

## 2024 Pelvic Health Physical Therapy Research Grant Application Guidelines

### 1. INTRODUCTION

The **Foundation for Physical Therapy Research** is the research funding organization for the American Physical Therapy Association (APTA) and is a registered 501(c)(3). Our vision is to shape the future of health through physical therapy research. Our mission is fund research and develop researchers to optimize movement and improve the health of society.

Through the generosity of our donors and community of supporters, our sole purpose for the past 45 years has been to fund physical therapy research and researchers through grants, scholarships, and fellowships. Through our investments in PhD students and early career researchers, we are creating a pipeline of highly skilled and capable researchers. They are building our knowledge of and evidence about effective and innovative physical therapy practices, tools, guidelines, and education across the spectrum of our professional specialties.

More recently, our growing number of larger grants allows us to fund both emerging and established researchers who have been helping build the physical therapy evidence base in priority areas and help define the value of physical therapy for patients and clients, health care professionals and payers.

Moreover, we are redoubling our efforts to ensure that we are fully supporting the advancement of our research community to address health disparities caused by inequalities and inequities based on sex, age, gender, race, ethnicity, sexual orientation, religion, or developmental or physical disabilities.

Through the generosity of our donors, we have created a sustained pipeline for future researchers and of research funding to help launch careers and advance the profession's evidence-based practices.

#### **Research Integrity**

The Foundation expects all grant recipients to adhere to the highest ethical standards and to comply with public laws and regulations when undertaking any type of research we support. We expect grant recipients to demonstrate the following characteristics:

- Be intellectually honest in proposing, performing, and reporting research;
- Be accurate in representing contributions in research proposals and reports;
- Act inclusively and without discrimination or bias in all aspects of research;

- Be collegial in scientific interactions, such as communication and sharing of resources;
- Be transparent in conflicts of interest or potential conflicts of interest;
- Ensure the protection of human subjects by conducting research in compliance with the Department of Health and Human Services' regulations governing the protection of human subjects, as well as adherence to a project's IRB approval and all the sponsoring institution's research and conduct policies;
- Ensure the humane care of animals by conducting research in compliance with the Public Health Service's policy on humane care and treatment of laboratory animals, if applicable; and
- Adhere to the mutual responsibilities between principal investigators and their research teams.

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*This grant is generously supported with the Research Excellence in Pelvic Health Physical Therapy Fund established by the APTA Academy of Pelvic Health.*

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## **2. GENERAL INFORMATION**

### **Award**

The Foundation expects to make one (1) award of \$40,000 for a period of either one or two years. The amount of the award will be the same, regardless of the period of performance. The Foundation reserves the right not to make this award.

All the funded research must be carried out in the United States (U.S.).

The deadline for submitting a completed application on ProposalCentral.com is **11:59PM EDT July 31, 2024**.

The Foundation expects to make research grant awards in early November. Awards are expected to start no later than two months after notification of the provisional award.

## **3. AREAS OF STUDY AND FUNDING PRIORITIES**

### **Areas of Study**

This grant supports research that investigates the advancement of pelvic health physical therapy that addresses one or more priority area(s) of the [APTA 2023 Research Agenda](#).

## Definition of Pelvic Health

Pelvic health physical therapy covers abdominal and pelvic concerns of individuals across the gender spectrum and lifespan. These concerns may include, but are not limited to, incontinence, pelvic pain, prenatal and postpartum pain, osteoporosis, rehabilitation following breast or urogynecological cancers, lower back and pelvic girdle pain, lymphedema, fibromyalgia, and wellness and exercise.

## Funding Objective and Priorities

The intent of this grant is to fund the highest quality, rigorous and relevant research carried out in the U.S. Priority will be given to research having the most immediate clinical application. Proposed studies should add to or refine the body of knowledge and evidence on which pelvic health physical therapy practice is based, using any recognized investigative designs, such as experimental, descriptive, or correlational, and using quantitative, mixed (including implementation science), or qualitative methods. Clinical trials must be registered.

Studies should seek to do one or more of the following:

- Assess the interaction between patient characteristics and therapeutic methods;
- Improve outcomes and reduce risk factors for pelvic health conditions;
- Explore the scientific basis for interventions used in pelvic health physical therapy; or
- Address health and/or health care disparities.

Priority will be given to studies with these elements:

- Studies that connect abdominal and pelvic health populations and/or conditions with the APTA research priorities;
- Have direct, real-world application to the practice of pelvic health physical therapy;
- Address the need for measurable outcomes;
- Ask a new question important to an intervention or its validation; or
- Address a previously asked question with a new methodology, different sampling strategy, or a different form of analysis.

A high potential for successful completion is a major consideration for the Foundation.

It is an advantage if a proposed study has obtained matching funds, includes in-kind services or will provide the basis for larger-scale submissions to other funding agencies (e.g., NIH, PCORI or Department of Defense).

## **4. ELIGIBILITY**

In general, the Foundation reserves the right, on the basis of statutory, regulatory, published policy limitations, changes to donor agreements or decisions by the Foundation Board of Trustees, under certain programs or types of awards, to limit eligibility to, or exclude from eligibility, classes, or types of entities.

One Principal Investigator must submit the application, whether they are applying as an individual working with key personnel or as Principal Investigator for a research team, and do so through the legally registered, US-based sponsoring organization or Institution at which the Principal Investigator is employed.

The Sponsoring Institution must meet the following requirements:

- Be legally registered in the U.S. as a domestically operating, public or private, non-profit or for-profit institution or organization;
- Sign the Letter of Agreement; and
- Be accountable for implementation of the research project as agreed in the Letter of Agreement and for the appropriate expenditure and accounting for funds according to Foundation requirements.

The Principal Investigator must meet these requirements:

- Be employed by a domestic, public or private, non-profit or for-profit organization or institution that is eligible to receive research grants that agrees to act as the Sponsoring Institution.
- Be a member of APTA<sup>1</sup> at the time of application and for the life of the grant.
- Be a member of the APTA Academy of Pelvic Health Physical Therapy at the time of application and for the life of the grant.
- Possess a license to practice physical therapy in the U.S. or in a U.S. jurisdiction **OR**
  - Have met all the requirements for physical therapy licensure in the U.S. or in a U.S. jurisdiction, including having received a passing score the licensing exam; **OR**
- Possess a physical therapist assistant license in the U.S. or in U.S. jurisdiction **OR**
  - Have met all the requirements for licensure as a physical therapist assistant in the U.S. or in a U.S. jurisdiction, including having received a passing score on the licensure exam.
- Be a U.S. citizen **OR** a permanent resident with a valid Green Card for the life of the grant **OR** be a non-immigrant foreign citizen with the right to work in the U.S. for the duration of the grant period.
- Have a substantive research and leadership role on the study and be responsible for its implementation.

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<sup>1</sup> You may become an APTA member [here](#). Once you are a member, you can join the academy.

- If a prior Foundation research grant recipient, the Principal Investigator must be in Good Standing with the Foundation.
- If the Principal Investigator currently holds any scholarship award or research grant from the Foundation, that award or grant must be successfully completed and closed prior to the start of this research grant. No recipient will hold more than one Foundation award or grant at one time.

### **Foundation Definition of a Principal investigator**

The Principal Investigator is the only investigator named on the research grant along with their Sponsoring Institution. They are the only investigator that signs the Letter of Agreement. They have a major ongoing role in the study and provide overall research leadership, have direct oversight of the research process, and are accountable for the quality of the study. They are fiscally accountable for the funds awarded. They are responsible for submitting all required reports to the Foundation. They are responsible for submitting all required reports to the Foundation. They are responsible for disseminating the results of the study through a research brief, submissions to peer-reviewed publications, public presentations, posters, and as appropriate, other channels, such as APTA or Foundation publications.

### **Considerations for Physical Therapist Assistant Applicants**

The Foundation only supports intervention studies in which the interventions are provided by physical therapists, or selected components of the interventions are provided by physical therapist assistants under the direction and supervision of physical therapists.

### **Ineligible Applications**

In addition to ineligibility due to not meeting one or more of the requirements listed above, there are some other conditions that would render an applicant ineligible.

**Academic degree requirements.** Research studies that are to be completed in fulfillment of requirements for an academic degree are not eligible to be funded by this grant.

**Foundation limit on awards or grants.** An applicant may not apply for this grant if they are concurrently applying for any other Foundation award or grant. There can be no overlap of award or grant periods of performance. Any current awards or grants must be completed and closed.

**Failure to complete award or grant requirements on a closed Foundation scholarship award or research grant.** The applicant will not be in Good Standing and will not be eligible to apply for any research grant.

**The Principal Investigator cannot be a student.** The grant does not require a specific degree level, but a student will have to have completed their degree by September 15, 2024 to be considered for this grant.

## **5. REQUIRED APPROVALS, ASSURANCES AND TRAINING**

### **Institutional Review Board Approval or Exemption**

The Foundation requires all applications' study proposals to be approved or exempted by the Sponsoring Institution's Institutional Review Board (IRB) or another similarly qualified entity by the time the Foundation issues the Letter of Agreement to awardees in November 2024. The Sponsoring Institution shall be responsible for ensuring that any required IRB approval is maintained for the life of the research project.

**The Foundation strongly suggests that applicants consider submitting their request for an IRB approval or exemption by the time the full application is submitted.** The Foundation is working to ensure that no award is delayed because IRB approval has not been given or exempted by the time Letters of Agreement are issued for signature in November 2024. No payments will be made until the duly executed (see below) IRB approval or exemption has been submitted to the Foundation. All grants are provisional until all required documents are submitted.

If data are to be collected on human subjects, or if data used in the study contain identifiable private information that can be linked to human subjects, the plan must include specific procedures for reviewing the protocol and for securing informed consent of subjects in compliance with federal policy on the protection of human subjects.

The IRB approval or exemption must be on the Sponsoring Institution's letterhead and signed by the appropriate institution official. If the proposed project has more than one site, IRB approval or exemption **must** be obtained for **every** site in the project.

### ***Standards for Privacy of Individually Identifiable Health Information***

The Privacy Rule is a federal regulation under the 1996 Health Insurance Portability and Accountability Act (HIPAA) that governs the protection of individually identifiable health information from covered entities through collaborative or contractual agreements. Decisions about whether and how to implement the Privacy Rule reside with the Principal Investigator and their institution.

## **Assurance Agreement**

The Sponsoring Institution must be covered by an assurance agreement indicating compliance with Department of Health and Human Services regulations governing the protection of human subjects.

## **Human Subjects' Protection Training**

If data are to be collected on human subjects, or if data used in the research project contain identifiable private information that can be linked to human subjects, the Principal Investigator and all key personnel involved in the conduct of the study must provide certificates demonstrating completion of a human subjects' protection training course. The applicant must submit, at a minimum, the training certificates. The certificate must be dated. **Letters cannot be substituted for certificates.**

The Foundation does not require or recommend a particular training course(s). If training is needed and not offered by the Sponsoring Institution, the NIH Human Participant Protections Education for Research Teams training course meets this requirement.

## **6. DATA SHARING POLICY**

To ensure that knowledge, including data, produced by the research supported by this grant can be accessed, used and built upon, the Foundation supports the goals and approaches taken in the [NIH's 2023 Data Sharing Policy](#). Foundation grant recipients are expected to follow their institution's data sharing policies and reflect them in their application as appropriate. Applicants that do not have any institutional data sharing requirements are still expected to include data sharing plans as part of their proposed study.

## **7. OVERVIEW OF LEGAL AND ADMINISTRATIVE REQUIREMENTS**

This section covers only the most salient information and is not exhaustive. If a Principal Investigator and their institution have specific questions, they should contact the Foundation at [info@foundation4PT.org](mailto:info@foundation4PT.org).

### **Letter of Agreement**

All Sponsoring Institutions will sign a Letter of Agreement (i.e., contract) with the Foundation either with or on behalf of the Principal Investigator. The Sponsoring Institution will agree to administer grant funds and ensure compliance with all institutional and Foundation requirements.

Indicative terms and conditions include, but are not limited to, reporting, payments, consent to publicity terms, changing principal investigators or institutions, changes to approved plans, breach or default, and the rights of the Foundation concerning patents, royalties, and licenses.

Sponsoring Institutions shall not be allowed to refuse any part of whole of any clause or add any whole clause. The Foundation is committed to working with Sponsoring Institutions to reach mutually agreeable text to address legitimate concerns, so long as they will be resolved without undue delay in finalizing the Agreement. The Foundation reserves the right to withdraw a provisional award due to unresolvable disagreements that prevent finalization of the Agreement.

### **Finalizing a Provisional Award**

All awards are provisional until the Foundation receives the following required documents or information:

- Letter of Agreement signed by the Sponsoring Institution and the Principal Investigator;
- IRB approval or exemption on letterhead and signed by the appropriate official;
- A publicity consent form signed by the Principal Investigator; and
- A statement signed by the Principal Investigator and the Sponsoring Institution signatory confirming the research project is ready to start within 10 days of receipt of grant funds.

The first payment of funds will not be made until all these requirements are fully met.

### **Payment of Funds**

Funds will be sent directly to a designated official of the US-based and legally registered sponsoring organization or institution for administration through its financial office. Payments will be made according to a schedule in the Letter of Agreement, which will usually be every six months. After the initial payment, further payments are conditional upon the timely submission and acceptance of interim progress reports that confirm implementation progress.

### **Use of Funds**

Funds are available for research done in the U.S. by legally registered U.S. institutions.

Funds may be requested to meet any type of expense reasonably associated with the research project, including salaries and fringe benefits (of employees of the institution, not consultants), purchase or rental of equipment, supplies, travel, publication costs, printing or postage, and special services, such as computer time, photographic services, and secretarial or research assistant support.



### ***Limitations on Use***

The following uses of Foundation funds are not permitted under any circumstance:

- **NO INDIRECT (OVERHEAD OR ADMINISTRATIVE) COSTS ARE ALLOWED. Please make your institution is fully aware of this restriction before you submit your Letter of Intent. There are no exceptions.**
- No funds may be used for expenses or debts incurred prior to the start of the grant period of performance stated in the finalized, signed Letter of Agreement.
- No funds will be approved to finance cost overruns or deficits on existing projects or to finance projects already in progress
- Support for the purchase of major pieces of permanent equipment is limited to **20 percent or less** of the total award

## **8. CRITERIA FOR THE EVALUATION OF APPLICATIONS**

### **Overview of the Process**

Guidelines for the distribution of funds and criteria for selecting research grant recipients are established and carried out by the Foundation Board of Trustees. The Scientific Review Committee is appointed by the Board to review and score applications. It is comprised of physical therapist researchers and others with experience preparing physical therapists and physical therapist assistants for research careers and with experience conducting successful and impactful research. The Research Committee of the Board considers the reviews and makes recommendations for a recipient to be awarded a grant. The Board makes final decisions on all research grant awards. The Board reserves the right not to make an award.

### **Overview of the Evaluative Criteria for Research Grant Applications**

This section is indicative of the scope and approach that the Scientific Review Committee takes in reviewing research grant applications. The Foundation reserves the right to update and refine the review criteria. The Foundation reserves the right not to review any application.

### **Significance**

- Does the project address an important problem or a critical barrier to progress in the field?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical technologies, treatments, services, or preventative instructions that drive this field be changed?
- Does the project address one or more APTA Research Agenda priority? Which one(s)?

## **Approach**

- Does the proposed methodology enable the investigator to answer the research question(s)?
- Are the overall strategy, methodology, and analysis well-reasoned and appropriate to accomplish the specific aims of the project?
- Are potential problems, alternative strategies, and benchmarks for success presented? Are particularly risky elements adequately mitigated and manageable?
- If the project is in the early stages of development, will the strategy establish feasibility?
- Are the sample size and its participant characteristics appropriate for the scientific goals and proposed research strategy?
  - Is the participant recruitment and retention plan well thought out?
  - Is adequate consideration given to recruiting participants using inclusion criteria that support equitable selection based on sex, gender, age, location, race and ethnicity, sexual orientation, socio-economic status, minority status, or other determinants of health disparities?
  - If children are included in or are the target population, is that inclusion justified in terms of the scientific goals and proposed research strategy, and are adequate protections in place?
  - If human or animal subjects are involved, are adequate protections in place?
- Are the assessment and outcome measures to be used appropriate?

## **Investigator and Research Team or Key Personnel**

- Are the Primary Investigator, collaborators, and other key personnel well-suited to the project?
- Do they have appropriate experience and training?
- If personnel are established researchers, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?

## **Innovation**

- Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of practice or novel in the broad sense?
- Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

### **Environment**

- Will the scientific environment in which the study will be done contribute to the probability of success?
- Are the institutional support, equipment, and other physical resources available to the researchers adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

### **Overall Impact**

As a cumulative step, reviewers consider the project's overall impact on the field. They weigh all the review criteria, addressing the strengths and weaknesses of the application in terms of the five review criteria listed above.

## **9. QUESTIONS**

Please submit any questions you have about these guidelines to [info@foundation4PT.org](mailto:info@foundation4PT.org).

### **End of the Pelvic Health Physical Therapy Research Grant Guidelines**