

Instructions for Applying for a Supplement to the P30 Cancer Center Support Grant

Letter RFA CA-00-502

RFA Title: Innovative Cancer Complementary and Alternative Medicine Initiative in Cancer Centers

Available Funds: \$2 million

Application Deadline: November 13, 2000

Award Date: July 1, 2001

Application Process: Use Standard Form PHS 398 (Rev. 4/98) and follow all its instructions in addition to the special instructions below.

- Cover Letter (optional): If included, should be signed by Cancer Center Director (P.I. of the Cancer Center Support Grant) and the appropriate institutional business official.
- Face Page: In Item 1, indicate the exact same title of the currently funded P30 Cancer Center Support Grant. In Item 2a, denote the Title of the RFA as “Innovative Cancer Complementary and Alternative Medicine Initiative in Cancer Centers.” In Item 2b, denote P30. The Principal Investigator for the supplement application should be the Principal Investigator of the P30 Cancer Center Support Grant. The face page should be signed by the P.I. of the Cancer Center Support Grant and the appropriate business official.
- Key personnel: List all the key personnel, including consultants and collaborators, for this initiative on p. 2 after the Description.
- Budget: A budget not exceeding \$400,000 total costs per year in developmental pilot projects for a period not to exceed three years may be requested. Each pilot project can not exceed \$150,000 in total cost per year. Since this is a developmental fund category, no administrative cost is allowed.
- Objectives (Limit to five pages): Include a brief overview of the anticipated Cancer Complementary and Alternative Medicine (CAM) Research Program, its scientific theme(s), its members, and its research base. Describe the potential of the Center for generating innovative pilot projects in CAM research, with particular attention to any special capabilities and collaboration with CAM practitioners. Provide a brief description of the pilot projects that will be supported with these developmental funds. Describe and highlight any pilot projects that interface with CAM practitioners. Describe the plans for managing the developmental funds, including (1) the intended processes for promoting the developmental funds; (2) the internal review and approval process and criteria used for selecting proposals for award; (3) the provisions for encouraging the investigators to submit R01 applications once the pilot phase is completed; (4) recent (up to three years)

accomplishments with ongoing P30 pilot projects; and (5) provide an appropriate senior leader (as defined in the P30 guidelines) who oversees this initiative.

- Introduction (Limit to two Pages for each pilot project): Provide an explanation of why the support for pilot projects being requested in the application is needed for building the research of the CAM program. How will this support contribute to the current and future needs and scientific direction of the Program? What is the potential benefit to the community and minority and underserved populations in the community?
- Pilot Projects (Limit to 10 Pages for each pilot project): Each application can include up to three pilot projects. Each of these projects is preferably for one year of support. The application should include justification for any project that is longer than one year. The research must be oriented toward the most critically needed areas of CAM research, and toward collaborative activities that address innovative possibilities in CAM research. Collaborations with appropriately certified, licensed or otherwise qualified CAM practitioners are strongly recommended. This letter RFA does not support a Phase III trial. For the purpose of this letter RFA, a Phase III trial is defined as a broadly based prospective investigation usually involving a substantial number of human subjects either at a single site or at multiple sites. The primary objective of such trials is to evaluate an experimental intervention in comparison with a standard or control intervention, or to compare two or more existing treatments. In Phase III trials, the primary endpoint is usually a significant change in some clinical outcome. The definition includes interventions given for disease prevention, prophylaxis, diagnosis, or therapy.

Provide a description of the proposed pilot projects. The description is for a pilot project and therefore need not be as detailed as that which would be required for an application for an R01. However, sufficient detail should be provided to allow the reviewers to grasp the background and thinking contributing to the project design; the hypothesis being proposed; the feasibility of the project; the significance of the project, particularly with respect to its cancer and complementary and alternative medicine relevance; and the innovativeness of the proposed research. Describe the importance of the projects to the development of the cancer complementary and alternative medicine research capability of the Cancer Center. Describe how they will contribute to interdisciplinary collaboration within, and cohesiveness of, the complementary and alternative medicine research program.

Collaborative arrangements within the Center, within the parent institution and with other institutions are encouraged. All collaborations with scientists outside the immediate Center should be documented with appropriate letters of commitment as applicable.

- Biographical Sketches: Include a biographical sketch for the Principal Investigator of each pilot project and the senior leader who oversees this initiative.
- Appendices

- Other Sections: Include all other sections of form PHS 398, e.g., Resources and Environment, Checklist, etc.

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 sub-populations 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 subject or the purpose of the research. This policy results from the NIH Revitalization Act of 1993.

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, Volume 23, Number 11, March 18, 1994 available electronically at <http://grants.nih.gov/grants/guide/notice-files/not94-100.html>.

Research components involving phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

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.

Submission

Before submitting the application, affix the RFA label in the application form PHS 398 (Rev. 4/98) to the bottom of the face page. Failure to use this label could result in delayed processing of your application such that it may not reach the review committee in time for review. The number (CA-00-502) and the title of the RFA must be typed on line 2 of the face page of the application form.

Submit a signed, typewritten original of the application (without appendices), including Checklist, and three (3), exact photocopies, in one package to the address below. The photocopies must be clear and single sided.

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

At the time of submission, send two (2) additional copies of the application and five sets of any appendix material to:

Ms. Toby Friedberg
Referral Officer
Division of Extramural Activities
National Cancer Institute
6116 Executive Boulevard Room 8062, MSC 8329
Rockville, MD 20852 (express courier)
Bethesda, MD 20892-8329

Deadline for Application. The application receipt deadline is November 13, 2000. Any applications received after November 13 will not be reviewed.

Budget Limitation. The request for developmental funds may not exceed \$400,000 total costs per year for up to three years. Only one request per Cancer Center will be considered.

Peer Review Process: All applications will be administratively reviewed for completeness and responsiveness by NCI staff. Incomplete and non-responsive applications will be returned to the applicants without further consideration. 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 NCI Division of Extramural Activities 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 applications 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 the applications under review, will be discussed, assigned a priority score, and receive a second level review by the National Cancer Advisory Board.

Review Criteria

1. Institutional Commitment
 - Commitment to develop a cancer complementary and alternative medicine research program.

- Adequacy of the plan for managing the developmental fund, e.g., provisions for promoting the developmental funds, review and project selection, and for encouraging subsequent applications for RO1s by providing a table listing all funded pilot projects in the past five years and identifying which ones resulted in funded RO1s.
- Availability of adequate resources for the proposed research in terms of funding, space and personnel. Adequacy of preparation and ability of the senior leader to lead and oversee this initiative.

2. CAM Content and Significance

- Documentation that linkages to the relevant CAM communities exist and that certified or licensed CAM practitioners provide appropriate input to, and participate in, the proposed pilot projects.
- Potential for initiating innovative pilot research projects in complementary and alternative medicine and initiating innovative collaborations with CAM practitioners.

3. Pilot Projects

- Likelihood that the pilot projects will result in R01 grant applications.
- Adequacy of preparation and ability of the investigators to do the proposed work.
- Adequacy of the hypothesis to be tested; innovativeness or promise of the research idea. Reasonableness of the proposed approach/methodology. Basis or grounding of the proposed research in the relevant literature or on evidence of widespread use by cancer patients.
- Reasonableness/appropriateness of the requested budget.
- Adequacy of the provision for protection of human and/or animal subjects, and provision for inclusion of children, women and minorities in clinical trials, where applicable

Awards. Awards will be issued as supplements to the P30 Cancer Center Support Grant with the earliest issue date(s) being July 1, 2001.

Authority and Regulations

The Cancer Centers Program is described in the Catalog of Federal Domestic Assistance Number 93.397, Cancer Centers Support. Awards will be made under authorization of the Public Health Service Act, (Public Law 100-607) and administered under NIH grant policies and Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92.

Inquiries.

We will post all the applicants' questions and answers as they arrive at our web site:
<http://occam.nci.nih.gov/2001letterfa/>

The Program Director representing the OCCAM, NCI, for this supplemental initiative is:

P. T. Kim Pham, Ph.D.
Program Director
National Cancer Institute
6130 Executive Boulevard
Executive Plaza North Room 102, MSC 7383
Bethesda, MD 20892-7383
(For Express mail use Rockville, MD 20852)
Phone: 301-496-3866
Fax: 301-480-0075
Email: pp64n@nih.gov

The Program Director representing the NCCAM for this supplemental initiative is:

Mary Ann Richardson, DrPH
Program Officer
National Institutes of Health
National Center for Complementary and Alternative Medicine
31 Center Dr; Room #5B-58
Bethesda, MD 20892-2182
Phone: 301-402-1272
Fax: 301-402-4741
Email: marich@od.nih.gov

The Program Director representing the CCB, NCI, for this supplemental initiative is:

Margaret Holmes, Ph.D.
Chief, Cancer Centers Branch
National Cancer Institute
6116 Executive Boulevard, Room 700
Bethesda, MD 20892-7383
Phone: 301-496-8531
Fax: 301-402-0181
Email: holmesm@dcbdcep1.nci.nih.gov

Address any fiscal or administrative inquiries to:

Ms. Eileen Natoli
Section Chief
Grants Administration Branch
National Cancer Institute
6120 Executive Boulevard
Executive Plaza South, Room 243
Bethesda, MD 20892
(For Express mail use Rockville, MD 20852)
Phone: (301) 496-8791
Fax: (301) 496-8601
Email: natolie@gab.nci.nih.gov