

# **Pilot and Early Career Grant**

2025 Program Manual



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#### **Pilot and Early Career Grants**

The Orthotics and Prosthetics Foundation for Education and Research Foundation (The O&P Foundation) provides funding to support clinically relevant, investigator-initiated research in orthotics and prosthetics (O&P).

The O&P Foundation's **Pilot and Early Career Grants** are one-year awards in the amount of \$30,000. These awards are intended to help investigators initiate lines of research that will be competitive for larger funding opportunities through funding agencies such as the National Institutes of Health (NIH), the Patient-Centered Outcomes Research Institute (PCORI), or the Department of Defense (DOD). The **Early Career Grant** is designed to support those investigators who are less than 10 years from their terminal degrees.

Both grants are awarded annually, and are based on the scientific merit, <u>clinical relevance</u> and the extent to which the research project aligns with the O&P Foundation's Research Priorities.

### **Eligibility Requirements**

- The principal investigator (PI) must have attained a doctoral degree or have equivalent research experience.
- For **Early Career Grant eligibility**, the PI must have completed their terminal degree <10 years prior to the application due date.
- The proposed research must include a clinician trained in O&P as the PI or coinvestigator.
- The host institution must be a not-for-profit located within the United States (US).
- The primary research site must be in the US.
- The proposed research must be clinically relevant based on the O&P Foundation Clinical Relevance Criteria

### **Submission Requirements**

### ☐ Letter of Intent (LOI)

- Applications will not be reviewed without the submission of an LOI.
- Feedback will <u>not</u> be provided in response to the LOI.
- The LOI is used only to assemble a review committee with appropriate expertise.
- The LOI must briefly describe the proposed research.



- The LOI must include the names of all collaborators.
- The LOI should be a maximum of two pages (12 pt font single spaced).

#### □ Application Cover Page

- The application cover page should be completed in the O&P Foundation application portal
- The Application Cover Page is also available for review/download on the O&P Foundation website

### **Proposal Sections**

The proposal should be uploaded as a PDF document with a <u>maximum of 10 pages</u> (12 pt font, single spaced, 1" borders, 8.5" x 11' page size).

**Note:** Page limits only apply to sections with an asterisk (\*).

#### ☐ Abstract

• Up to 500 words

#### ☐ Specific Aims\*

- Provide a concise statement of the goals of the proposed research.
- List succinctly the specific objectives of the proposed research (e.g., to test a stated hypothesis, solve a specific clinical problem, challenge an existing paradigm, address clinical barriers, or develop new technology)
   Describe how these objectives address the O&P Foundation Research Priorities
- If applicable, state testable hypotheses. If hypotheses are not appliable (e.g., the proposed research is qualitative or exploratory in nature), describe the expected outcomes.
- Describe the clinical relevance to the orthotics and prosthetics field using the O&P Foundation Clinical Relevance criteria as reference.

#### ☐ Background and Significance\*

- Provide rationale for proposed research, relevant background history, and the need for the research. Identify how this work is novel, unique, or original, and the knowledge gap that this research addresses.
- Indicate how the proposed research relates to current literature on the topic.
- Explain the importance of the problem or critical barrier to progress that will be addressed by the proposed research. The O&P Foundation Research Priorities



 Address clinical relevance by describing how the concepts, treatments, services, or interventions that drive O&P will be changed if the proposed aims are achieved. O&P Foundation Clinical Relevance criteria.

### ☐ Previous Research (if applicable)\*

• Describe previous research (e.g., pilot data) conducted that supports the proposed study.

#### ☐ Methodology\*

- Describe the overall study design and research strategy that will be used to accomplish the specific aims of the proposed research.
- If the proposed study is human subjects research, describe the sample, including proposed sample size, eligibility criteria, and sampling processes.
- Clearly describe and justify outcome measures used in the study and describe how data will be collected.
- Clearly describe how data will be analyzed and interpreted to address the study aims. If applicable, describe any confounding variables and/or effect modifiers and how they will be accounted for in the analysis.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

### ☐ **Project Timeline** (include milestones and deliverables)\*

- Depict the project timeline with a graphic that shows the timing and duration of each aim and task within the proposed research. Include the funding start and end dates in your timeline.
- Indicate when each milestone/deliverable is to be achieved.

### ☐ Anticipated Results\*

- Summarize the expected outcome(s) of the proposed research
- Describe the potential impact that the results of the proposed research will have on the O&P field and/or clinical practice. Reference the O&P Foundation <u>Research Priorities</u>.
- Demonstrate commitment to the impact of this work by describing future plans for this line of research and/or how findings will be disseminated to the clinical community.

#### □ References

- Include a list of references used within the application to support the need, rationale, and approach for the proposed research.
- Format your citations and references using an accepted citing/referencing style (e.g., AMA or Vancouver)



#### ☐ Budget, Justifications, and Facilities Description

- Provide a budget that itemizes the cost of each item to be paid for with the award. Present this information in table format.
- A budget justification should accompany the budget and should provide a narrative description of the costs included in the research budget to include individual line items leading to the total cost of the project.
- Provide a brief description of the facilities and resources that are available to the research team that will facilitate successful completion of the project.

### □ Current or Pending Support Requests

- Indicate for the PI and each collaborator any current or pending funding support related to the proposed research.
- Pending support refers to any applications for funding that have been submitted and for which the outcome is not yet known.
- Indicate what overlap may exist with funding that has already been received or is pending for the proposed research.

#### □ PI and Collaborators

- Biosketch for the principal investigator (use NIH formatting)
- List of collaborators (including a short biosketch for each)

#### □ Letters of Support

- Include a letter or letters that indicate that the applicant's institution is aware that this application is being submitted and will support the research if funded;
- Include a letter or letters from external collaborators that have agreed to be involved in the proposed research if funded;
- Include a letter or letters that provide evidence that the PI has access to any additional resources or support needed to complete the proposed research.

### **Pilot and Early Career Grant Program Funding Cycle**

The following are key dates and deadlines for The O&P Foundation's 2024 Pilot and Early Career Grant Programs. Applicants are responsible for ensuring all materials are received by the due dates.



Award notification	`Jul	y 2025
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\*Award notification date is approximate and based on anticipated number of submitted applications. A greater number of submissions than expected may delay notification. Applicants will be notified if delays occur.

#### **Grant Disbursement**

- o Grant funds will be paid directly to the award recipient's host institution.
  - A maximum indirect rate (i.e., facilities and administrative costs) of 10 percent of the total direct costs will be allowed under The O&P Foundation Pilot and Early Career Grant programs.
    (maximum direct and indirect costs are not to exceed \$30,000).
- o Grant funds will be disbursed in two installments to the host institution.
  - The first installment of 50% of the total award will be disbursed upon commencement of the award and the second installment of 50% of the total award will be disbursed at approximately 6 months after commencement of the research.
  - Disbursement of the second installment is contingent upon a satisfactory progress report as evaluated by The O&P Foundation Research Committee Chair.
- o If human or animal subjects are included in the proposed research, the applicant will be required to provide evidence of Institutional Review Board (IRB) or Animal Care and Use Committee (ACUC) approval from the host institution before funds are disbursed. Approval is not due at the time of submission, but it will be required to receive award funds.

### **Complimentary Funding/Support**

- The O&P Foundation Pilot and Early Career Grant applicants are required to identify existing and/or pending funding related to the application.
- o If complimentary funding is obtained by the investigator prior to award announcement or during the award period, award recipients are required to inform The O&P Foundation Research Committee Chair in writing.
- o When contacting The O&P Foundation Research Committee Chair, investigators are encouraged to submit a modified budget that reflects the complimentary support obtained for the proposed research.



- The O&P Foundation reserves the right to modify the provided funding based upon the receipt of alternative support received by the investigator(s).
- Decisions regarding the modification of funding will require approval of The O&P Foundation Board of Directors.
- If a modification to the funding amount is made after disbursement of funds, The O&P Foundation reserves the right to request that funds be returned.

### **Grant Reporting**

#### ☐ 6 Month Progress Report

- o Investigators must submit a 6-month progress report at least five months after the initial funds are received by the host institution.
- o The principal investigator is responsible for the timely submission of the progress report.
- o The report should be typed and single-spaced using 10–12-point font
- o The report should describe progress over the first 6 months of the award period and any challenges encountered.
- o Legible figures may be included in the report.

### ☐ Final Report

- Grant recipients must submit a 2–5-page final report no later than 30 days after the award ends.
- o The principal investigator is responsible for the timely submission of the progress report.
- o The report should be typed and single spaced using 10–12-point font
- Legible figures may be included in the report.
- o The final report should detail the work performed during the study period, summarize the expenditure of the award budget, and include a list of any submitted and/or anticipated publications and further research directions, including additional grant opportunities that may result from the O&P Foundation funded research.

#### **Dissemination Fund**

 The O&P Foundation maintains a fund to support recipients of the Pilot and Early Career grants with an additional \$2500 for the costs



- associated with broad dissemination of the results of the research conducted under this program.
- These expenses include but are not limited to: conference registration, travel, accommodations and/or publication fees.
- These funds are available by request and are for use by the PI for a period of up to three years following the initial receipt of the grant.

#### **Review Process**

- All of The O&P Foundation grant submissions will be reviewed by a Review Panel composed of O&P Foundation Research Committee members and ad-hoc members, as needed.
- Composition of the panel will be determined by the type and number of award submissions.
- The O&P Foundation Pilot and Early Career Program Managers will serve as the Review Chair and serve as the point-of-contact for the awards program.

#### **Review Panel**

- o The function of the Review Panel is to evaluate applications, including the clinical relevance of the research topic, the merit of the research design, and the appropriateness of the personnel and environment.
- The Review Panel will score the Pilot and Early Career Grant applications using <u>The O&P Foundation Review Form</u> (available on the O&P Foundation website)

#### **Review**

- Complete applications will be assigned to two or more Review Panel members for review.
- Proposals will be evaluated and scored on scientific merit and clinical relevance using <u>The O&P Foundation Review Form</u> and <u>Clinical</u> <u>Relevance Criteria.</u>
- All submissions will be given a numerical score by each reviewer, and a consensus score will be generated.
- Blinded consensus scores, summary comments, and written reviews will be provided to all applicants upon completion of the review process.



The O&P Foundation reserves the right to reduce the terms of the award, both in time and in funds, as deemed appropriate by the scope of the proposed research. The Review Panel may also request that applicants respond to reviewer comments regarding any part of the submission prior to rendering a final award decision.

#### **Conflict of Interest Procedures**

- The Review Panel is required to maintain confidentiality regarding all aspects of the grant review process, the proposed research, and the identity of award applicants.
- The O&P Foundation will strive to review all submissions fairly and without bias.
- o In cases where a proposal is submitted by (1) a member of the Review Panel; (2) a Review Panel member's organization(3) a Review Panel member's student, resident, or mentee; or (4) a Review Panel member's colleague who lists the Review Panel member as having any responsibility or involvement in the research being reviewed or who collaborates or currently associates with the panel member in other capacities, which may or may not involve the application under consideration, the Review Panel member in question will be excused from review of the proposal.
- O When this situation applies to the Chair of the Research Committee, the Chair will turn over management of the review of the application in question to another Research Committee member. That Committee member will be responsible for identifying suitable reviewers; receiving from reviewers The O&P Foundation Conflict of Interest, Confidentiality, and Non-Disclosure Statement and Review Forms; and chairing the portion of the any review meeting during which the application in question is discussed. Furthermore, if the application in question is successfully funded, the Chair of the Research Committee will turn over management of the funded project to another member of the Research Committee. That Committee member will then be responsible for receiving and reviewing reports, confirming IRB approval (if applicable), and handling requests from the award recipient, as well as any issues that might arise with that grant.
- Reviewers for each application are required to complete The Foundation Conflict of Interest, Confidentiality, and Non-Disclosure Statement) prior to review.
- If a submission includes proprietary or confidential information, this should be noted on the cover sheet and relevant sections of the proposal.



### **Notification of Applicants**

- All applicants will be notified of the status of their application following review.
- Notification will include the blinded consensus scores, summary comments, and written reviews.
- o For the successful applicant, notification will also include information about how and when funds will be made available.
- Disbursement of the second installment is dependent on submission of an adequate progress report to The O&P Foundation Research Committee Chair. In cases where revisions to the progress report are needed, notification may include instructions and a deadline for the appropriate revisions. In such cases, award status may be listed as pending until satisfactory responses to comments are received.

### **Ownership of Work**

- Ownership of intellectual property arising from The O&P Foundation sponsored funding is vested in the award recipient, per the policies of the applicant's host institution.
- The O&P Foundation reserves the right to publicize all materials received while funding a particular research project; (e.g., proposals, progress reports, final reports, etc.), except for materials marked "confidential" or "proprietary."
- Award recipients are required to acknowledge The O&P Foundation funding in any publication or presentation of the funded research by including the following statement:

"This presentation/work was supported (or "supported in-part" if the project was also supported by other sources) through funding from The Orthotics and Prosthetics Foundation for Education and Research (The O&P Foundation)"

#### **No-Cost Extension**

- A one year no-cost extension may be applied for by investigators who have been awarded a Pilot or Early Career Grant if their project requires additional time to complete.
- A written request for a no-cost extension must be submitted to the O&P Foundation Research Committee Chair one month prior to expiration of the current award.



#### Resubmission

- Proposals that are not awarded a Pilot or Early Career Grant may be resubmitted for another award cycle.
- o A maximum of two resubmissions following the original submission will be accepted.
- o The cover letter should indicate that the proposal is a resubmission, and a separate document should indicate any changes made to the proposal in response to reviewer concerns from the previous submission.
- This supplemental document should be no more than two pages in length (page count is not included in the submission page limit).

#### **Portal Instructions**

- Applicant will create an account in The O&P Foundation <u>Application</u>
  <u>Portal</u>
- Once an account has been created in the portal, applicants can select the Pilot and Early Career Grant program and follow the prompts for applications.

#### **Contact Information**

Questions may be directed to <u>info@oandpfoundation.org</u> or to the Research Chair directly at <u>research@oandpfoundation.org</u>

