

CHIROPRACTIC AND OSTEOPATHIC CLINICAL TRIAL PILOT GRANTS

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P.T.

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

PURPOSE

The National Institutes of Health (NIH) is committed to investigating the efficacy and effectiveness of chiropractic and osteopathy for treatment of, and rehabilitation associated with, musculoskeletal injuries and disorders by supporting well-designed, well-executed, randomized clinical trials (RCT). Before proceeding to a full-scale, definitive RCT (Phase III trial) in which the main objective is to determine whether the intervention is more effective than that used in a control (or comparison) group, pilot clinical studies are often required. In the present program announcement (PA), the NIH announces its interest in supporting pilot studies to establish the methodological feasibility and strengthen the scientific rationale for proceeding to full-scale RCTs on the use of chiropractic or osteopathy to manage or treat musculoskeletal injuries and disorders. The emphasis of these pilot trials should be placed on the development of appropriate study designs to investigate safety and efficacy. These "proof of concept" trials could potentially lead to subsequent, large RCTs. For the purposes of this PA, trials of chiropractic and osteopathy are limited to manual manipulations.

HEALTHY PEOPLE 2000

The Public Health Service is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," an initiative for setting national health policy and priorities. Although "Healthy People 2000" does not have a chiropractic objective, this PA involves priority areas within the "Healthy People 2000" objectives, such as the area of chronic disabling conditions. 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 foreign and domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

The mechanisms of support will be the NIH research project grants (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Since the proposed research is pilot in nature, grants may not exceed \$150,000 per year in direct costs.

RESEARCH OBJECTIVES

The objective of Chiropractic and Osteopathic Clinical Trial Pilot Grants is to increase the quality of clinical research evaluating the efficacy of chiropractic and osteopathy for the management of musculoskeletal injuries and disorders, and their accompanying symptoms, particularly in children and in the physically disabled. To meet this objective, the proposed pilot study must successfully incorporate creative and realistic solutions to difficult problems in clinical research for the particular disease/condition under study. The focus should be on diagnostic and treatment procedures for specific musculoskeletal injuries and disorders that are selected according to public health and clinical significance, scientific rationale as provided by the appropriate research literature, and availability of a patient population.

The application should directly address how the pilot grant will advance the design of a subsequent full-scale RCT (Phase III trial). In preparing for the definitive RCT, these pilot studies should address questions that are formulated to optimize the design of the eventual RCT rather than address the clinical question with lower power. The application should also address the intrinsic scientific merit of the study conducted under the pilot grant, regardless of whether a full-scale trial is eventually performed. For the purposes of this PA, trials of chiropractic and osteopathy are limited to manual manipulations. Full-scale RCTs (Phase III trials in which the

main objective is to determine whether the intervention is more effective than that used in a control or comparison group) will not be accepted under this Program Announcement.

Applications in response to this program announcement may include, but are not limited to:

1. Studies to refine the intervention strategy including: duration and frequency of treatment; type of treatment; evaluations of different systems of manipulation.
2. Studies to refine the control strategy including comparisons of different types of controls (e.g., invasive control [sham] versus non-invasive control [placebo, standard therapy, wait list, etc.]).
3. Studies to define and refine the target population (e.g., inclusion/exclusion criteria) and develop adequate recruitment procedures.
4. Collection of preliminary data for establishing measures of efficacy and safety.
5. Studies to determine the feasibility and/or safety of the treatment strategy and develop realistic protocols.
6. Studies to establish the anticipated benefit of the treatment and to ascertain even rates (success and complications).
7. Studies to establish the clinical usefulness (validity, reliability, responsiveness and utility) and appropriateness of commonly used assessment procedures, especially quality-of-life measures, as well as functional and physiological measures of manipulation;

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 is 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 20, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Vol. 23, No. 11, March 28, 1994.

NIH POLICY AND GUIDELINES ON THE 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://www.nih.gov/grants/guide/notice-files/not98-024.html>

APPLICATION PROCEDURES

Applications are to be submitted on grant application form PHS 398 (rev. 5/95) and will be accepted at the standard application deadlines as indicated in the application kit. Application 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, email: Grantsinfo@nih.gov.

The title and number of the program announcement must be typed in section 2 on the face page of the application.

The complete original application and five legible copies must be sent or delivered 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/courier service)

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established PHS referral guidelines. Applications that are complete will be evaluated for scientific and technical merit by an appropriate peer review group convened in accordance with the standard NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique. Applications will also undergo a process in which only those deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board, when applicable.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application 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 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 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? If the aims of the application are achieved, how will scientific knowledge 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?

(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.

AWARD CRITERIA

The following will be considered in making funding decisions: Quality of the proposed project as determined by peer review, availability of funds, and program priority.

INQUIRIES

Applicants are strongly encouraged to contact the individuals designated below, in advance of preparing an application, for additional information concerning the areas of research and other types of pre-applications consultation.

Dr. Richard L. Nahin
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National Institutes of Health
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Bethesda, MD 20892-2182
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Dr. James Panagis
Orthopaedics Program
National Institute of Arthritis and Musculoskeletal and Skin Diseases
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Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: panagisj@ep.niams.nih.gov

Dr. Stephen M. Tuel
National Center for Medical Rehabilitation Research
National Institute of Child Health and Human Development
Building 61E, Room 2A03
Bethesda, MD 20892-7510
Telephone: (301) 402-2242
FAX: (301) 402-0832
Email: tuels@exchange.nih.gov

Direct inquiries regarding fiscal matters to:

Mary Ellen Colvin
Grants Management Branch
National Institute of Child Health and Human Development
Building 61E, Room 8A17
Bethesda, MD 20892-7510
Telephone: (301) 496-1303
FAX: (301) 402-0915
Email: mc113b@nih.gov

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.213, 93.846, and 93.929. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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.

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