



## THE AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION

### **Title: Osteoarthritis of the Knee: Addressing Knee Instability, Restoring Function, and Reducing Pain & Opioid Usage**

#### **Research Objectives**

The purpose of this funding opportunity is to encourage clinical research proposals that can assess the role of orthopedic knee bracing (potentially in comparison to other therapies and/or in comparison to patients not prescribed a brace) in patient outcomes relating to osteoarthritis of the knee(s).

#### **Overview and Background**

##### **Orthopedic Knee Bracing**

Economics have driven changes to the treatment of OA patients (Medicare beneficiaries and others) including certain requirements for conservative treatment prior to surgery, including the potential use of knee braces. Some economic data point to the need for a prospective clinical and even comparative effectiveness study relating to orthopedic knee bracing in treatment of osteoarthritis of the knee.

Across a range of 20+ etiologies of predisposing conditions, the cost of orthopedic bracing comprises less than 1% of the total average Medicare payments for a beneficiary's episode of care (average costs of \$140,000 to \$150,000). Payers have indicated and/or required a diagnosis including knee instability as criteria for payment of an OA knee brace. Is this an appropriate measure? Valuable outcomes measures might relate to restoration of function, or pain reduction and reduction of risk associated with opioid medication usage. A prospective clinical, or comparative effectiveness study may help us determine whether that conclusion is accurate.

#### **Research Objectives and Scope**

This RFP anticipates proposals for a clinical and/or comparative effectiveness study relating to osteoarthritis of the knee, treatment by orthopedic bracing and resulting patient outcomes. Key questions that might be resolved by such a study might include:

- Knee instability as a primary criteria for payer payment—is this an appropriate measure, and are there others which would be as appropriate or more appropriate?
- By clinical measures, are there differences in patient outcomes in terms of mobility and overall health outcomes across the range of etiologies/predisposing conditions relating to whether or not the patient receives an orthopedic knee brace?
- How do patient outcomes compare among patients who receive an orthopedic knee brace vs. patients with comparable conditions and demographics who do not receive an orthopedic knee brace?

- Is the value of including an orthopedic knee brace in the treatment of an episode of care greater or lesser relating to specific etiologies/predisposing conditions?
- What are patient outcomes measures relating to restoration of function associated to orthopedic knee brace treatment?
- What are patient outcomes measures relating to pain reduction and reduction of risk associated with opioid medication usage in patients who receive orthopedic knee brace treatment?

Additional secondary topics, which might be explored could include:

1. Looking at a randomized study of OA patients—half treated with bracing and half not braced—what is their status after six months, and how many (which ones) eventually have surgery within 1-5 years?
2. Retrospective study on how many OA patients become addicted to (or have health problems due to abuse of) pain killers. Is there any relationship to whether they received bracing or not?
3. Should a trial with an OA brace be a prerequisite therapy before joint replacement surgery?
4. Measure the quality of the bracing across multiple orthotists, and do the patient outcomes bear any relationship to the quality of the clinical care/proper fit of the brace?
5. Provide Medicare beneficiaries with the manufacturer's labeling for devices and Instructions For Use (IFU) to assess their understanding and ability to comply with directions.

## **Study Subjects**

**Suggested Protocol Considerations**—while not considered requirements, investigators are encouraged to consider the following factors that may enhance value:

### **Literature Review**

A comprehensive review of the literature is recommended.

### **Award Information**

This AOPA RFP solicits, and will consider high-quality, cost-efficient proposals for a single project with a one-time award up to \$75,000 (total of **all** costs). The study must be completed within six months from the date of the award, pending manuscript submission for publication. Funding of the requested proposals is at the discretion of AOPA, which reserves the right not to fund any proposals submitted in response to this RFP. Results should be suitable for submission for publication in peer-reviewed literature, to achieve robust results within a realistic budgetary structure.

### **Eligibility**

Responsive grant applications must involve a formal collaboration with a healthcare provider or other healthcare organization serving a lower limb limitation population. Note that physicians, prosthetists, orthotists, occupational therapists, physical therapists, engineers, and others (e.g. non-profits, and educational institutions) with suitable experience in physical or biological sciences (ideally, applications from those in engineering and science fields will include at least one investigator who has attained a Ph.D. in the appropriate discipline), as well as those in training (interns, residents, fellows) are eligible to apply provided that the work is conducted under the preceptorship of a more senior or experienced investigator (as determined by AOPA).

Successful applicants must agree to acknowledge AOPA support in any publications that result from the research, and to submit a final report within six months of receipt of funding. The awardees are required to provide a midterm report on the progress of the research.

### **Selection Criteria**

Awardees will be selected based on feasibility, scientific and clinical significance, originality, and anticipated contribution of the research to clinical practice. Applications will also be evaluated on the availability of adequate resources, including personnel and facilities.

### **Review Process**

A Research Committee, or other body constituted or designated by AOPA will review the grant proposals. This research committee/review body will not include any employee of any company that is engaged in the manufacture of OA knee braces.

### **Deadline**

[Submit your proposal online](#) by April 30, 2018. Successful applicants will be notified by June 20, 2018, with availability of this support to begin approximately July 1, 2018 contingent on necessary IRB, and related documentation. For research involving human subjects, Institutional Review Board (“IRB”) approval must be obtained prior to onset of research. AOPA reserves the right to consider timeline extensions related to IRB review. See A. 4.

### **Application Instructions**

ASSEMBLE THE APPLICATION MATERIALS IN THE ORDER LISTED BELOW. BEGIN WITH ITEM A (TITLE PAGE), AND END WITH ITEM I (APPENDICES).

#### **A. Title Page**

1. Use the attached form as a cover page. Type the responses.
2. List the Principal Investigator and all Co-Investigators, including credentials. List any collaborating healthcare providers or organizations.
3. In the case in which a trainee is listed as the Principal Investigator, indicate the name of the responsible investigator. This individual agrees to serve as the trainee’s preceptor and to be responsible for scientific and administrative oversight of the project.
4. Institutional Review Board status — Include the IRB approval letter in the application (see below). If IRB approval is pending at the time of submission and the grant proposal is subsequently approved for funding, funds will not be released until the IRB approval letter is received by AOPA. If the proposal is requesting funds for reimbursement of human subjects, a copy of the IRB approved consent form is required prior to funding as well.
5. Conflict of interest — A potential conflict of interest exists when the research involves a device from which any investigator(s) or a company may benefit. A conflict of interest exists if any investigator holds or has submitted a patent on a device or is a major shareholder in a company involved in the research. If applicable, attach a detailed letter of explanation (see below). It is the responsibility of the Principal Investigator to inform AOPA of any changes to conflicts during the conduct of the study. AOPA reserves the right to evaluate said conflicts to determine appropriateness of PI and/or affected research staff with apparent or perceived conflicts.

#### **B. Abstract**

Put on a separate page immediately following the title page. Limit to 200 words. Use the abstract to summarize the proposed research.

C. Research Grant Proposal

Begin on a separate page immediately following the abstract. Limit to 8 pages (excluding references and budget). Use 1" margins with font size no smaller than 11 point.

ASSEMBLE THE GRANT PROPOSAL AS DIRECTED BELOW, IN THE ORDER LISTED BELOW. FAILURE TO ADHERE TO THESE INSTRUCTIONS WILL CAUSE THE GRANT APPLICATION TO BE RETURNED UNREVIEWED.

**Specific Aims** — Provide a clear description of the study objectives.

**Background/Significance** — State how the proposed work bears on prior work and indicate how it will extend the boundaries of current knowledge. Include a current literature review relating to the rationale for the proposed research.

**Research Plan** — Give the details of the research plan, including the inclusion/exclusion criteria for enrollment, scientific methods to be used, examples of data that are to be collected, and how these data will be analyzed. Provide detailed sample size estimates and action plan on obtaining the appropriate sample size.

**References** — Begin on a separate page. Be judicious in the use of references.

**Budget** — Begin on a separate page. Indicate how the funds will be allocated and justify each budget item, including facility fees if funds are requested for this purpose. Salary support will be provided for other personnel (research nurse, computer programmer) if adequately justified. Support will be provided for supplies and equipment. In general, major equipment acquisitions are not supported. Travel and manuscript preparation costs are not supported. Indirect costs (i.e., university overhead) are limited so as to constitute no more than 10% of the total budget/requested grant amount. Include facility overhead and fringe rates (if applicable).

D. Other Support

For each investigator, list the title, funding agency, total direct costs, dates (including expected dates of notification) of all active awards and pending funding. Use NIH format (available at: <http://grants.nih.gov/grants/oer.htm>). Indicate whether any scientific or budgetary overlap exists, and if so, indicate how this will be addressed.

E. IRB Approval Letter

Include (see above).

F. Conflict of Interest Statement

Include, if applicable (see above).

G. Curriculum Vitae

Provide for principal investigator, and co-investigators. Use NIH format and adhere to the NIH 2-page limit.

H. Supporting Letters

Provide letters from collaborators, such as those supplying patient referrals, if applicable. Applications in which a physician in training, or individual who a resident in a orthotics training program serves as Principal Investigator must be accompanied by a supporting letter from the individual's program director.

I. Appendices

Use (if needed) for data collection forms. Do not use to expand Section C (above).

J. Facilities and Resources

Your proposal should document how the facilities at the host institution match with the needs of the project, unique resources and talents that could be deployed in support of the project, including any assurance of how dedicated time would be allocated to the investigator(s) in the event the application is accepted.

**Closing Comments and Caveats**

Finally, this RFP includes many suggestions, recommendations and listings to help assure that applicants have a clear understanding of the target of this project. Surely there are other good and responsive ideas which are not specifically referred to in this RFP.

**[Submit your proposal online](#) by April 30, 2018**

American Orthotic & Prosthetic Association  
330 John Carlyle Street  
Suite 200  
Alexandria, VA 22314

**Title:** Osteoarthritis of the Knee: Clinical and/or Comparative Effectiveness in Addressing Knee Instability, Restoring Function, And Reducing Pain & Opioid Usage - Request for Proposals  
2018 American Orthotics and Prosthetics Association (AOPA)

The American Orthotic & Prosthetic Association is interested in promoting research focused on improving the knowledge about the use and benefits of orthopedic braces as conservative treatment for knee osteoarthritis and how this relates to payer approval and payment of these devices.

TITLE OF PROJECT: \_\_\_\_\_

**INVESTIGATORS:**

Name(s): (list Principal investigator on line 1)				
1.				
2.				
3.				
4.				

FUNDS REQUESTED: \_\_\_\_\_

NAME OF RESPONSIBLE INVESTIGATOR: \_\_\_\_\_  
(to be completed if Principal Investigator is a trainee)

**IRB STATUS:**

Approved	Pending	Approval Not Required

**CONFLICT OF INTEREST:**

None	Potential	Yes

*As the principal (or responsible investigator, if applicable), I agree that if this grant proposal is funded, I will acknowledge the AOPA's support in all publications that arise from the research. I also will submit to the AOPA Research Committee, or other entity so designated, a final report 6 months after the receipt of funding.*

Signature of Principal Investigator: \_\_\_\_\_

Signature of Responsible Investigator (required if Principal Investigator is a trainee): \_\_\_\_\_

Institution: \_\_\_\_\_

Address: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_ Country: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_