



AMERICAN OSTEOPATHIC ASSOCIATION

TREATING OUR FAMILY AND YOURS

Request for Applications

Acute/Chronic Pain Management Grant (ACPM)

Table of Contents

THE AMERICAN OSTEOPATHIC ASSOCIATION (AOA)	2
AOA RESEARCH PRIORITIES	2
FUNDING OPPORTUNITY	3
DEADLINE FOR APPLICATION	5
GRANT PERIOD	5
FUNDS AVAILABLE	5
ELIGIBILITY CRITERIA	5
GRANT REVIEW CRITERIA	5
APPLICATION PROCESS	7
TECHNICAL ASSISTANCE/QUESTIONS	9

THE AMERICAN OSTEOPATHIC ASSOCIATION (AOA)

AOA's Mission: To advance the distinctive philosophy and practice of osteopathic medicine.

AOA's Vision: To be the professional home for all physicians who practice osteopathically.

About the AOA: Serving as the professional family for more than 145,000 osteopathic physicians (DOs) and osteopathic medical students, the American Osteopathic Association (AOA) promotes public health and encourages scientific research. In addition to serving as the primary certifying body for DOs, the AOA is the accrediting agency for all osteopathic medical schools.

Continually striving to advance the distinctive philosophy and practice of osteopathic medicine, the AOA stands for the following universal principles:

- Enhancing the value of AOA membership
- Protecting and promoting the rights of all osteopathic physicians
- Accentuating the distinctiveness of osteopathic principles and the diversity of the profession
- Supporting DOs' efforts to provide quality, cost-effective care to all Americans
- Collaborating with others to advance the practice of osteopathic medicine

The AOA stands firmly behind osteopathic physicians' ethical and professional responsibilities to patients and the medical profession. We offer an in-depth look at our ethical standards in our official Code of Ethics. Our policies and positions also outline the AOA's stance on major health issues affecting all areas of society.

AOA RESEARCH PRIORITIES

AOA will support the development of research projects grounded in osteopathic medicine that have the most promising potential to impact both individual patient outcomes and evidence-based medicine; facilitate collaboration within and outside the osteopathic community, and enhance the visibility of the osteopathic profession.

AOA has identified two areas of emphasis to help focus funding opportunities and develop collaborative research studies. The two recommended areas of emphasis cover topics in Osteopathic Manipulative Medicine and Osteopathic Manipulative Treatment (OMM/OMT). These topics include fall prevention, vestibular problems, and concussions, and topics in Acute and Chronic Pain Management emphasizing various treatments and patient outcomes. These categories reflect the concept that while OMM/OMT remains a strong tradition of the osteopathic profession, osteopathic medicine encompasses a broader philosophy that includes patient-centered care, empathy, and the mind/body/spirit approach. The osteopathic philosophy embraces an approach that while seeking and promoting health, it also addresses disease states, as well as the spectrum of patient care (e.g., primary, secondary, and tertiary).

FUNDING OPPORTUNITY

The AOA, with the guidance from the Bureau of Osteopathic Clinical Education and Research (BOCER), has available funding for projects focusing on osteopathic approaches to acute and chronic pain management with an emphasis on various treatment and patient outcomes.

The Osteopathic Approach is based on the tenets of osteopathic medicine. The osteopathic tenets are a foundation of the osteopathic profession from which emerges the osteopathic philosophy of the holistic approach to care by helping patients be truly healthy in mind, body, and spirit – not just free of symptoms. The tenets of osteopathic medicine are defined as follows:

- (1) The body is a unit; the person is a unity of body, mind, and spirit.
- (2) The body is capable of self-regulation, self-healing and health maintenance.
- (3) Structure and function are reciprocally interrelated.
- (4) Rational treatment is based upon an understanding of the basic principles of body unity, self-regulation and the interrelationship of structure and function.¹

Requirements for RFA:

Proposals in response to this RFA should explore the osteopathic approaches to acute and chronic pain management with an emphasis on treatments and patient outcomes. The International Association for the Study of Pain defines pain as “ an unpleasant sensory and emotional experience associated with actual or potential tissue damage , or described in terms of such damage.” Acute pain is the immediate and ongoing response of the body to noxious stimuli that lasts up to twelve weeks. Chronic pain is defined as pain that persists longer than 12 weeks. While there may be physiologic differences between the nature of acute and chronic pain it is a basic premise of this grant that pain inflicts physical, emotional, psychosocial and spiritual suffering the relief of which is a fundamental goal and obligation of the osteopathic profession

Proposals should address one or more of the following:

1. The role of OMM/OMT, as well as other osteopathic modalities such as touch and communication in surgical recovery.
2. The role of the effects of OMM/OMT on reducing opioid prescribing (consumption). Studies should measure acute pain control.
3. The identification and investigation of the role of biomarkers in substantiating that OMT works mechanistically and defining how biomarkers can be used as a more reliable measurement of pain reduction than the use of traditional pain scales.

Patient outcomes include, but are not limited to:

¹ H622-A/13 TENETS OF OSTEOPATHIC MEDICINE – AOA Policy Compendium, <http://policysearch.wpengine.com/wp-content/uploads/H617-A2018-TENETS-OF-OSTEOPATHIC-MEDICINE.pdf>

1. **Medication Usage** (e.g., studies proposing non-pharmacological and/or pharmacological interventions in assessing the most effective acute and/or chronic pain management regimen)
2. **Functional Measures** (e.g., studies may examine objective and/or subjective functional measures)
3. **Costs** (e.g., studies may examine direct and/or indirect costs pertaining to system utilization)

All proposed projects must utilize a biopsychosocial model. Preference will be given to proposals that include collaboration with appropriate partners and subject matter experts.

Both protocol and pragmatic studies will be considered. The investigator must have a cogent argument for the study design that addresses the specific research question(s). For interventional studies, the intervention(s) needs to have a clear, evidence-based, or evidence-informed rationale and be summarized with a data collection plan consistently applied by all of the providers involved in the project.

The proposal must have clear instructions for accurately and consistently reporting the diagnostic findings that drive the intervention(s). The inclusion of methods demonstrating an assessment of the reliability of diagnostic and therapeutic procedures is encouraged. There must be a clear description of how the intervention(s) are being defined and recorded to promote the reproducibility and scalability of the study.

The proposal should pay particular attention to the appropriate use of treatment and control groups and potential placebo effects. The investigator should include methods that assess the influence of the placebo effect on the intervention(s) and support this by previous publications and research.

Preference will be given to proposals that include collaboration with appropriate partners and subject matter experts.

The proposal should include a well-executed and explicitly reported section of data analysis and expected outcomes, with a statistical plan and power analysis to increase the likelihood of having adequate numbers to answer the primary research question.

All well-written proposals that are observational, interventional or a combination of both will be accepted and reviewed

AOA has a preference for proposals that: (1) use novel approaches to addressing acute and/or chronic pain management; and (2) lead to results/outcomes that could be translated to physician practices. AOA, however, will also support supplemental projects of existing research studies. Supplemental projects must have research questions and specific aims distinct from the existing (parent) study. Applicants will be required to provide information regarding the parent study.

DEADLINE FOR APPLICATION

January 31, 2020 - All applications must be submitted via the AOA online application system by 5:00 pm (CST). Awards will be announced on June 15, 2020.

GRANT PERIOD

18 months (beginning September 1, 2020)

FUNDS AVAILABLE

Awards provide up to \$100,000 in total costs

The AOA does not fund:

1. Physical plant renovations or improvements.
2. Professional development activities, including dues for professional society memberships, tuition for continuing education activities, and tuition for continuing medical education activities.
3. Indirect costs to the applicant's institution, or any other participating institutions.
4. Development and/or engineering of equipment.
5. Provider payments for treatment.

If an applicant or an applicant's institution is uncertain whether a particular expense is allowable, he/she should contact the Department of Research and Development prior to preparing the final budget for submission.

ELIGIBILITY CRITERIA

1. Osteopathic Physician (DO); or
2. MD, PhD, or other individuals holding an equivalent doctoral degree (applicants not affiliated with an osteopathic institution or osteopathic recognized programs must have a DO as key personnel on the Research Team)

Ineligible to apply:

- Medical students, residents, interns, and fellows (see information regarding Research Team).
- An investigator with an active AOA grant who is in the first year of his/her existing grant period.
- A previous or current AOA investigator that has failed to meet milestones and/or submit timely progress and financial reports.
- Investigators conducting research outside of the United States.
- Investigators conducting research on non-US populations.

NOTE:

1. An investigator can be a PI on only one application (RFA) per grant cycle but may serve as the Co-Investigator on multiple grant proposals.

2. An unsuccessful applicant can resubmit the same proposed project twice, for a total of three (3) submissions (original submission plus two resubmissions whether the resubmissions are identical or revised).

GRANT REVIEW CRITERIA

1. **Scientific Significance:** Reviewers will assess the scientific significance of the research project. Specifically, they will assess the purpose of the study, specific aims/hypothesis(es) quality of the scientific literature and how it supports the specific aims and hypotheses. Special consideration for projects that have the potential for external funding.
2. **Osteopathic Significance:** Reviewers will assess the osteopathic significance of the research project. The proposal must address the tenets of osteopathic medicine. Specifically, they will assess whether the investigator presents a persuasive argument on the osteopathic significance of the research question and study design, the quality of the osteopathic literature and how it supports the research proposal, and how the research project will advance the field of osteopathic medicine.
3. **Approach:** Reviewers will assess the overall strategy, methodology, and analyses (including power analysis, timelines, and milestones) to ensure that the proposal is logical and appropriate to accomplish the specific aims of the project. Also, they will assess whether the proposal discusses the potential problems, alternative strategies, and milestones for success.

For projects involving human subjects, reviewers will assess whether the proposed plan addresses: (1) the protection of human subjects from research risks; and (2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children.

4. **Innovation:** Reviewers will assess if the proposed project challenges and seeks to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions. Reviewers will also consider whether the concepts, approaches or methodologies, instrumentation, or interventions are novel to one field of research or novel in a broad sense. Another consideration under innovation will be whether the proposed project is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
5. **Research Team & Scientific Environment:** Reviewers will assess if the research team is well suited to conduct the project successfully. If the Principal Investigator (PI) is a new investigator (5 years or less since completion of training), Reviewers will assess if he/she has appropriate experience, training, and mentorship. If the PI is established (more than five (5) years since completion of training), reviewers will assess if he/she has demonstrated an ongoing record of accomplishments that have advanced his/her field(s) of study.

Reviewers will look at the scientific environment in which the work will be done to determine if the environment will contribute to the probability of success. Collaboration with appropriate research partners should be addressed. Specifically, reviewers will assess the institutional support, mentorship, collaboration, equipment and other resources available to the investigators and determine if they are adequate for the proposed project. Preference will be given to proposals that include collaboration with appropriate partners and subject matter experts. Other resources include the availability of well-qualified students, residents, interns, and fellows to participate in the research project.

6. **Overall Impact:** Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved. The budget and budget justifications will be reviewed. Finally, the impact score will also reflect the quality of the proposal (i.e., clarity, conciseness, organization and presentation.)

APPLICATION PROCESS

1. Prior to beginning the application process, applicants should read the Request for Application thoroughly and confirm their organization and project qualify for the funding being offered.
2. All applicants must electronically submit:

Form	Name	Instructions
A	Application Face Page	<ul style="list-style-type: none"> • Complete all sections keeping in mind that the project title must contain a reference to the clinical relevance of the project. • Indicate if this is a new or resubmitted application and enter specific titles, departments, addresses, telephone, and e-mail addresses, where requested. • Ensure all required signatures are provided. Signatures are required for the applicant, department chair, other investigators associated with the project (if applicable), the financial officer/grant administrator, and the official authorized to sign for the institution. No “per” signatures are permitted. • Indicate the type of project (basic, clinical, or health services), the research focus areas and the keyword descriptors. In addition, please indicate all other relevant categories.
B	Key Personnel	Provide information on the following: <ul style="list-style-type: none"> • Individuals whose effort is central to the project, both salaried and unsalaried, including experts in the field of this study that should be included on the project as well as other contributors. • Biostatistician whose effort is central to the project, either salaried or unsalaried. • Include a biosketch for each individual listed.
C	Biosketch	<ul style="list-style-type: none"> • Provide information for all personnel on the Research Team. • Follow the format on the form for each person. • DO NOT EXCEED FIVE PAGES per person.
D	Principal Investigator’s Career Goals	Provide a statement describing your career goals, including a summary of past accomplishments in research, future research goals, and how successful completion of this research grant will enhance your potential for future NIH and other large-scale funding.

Form	Name	Instructions
E	Budget Worksheet	<ul style="list-style-type: none"> Provide a specific budget for the proposed expenditures. The budget should show the items and the amounts requested from the AOA. Only direct costs will be funded. Each budget item should be itemized and justified. <p>NOTE: See document entitled, "Budget Worksheet Instructions" for detailed guidelines.</p>
F	Budget Justification	Provide detailed justifications on all expenditures listed on the budget worksheet.
G	Resources (Facilities and Other)	Describe facilities and resources to be used to conduct the research.
H	Project Summary/Abstract	Provide a summary of the proposed activity suitable for dissemination to the public. The abstract/summary is meant to serve as a succinct and accurate description of the proposed work when separated from the application. DO NOT EXCEED 7,500 CHARACTERS
I	Statement of Relevance	<ul style="list-style-type: none"> Provide a statement describing the relevance of the project to the AOA's mission. Provide a statement that explicitly and clearly describes how the research will impact the field of osteopathic medicine and addresses the tenets of osteopathic medicine.
J	Resubmissions ONLY APPLICABLE IF YOU ARE RESUBMITTING AN APPLICATION	Provide a report that acknowledges the previous comments and note whether or not any changes were made to the proposal. Applicants must indicate what action they took or did not take regarding each comment. DO NOT EXCEED 9,000 CHARACTERS
The Research Plan		<p>Complete each section on continuous pages. Begin each section with the section headers below:</p> <ul style="list-style-type: none"> Research Question(s)/Specific Aims (Max. 1 page) Background and Significance (Max. 3 pages) Preliminary Studies <i>(if applicable)</i> (Max. 6 pages) Power Analysis/Methods (Max. 2 pages) Research Design & Methods (Max. 10 pages) Human Subjects <i>(if applicable)</i> (Max. 3 pages) Vertebrate Animals <i>(if applicable)</i> (Max. 3 pages) Bibliography (Max. 6 pages) Collaboration (Max. 2 pages) Prepare a proposed timeline for each of the project's specific aims, demonstrating progress expected at 6, 12, 18 and 24 months Set forth two to three specific milestones to be achieved per reporting period (Complete chart) Describe your dissemination plan of the study findings (1/2 page) <p>NOTE: See the document entitled, "The Research Plan Instructions" for detailed guidelines.</p>
K	Required Reports ONLY APPLICABLE IF YOU RECEIVE A GRANT	<ul style="list-style-type: none"> Progress reports should be a brief presentation of the accomplishments of the research project during the reporting period, in a language understandable to a biomedical scientist who may not be a specialist in the project's research field. Progress reports are due semi-annually (every six (6 months)). A final report for the study shall be submitted within 90 days following the close of the grant period. A grant that is extended beyond the original funding period shall continue submitting progress reports semi-annually (every six (6 months)).
L	Budget Report Worksheet ONLY APPLICABLE IF YOU RECEIVE A GRANT	<ul style="list-style-type: none"> Detailed financial reports should be an itemized listing of expenditures used. Financial reports are due semi-annually (every six (6 months)). A final financial report for the study shall be submitted within 90 days following the close of the grant period. A grant that is extended beyond the original funding period shall continue submitting financial reports semi-annually (every six (6 months)).

Submit your proposal via the AOA online grant submission software program at <https://www.grantinterface.com/Home/Logon?urlkey=osteopathic>.

TECHNICAL ASSISTANCE/QUESTIONS

Questions should be directed to the AOA Department of Research and Development at:

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