THE AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION

Title: Comparative Effectiveness of Prosthetic Feet, Lower Function

Research Objectives

The purpose of this funding opportunity is to conduct a comparative effectiveness study between the performance and patient outcomes, in the laboratory and/or in community mobility and activities of daily living between lower function prosthetic feet that are available without pre-payment audit or delay vs. those codes/prosthetic feet that typically have been identified by Medicare contractors for greater scrutiny and often promises of universal prepayment audit.

Overview and Background

Prosthetic Feet, Lower Function

In the audit intensive environment of the post-ACA period, specific CMS/Medicare contractors, e.g., Jurisdiction D, have explicitly challenged O&P patient care providers promising pre-payment audits of every claim filed for more advanced technology prosthetic foot codes, with no comparable intensive scrutiny for less costly, less advanced prosthetic foot alternatives. This has placed prosthetists in a very difficult quandary—they face the choice between providing a less advanced technology which may well be less appropriate for the patient NOW, without bureaucratic impediments vs. having the Medicare patient wait, immobile and without a prosthesis during a potentially lengthy period of pre-payment audit.

This RFP is intended to focus on a subsidiary question from these bureaucratic challenges. If the prosthetist chooses to provide the less advanced technology prosthetic foot (obtainable without prepayment audit) is there a demonstrable difference in the patient outcomes and quality of care?

This RFP seeks proposals for a comparative effectiveness study between the performance and patient outcomes, in the laboratory and/or in community mobility and activities of daily living between lower function prosthetic feet that are available without pre-payment audit or delay vs. those codes/prosthetic feet that typically have been identified by Medicare contractors for greater scrutiny and often promises of universal prepayment audit.

Specific codes falling into the two categories are:

- No pre-payment audits
- Frequent, if not universal pre-payment audits

Research Objectives and Scope

- A comparative effectiveness study to compare performance and patient outcomes between lower function prosthetic feet that are available without pre-payment audit or delay vs. those codes/prosthetic feet that typically have been identified by Medicare contractors for greater scrutiny and/or pre-payment audits, which generally operate to delay the patient's access to receiving the prosthetic limb.

Study Subjects

Suggested Protocol Considerations—Investigators are encouraged to consider the following factors; though these are not requirements, they may well enhance value:

Literature Review

To provide a framework and rational for the research project applicants are expected to conduct a comprehensive review of the literature.

Award Information

This AOPA RFP solicits, and will consider high-quality, cost-efficient proposals for a single project. Amount of award is expected to be in the range of $175,000. The investigator should include a detailed budget with justification for the amounted needed to complete the study in a one-time award (total to include all costs). The study must be completed within one year of 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 amputee 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 May 1, 2016. The awardees are required to provide quarterly deliverables 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 prosthetic feet.

Deadline

The completed application package should be submitted electronically to info@aopanet.org by April 1, 2015. Successful applicants will be notified by April 30, 2015, with availability of this support to begin May 15, 2015. For research involving human subject, 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 infra.

Timeline

Submission April 1st 2015
Award April 30th 2015
Completion May 1st 2016
Submission to Peer Reviewed Journal July 1st 2016
Presentation at AOPA National Assembly October 2016.

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 share-holder 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. 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 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 prosthetics 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 that 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.

Applications should be sent electronically to info@aopanet.org on or before April 1, 2015)

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

Effectiveness of Prosthetic Feet, Lower Function - Request for Proposals 2015
American Orthotics and Prosthetics Association (AOPA)

The American Orthotic & Prosthetic Association is interested in promoting research focused on improving the knowledge about prosthetic feet, specifically a comparison of performance and patient outcomes of lower function prosthetic feet that are available without pre-payment audit or delay vs. those codes/prosthetic feet that typically have been identified by Medicare contractors for greater scrutiny and often promises of universal prepayment audit.

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 18 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: