientific intent identified in the RFA or to the timeframe and budget guidelines will be returned to DRG for review with other unsolicited grant applications during the next available NIH review cycle.

Applications may be subjected to triage by a peer review group to determine their scientific merit relative to other applications received in response to this RFA. The NIH will administratively withdraw those applications judged to be noncompetitive and notify the applicant and institutional official. Those applications judged to be complete, responsive, and competitive will be evaluated in accordance with the NIH review criteria for scientific/technical merit by an appropriate peer review group convened by the NCNR and NIA. The second level of review will be provided by the NCNR and NIA National Advisory Councils.

Although not a prerequisite for applying, potential applicants are encouraged to submit a non-binding letter of intent by April 8, 1991, to John C. Chah, PhD, National Center for Nursing Research, Building 31, Room 5B19, 9000 Rockville Pike, Bethesda, MD 20892. The letter of intent should include a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the names of other key personnel, and any other participating institution(s). Applications must be received by May 20, 1991.

Potential applicants are strongly encouraged to obtain the full Request for Applications (RFA) and to direct inquiries to:

Mary D. Lucas, PhD, RN
Chief, Acute & Chronic Illness Branch
National Center for Nursing Research
Building 31, Room 5B03
Bethesda, MD 20892
Telephone: (301) 496-0523

Teresa S. Radebaugh, Sc.D.
Chief, Dementias of Aging
Neuroscience and Neuropsychology of Aging
National Institute on Aging
Building 31, Room 5C21
Bethesda, MD 20892
Telephone: (301) 496-9350

Other institutes and agencies are also interested in research dealing with Alzheimer's disease and related disorders, including:

The National Institute of Mental Health (NIMH) is interested in research dealing with the behavioral and emotional consequences of Alzheimer's disease and related disorders. The scope of NIMH interest is delineated in the announcement "Alzheimer's Disease Treatment and Family Stress." For more information, contact Enid Light, PhD, NIMH, Room 11C-03, 5600 Fishers Lane, Rockville, MD 20857, telephone (301) 443-1185.

The National Institute of Neurological Disease and Stroke program contact for Alzheimer's disease related research is Dr. Eugene J. Oliver, NINDS, Federal Building, Room 806, Bethesda, MD 20892, telephone (301) 496-1431.

This RFA is in addition to the ongoing program announcement on "Alzheimer's Disease and Related Disorders: Issues in Caregiving," published in the NIH Guide for Grants and Contracts, Vol. 18, No. 6, February 24, 1989, sponsored by the National Institute on Aging, National Center for Nursing Research, National Institute of Mental Health, and the National Center for Health Services Research (now the Agency for Health Care Policy Research).

ANALYSES AND PHYSIOLOGY OF ANTICARCINOGENS IN SOYBEANS

RFA AVAILABLE: CA-91-06

P.T. 34; K.W. 0715035, 1007009, 0745027, 0710095

National Cancer Institute

Letter of Intent Receipt Date: March 1, 1991
Application Receipt Date: April 29, 1991

The Division of Cancer Prevention and Control, National Cancer Institute (NCI), invites applications for grants to quantify levels of total and individual anticarcinogens in soybeans and soy products and to study their absorption and metabolism in humans.

BACKGROUND

Epidemiologic and animal studies suggest soybean-rich diets may reduce cancer risk. Populations consuming predominantly plant-based diets, for whom legumes frequently represent an important protein source, tend to have lower rates of several cancers than populations who rely heavily on animal products. One legume, soybeans, via a variety of soy products (tofu, miso, tempeh, soymilk, natto), is commonly consumed throughout much of East Asia where breast and colon cancer rates are low in comparison to Western countries. Soybeans contain several classes of compounds in particularly high concentrations with demonstrated anticancer activity, such as isoflavones, protease inhibitors, phytosterols, saponins, and inositol hexaphosphate. Others may also exist. Basic research on the absorption and metabolism of these compounds in humans and accurate analytical data on the levels of these compounds in commonly consumed soy products are needed. These data will help to determine the potential impact of soybeans on cancer prevention.

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 RFA, "Analyses and Physiology of Anticarcinogens in Soybeans," is related to the priority area of cancer prevention.

OBJECTIVES AND SCOPE

The purpose of this Request for Applications (RFA) is to solicit applications from qualified investigators to quantify levels of total and individual anticarcinogens in soybeans and soy products and to study their absorption and metabolism in humans. The analytical work should focus only on those compounds in soybeans and soy products that have demonstrated anticancer activity and are unique to soybeans and soy products or present at substantially high levels (relative to other foods). Total as well as individual anticarcinogens (e.g., total isoflavones and individual isoflavones, daidzein, genistein) should be quantified. All factors potentially effecting anticarcinogen levels/activity should be considered for investigation.

For the clinical work, studies on the absorption and metabolism of compounds in soybeans and soy products with demonstrated anticancer activity are to be conducted. When feasible, dose-response relationships between soy product/anticarcinogen intake and anticarcinogen levels in blood and urine, and/or feces and bile should be conducted. When available, both commonly consumed soy products as well as soybean extracts or pure soybean anticarcinogens should be studied. Both long-term feeding studies, in which anticarcinogen levels in subjects consuming soy products/extracts over an extended period of time, and short-term studies, in which anticarcinogen levels for a minimal period after the consumption of a single administration of soy products, extracts, or pure compounds are studied, are appropriate under 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 or minorities are not included or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such documentation will not be accepted for review.

MECHANISM OF SUPPORT

The support mechanism for this program will be the individual research grant (R01). 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). Approximately $900,000 in total costs per year for 3 years will be committed to specifically fund applications that are submitted in response to this RFA. It is anticipated that 3 to 4 awards will be made.

REVIEW PROCESS

All applications submitted in response to this RFA will be evaluated for scientific and technical merit by an initial review group that will be convened for this purpose by the Division of Extramural Affairs. Those applications judged to be both competitive and responsive will be further evaluated for scientific and technical merit by an appropriate peer review group convened by the Division of Extramural Activities, NCI. The second level of review by the National Cancer Advisory Board considers the special needs of the Institute and the priorities of the National Cancer Program.

METHOD OF APPLYING

Potential applicants are asked to submit a letter of intent and that includes a descriptive title of the proposed research, the name and address of the principal investigator, the names of other key personnel, the participating institutions, and the number and title of the RFA in response to which the application is being submitted. This letter should be received no later than March 1, 1991. Potential applicants should write or phone the individual listed below for the full RFA document:

Mark J. Messina, Ph.D., Program Director
National Cancer Institute, DCPC
9000 Rockville Pike, EPN 212C
Bethesda, MD 20892
Telephone: (301) 496-8573

The RFA label available in the 10/88 revision of Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review.

SITES TESTING OSTEOPOROSIS PREVENTION/INTERVENTION TREATMENTS

RFA AVAILABLE: AG-91-04

P.T. 34; K.W. 0705050, 0745027, 0755015, 0710010

National Institute on Aging

Letter of Intent Receipt Date: March 15, 1991
Application Receipt Date: April 29, 1991

The National Institute on Aging (NIA) invites applications for cooperative agreements to develop and test interventions to lessen, prevent, or reverse loss of bone strength in the hip to reduce risk of hip fractures in older persons.

BACKGROUND, GOALS, SCOPE, AND ELIGIBILITY REQUIREMENTS

The enormous public health impact of osteoporosis is concentrated heavily among persons 65 years old and older. In particular, the vast majority of hip fractures occur in this age range. Several clinical trials of interventions against osteoporosis have reported promising results, but trials have included few subjects over age 65, few trials have studied effects on bone density in

the hip, and no trials have adequate statistical power to determine the effect of interventions on hip fractures in this population.

The Request for Applications (RFA) solicits projects which will test the efficacy of interventions (or combinations of interventions) against osteoporosis of the hip in persons aged 65 or older. Proposed studies must measure effects in the hip but may also include measures of effects at additional skeletal sites. Subjects for inclusion in proposed trials must be age 65 or over. Studies may also measure effects of osteoporosis treatment on fractures of the hip and other sites. A pilot phase for safety and feasibility testing and protocol refinement of intervention studies may be proposed. The Principal Investigators and key staff of STOP/IT (Sites Testing Osteoporosis Prevention/Intervention Treatments) projects, under the terms of awards, will meet with the NIA Program Administrator every six months to review the progress of their studies. Funds for such travel will be included in awards.

A maximum of $550,000 first year total (direct plus indirect) costs may be requested per application and a total of no more than $3.1 million may be requested per application for the entire project duration. This RFA is a one-time solicitation. Up to $2.1 million (total cost) for first-year expenses and additional approved expenses for up to five years will be committed in Fiscal Year 1991 to fund applications in response to this RFA. It is anticipated that up to four awards will be made in FY 1991. Additional proposals in response to this RFA may be funded in Fiscal Year 1992 depending on quality of applications and availability of funds. Issuance of awards pursuant to this RFA is contingent on the availability of funds for this purpose. The earliest feasible start date for the initial awards will be September 30, 1991.

Applicants responding to this RFA are also encouraged to submit concurrent companion research project grant applications for studies on the pathophysiology of osteoporosis in advanced age and the mechanisms affecting response to treatment in older persons, as described in NIA RFA AG-91-08 in this issue of the NIH Guide for Grants and Contracts. No elements of these proposed companion studies should duplicate any elements of studies proposed in response to this RFA (AG-91-04).

MECHANISM OF SUPPORT

Support of this program will be through cooperative agreements (U01) between each awardee and NIA. Under the terms of these cooperative agreements, the awardee defines the design and details of the project under the terms of this RFA, retains primary responsibility for performance of the research and for analyzing and publishing results, and agrees to accept assistance from the NIA Program Administrator in the following:

- Participation in the monitoring of intervention study issues relating to recruitment, treatment, follow-up, quality control, and adherence to protocol.
- Consideration of adjustments of intervention study designs and protocols.
- Assistance in analysis and reporting of intervention study results.

REVIEW PROCEDURES AND CRITERIA

Applications will be received by the NIH Division of Research Grants and will be assigned to the NIA. Responsive applications will be assigned to a special review group organized by NIA. Following this review, applications will be considered by the National Advisory Council on Aging. Applications will be evaluated on customary criteria for scientific merit and the adequacy of applicants' plans for meeting the special program requirements of this RFA. Applications will be evaluated regarding issues relating to inclusion of women and minorities. (Note following special instructions.)

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 or adequately represented in the study populations for clinical studies, a specific justification for this exclusion or inadequate representation must be provided. Applications without such justification will not be accepted for review.

METHOD OF APPLYING: Applicants should request the full RFA from the NIA staff contact listed below. A letter of intent to submit an application, while not required, is requested to be sent to the same staff contact by March 15, 1991. The deadline for receipt of applications is April 29, 1991. The full RFA may be obtained from:

Stanley L. Slater, M.D.
Geriatrics Program
National Institute on Aging
Building 31, Room 5C27
National Institutes of Health
Bethesda, MD 20892
Telephone: (301) 496-6761

SITES TESTING OSTEOPOROSIS PREVENTION/INTERVENTION TREATMENTS: COMPANION STUDIES OF PATHOPHYSIOLOGY AND MECHANISMS

RFA AVAILABLE: AG-91-08

P.T. 34; K.W. 0705050, 0745027, 0710010, 0765035

National Institute on Aging

Application Receipt Date: April 29, 1991

BACKGROUND: The National Institute on Aging (NIA) has issued a Request for Applications (RFA): SITES TESTING OSTEOPOROSIS PREVENTION/INTERVENTION TREATMENTS (STOP/IT) (AG-91-04), soliciting projects to test the efficacy of interventions (or combinations of interventions) against osteoporosis in the hip, in persons aged 65 or more. That RFA provides funds for intervention studies only. Because evidence is increasing that the disease process may differ in significant respects in this age range compared to younger ages, and because much remains to be learned about mechanisms accounting for these differences, NIA wishes to increase gains in knowledge from these intervention studies by supporting companion studies to explore mechanisms underlying the interaction of the disease process with interventions being explored in the clinical trials funded under AG-91-04. Therefore, only institutions responding to AG-91-04 may submit applications in response to this RFA. Those not eligible for this RFA who wish support for studies on osteoporosis in advanced age are encouraged to submit applications at any regularly scheduled submission deadline, as described in the NIA/NIAMS program announcement: Type II Osteoporosis (NIH Guide for Grants and Contracts 17, No. 28, September 2, 1988).

RESEARCH GOALS AND SCOPE: The screening and recruitment of subjects over age 65, as requested in AG-91-04, will provide opportunities for studies on the pathophysiology of osteoporosis in advanced age, and the mechanisms affecting response to treatment in older persons. Studies are encouraged on factors affecting the progress of the disease in women many years after menopause and in older men, as well as studies of factors specifically affecting bone loss in the hip in this age range. Applicants responding to this RFA are also invited to explore or verify mechanisms underlying the effects (or lack of effects) of interventions on bone mass, bone density, and/or bone strength in older persons. Because comorbidity and use of multiple medications are extremely common among persons over age 65, studies of the impact of these complicating factors on the disease process and responses to interventions are also appropriate.

MECHANISM OF SUPPORT: Support of this program will be through the Public Health Service grant-in-aid. Only the R01 grant mechanism can be used. Awards will be administered under PHS grants policy as stated in the Public Health Service Grants policy statement, DHHS Publication No. (OASH) 82-50,000, revised October 1, 1990.

This RFA is a one-time solicitation. Up to $1.2 million has been set aside for total (direct plus indirect) first-year costs and additional approved expenses for up to five years to fund applications submitted in response to this RFA. (NIA and the National Institute of Arthritis, Musculoskeletal and Skin Diseases will contribute equal shares of this funding.) No single proposal should request more than $150,000 (direct plus indirect costs) for first-year expenses. Future year annual increases will generally be limited to no more than four percent. Multiple proposals may be submitted by each applicant institution. It is anticipated that approximately 8 awards will be made in Fiscal Year 1991. Additional applications submitted in response to this RFA may be funded in Fiscal Year 1992. The award of grants pursuant to this RFA is contingent on receipt of applications of high scientific merit and the availability of funds for this purpose.

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.

REVIEW PROCEDURES AND CRITERIA: Applications will be received by the NIH Division of Research Grants and will be assigned to NIA. Responsive applications will be assigned to a special review group convened by NIA for review. Following this review, applications will be considered by the National Advisory Council on Aging. Scientific review criteria to be used in the evaluation of the applications received in response to this RFA are listed in the full RFA.

METHOD OF APPLYING: Applicants should request the full RFA from the NIA staff contact listed at the end of this announcement. A letter of intent to submit an application, while not required, is requested to be sent to the same staff contact by March 15, 1991. Applications should be submitted on the standard PHS 398 application form (revised October 1988), available at most institutional business offices and the Division of Research Grants, NIH, telephone (301) 496-7441. On item 2 of the face page of the application, applicants should enter: NIA (STOP/IT) Companion Studies, AG-91-08. The RFA label available in the 10/88 revision of the Application Form 398 must be affixed to the bottom of the face page. Failure to use this label could result in delayed processing of the application and prevent it from reaching the review committee in time for review. The deadline for receipt of applications is April 29, 1991.

The full RFA may be obtained from:

Stanley L. Slater, M.D.
Geriatrics Program
National Institute on Aging
Room 5C27, Building 31, NIH
Bethesda, MD 20892
Telephone: (301) 496-6761

* U.S. G.P.O.:1991-281-826:20029