



## **THE AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION**

**Title: Orthotic Treatment for Plagiocephaly in Pediatric Patients: What Are Findings (Evidence Categories) on Meta-analysis; Multi-Year Clinical Study of Patient Outcomes; and Potential Improvements to Measuring/Testing Over Anthropometrics**

### **Research Objectives**

The purpose of this funding opportunity is to encourage combined retrospective evidence reviews and clinical research proposals as to treatment of pediatric patients with plagiocephaly, as well as measurement tests/tools.

### **Overview and Background**

#### **Orthopedic Bracing Via Cranial Helmets**

The medical literature has, of late, had several controversies with respect to respective value of using cranial helmets in pediatric patients to treat plagiocephaly. A combination of locations for the studies, questions regarding fitting issues and other factors have added to questions about the conclusions. An (a) more disciplined, comprehensive approach from the standpoint both of looking at the literature, levels of evidence, and preponderance of evidence via retrospective meta-analysis; and (b) a multi-year, clinical study focusing on patient outcomes that inspired strong confidence factors could go a long way toward reliably resolving the current controversies.

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

This RFP anticipates proposals for a combined retrospective evidence reviews and clinical research proposals as to treatment of pediatric patients with plagiocephaly, resulting in evidence-level assessment and measurable patient outcomes. Key priority questions that might be resolved by such a study might include the following:

- meta-analysis of the issue of “do helmets deliver better measurable patient outcomes for plagiocephaly than absence of any treatment;”
- a multi-year prospective trial around that same question, with cohorts of treated and untreated patients being tracked; and
- prospects for an alternative measurement process/tool that might replace anthropometrics
- Is orthotic intervention with a cranial helmet associated with cost savings and economic benefit and quality of life improvement compared to other patients with comparable symptoms who do not receive treatment with a cranial helmet?
- A structure for the study that would assess clinically: (a) does cranial helmet intervention have a positive effect on patient outcome? (b) what are the most appropriate identifiable patient outcomes measures relating to cranial helmets and plagiocephaly?

## **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**

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 combined retrospective evidence reviews and clinical research proposals as to treatment of pediatric patients with plagiocephaly, a multi-year staged award up to \$75,000 (total of **all** costs over all years). The retrospective study must be completed within six months of the date of the award, pending manuscript submission for publication, while the prospective clinical study may span three, to five, to an even longer number of years. 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 pediatric patient population which will include an ample supply of plagiocephaly patients. 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 6 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.

### **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. 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.

## **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 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.

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

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

**Title:** Orthotic Treatment for Plagiocephaly in Pediatric Patients: What Are Findings (Evidence Categories) on Meta-analysis; Multi-Year Clinical Study of Patient Outcomes; and Potential Improvements to Measuring/Testing Over Anthropometrics

The American Orthotic & Prosthetic Association is interested in promoting research focused on improving knowledge about plagiocephaly, and use of cranial helmets in its treatment, specifically disciplined, comprehensive approach from the standpoint both of the looking at the literature, levels of evidence, and preponderance of evidence via retrospective meta-analysis, and a multi-year, clinical study focusing on patient outcomes that inspired strong confidence factors could go a long way toward reliably resolving the current controversies.

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: \_\_\_\_\_