

## PREVENTION OF ONSET, PROGRESSION, AND DISABILITY OF OSTEOARTHRITIS

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RFA: AR-00-006

National Institute of Arthritis and Musculoskeletal and Skin Diseases  
National Institute of Child Health and Human Development  
National Center for Complementary and Alternative Medicine  
National Institute of Nursing Research

Letter of Intent Receipt Date: June 1, 2001

Application Receipt Date: August 21, 2001

THIS RFA USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS RFA/PA.

### PURPOSE

The goal of this Request for Applications (RFA) is to promote the design, development and pilot testing of hypothesis-driven innovative approaches to the prevention of osteoarthritis onset, progression and disability. Osteoarthritis (OA) is a complex disease whose etiology bridges genetics, biomechanics and biochemistry. Understanding the relationships between modifying systemic risk factors such as dietary intake, estrogen use and bone density, local biomechanical factors such as muscle weakness, obesity and joint laxity and disease pathogenesis may lead to the identification of new approaches to the prevention of OA related pain and disability. This RFA is based on the many scientific opportunities identified in the conference "Stepping Away from OA: Prevention of Onset, Progression and Disability." A summary of the conference and research questions raised can be found at: <http://www.nih.gov/niams/reports/oa/oareport.htm>

### HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a PHS-led national activity for setting priority areas. This RFA is related to several objectives, particularly those listed in the chapter Arthritis,

Osteoporosis, and Chronic Back Conditions. Potential applicants may obtain Healthy People 2010 at <http://www.health.gov/healthypeople>.

## ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic for-profit and non-profit organizations, public or private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Foreign institutions are eligible to apply for these grants; in addition, applicants may collaborate, through consultation or contractual agreements, with investigators at foreign institutions. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

## MECHANISM OF SUPPORT

The mechanisms of support will include the investigator-initiated research project grant (R01) and the exploratory/developmental research grant (R21).

The exploratory/developmental research grant (R21) encourages the development of new research activities. In this solicitation the R21 is intended for use by 1) investigators experienced in osteoarthritis research who wish to adapt methods or techniques in pathogenesis, epidemiology, or clinical research established in other fields to osteoarthritis prevention, 2) established investigators with demonstrated expertise in fields other than osteoarthritis who wish to establish new research programs on osteoarthritis prevention; and, 3) investigators proposing high risk-high yield research projects. R21 applications are expected to include very limited or no preliminary data. The R21 mechanism is not appropriate for large-scale undertakings. This mechanism is also not appropriate for support or supplementation of ongoing research. Instead, investigators using this mechanism are encouraged to submit applications that explore the feasibility of an innovative research question or approach, which may not be ready to compete for funding as a standard research project grant (e.g., R01). Further, the R21 mechanism may also be used to develop a research basis for a subsequent R01 or P01 application. If desired, the specific aims of the R21 project may be incorporated into a research project grant application (R01) submitted prior to the termination of the R21 award. New investigators interested in developing small grants in the area of OA prevention are encouraged to apply under the NIAMS Small Grant Program for New Investigators (PAR-99-099, <http://www.nih.gov/niams/grants/pa/par99-099.html>). NINR does not routinely support R21s.

Exploratory/developmental (R21) grants, may not exceed \$75,000 per year in direct costs, including Facilities and Administrative costs for collaborating institutions, if any. The total project period for an R21 application submitted in response to this RFA may not exceed three years. These grants are non-renewable and continuation of projects developed under the R21 program will be through the traditional unsolicited (R01 or P01) grant programs.

Because the nature and scope of the research proposed in response to this RFA may vary, it is anticipated that the size of an award will vary also. Modular budgeting procedures apply for R21 and for R01 grants up to \$250 thousand. Specific R01 application instructions have been modified to reflect "Modular grant" and "Just-in-time" streamlining efforts. Complete instructions and information on Modular Grants can be found at <http://grants.nih.gov/grants/funding/modular/modular.htm>.

R01 applications are limited to no more than \$500,000 per year in direct costs, although exceptions may be permitted under certain circumstances. An applicant planning to submit a R01 application requesting \$500,000 or more in direct costs for any year is advised that he or she must contact IC program staff, listed under INQUIRIES, before submitting the application, i.e., as plans for the study are developed. Furthermore, the applicant must obtain agreement from IC staff that the IC will accept the application for consideration for award.

## FUNDS AVAILABLE

It is anticipated that for FY 2002, approximately \$4.1 million total costs will be available for the first year of support for this initiative. Award of grants is contingent upon the receipt of such funds for this purpose. The specific number to be funded will depend on the merit and scope of the applications received and on the availability of funds. Applicants may request up to five years of support for the R01 and up to three years for the R21. Direct costs will be awarded in modules of \$25,000 less any overlap or other necessary administrative adjustments. Facilities and Administrative costs will be awarded based on the negotiated rates.

## RESEARCH OBJECTIVES

### Background

OA is a significant public health challenge. Approximately 9 percent of the U.S. population aged 30 and older have clinical OA of the hip or knee. OA is a disease that is most commonly found in the hands, feet, knees, and hips.

Prevalence increases with age. In general, after age 50, OA is more common in women than in men. OA accounts for most hip and knee replacements. The disease is difficult to characterize because X rays sometimes show evidence of OA when the patient has no symptoms. The converse is also true, with pain occurring when no radiographic signs exist. The biochemistry, pathology, biomechanics, genetics, clinical aspects, and psycho-social issues make OA difficult to label and understand. Research on the use of traditional and complementary and alternative medicine approaches for the prevention of OA onset, progression and disability is ongoing. Among the complementary medicine approaches, acupuncture for joint pain, nutritional products such as green tea, dietary supplements such as glucosamine and chondroitin are currently being tested for the treatment of established OA. Other widely used but understudied treatments for OA include the dietary supplement, magnet therapy, and various types of manual therapies (e.g., manipulation and massage). However, the underlying biological mechanisms for these interventions remain unexplained, as do their usefulness for OA prevention

The goal of this solicitation is to promote hypothesis-driven research projects that 1) expand the repertoire of potential prevention strategies, 2) assess the role of and interactions among OA risk factors, 3) design and test new prevention strategies based on current knowledge, and 4) develop new approaches for deployment of existing prevention modalities in order to improve their impact. Translational and clinical research projects are encouraged, but such applications should clearly state how the research findings could or will be used to develop a prevention strategy. NINR is particularly interested in R01 applications on nursing prevention strategies or interventions that are consistent with the NINR mission. Potential applicants should contact the NINR program officer with any questions regarding the appropriateness of their topic. Large, observational and intervention studies are not within the scope of this RFA.

Specific areas of interest include but are not limited to the following:

Development of disease prevention strategies based on the molecular and cellular processes involved in pathogenesis.

Approaches to improve understanding of the relation between race and ethnicity on disease onset and progression that may provide the rationale for targeted prevention strategies.

Hypothesis-driven research on the effects of estrogen on bone, muscle, soft tissue, and joint degradation versus its effects on joint symptoms that may provide a rationale for intervention or improve understanding of risk factors.

Focused studies on the contribution of genetic factors to disease onset and progression, and their interaction with environmental factors leading to the development of prevention strategies.

Studies to identify metabolic factors that explain some of the associations between weight and hand, knee, and hip OA. Investigators are encouraged to seek out opportunities to join the obesity research community in accessing available patient populations. A current opportunity may exist to link up with the Study of Health Outcomes of Weight-Loss (SHOW) clinical trial.

Description of this and other cohorts that may be available for ancillary or mechanistic studies may be found at <http://www.nih.gov/niams/news/oisg/oaepip.htm> and <http://www.niddk.nih.gov/fund/divisions/DDN/DDNintro.htm>

Small, pilot prevention projects based on modification of mechanical factors known to affect OA onset and progression.

Preliminary studies on high risk populations for the evaluation of new prevention strategies.

Mechanistic studies to explain the effects of exercise in the prevention of disability and to develop strategies aimed at the expansion of this approach to prevention programs at the population level.

Studies to establish whether symptomatic treatments have the potential of delaying or halting disease progression and disability.

Studies to determine the benefits of specific vitamin supplementation and its potential role in treatment and prevention, and projects aimed at establishing the underlying mechanisms of beneficial effects.

Test interventions that improve quality of life, self-management, activities of daily living, and that relieve depression or other detrimental aspects of osteoarthritis.

Research on the use of complementary and alternative medicine approaches for the prevention of OA onset, progression and disability.

Design, development and preliminary testing of cost-effective socio-behavioral interventions that include selection of target populations that might benefit from the interventions.

Studies that model incorporating interventions into mainstream clinical practice or health care delivery in a cost effective way are needed.

Prevention strategies aimed at high risk or disproportionately affected patient populations are strongly encouraged. Community-based outreach and demonstration projects aimed at development, testing and application of a) newly designed prevention programs or b) new strategies for deployment of existing programs of recognized efficacy are also within the scope of this RFA. Investigators interested in applying for outreach and demonstrations projects are encouraged to contact the CDC Chronic Disease Prevention Office Web Site:

<http://www.cdc.gov/nccdphp/arthritis.htm>. In November 1998, the first comprehensive public health approach to reducing the burden of arthritis in the United States was released by the Arthritis Foundation, the Centers for Disease Control and Prevention (CDC), and the Association of State and Territorial Health Officials. The National Arthritis Action Plan: A Public Health Strategy proposes strategies in three major areas: 1) surveillance, epidemiology, and prevention research; 2) communication and education; and 3) programs, policies, and systems. The CDC is currently funding several State Public Health Office Programs to conduct arthritis prevention and surveillance projects.

#### INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

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 UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html>); a complete copy of the updated Guidelines are available at [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_update.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm): The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

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.

## INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address:  
<http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

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

## LETTER OF INTENT

Prospective applicants are asked to submit, by March 12, 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, does not commit the sender to submit an application, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and avoid conflict of interest in the review. The letter of intent is to be sent (e-mail, fax or post) to Dr. Tommy Broadwater at the address listed under INQUIRIES.

## URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no

obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

## APPLICATION PROCEDURES

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff. The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants, with the modifications noted below.

## BUDGET INSTRUCTIONS

Modular Grant applications (R01 and R21) will request direct costs in \$25,000 modules, up to a total direct cost request of \$250,000 per year. (Applications that request more than \$250,000 direct costs in any year must follow the traditional PHS398 application instructions.) In addition, applications with direct costs in excess of \$500,000/direct costs per year should obtain prior approval from the NIAMS, NCCAM, NCNR or NICHD before the applications are submitted. Direct costs will be awarded in modules of \$25,000 less any overlap or other necessary administrative adjustments. Facilities and Administrative costs will be awarded based on the negotiated rates.

Exploratory/developmental (R21) grants may not exceed \$75,000 per year in direct costs, including Facilities and Administrative costs for collaborating institutions, if any. The total project period for an R21 application submitted in response to this RFA may not exceed three years. The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

### PHS 398

o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in \$25,000 increments up to a maximum of \$250,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See <http://grants.nih.gov/grants/funding/modular/modular.htm> for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form page.

o Under Personnel, List all project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest \$1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of all personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at:

<http://grants.nih.gov/grants/funding/modular/modular.htm>

Complete the educational block at the top of the form page;

- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years;
- List selected peer-reviewed publications, with full citations.

RESEARCH PLAN - The research plan (a-d) is limited to 25 pages for R01s and 10 pages for R21 applications. The Background and Significance Section of R01 and R21 applications should specifically state the relevance of the proposed research for OA prevention. The Preliminary Data section in R21 applications must not exceed 1 page. Applications that exceed the page limit will be returned without review. An appendix may be included in the application; however, the appendix is not to be used to circumvent the page limit of the research plan.

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

Applications are to be submitted on the grant application form PHS 398 (rev. 4/98). These forms are available at most institutional offices of sponsored research; 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, email: [grantsinfo@nih.gov](mailto:grantsinfo@nih.gov); and on the internet at <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

For purposes of identification and processing, item 2a on the face page of the application must be marked "YES" and the RFA number "AR-00-006" and the words "PREVENTION OF ONSET, PROGRESSION, AND DISABILITY OF OSTEOARTHRITIS" must be entered on the face page.

The RFA label and line 2 of the application should both indicate the RFA number. The RFA label 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.

The sample RFA label available at: <http://grants.nih.gov/grants/funding/phs398/label-bk.pdf> has been modified to allow for this change. Please note that this is in pdf format.

Applications must be received by August 21, 2001. Applications not received as a single package on the receipt date or not conforming to the instructions contained in PHS 398 (rev. 4/98)

Application Kit (as modified in, and superseded by, the special instructions below, for the purposes of this RFA), will be judged non-responsive and will be returned to the applicant.

If the application submitted in response to this RFA is substantially similar to a grant application already submitted to the NIH for review, but that 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 that is essentially identical to one that has already been reviewed cannot be submitted in response to this RFA. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

Submit a signed, typewritten original of the application, including the checklist, and three signed, exact, single-sided photocopies, in one package to:

Center for Scientific Review  
National Institutes of Health  
6701 Rockledge Drive, Room 1040 - MSC 7710  
Bethesda, MD 20892-7710  
Bethesda, MD 20817 (for express mail or courier service)

At the time of submission, two additional exact copies of the grant application and all five sets of any appendix material must be sent to Dr. Tommy Broadwater at the address listed under INQUIRIES.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. If so, a letter of agreement from either the GCRC Program Director or Principal Investigator should be included with the application.

#### REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the NIH Center for Scientific Review and for responsiveness by staff of the participating Institutes; those judged to be incomplete or not in the format specified in this RFA will be returned to the applicant without review. Those considered to be non-responsive will be returned without review.

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 NIAMS in accordance with the review criteria stated below. As part of the initial merit review, a process will be used by the initial review group in which all applications will receive a written critique but only those applications deemed to have the highest scientific merit will be discussed, assigned a priority score, and receive a second level review by the NIAMS, NCHD, NCCAM, and NCNR National Advisory Councils.

## Review Criteria

The five criteria to be used in the evaluation of grant applications are listed below. To put those criteria in context, the following information is contained in instructions to the peer reviewers.

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. The reviewers will comment on the following aspects of the application in their written critiques in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered by the reviewers in assigning the overall score weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem relevant to OA prevention? If the aims of the application are achieved, how will scientific knowledge and prevention strategies for OA be advanced? What will be the effect of these studies on the concepts or methods that drive this field?
2. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? If a prevention approach is being tested, is it likely to have immediate broad applicability? If not, does the application adequately address how this could be achieved at a later time?
3. Innovation. Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. Investigator. Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

- o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

- o The reasonableness of the proposed budget and duration in relation to the proposed research

- o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application

The personnel category will be reviewed for appropriate staffing based on the requested percent effort. The direct costs budget request will be reviewed for consistency with the proposed methods and specific aims. For modular grant applications, any budgetary adjustments recommended by the reviewers will be in \$25,000 modules. The duration of support will be reviewed to determine if it is appropriate to ensure successful completion of the requested scope of the project.

#### AWARD CRITERIA

Award criteria that will be used to make award decisions include:

- o scientific merit (as determined by peer review)

- o availability of funds

- o programmatic priorities

#### INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Direct inquiries regarding programmatic issues to:

Dr. Susana A. Serrate-Sztein  
Rheumatic Diseases Branch  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
45 Center Drive, Room 5AS-37G  
Bethesda, MD 20892-6500  
Telephone: (301) 594-5032  
FAX: (301) 480-4543  
Email: [szteins@mail.nih.gov](mailto:szteins@mail.nih.gov)

Dr. Bernadette Tyree  
Cartilage and Connective Tissue Program  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
45 Center Drive, Room 5AS-37J  
Bethesda, MD 20892-6500  
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FAX: (301) 594-4543  
Email: [bt16w@nih.gov](mailto:bt16w@nih.gov)

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6707 Democracy Blvd. St. 106  
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National Center for Medical Rehabilitation Research  
National Institute of Child Health and Human Development  
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FAX : (301) 402-0832  
Email [rn21e@nih.gov](mailto:rn21e@nih.gov)

Nell Armstrong, PhD, RN  
Program Director  
National Institute of Nursing Research  
Building 45, Room 3AN12  
Bethesda MD 20892-6300  
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Fax: 301-480-8260  
email: [nell\\_armstrong@nih.gov](mailto:nell_armstrong@nih.gov)

Direct review inquiries to:

Tommy Broadwater, Ph.D.  
Scientific Review Branch,  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
45 Center Drive, Natcher Bldg. Rm. 5A25U  
Bethesda Md 20892-6500  
Telephone: (3101) 594-4953  
FAX (301) 480-4543  
Email: [broadwatert@mail.nih.gov](mailto:broadwatert@mail.nih.gov)

Direct inquiries regarding fiscal matters to:

Ms. Melinda Nelson  
Grants Management Officer  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
45 Center Drive, Natcher Bldg. Rm. 5A49F  
Bethesda, MD 20892-6500

Telephone: (3101) 594-3505  
FAX (301) 480-4543  
Email: [nelsonm@mail.nih.gov](mailto:nelsonm@mail.nih.gov)

Ms. Mary Ellen Colvin  
Grants Management Branch  
National Institute of Child Health and Human Development  
Building 61E, Room 8A17G, MSC 7510  
6100 Executive Boulevard  
Bethesda, MD 20892-7510  
Telephone: 301-496-1304  
Email: [mc113b@nih.gov](mailto:mc113b@nih.gov)

Robert L. Tarwater  
Grants Management Specialist  
Office of Grants and Contracts Management  
Division of Extramural Activities  
National Institute of Nursing Research  
Building 45, Room 3An.12  
Bethesda, Maryland 20892-6300  
Telephone: (301) 594-2807  
FAX: (301) 480-8260  
Email: [tarwater@nih.gov](mailto:tarwater@nih.gov)

Schedule:

Letter of Intent Receipt Date: June 1, 2001  
Application Receipt Date: August 21, 2001  
Peer Review Date: November, 2001  
Council Review: January/February, 2002  
Earliest Anticipated Start Date: March 1, 2001

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No.93.846, Arthritis, Musculoskeletal and Skin Diseases Research and No. 93,929 Child Health and Human Development Research. Awards are made under authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241, 284 and 285) and administered under NIH

grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The Public Health Service 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.

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