

## ACUPUNCTURE CLINICAL TRIAL PILOT GRANTS

Release Date: February 25, 1998

PA NUMBER: PAS-98-033

P.T.

Office of Alternative Medicine

National Cancer Institute

National Heart, Lung and Blood Institute

National Institute of Dental Research

National Institute of Arthritis and Musculoskeletal and Skin Disorders

National Institute of Neurological Disorders and Stroke

National Institute on Drug Abuse

Agency for Health Care Policy and Research

Letter of Intent Receipt Date: April 10, 1998

Application Receipt Date: May 13, 1998

### PURPOSE

The National Institutes of Health (NIH) is committed to investigating the efficacy of acupuncture for treating or preventing disease and accompanying symptoms by supporting well-designed, well-executed, randomized clinical trials (RCT). Before proceeding to a full-scale RCT, 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 acupuncture to prevent, manage, or treat various symptoms/disorders. The emphasis of these pilot trials should be placed on the development of appropriate study design rather than on attempts to complete an insufficiently powered RCT. For the purposes of this PA, trials of acupuncture incorporating moxibustion or herbal medicine will not be considered. Under this PA, applications will be accepted on a single application receipt date and reviewed by a Special Emphasis Panel (SEP) administered through the Center for Scientific Review (CSR).

## 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 an acupuncture 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 mechanism of support for this PA is the research project grant (R01). Since the proposed research is pilot in nature, grants may not exceed \$350,000 per year in total costs (direct and indirect) nor extend beyond three years. This PA is a one-time solicitation with a single receipt date. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and be reviewed according to the customary peer review procedures.

## FUNDS AVAILABLE

Up to \$700,000 in total costs (direct plus indirect) in the first year will be available from the Office of Alternative Medicine (OAM) to fund 2-3 awards from meritorious, qualified applicants. In addition, the National Cancer Institute (NCI), the National Heart, Lung and Blood Institute (NHLBI), the National Institute of Dental Research (NIDR), the National Institute of Arthritis and Musculoskeletal and Skin Disorders (NIAMS), the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute on Drug Abuse (NIDA), and the Agency for Health Care Policy and Research (AHCPR) will support other meritorious applications that fit their program objectives. Funding levels are dependent on the receipt of applications of high technical and

scientific merit, and the continued availability of funds. Because the nature and scope of applications may vary, it is anticipated that the award size will vary. Although this program is provided for in the financial plans of the OAM, awards pursuant to this PA are contingent upon availability of funds for this purpose. Funding beyond the first and subsequent years of the grant will be contingent upon satisfactory progress during the preceding years and availability of funds.

## RESEARCH OBJECTIVES

The objective of "Acupuncture Clinical Trial Pilot Grants" is to increase the quality of clinical research evaluating the efficacy of acupuncture for the treatment or prevention of disease and accompanying symptoms. 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 application should directly address how the pilot grant will advance the design of a subsequent full-scale RCT. 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 acupuncture incorporating moxibustion or herbal medicine will not be considered.

Applications in response to "Acupuncture Clinical Trial Pilot Grants" may include, but are not limited to:

1. Studies to refine the intervention strategy including: duration and frequency of treatment; type of treatment (needling versus electroacupuncture versus laser acupuncture); evaluations of different systems of acupuncture (Chinese, Japanese, French, etc.).
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 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 leading to large scale patient outcomes trials and cost-effectiveness analysis, may include, but are not limited to, the following areas: methods, health-related quality of life measures, common health conditions treated, types of providers, types of individuals seeking acupuncture, treatment and duration, and treatment setting. Inquiries concerning these topics should be addressed to the appropriate contact at AHCPR (see INQUIRIES).

Possible diseases/conditions of interest include, but are not limited to:

- o Acute pain associated with surgery, dental procedures, low back pain, cancer breakthrough pain, and vaso-occlusive crises in sickle cell disease;
- o Angina Pectoris and cardiac arrhythmias;
- o Asthma as an adjuvant to standard care, and dyspnea;
- o Carpal tunnel syndrome;
- o Chronic pain associated with back pain, cancer, fibromyalgia, temporomandibular disorders, HIV/AIDS, or Reflex Sympathetic Dystrophy;
- o Hypertension and vascular disease;
- o Stroke;
- o Nausea and vomiting associated with chemotherapy or pregnancy;
- o Drug abuse and addiction;

Applicants are strongly encouraged to contact the designated staff (see Inquiries) at participating NIH institutes and AHCPR to discuss other possible research areas.

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

## LETTER OF INTENT

Applicants are asked to submit, by April 10, 1998 a letter of intent that includes the number and title of this PA; the name, address, and telephone number of the Principal Investigator (s); the identities of other key personnel and participating organizations or institutions, if any; and a title describing the proposed research.

Although a letter of intent is not required, is not binding, and does not enter into the review of applications, the information that it contains will be especially helpful in planning for the review of applications, estimating the potential work-load, and avoiding conflicts of interest in the review process.

Mail/Fax letters of intent to:

Dr. Richard L. Nahin  
Office of Alternative Medicine  
National Institutes of Health  
Building 31, Room 5B36  
Bethesda, MD 20892-2182  
Telephone: (301) 435-5042  
FAX: (301) 402-4741  
Email: [NahinR@OD31EM1.OD.NIH.GOV](mailto:NahinR@OD31EM1.OD.NIH.GOV)

## APPLICATION PROCEDURES

Applications are to be submitted on the grant application form PHS 398 (rev. 5/95) with a one time receipt date. 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: [ASKNIH@od.nih.gov](mailto:ASKNIH@od.nih.gov).

The title and number of the program announcement must be typed in Section 2 on the face page of the application. As with most applications to NIH, the research plan is limited to 25 pages.

The completed original application and four 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  
BETHESDA, MD 20817 (for express/courier service)

In order to facilitate the review of applications, the applicant must at the same time, mail or deliver one copy of the application to:

Richard L. Nahin, M.P.H., Ph.D.  
Office of Alternative Medicine  
National Institutes of Health  
Building 31, Room 5B36  
Bethesda, MD 20892-2182  
Telephone: (301) 435-5042  
FAX: (301) 402-4741

## REVIEW CONSIDERATIONS

### General Considerations

Upon receipt, applications will be reviewed for completeness by the CSR. Incomplete applications will be returned to the applicant without further consideration. Applications that are complete will be evaluated for scientific and technical merit by an appropriate SEP convened by

the CSR in accordance with the NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications 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.

## Review Criteria

All applications submitted in response to this PA will be reviewed according to the following review criteria. Reviewers will consider these criteria when assigning a single overall score to each application. This single score should reflect their judgment that the proposed research will have a substantial impact on the pursuit of its goals.

(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? In addition, the following must be addressed:

- The scientific basis for the proposed intervention including discussion of current practice and alternative interventions;
- Impact of the proposed intervention on health care and quality of life.

(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? In addition, the following should be addressed:

### (a) Study Design and Procedures

- Sequence of clinical studies, including the proposed pilot study, that will produce a definitive clinical trial;
- Translation of the clinical question into statistical hypotheses;
- Selection of outcome measure(s);
- Inclusion and exclusion criteria;
- Secondary questions (including capacity for post hoc analyses);
- Detailed protocol with standardized procedures that will be used for this pilot study;
- Ethical and safety issues, and quality control procedures;
- Necessity for randomization and masking;

### (b) Data Analysis

- Specific methods to be used for data analysis;

- The sample size for the pilot study may not be adequate to detect any but the largest treatment differences; however, the data from this study should provide a basis for providing sample size estimates for future trials;

- Population and demographics of the clinical condition;

(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)? In addition, the following should be addressed:

- Training and expertise in the clinical problem and in acupuncture;

- Training and expertise in clinical trials;

(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?

Each project will be reviewed for the adequacy of plans to include genders, minorities, and their subgroups as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects also will be evaluated.

The adequacy of the proposed protection for humans, animals or the environment will be evaluated 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. Patricia S. Bryant  
Division of Extramural Research  
National Institute of Dental Research  
Natcher Building, Room 4AN-24E  
Bethesda, MD 20892-6500  
Telephone: (301) 594-2095  
FAX: (301) 480-8318  
Email: [BryantP@de45.nidr.nih.gov](mailto:BryantP@de45.nidr.nih.gov)

Dr. Mary A. Cummings  
Center for Outcomes and Effectiveness Research  
Agency for Health Care Policy and Research  
2101 East Jefferson Street, Suite 605  
Rockville, MD 20852  
Telephone: (301) 594-1485  
FAX: (301) 594-3211  
Email: [mcumming@ahcpr.gov](mailto:mcumming@ahcpr.gov)

Debra Grossman  
Division of Clinical and Services Research  
National Institute on Drug Abuse  
Parklawn Building, Room 10A-10  
Bethesda, MD 20892-8025  
Telephone: (301) 443-0107  
FAX: (301) 443-8674  
Email: [dg79a@nih.gov](mailto:dg79a@nih.gov)

Dr. Cheryl A. Kitt  
Division of Convulsive, Infectious and Immune Disorders  
National Institute of Neurological Disorders and Stroke  
7550 Wisconsin Avenue, Room 504  
Bethesda, MD 20892  
Telephone: (301) 496-1431  
FAX: (301) 402-2060  
Email: [KittC@ninds.nih.gov](mailto:KittC@ninds.nih.gov)

Dr. Michael C. Lin  
Division of Heart and Vascular Diseases  
National Heart, Lung and Blood Institute  
6701 Rockledge Drive, Suite 10193  
Bethesda, MD 20892-7956  
Telephone: (301) 435-0560  
FAX: (301) 480-2948  
Email: [ml50z@NIH.GOV](mailto:ml50z@NIH.GOV)

Dr. Richard L. Nahin  
Office of Alternative Medicine  
National Institutes of Health  
Building 31, Room 5B36  
Bethesda, MD 20892-2182  
Telephone: (301) 435-5042  
FAX: (301) 402-4741  
Email: [NahinR@OD31EM1.OD.NIH.GOV](mailto:NahinR@OD31EM1.OD.NIH.GOV)

Dr. James Panagis  
Orthopaedics Program  
National Institute of Arthritis and Musculoskeletal and Skin Diseases  
Natcher Building, Room 5AS-37K - MSC 6500  
Bethesda, MD 20892-6500  
Telephone: (301) 594-5055  
FAX: (301) 480-4543  
Email: [panagisj@ep.niams.nih.gov](mailto:panagisj@ep.niams.nih.gov)

Dr. Claudette Varricchio  
Division of Cancer Prevention  
National Cancer Institute  
6130 Executive Boulevard, Room 300  
Rockville, MD 20852-7340  
Telephone: (301) 496-8541  
FAX: (301) 496-8667  
Email: [VarriccC@dcpcepn.nci.nih.gov](mailto:VarriccC@dcpcepn.nci.nih.gov)

Direct inquiries regarding fiscal matters to:

Vicki Maurer

Grants Management Branch

National Institute of Arthritis and Musculoskeletal and Skin Diseases

45 Center Drive, Room 5AS-37H

Bethesda, MD 20892-7510

Telephone: (301) 594-3504

FAX: (301) 480-5450

Email: [maurerv@ep.niams.nih.gov](mailto:maurerv@ep.niams.nih.gov)

Martin R. Rubinstein

Grants Management Office

National Institute of Dental Research

45 Center Drive, Room 4AN-44A

Bethesda, MD 20892-6420

Telephone: (301) 594-4800

FAX: (301) 480-8301

Email: [Rubinstein@de45.nidr.nih.gov](mailto:Rubinstein@de45.nidr.nih.gov)

Karen D. Shields

Grants Management Branch

National Institute of Neurological Disorders and Stroke

Federal Building, Room 1004

Bethesda, MD 20892

Telephone: (301) 496-9231

FAX: (301) 402-0219

Email: [ks26n@nih.gov](mailto:ks26n@nih.gov)

#### AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.121, 93.180, 93.213, 93.226, 93.279, 93.396, 93.837, 93.838, 93.846, and 93.853. 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.

---

[Return to Volume Index](#)

[Return to NIH Guide Main Index](#)