

**AMERICAN OSTEOPATHIC ASSOCIATION**

**COUNCIL ON RESEARCH - REQUEST FOR PROPOSALS:**

**SYSTEMATIC REVIEW OF DATA ON  
OSTEOPATHIC MANIPULATIVE TREATMENT**

**RELEASE DATE:** December 22, 2005

**SUBMISSION DATE:** Must be postmarked no later than 11:59 pm February 27, 2006

**AWARD DATE:** April 10, 2006

**FINAL REPORT DUE DATE:** October 31, 2006

**Summary Interim Report Dates:** August 15, 2006

**BACKGROUND**

The overall mission of the American Osteopathic Association (AOA) is to improve the nation's health care through the contributions of osteopathic medicine. A fundamental aspect of this mission involves scientific and clinical research that adds to our knowledge of osteopathic manipulative medicine (OMM) and the role of osteopathic manipulative treatment (OMT).

Contemporary health care has evolved with a strong focus on evidence-based medicine. In this environment, the efficacy and cost-effectiveness of interventions such as OMT are evaluated by scientists, clinical investigators, and health service and policy analysts, as well as by other parties, including but not limited to insurers, health maintenance organizations, and Federal agencies with Medicare and Medicaid oversight.

Ongoing osteopathic research of high quality is needed to demonstrate the efficacy, appropriateness and cost-effectiveness of OMT for a variety of clinical entities. At present there is also a critical need to systematically identify, evaluate, and summarize the current body of knowledge as it relates to OMT. This request for proposals (RFP) has been developed in response to this need. The AOA Bureau of Osteopathic Clinical Education and Research, the Council on Research, and the Committee on Socioeconomic Affairs are working in collaboration with AOA staff in Chicago and Washington to address this need in an expedited action.

**RESEARCH OBJECTIVES**

The primary intent of this RFP is to solicit the review and summarization of data to serve as the foundation for AOA recommendations on the efficacy or effectiveness of OMT techniques commonly used by osteopathic physicians in the United States. Thus, the proposed research must address the efficacy or effectiveness of OMT as practiced in the United States. To the extent that OMT techniques used by osteopaths trained outside the United States are relevant to clinical practice in the United States, they may also be included in the research plan. Likewise, to the extent that manual medicine techniques are integrated by other full-spectrum practice physicians (MD) in a manner relevant to the clinical practice employed by osteopathic clinicians integrating OMM/OMT in the United States, they may also be included in the research plan. Applications proposing to include manipulation techniques performed by non-osteopathic practitioners (i.e. chiropractors, physical therapists, or other) as part of the research objectives listed above will be considered non-responsive to this RFP.

Beyond the efficacy or effectiveness of OMT, a secondary intent of this RFP is to solicit the review and summarization of available economic data to evaluate the cost-effectiveness of OMT as practiced in the United States. The applicant is encouraged to search for and include outcomes or cost data from state or HMO reviews.

At a minimum, applicants responding to this RFP are expected to meet the following objectives:

- (1) Perform a systematic review of the biomedical literature to identify relevant publications involving OMT;
- (2) Contribute comprehensive citations from the literature which can be integrated into a consensus bibliography, defined by levels of evidence;
- (3) Perform a critical appraisal of the biomedical literature on OMT by evaluating the content, methodological quality, and results of the retrieved publications;
- (4) Perform statistical pooling or meta-analysis of data from the retrieved publications; and,
- (5) Submit a written report to the American Osteopathic Association – Council on Research describing the methodological processes involved in meeting objectives 1-4 above, presenting the research findings, and discussing the implications specifically for OMT and more broadly for osteopathic medicine.

## **FINAL REPORT**

The Final Report will be publishable in a peer-reviewed journal, and will include an abstract and an Executive Summary. This report will serve as documentation of the foundations of evidence-based medicine in OMM/OMT as well as evidence levels of quality indicators. The report may include, or provide the foundation for, abstracts that meet the evidence levels of quality indicators for specific clinical entities.

The report will also provide a foundation for continuing documentation to be used in support of practicing physicians and osteopathic medicine. The most immediate application of the final report will be to update or create documentation on OMM/OMT for coding and reimbursement purposes (Committee on Socioeconomic Affairs). Future applications may include but are not limited to quality measures, CMS, and guidance for research programs.

The Final Report shall be considered a Work Made for Hire as defined in Section 101 of the Copyright Act of 1976 (17 USC Section 101, et seq.). In consideration for the Applicants will be expected to agree to transfer all right, title and interest in and to the Final Report to the American Osteopathic Association (AOA). By submitting responses to this RFP, Applicants acknowledge and agree that the Final Report and all rights therein, including, without limitation, copyright and other intellectual property rights, shall be the sole and exclusive property of the AOA.

## **ELIGIBLE APPLICANTS**

Applications will be considered from principal investigators who meet any of the following criteria: (1) A physician who holds a faculty appointment at an AOA accredited, affiliated, or approved osteopathic institution; (2) A doctoral level biomedical researcher who demonstrates evidence of professional training and experience consistent with the objectives of this RFP; or (3) An osteopathic physician who holds a faculty appointment at a non-osteopathic institution having accreditation, affiliation, or approval as appropriate for that institution's activities and who demonstrates evidence of professional training and experience consistent with the objectives of this RFP. Co-investigators are acceptable. All decisions regarding an applicant's eligibility will be at the sole discretion of the funding agency.

## **RESEARCH PLAN**

The Research Plan must include the following sections. Refer to guidelines on “The Research Proposal” in the AOA Research Handbook. For this RFP, the Research Plan, including specific aims, background and significance, preliminary studies, and research design and methods, will not exceed a total of 15 (fifteen) pages.

- Description of performance site; key personnel and significant contributors (including role and organization)
- Specific aims
- Background and significance
- Preliminary studies
- Research design and methods
- Human subjects research including protection of human subjects, inclusion of women and minorities, and inclusion of children. (Although this is primarily a literature review, it is felt that IRB clearance is advisable *pro forma*.)
- Literature cited (published or “in-press” citations are acceptable; however, personal communications, “submitted”, and non-published citations are not acceptable).

Letters of support and appendix materials are optional but may be included. Appendix materials may include up to 10 publications or manuscripts accepted for publication, as well as other items relevant to the proposed project.

## **BUDGET**

Direct costs of up to \$100,000 will be supported. Budget justification must be provided on Form E (Modified) 2006 and continuation page(s), if needed. No Facilities and Administrative costs (F&A) / Indirect costs will be allowed. Investigator and staff salaries are eligible for funding, as well as project-related expenses and expendable supplies. Capital expenditures, major equipment (greater than \$5,000), and non-project related travel are not eligible for support. Applicants will be solely responsible for planning, directing, and executing the proposed project.

Funds will be disbursed under the following schedule: 50% of the award will be disbursed on approval of the RFP by the Council on Research and the Bureau of Osteopathic Clinical Education and Research; 25% of the award will be disbursed on receipt of an interim report; and 25% of the award will be disbursed on receipt of the Final Report.

## **REVIEW PROCESS AND CRITERIA**

The primary criteria for funding will include: (1) Technical soundness of the proposed research plan, including feasibility of time lines; (2) Experience of the principal investigator; (3) The institutional environment and support for the research plan. In addition to the funding decision, each applicant will receive a written summary critique. It is anticipated that only one proposal will be selected to receive this funding award.

All eligible applications will undergo a peer review process sponsored by the funding agency, including consideration by a scientific review group and not limited to the Council on Research. The parameters for this project fall outside of those specific programs outlined in the AOA Research Handbook (BOT 2005). However, general rules for submission, review and oversight, and the conduct of the research project shall apply except as otherwise specifically indicated in this RFP. Application deadline, project report deadline, and applications forms and format are as described in this RFP; the duration of the project and time line are also as described in this RFP.

## **GRANT APPLICATION FORMAT and INSTRUCTIONS**

All forms and instructions needed to complete the application process may be downloaded at: [http://www.do-online.osteotech.org/index.cfm?PageID=res\\_main](http://www.do-online.osteotech.org/index.cfm?PageID=res_main) and are also available by e-mail to [research@osteopathic.org](mailto:research@osteopathic.org)

- Face page - AOA Form A
- Funding Date Sheet - AOA Form B (Modified)
- Protection of Research Subjects - AOA Form D (May be submitted up to 30days after initial deadline, but evidence of institutional intent must be filed with the application.)
- Budget for the entire proposed period of study - AOA Form E (Modified)
- Summary of Proposal - AOA Form F (Modified)
- Biosketch for principal investigator and key personnel - AOA Form F or NIH Biographical Sketch
- Research Plan (See Above)

## **INQUIRIES and APPLICATION SUBMISSION**

Applicants must include a signed, typewritten original of the application and 10 single-sided copies. A total of six copies of any appendix materials must also be provided. Submit all application materials in one package to:

Beth Freeman, Manager  
Division of Research Development  
American Osteopathic Association  
142 E. Ontario  
Chicago, IL 60611  
(800) 621-1773, Ext. 8006 or (312) 202-8006  
Fax: (312) 202-8306  
[bfreeman@osteopathic.org](mailto:bfreeman@osteopathic.org)