

THE NIH OSTEOPOROSIS AND RELATED BONE DISEASES RESOURCE CENTER

Release Date: February 11, 1998

P.T.

RFA: AR-98-007

National Institute of Arthritis and Musculoskeletal and Skin Diseases

National Institute on Aging

National Institute of Child Health and Human Development

National Institute of Dental Research

National Institute of Environmental Health Sciences

Office of Research on Women's Health

Letter of Intent Receipt Date: March 15, 1998

Application Receipt Date: April 28, 1998

PURPOSE

The National Institutes of Health invites cooperative agreement applications to support research and education through a resource center for osteoporosis and related bone disorders in order to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through effective dissemination of information.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), The National Institutes of Health Osteoporosis and Related Bone Diseases National Resource Center, is related to the priority area of educational and community-based programs. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic non-profit and for-profit organizations, public and private, such as universities, public health departments, hospitals, voluntary organizations, units of state and local governments, and eligible agencies of the Federal government. Applications from minority and women investigators are encouraged. Investigators should be capable of assembling a multidisciplinary team including health education and communication specialists.

MECHANISM OF SUPPORT

The administrative and funding instrument to be used for this program will be a cooperative agreement (U24), an assistance mechanism (rather than an acquisition mechanism), in which substantial NIH scientific and/or programmatic involvement with the awardee is anticipated during performance of the activity. Under a cooperative agreement, the NIH purpose is to support, stimulate, and expedite the recipient's activities by jointly being involved with them. NIH staff work cooperatively with the award recipients in a partner role and do not assume direction, prime responsibility, or a dominant role in the activity. Details of the responsibilities, relationships, and governance of the activities to be funded under the cooperative agreements awarded for this Program are discussed later in this document under the section "Terms and Conditions."

The total project period for applications submitted in response to the present RFA may not exceed five years. The anticipated award date is September 30, 1998. Future competitions for this project will be solicited by RFA.

FUNDS AVAILABLE

The estimated funds available for the first year of support are \$600,000 total costs. The NIAMS expects to make one award. Although this program is provided for in the financial plans of the NIAMS, awards pursuant to this RFA are contingent upon the availability of funds for this purpose.

RESEARCH OBJECTIVES

Background

Osteoporosis is an important and potentially growing public health problem in which weakened bones are easily fractured. More than 1.3 million hip, spine and wrist fractures each year are

attributable to osteoporosis. Low bone density is a major cause of fractures. Data from the National Health and Nutrition Examination Survey, using a definition of osteoporosis developed by the World Health Organization, determined that up to 20% of white women over 50 have osteoporosis and up to 50% have low bone mass. Non-white women and men have lower rates of osteoporosis but contribute up to 25% of the fractures annually (Looker et al., 1995). Low trauma fractures at any site in the elderly are largely due to low bone mass. Hip fractures are the most devastating and costly osteoporotic fractures. Death in the months immediately following hip fracture is not uncommon but is often attributed to other causes such as pneumonia. Fifty percent of surviving individuals will need help with daily living activities, and 15 to 25 percent will need to enter a long-term care institution shortly after the fracture (Chrischilles et al, 1991). In 1995 the annual national cost of all osteoporosis-related fractures was estimated at \$13.8 billion dollars (Ray et al., 1997). Some projections have forecast a more than 3-fold increase in the number of hip fractures due to the aging of the U.S. population (Schneider and Guralnik, 1990). Clearly primary prevention as well as adequate and early diagnosis and treatment of osteoporosis before a fracture occurs requires a concerted effort of education and information dissemination.

Although accurate national cost and personal impact data are less available for drug-induced osteoporosis, other secondary types of osteoporosis, Paget's disease, osteogenesis imperfecta, and other bone diseases, these diseases present significant public health problems that require outreach to both health care professionals and the public. A coordinated effort to provide education and information dissemination for all the related bone diseases makes sense since so much of the underlying scientific understanding of bone biology contributes to all the related diseases.

In the past decade there have been extraordinary advances in the understanding of basic bone biology leading to very targeted approaches both in the prevention and effective treatment of several types of osteoporosis and related bone diseases, but wide application to clinical care has lagged behind. Further education of health care professionals, patients, and the public at large is needed. In particular, the teaching of osteoporosis prevention to children and adolescents and the need to reach all segments of an ethnically, economically, and geographically diverse American population have been identified as priorities.

The National Institutes of Health Revitalization Act of 1993 [P.L. 103-43] provided for "the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information."

Awardees will be expected to participate actively in carrying out a national bone diseases educational and information program whose objectives are to:

1. Document the barriers and test strategies to improve the appropriate identification, diagnosis, and treatment of osteoporosis and related bone diseases among primary care physicians, family practitioners, rheumatologists, pediatricians and gynecologists and other health professionals, and target populations at high risk of these diseases. Address access to care issues including cultural, language and educational barriers in specific populations.
2. Design, implement, and evaluate the bone diseases education and information program in several regions of the U.S., to increase knowledge about bone diseases and to improve the early detection, diagnosis, treatment and prevention of osteoporosis and related bone diseases in target populations.
3. Organize working groups of medical experts and consumer representatives to review available data and prepare publications relevant to osteoporosis and related bone diseases education. The National Osteoporosis Data Group is an example of such a group designed to provide the government with periodic updates on the prevalence and impact of osteoporosis.

Program Implementation

Since there are a significant number of medical specialties responsible for the detection, diagnosis, and treatment of osteoporosis, the use of medical intermediary organizations is crucial for the education of health care providers currently in practice. Primary care physicians, oncologists, pediatricians, and other health professionals can be the focal point for the provider education program.

High priority will be given to the establishment of an infrastructure that can continue to inform the public and their health care providers with new medical findings as they become available. Applicants should include a description of the resources and facilities that will enable their project to conduct the necessary outreach.

Objectives

- o make research-based information on osteoporosis and related bone diseases available to requester via phone, FAX, e-mail or World Wide Web
- o explore new modes of dissemination and communication

- o develop novel approaches to particular target groups of at risk individuals
- o publish a yearly report on the state of osteoporosis and related bone diseases - progress toward goals
- o monitor efforts to affect prevention
- o develop relationships with Federal Agencies and private groups involved with osteoporosis and coordinate efforts
- o conduct research on outreach efforts to particular target groups
- o develop and coordinate the National Osteoporosis Data Group effort to collect and disseminate information on the prevalence and incidence of osteoporosis and osteoporosis-related fractures

SPECIAL REQUIREMENTS

Terms and Conditions of Award

The following terms and conditions will be incorporated into the award statement and provided to the Principal Investigator as well as the institutional official at the time of the award.

These special Terms and Conditions of Award are in addition to and not in lieu of otherwise applicable OMB administrative guidelines, HHS grant administration regulations in 45 CFR part 74 and 92, and other HHS, PHS and NIH grant administration policy statements.

The National Institutes of Health Osteoporosis and Related Bone Diseases National Resource Center will be viewed as a partnership between the NIH participating institutes, and the awardee with the goal of developing and providing high quality information to the public, physicians and health care providers using targeted and validated approaches. Awardees will be responsible for the planning, direction, and execution of the proposed project.

The resource center developed as a result of this award is to be called the "NIH Osteoporosis and Related Bone Diseases National Resource Center"

1. Awardee Rights and Responsibilities

Awardee has primary responsibilities to define the objectives and approaches of the center as well as to plan and conduct the necessary studies and tasks. Awardees will retain custody of and have primary rights to the data developed under the award, subject to Government rights of access consistent with current HHS and NIH policies. In addition, awardees will;

- o Form an Advisory Committee to provide guidance and advice on the conduct of the study to the Awardee and the NIH. This body will be composed of members from the scientific and medical community as well as members of the public. The advisory committee shall meet at least twice per year.

- o Designate the Principal Investigator or assignee to serve as Executive Secretary of the Advisory Committee and to oversee the conduct of this study.

- o Cooperate with the NIAMS Program Director in the selection of topics to develop and in the education and information evaluation strategies

- o Establish and maintain quality control in all data and materials collection and management procedures

2. Institute Staff Responsibilities

The Program Director will be the Chief, Musculoskeletal Diseases Branch, NIAMS, or assignee.

The NIAMS Program Director and other NIH representatives will participate in the Advisory Committee activities and serve on any relevant sub-committees, providing expert scientific advice as needed. Such service would be expected to relate to the mission and interests of the participating institutes and serve to integrate the full spectrum of NIH mission-related issues in osteoporosis and related bone diseases. In addition, the NIAMS Program Director will provide linkages with other NIH programs and government-wide programs and grants that are involved in educational outreach activities.

Decisions for continued funding will be based on overall study progress, cooperation in research (i.e., coordination and attendance at Advisory Committee meetings, implementation of Advisory Committee recommendations, compliance with reporting requirements). The inability of a cooperative agreement recipient to meet the performance requirements, or significant changes in the level of performance, may result in an adjustment of funding, withholding of support, suspension or termination of the award.

3. Collaborative Responsibilities

It is anticipated that the awardee will have lead responsibilities for implementing all joint tasks and activities including the recommendations of the advisory group. The NIAMS Program Director

and other NIH staff may participate in the Advisory group meetings and may assist in the implementation of some of the projects.

A meeting of the Advisory Committee will be convened early after award by the awardee to discuss strategies for the upcoming year. Peer-reviewed publications may be planned and prepared by award recipients, with assistance as needed from NIH program staff.

4. Arbitration Procedures

In the event of a major scientific/programmatic disagreement between NIH and the awardee that cannot be resolved by appropriate negotiations, an ad hoc arbitration panel will be assembled to consist of the awardee, one NIH nominee, and a third member with appropriate expertise chosen by the other two. This NIH arbitration process in no way affects the awardee's right to appeal an adverse determination under the terms of 42 CFR Part 50, Subpart D, and 45 CFR Part 16.

STUDY POPULATIONS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59-14508-14513) and the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994.

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

LETTER OF INTENT

Prospective applicants are requested to submit, by March 15, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of this RFA.

Although a letter of intent is not required, is not binding, and does not enter into the review of the subsequent application, the information that it contains is helpful in planning for the review of applications. It allows NIAMS staff to estimate the potential review workload, and helps to avoid conflict of interest among reviewers.

The letter of intent is to be sent to Dr. Joan A. McGowan at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 5/95) is to be used in applying for these grants. Applications kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, E-mail: asknih@od.nih.gov.

The RFA label available in the application form PHS 398 (rev. 5/95) must be affixed to the bottom of the face page of the application. 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. In addition, the RFA title and number must be typed on line 2 of the face page of the application and the YES box must be checked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, exact photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW (formerly DRG)
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, SUITE 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must also be sent to:

Tommy L. Broadwater, Ph.D.
Chief, Grants Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS-25U, MSC 6500
Bethesda, MD 20892-6500

Telephone: (301) 594-4952

FAX: (301) 402-2406 or (301) 480-4543

Email: broadwater@nih.gov

Applications prepared in response to this RFA must be received by April 28, 1998.

If an application is received after that date, it will be returned to the applicant without review. The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already 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.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the NIAMS staff for completeness and responsiveness. Incomplete applications will be returned to the sender without further consideration. If the application is not responsive to the RFA, NIAMS staff will return the application to the applicant. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIAMS in accordance with the review criteria stated below. As part of the initial merit review, a process may be used in which applications will be determined to be competitive or noncompetitive based on their scientific merit relative to other applications received in response to this RFA. Applications determined to be noncompetitive by the review committee will be withdrawn from further consideration, and the principal investigator will receive a summary statement reflecting the reviewers' evaluation. Applications judged to be competitive will be further discussed and assigned a priority score. They will then receive a second level review by the Arthritis and Musculoskeletal Diseases Advisory Council.

The applications will be evaluated on the basis of the following criteria:

1. Extent to which the overall goals and objectives of the RFA are addressed by the applicant;
2. Scientific merit of the research design and intervention approach:
 - o Soundness of the rationale for the choice of interventions, target populations and approaches,
 - o Quality and rigor of outcome evaluation designs,

- o Quality of methods for identifying persons at risk for osteoporosis, particularly those unaware of their risks;
- o Feasibility of the proposed interventions,
- o Qualifications and competence of the proposed research and management team for the intervention components chosen,
- o Demonstrated previous relevant experience of the research team in health education, information dissemination, physician interventions, community interventions, and the like,
- o Adequacy of time commitments of key personnel,

Adequacy of resources and facilities:

- o Adequacy of resources available to implement the interventions including personnel, equipment, and data processing capacity,
- o Adequacy of data management and data quality control,
- o Adequacy of the capacity of the organization for managing the project.

The review group will also critically examine the submitted budget and will recommend an appropriate budget and period of support for each approved application.

AWARD CRITERIA

The anticipated date of award is September 30, 1998. Availability of funds and other programmatic priorities are important criteria in making grant awards.

INQUIRIES

The NIAMS Program Director and the other NIH representatives welcome the opportunity to clarify any issues or questions from potential applicants.

Written and telephone inquiries concerning the objectives and scope of this RFA, whether or not specific proposed research is responsive, the scientific content and objectives of an application,

the size and focus of a research program, and the organization of an application, are strongly encouraged and may be directed to:

Joan A. McGowan, Ph.D.
Musculoskeletal Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Natcher Building, Room 5AS-43E
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: joan_mcgowan@nih.gov

Direct inquiries regarding fiscal matters to:

Vicki Maurer
Grants Management Specialist
Natcher Building, Room 5AS-37H
Bethesda, MD 20892-6500
Telephone: (301) 594-3504
FAX: (301) 480-5450
Email: vicki_maurer@nih.gov

AUTHORITY AND REGULATIONS

Awards made in this program are described in the Catalog of Federal Domestic Assistance Nos. 93.846 and 98.853. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grant policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

REFERENCES

Chrischilles EA, Butler CD, Davis CS, Wallace RB (1991) A model of lifetime osteoporosis impact. *Arch Intern Med* 151 (10):2026-2032.

Looker AC, Johnston CC Jr, Wahner HW, Dunn WL, Calvo MS, Harris TB, Heyse SP, Lindsay RL (1995) Prevalence of low femoral bone density in older U.S. women from NHANES III. *J Bone Miner Res* 10 (5): 796-802.

Ray NF, Chan JK, Thamer M, Melton LJ 3rd. (1997) Medical expenditures for the treatment of osteoporotic fractures in the United States in 1995: report from the National Osteoporosis Foundation. *J Bone Miner Res* 12 (1):24-35.

Schneider EL, Guralnik JM. (1990) The aging of America. Impact on health care costs. *JAMA* 263 (17): 2335-2340.

[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)