# **Opportunities for Clinical O&P Research Support**

Bid Number: EBP-043020

The American Orthotic & Prosthetic Association is proud to announce a Request for Pilot Grant Proposals in 10 potential areas of Orthotic and Prosthetic (O&P) research including an open topic. For 2020-2021, the association is seeking proposals at two funding levels for one-time grants; \$15,000 and up to two exceptional proposals for \$30,000 for one year. The leadership of AOPA, working in conjunction with the Center for Orthotic and Prosthetic Learning and Outcomes/Evidence-Based Practice (COPL) and its Board of Directors comprised of representatives from eight leading O&P organizations recognizes that there is a modest amount of original evidence-based or outcomes research in orthotics and prosthetics. Consequently, AOPA is interested in funding original pilot research that will lead to larger trials that may qualify for government or other research funding support in the following areas:

- Study/develop outcomes measures, evaluation of clinical benefit, and quality of life metrics related to orthotic management (Note: submissions should be pathology and/or condition appropriate, e.g. Stroke, Cerebral Palsy, Multiple Sclerosis, Polio, OA)
- 2. Demonstrate methods to record primary health outcomes such as falls and lower back pain in amputees.
- 3. Study novel innovations around choice of socket during prosthetic intervention. Factors should include cost savings, adaptability, patient-preference, etc.
- 4. Study the functional impacts and proven clinical benefits of vacuum-assisted socket suspension systems, elevated vacuum. Develop guidelines and clinical decision support for elevated vacuum suspension systems.
- 5. Develop a validated instrument to assess prosthetic interface (socket, liner, and suspension) fit, comfort and performance.
- 6. Documentation of the clinical efficacy of spinal orthoses as and treatment intervention for traumatic spinal injury.
- 7. Study the current prosthetic prescribing patterns with respect to goal-oriented care and longitudinal clinical outcomes.
- 8. Study health inequity/health disparity within orthotic and prosthetic patient populations.
- 9. Study transitional care; changes in orthotic care as patient transitions from pediatric to adult care models (brace design, payer policies)
- 10. Prevalence/Incidence of chronic wound progressing to amputation.

The above list represents the topics, identified by AOPA and the COPL Board, as areas in need of evidence development. Additional topics beyond those listed will also be considered for funding.

AOPA and the Center will give preference to grants that address evidence-based clinical application in orthotics and prosthetics. To learn more about eligibility requirements for this RFP, please see the announcement attached to this document. Please post this RFP and share it with your colleagues. The deadline for proposals under the Request for Pilot Grant Proposals is April 30, 2020.

The study must be completed within one year of the date of the award. Request for Proposal: **Bid Number EBP-043020** 

Inquiries should be sent directly to Ashlie White at awhite@AOPAnet.org or 571-431-0812

# Eligibility

Note that in addition to O&P professionals, physicians 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. Successful applicants must agree to acknowledge the support from AOPA in any publications or presentations that result from the research, and to submit a final report within 12 months of the date of the award.

#### **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**

All proposals will be submitted to the Center for O&P Learning's (COPL) Board of Directors for review and scoring. The COPL Board of Directors will send a funding recommendation to the AOPA Board of Directors, which shall have the final decision on whether any research can be funded and in what amount.

**Deadline**: Apply Online by **May 21, 2020**. Successful applicants will be notified on or about July 1, 2020 with availability of this support to begin approximately August 1, 2020 contingent on IRB approval.

Apply online at https://aopa.wufoo.com/forms/wgohem208q5djp/.

# **Application Instructions**

ASSEMBLE THE APPLICATION MATERIALS IN THE ORDER LISTED BELOW. BEGIN WITH ITEM A (TITLE PAGE), AND END WITH ITEM I (APPENDICES). Please submit all materials as one (1) PDF file, with the pages below included as the beginning of the application. Applications not following instructions will not be eligible for funding.

### A. Title Page

- 1. List the Principal Investigator and all Co-Investigators -- 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.
- 2. Institutional Review Board (IRB) status If the research to be conducted involves prospective work with human subjects, and is being conducted at a hospital, university or other health care institution, such institution likely requires approval of any proposal by its Institutional Review Board (IRB). Full compliance with applicable IRB requirements are a prerequisite before any grant funds will be distributed. If IRB approval is pending or has not yet been applied for 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.
- 3. **Conflict of interest** A potential conflict of interest exists when the research involves a device from which any investigator(s) or a company may profit. It also exists when the research involves any product used in patient treatment that is not FDA-approved (if applicable) for any indication. A conflict of interest exists if any investigator holds or has submitted a patent on a device or other product or is a major share-holder in a company involved in the research. If applicable, attach a detailed letter of explanation (see below).

## 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 3 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.

**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.

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

**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. Note that salary support for the Principal Investigator and Co-Investigators will not be provided. 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 to 10% of total budget.

# 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.

# E. IRB Approval Letter

If received at time of submission, please include (see above).

#### F. Conflict of Interest Statement

Include, if applicable (see above).

G. **Biographical Sketch** of principle investigator, using NIH format.

# **H. Supporting Letters**

Provide letters from collaborators, such as those supplying patient referrals, if applicable.

Applications in which a physician/practitioner in training 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).

REQUEST FOR PILOT GRANT PROPOSALS IN O&P RESEARCH (This form should be used as the first page of your application.) TITLE OF PROJECT: INVESTIGATORS: NAME OF RESPONSIBLE INVESTIGATOR: \_\_\_\_\_ (to be completed if Principal Investigator is a trainee) FUNDS REQUESTED: IRB STATUS: \_\_\_\_\_ CONFLICT OF INTEREST: 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 AOPA a final report within 12 months after the date of the award. Signature of Principal Investigator: Signature of Responsible Investigator (required if PI is trainee): Institution: Address: \_\_\_\_\_ \_\_\_\_\_City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_ Country: \_\_\_\_\_ Phone: \_\_\_\_\_

Email: