Osteopathic Approach to Diabetes: Pathophysiology, Treatment, Outcomes and Complications

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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 osteopathic physicians.

About the AOA: Serving as the professional family for more than 122,000 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 and has federal authority to accredit hospitals and other health care facilities.

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 five areas of emphasis to help focus funding opportunities and develop collaborative research studies. The five recommended areas of emphasis cover an array of topics ranging from the broad and inclusive category of Osteopathic Philosophy to the narrower focus of osteopathic manipulative medicine (OMM) and osteopathic manipulative treatment (OMT), including chronic diseases and conditions, pain management and Musculoskeletal Injuries and Prevention. These categories reflect the notion 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 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 designed to assess the effect of Osteopathic Medicine on prevention, diagnosis and/or treatment of Chronic Diseases & Conditions, specifically, the effect of the Osteopathic Approach to Diabetes: Pathophysiology, Treatment, Outcomes, and Complications. Funding for this RFP will support studies that address the unique osteopathic approach to address diabetic related disorders. Both clinical and basic science proposals are eligible for this RFA.

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 this RFP:

Proposed research for the Osteopathic Approach to Diabetes: Pathophysiology, Treatment, Outcomes and Complications should focus on ongoing or new areas of research. Preference will be given to proposals that: (1) use novel approaches to address diabetes including pathophysiology, treatment, complications and/or outcomes; and (2) leads to results/outcomes that could be translated to physician practices. Please note that while the AOA has a preference for novel projects it will also supports 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.

The proposal must identify measures that evaluate and quantify the unique osteopathic approach when addressing diabetic related disorders. These outcome measures may include but are not limited to:

a. Patient centered: satisfaction, quality of life, absenteeism, presenteeism, confidence in care, health literacy, behavioral habits that address the chronic disease, patient perception of treatment by DO’s vs. MD’s.

b. **Outcomes:** prevention of diabetes, its comorbidity and complications such as hypertension, cardiovascular disease, obstructive sleep apnea, musculoskeletal and neurodegenerative complications, microvascular complications (ophthalmologic, renal and neurologic), macrovascular complications (cardiovascular, peripheral vascular, cerebrovascular), patient adherence to therapy, intermediate outcomes and diabetes related processes of care.

c. **System:** adherence to appointments, adherence to medications, cost effectiveness (ie. use of pharmacological agents, or patient education), patient determined resolution of the problem, practice level goal outcome achievement (BP, A1C, lipid level, meeting physical activity guidelines, smoking cessation), more likely to refer the provider. Utilization of diabetes educators, registered dieticians, etc. to enhance patient education. *Educational programs for health care providers will not be funded.*

d. **Novel outcomes:** community based population health (patients who lead community-family health), a biochemical parameter(known or unknown), a novel mechanism for screening for diabetes, new technologies in diagnosis and treatment.

e. **Pathophysiology:** Exploration of pathophysiology of Type 1 or type 2 Diabetes, mechanisms of disease, mechanism and treatment of complications.

**Types of Studies that could be proposed include:**

- Comparative studies that focus on the medical care of the patient with diabetes from DOs versus other health professionals in such areas as quality of life, weight loss and maintenance, patient satisfaction, prevention/diagnosis and/or treatment of co-morbidities, improvement in metabolic parameters, diabetes related microvascular or macrovascular complications, patient adherence to therapy, cost effectiveness of therapy,

- Examination of the unique contribution of the osteopathic approach in improving patient adherence to efficacious self-management and treatments, such as, lifestyle change (diet and exercise), medication adherence, or other aspects of diabetes care or prevention.

- Investigations into approaches to care (medications, exercise regimens, etc.).

- Investigations into the pathophysiology of diabetes or complications, including mechanism of the disease or mechanism of disease complications linked to other diseases and treatments of such.
**DEADLINE FOR APPLICATION**
January 31, 2017 - All applications must be submitted via the AOA online application system by 5:00 pm (CST). Awards will be announced on June 15, 2017.

**GRANT PERIOD**
18 - 24 months

**FUNDS AVAILABLE**
Eighteen-month (18-month) awards provided up to $100,000 total costs. Twenty-four – month (24-month) awards provided up to $150,000 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.
6. PI’s that have an active AOA grant project.

*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).
- Investigators conducting research outside of the United States.
- Investigators conducting research on non-US populations.

*NOTE:* An investigator can be a PI on only one application per grant cycle, but may serve as the Co-Investigator on multiple grant proposals.
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 has 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:

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| A    | Application Face Page              | • 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 applicant, department chair, other investigators associated with 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:  
• 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                          | • 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. |
| E    | Budget Worksheet                   | • 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.  
**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. |</p>
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<td>G</td>
<td>Resources (Facilities and Other)</td>
<td>Describe facilities and resources to be used to conduct the research.</td>
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<tr>
<td>H</td>
<td>Project Summary/Abstract</td>
<td>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. <strong>DO NOT EXCEED 7,500 CHARACTERS</strong></td>
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| I    | Statement of Relevance | • 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.  
• Provide a one page report that explains how the previous reviewers’ critiques have been addressed in your application. Make sure that you address all of the reviewers’ critiques.  
**DO NOT EXCEED 15,000 CHARACTERS** |
| J    | Resubmissions ONLY APPLICABLE IF YOU ARE RESUBMITTING AN APPLICATION | • Provide a one page report that explains how the previous reviewers’ critiques have been addressed in your application. Make sure that you address all of the reviewers’ critiques.  
**DO NOT EXCEED 15,000 CHARACTERS** |
|      | **The Research Plan** | Complete each section on continuous pages. Begin each section with the section headers below:  
• Research Question(s)/Specific Aims (Max. 1 page)  
• Background and Significance (Max. 3 pages)  
• Preliminary Studies (if applicable) (Max. 6 pages)  
• Power Analysis/Methods (Max. 2 pages)  
• Research Design & Methods (Max. 10 pages)  
• Human Subjects (if applicable) (Max. 3 pages)  
• Vertebrate Animals (if applicable) (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)  
**NOTE:** See document entitled, “The Research Plan Instructions” for detailed guidelines. |
| K    | Required Reports ONLY APPLICABLE IF YOU RECEIVE A GRANT | • Progress reports should be a brief presentation of the accomplishments of the research project during the reporting period, in 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 | • Detailed financial reports should be an itemized listing of expenditures is use. 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 [http://grants.osteopathic.org/Accounts/LogOn](http://grants.osteopathic.org/Accounts/LogOn)
TECHNICAL ASSISTANCE/QUESTIONS
Questions should be directed to the AOA Department of Research and Development at:

Gloria Dillard, MPH, Research Manager
American Osteopathic Association
142 E. Ontario Street
Chicago, IL 60611-2864
Toll Free: (800) 621-1773 x8006
Phone: (312) 202-8006
Fax: (312) 202-8306
Email: gdillard@osteopathic.org
Website: www.osteopathic.org/research