FOUNDATION FOR PHYSICAL THERAPY RESEARCH

PREFACE Pelvic Health Research Grant (PHRG)

The **Foundation for Physical Therapy Research (FPTR)** funds research and develops researchers to optimize movement and health. The vision of **FPTR** is shaping the future of healthcare physical therapy research.

GENERAL INFORMATION Pelvic Health Research Grant

Grant Amount \$40,000 maximum

Funds are available for research done in U.S. institutions only.

Grant Period

A proposed project may have a Period of Performance of 1- or 2-years. At the time of application, the investigator must request either a 1- or 2-year grant period. The amount of the Pelvic Health Research Grant will be the same, \$40,000, for a 1- or a 2-year award. A grant year will begin January 1 and end December 31 unless another Period of Performance has been requested and approved by FPTR in advance of application submission.

Use of Funds

Funds may be requested to meet any type of expense reasonably associated with the research project, including salaries and fringe benefits, 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.

NO OVERHEAD IS ALLOWED. Please make your institution fully aware of this restriction.

Areas of Study

One **Pelvic Health Research Grant** is to be awarded from the Fund to individuals to investigate the advancement of pelvic health physical therapy and closely align with the research priorities of the Section.

This grant is generously supported through the Research Excellence in Pelvic Health Physical Therapy Fund established by the APTA Pelvic Health.

PELVIC HEALTH RESEARCH GRANT PROGRAM OBJECTIVES AND FUNDING PRIORITIES

Statement of Intent for Funding

FPTR, like the physical therapy profession, is dedicated to the goal of improving the quality and delivery of patient care. **FPTR** accomplishes this goal by providing support to emerging investigators to promote scientifically based and clinically relevant research related to the effectiveness of physical therapist practice.

FPTR supports only those 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.

The purpose of **FPTR**'s research grant program is to fund research studies in specified areas initiated by emerging investigators. Specific eligibility requirements and criteria for review and selection are contained in these guidelines.

FPTR defines "emerging investigator" as one who has not previously acquired a substantive extramural research award as an independent principal investigator (e.g., National Institutes of Health [NIH] R01, Veterans Administration Merit Award, National Institutes of Disability and Rehabilitation Research Field-Initiated Project).

Generally, those who have **not** received any federal funding are considered emerging investigators. However, an applicant may have received some types of federal funding and still be eligible for **FPTR** grants. Examples of acceptable types of federal funding are: R03 (Small Research Grant), R21 (Exploratory/Developmental Grant), R15 (Academic Research Enhancement or AREA award), K01 (Research Scientist Development Award - Research and Training), K23 (Mentored Patient Oriented Research Career Development Award), F32 (National Research Service Award - Postdoctoral Fellowship) or funding via a T32 Institutional National Research Service Award.

Guidelines for distribution of funds and criteria for selecting recipients are established by and carried out by **FPTR**'s Board of Trustees (BOT). The Scientific Review Committee (SRC) reviews and scores applications. The SRC is appointed by the BOT, is comprised of physical therapist researchers and others with experience preparing physical therapists and physical therapist assistants for research careers. The **FPTR**'s BOT makes all funding decisions.

Funding Objectives

The intent of **FPTR** is to fund the highest quality scientifically based and clinically relevant research with priority given to projects having the most immediate clinical application. Proposed studies should add to or refine the body of knowledge on which physical therapist practice is based using any of a variety of recognized investigative methods, such as experimental, descriptive, or correlational. Proposed studies should begin to address the most critical questions regarding clinical research. The APTA Research Agenda is provided as a guide to identification of those critical research questions.

FPTR Funding Priorities

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

- Investigate the clinical effectiveness of therapeutic interventions
- Assess the interaction between patient characteristics and therapeutic methods
- Explore the scientific basis for interventions used in physical therapy
- Address an item identified in the APTA Research Agenda

In addition, priority will be given to studies which:

- Have direct application to the practice of physical therapy
- Address the need for measurable outcomes
- Ask a new question important to intervention or its validation
- Address a previously asked question with a new methodology, different sampling strategy or a different form of analysis

FPTR would prefer that proposed studies:

- Have obtained matching funds or in-kind services
- Provide the basis for larger-scale submissions for funding to external agencies (e.g., NIH)

Limitations of Use

- No funds will be approved to finance cost overruns or deficits on existing projects or to finance projects already in progress
- Support for purchase of major pieces of permanent equipment is limited to 20% or less of the total award

Other Support

All sources of support for the proposed project must be identified in the on-line application.

Payment of Funds

Funds will be sent directly to a designated official of the U.S. Sponsoring Organization/Institution for administration through its financial office. Funds are only available for research done at U.S. Institutions. **The Sponsoring Organization/Institution must indicate at the time of application the fringe benefit rate, if any, that shall be applied to the Pelvic Health Research Grant.**

Schedule of Payment

For a 1-year grant, funding will be delivered in two payments:

- \$20,000 (50% of \$40,000) January
- \$20,000 (50% of \$40,000) July

For a 2-year grant, funding will be delivered in four payments:

- \$10,000 (25% of \$40,000) January, Year One
- \$10,000 (25% of \$40,000) July, Year One
- \$10,000 (25% of \$40,000) January, Year Two
- \$10,000 (25% of \$40,000) July, Year Two

The Schedule of Payment is based on execution of the Letter of Agreement by January 1. Any deviation from this schedule must be requested in the application and approved in writing by **FPTR** prior to the beginning of the **Pelvic Health Research Grant** period of performance. Payment will be contingent upon receipt of Progress Report(s) indicating satisfactory progress has been made in completing work on the proposed timetable. Failure to supply Progress Report(s) will result in termination of the **Pelvic Health Research Grant**.

Completion of Project

The potential for successful completion of the project is a major consideration in awarding the Pelvic Health Research Grant.

Policy Governing Use of Subjects in Research

Vertebrate Experimental Animals: If vertebrate experimental animals are involved in the study, the plan must include specific procedures for review of the protocol in compliance with federal policy on the humane handling of animal subjects. Also, the institution's Animal Care Use Committee (IACUC) must have approved or given a waiver for the project.

<u>Human Subjects</u>: If data is to be collected on human subjects, or if data used in the project contains identifiable private information that can be linked to human subjects, the plan must include specific procedures for review of the protocol and securing informed consent of subjects in compliance with federal policy on protection of human subjects.

Proof of IRB Approval is not required at the time of application. If your project is awarded, the first award payment will not be issued until proof of IRB Approval is submitted to the Scientific Program Administrator. It 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. Also, the institution sponsoring the project's research must be covered by an assurance agreement indicating compliance with Department of Health and Human Services (DHHS) regulations governing the protection of human subjects.

In addition, if data is to be collected on human subjects, or if data used in the project contains 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. You must provide training validity dates for your particular course as part of your application package and the training must be current according to the dates listed on the certificate.

The NIH, Human Participant Protections Education for Research Teams training course is an example of a course that meets this requirement. (<u>http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp</u>) Should this link not work, please go to

the main website for NIH's National Cancer Institute (NCI), www.cancer.gov, and type "human participant protections" into the search engine window. The course will be the first link on the page of search results.

FPTR will *not* accept a letter in lieu of a certificate indicating that a human subjects' protection training course has been taken.

Standards for Privacy of Individually Identifiable Health Information, the "Privacy Rule," is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 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 researcher and his/her institution.

Applicant Eligibility

Proposals may be submitted by an individual or a group of investigators through a U.S. Sponsoring Organization/ Institution with which they are affiliated. Groups must designate one (1) member as the Principal Investigator responsible for directing the project. Other members of the group may be physical therapists, physical therapist assistants, or persons from other disciplines that are relevant to the proposed study. Principal Investigator must be a member of the APTA and specifically the Pelvic Health Academy to be considered for this Award.

Principal Investigator

Pelvic Health Research Grant award is made only to eligible Principal Investigators. Continued funding is dependent upon the Principal Investigator maintaining eligibility. **FPTR** will make research awards only to a legal entity that will be accountable for both the performance of the approved project or activity and the appropriate expenditure of funds. **FPTR** will not make an award to an applicant who is not the Principal Investigator and/or does not have a substantive role in the project and would simply serve as a conduit for another entity.

Principal Investigators supported by **FPTR** research grants are required to meet one of the following criteria: 1) be a U.S. citizen; 2) have been lawfully admitted for permanent residence in the U.S.; or 3) have made an official application for permanent residence in the U.S. **FPTR** requires the applicant to demonstrate their residence status and visa status that will allow them to carry out the research. **The applicant should contact the Scientific Program Administrator before applying if there is any question as to meeting one of the above three criteria.**

FPTR expects grantee organizations to have policies, consistently applied regardless of the source of funds, to address this area. If a grant is awarded and an individual's visa will not allow a long enough time to complete the project, **FPTR** may terminate the grant. **FPTR** reserves the right to impose specific citizenship requirement on grant programs as communicated in the guidelines for each specific grant program (e.g., grantor specifies that Principal Investigator must be a U.S. citizen). **The determination of eligibility includes verification of the applicant's status.** The applicant may be required to provide proof if its status by submitting documentation; otherwise **the authorizing organization signature on the application certifies that the applicant is eligible to apply for and receive an award.** Please make sure the Sponsoring Organization/Institution is aware of this statement.

In addition to reviewing the organizational eligibility, **FPTR** may consider other factors relating to the applicant's ability to responsibly handle and account for **FPTR** funds and to carry out the project. These factors include the applicant's intended role in the project, the location where the project will be performed, the role of the Principal Investigator in the project, and the Principal Investigator's employment and citizenship status.

The Principal Investigator must be employed by a domestic, public or private, non-profit or for-profit organization that is eligible to receive **FPTR** research grants. However, on the basis of statutory, regulatory, or published policy limitations, under certain programs or types of awards, **FPTR** may limit eligibility to, or exclude from eligibility, classes or types of entities.

In addition to the above, at the time of application the Principal Investigator must:

- 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 on the licensure 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.

******If you are a physical therapist assistant who has graduated from a fully accredited physical therapist assistant program and reside in a state or jurisdiction that does not require licensure (Hawaii, Colorado, and Michigan), a copy of your certificate of completion of studies must be included in your application.

Please note that the Principal Investigator's responsibilities include:

- Fiscal accountability for funds awarded.
- Direct oversight of the scientific process with accountability for the quality of the study as conducted.
- Submission of all progress and final reports to the Foundation.
- Dissemination of results of the study through peer-reviewed publications and public presentation.

If the applicant is a current or prior FPTR funding recipient, he/she must be considered in GOOD STANDING with FPTR in order to be eligible to apply.

If award is made to an applicant that is currently supported by another **FPTR** funding mechanism at this mechanism's application deadline but concludes before the Period of Performance begins (January 1st), then **award is contingent upon the** successful submission and approval of the current funding mechanism's Final Report. Further, there can be no overlap between FPTR funding mechanism periods of performance.

Physical Therapist Assistant applicants, please note: FPTR supports only those 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 Requests

Projects to be completed in fulfillment of requirements for an academic degree are *not* eligible to be funded by the **Pelvic** Health Research Grant. A doctoral student in the latter stage of the dissertation phase of his/her program may submit an application but must provide evidence of completion of the degree **by October 15.** If this evidence is not provided by this date, the proposed project will not be funded.

The proposed study must differ substantially from any thesis research being conducted by graduate assistant(s) to be supported by the **Pelvic Health Research Grant**.

Projects sponsored by an organization or institution outside the United States are ineligible for the Pelvic Health Research Grant.

Under no circumstances will funding be provided for expenses or debts incurred before the award date of the Pelvic Health Research Grant.

An applicant may not apply for the **Pelvic Health Research Grant** if they are concurrently applying for another **FPTR** funding mechanism.

If the applicant is a current FPTR funding recipient and is operating under a No-Cost Extension (NCE) agreement, no PENDING applications for this funding mechanism will be considered. Further, there can be no overlap between FPTR funding mechanism periods of performance.

If the applicant is a current or prior FPTR funding recipient and has not complied with reporting or obligation requirements associated with the prior current or prior award, he/she will NOT be considered in GOOD STANDING with FPTR and is NOT eligible to apply for a FPTR funding mechanism.

TERMS AND CONDITIONS OF PELVIC HEALTH RESEARCH GRANT

Non-Compliance

A grantee is defined as the Principal Investigator. Failure on the part of the grantee to comply with the policies governing the grant (including policies governing publications, presentations, and press releases) may be grounds for early termination of the grant and/or denial of any future consideration for funding from FPTR. Failure to comply with the policies governing this award will result in the grantee NOT being considered in GOOD STANDING with FPTR. If the grantee is NOT considered in GOOD STANDING with FPTR, the grantee is NOT eligible to apply for any other FPTR funding mechanism.

Should the grantee encounter problems during the **Pelvic Health Research Grant** Period of Performance related to progress or other matters related to the grant, **FPTR** may request additional information from which a decision to continue or to terminate the **Pelvic Health Research Grant** can be made. In **cases of early termination of the Pelvic Health Research Grant**, **the grantee and Sponsoring Institution will be notified in writing sixty (60) days before the grant is terminated**.

Research Integrity

FPTR expects that the highest ethical standards and compliance with public laws and regulations will be adhered to by all recipients when undertaking any type of research supported by **FPTR** funds. It is expected that grantees will:

- Be intellectually honest in proposing, performing, and reporting research
- Be accurate in representing contribution in research proposals and reports
- Be fair in peer reviews
- Be collegial in scientific interactions, including communications and sharing of resources
- Be transparent in conflicts of interest or potential conflicts of interest
- Ensure the protection of human subjects in the conduct of research in compliance with the Department of Health and Human Services' regulations governing the protection of human subjects
- Ensure humane care of animals in the conduct of research in compliance with Public Health Service's policy on humane care and treatment of laboratory animals
- Adhere to the mutual responsibilities between investigators and their research teams.

Reporting

Grantees shall provide reports to FPTR following the schedule guidelines described below. Failure to submit a report by the stated deadline will delay or jeopardize continued or future support by the FPTR. If the grantee fails to comply with reporting requirements, he/she will NOT be considered in GOOD STANDING with FPTR and will NOT be eligible to apply for any other FPTR funding mechanism. If funds are to be paid on an alternate payment schedule, the reporting schedule will be adjusted accordingly.

Progress Report: All grantees Progress Report(s) shall be submitted online through FPTR submission portal. See FPTR Grant Reporting Instructions. For a 1-year grant, one Progress Report is due 6 months into the grant year. A grant with a 2-year Period of Performance will require Progress Reports at 6 months, 12 months and 18 months. A Progress Report shall include:

- 1. a brief summary of work completed to date, including a discussion of major problems (if any) encountered,
- such as reasons for not being able to recruit sufficient subjects for the study (if applicable);
- 2. A plan to remedy the problems;
- 3. An explanation and justification for any deviation from the original plan of action; and
- 4. An explanation of any proposed changes to the plan.

In addition, the report(s) should include a list of presentations, abstracts, and articles published or submitted for publication related to this study.

The grantee is also required to submit electronic copies (hard copies are acceptable only when electronic copies are unavailable) of the following:

- 1. Copies of abstracts and articles related to this project
- 2. Copies of any survey instruments developed or used in the course of the project
- 3. Copies of measurement instruments developed or used in the project
- 4. Any other information pertinent to the research project

Failure to submit a Progress Report on time may delay or forfeit the release of the next increment of funding. In addition, the Research Committee of the BOT may review Progress Reports and make recommendations for non-competitive renewal for Year 2.

Final Report: All grantees are expected to submit a Final Report to **FPTR** within thirty (30) days of completion of the **Pelvic Health Research Grant** Period of Performance. **Failure to submit a Final Report will be the grantee from any future FPTR funding as the grantee will NOT be considered in GOOD STANDING with FPTR. Further, any PENDING funding award from FPTR will be contingent upon the submission and approval of a Pelvic Health Research Grant Final Report if there is overlap between the current Period of Performance and the other funding mechanism's application deadline.** The Final Report should be submitted electronically through the online portal.

Final Report must include:

- 1. a detailed account of expenditures from the Sponsoring Institution (including but not limited to that portion paid for by the grant)
- 2. work completed during the course of the research
- 3. explanation of any changes to the original plan
- 4. plans for future research projects related to the study
- 5. plans for dissemination of information related to the study
- 6. copies of abstracts and articles since the last Progress Report that are related to this project

Grantees are also required to update the electronic abstract with the following information and e-mail it to the Scientific Program Administrator at the time the Final Report is submitted:

- 1. Findings: Results from the project.
- 2. Lay Language Summary: An *updated* description of the project in terms a non-physical therapist can understand that includes *a summary of the project findings*, suitable for distribution and publication by FPTR.
- 3. A complete list of all presentations, abstracts, and articles submitted, in press, or published that are related to this study.

Request for Approval of Changes

<u>Changes to the Budget</u>: A budget shall be submitted by the grantee and approved by FPTR prior to the commencement of any research. The grantee must obtain written approval from FPTR if expenditures are expected to deviate significantly (see below) from the distribution in the approved budget. If the deviation is significant, a revised budget must be submitted to FPTR for consideration. FPTR shall have thirty (30) days to review any request for approval of a revised budget. FPTR may approve or not approve changes at its discretion.

Changes less than 20%: **FPTR** does not require pre-approval of a departure from budgeted amounts as long as the departure does not exceed twenty per cent (20%) in any line item. However, any departure from the original budget must be explained fully in the progress and yearly reports.

Changes greater than 20%: Transfers between line item more than twenty per cent (20%) and requests for expenditures in categories not initially included in the approved budget may be interpreted as representing changes in the overall plan of action. Accordingly, prior **FPTR** approval is required for all changes in line items of greater than 20%.

<u>Changes to the Plan of Action</u>: The grantee must obtain written approval from FPTR before making any material change in the plan of action, timetable for completion (including no-cost extensions), acquisition of subjects, etc. Requests for changes to the plan must be made in writing. FPTR shall have thirty (30) days to review such requests and respond in writing to the grantee. If the request is made less than thirty (30) days prior to the next scheduled payment, the monies may be held until approval of any changes is given.

Extension of Study: A request for additional funding to extend work on an approved **Pelvic Health Research Grant** will be treated as a new application in response to a request for proposals. A written request for extension of reporting deadlines with no additional funding, a no-cost extension (NCE), must outline in detail the reasons for the request. **The request must be received by FPTR thirty days (30) prior to the expiration of the original grant Period of Performance.**

In the event that a NCE is granted, no PENDING applications for another FPTR funding mechanism from the grantee will be considered until the term of the extension has expired and the grantee has met the reporting and obligation requirements of the award.

<u>Changes in Status of Grantee</u>: The grantee must notify FPTR upon becoming aware of any changes or pending changes (e.g., changes in key personnel) that may prevent accomplishment or substantially alter the goals and objectives of the research program. Such notice must be received by FPTR within five (5) days of the grantee's becoming aware of any such change or pending change. FPTR may request additional information from which a decision to continue or to terminate the Pelvic Health Research Grant can be made. FPTR, in its sole discretion, shall determine whether the change jeopardizes the Principal Investigator's ability to complete the research program and whether funding of the project shall continue. In cases of early termination, the grantee and Sponsoring Institution shall be notified by FPTR in writing sixty (60) days prior to the termination of the Pelvic Health Research Grant. The Sponsoring Institution should be aware that if the decision is made by any party to terminate the grant, any unpaid award increments may be forfeited or pro-rated and/or unused funds already awarded will be requested to be returned to FPTR.

If the grantee fails to notify FPTR at all or not within the specified time period, they will NOT be considered in GOOD STANDING with FPTR and will NOT be eligible to apply for any other FPTR funding mechanism.

Ownership of Equipment

Title to all apparatus, equipment, material, instruments, and products purchased, built, prepared or fabricated by an agency with **FPTR** research grant funds will normally vest in the grantee, with the understanding that such equipment will remain in use for the specific project for which it was obtained.

For items of equipment having a unity acquisition cost of \$1,000 or more, the award letter may reserve the right to transfer title to **FPTR** or to a third party named by **FPTR** when such third party is otherwise eligible.

Data Sharing Policy

The Foundation, like the physical therapy profession, is dedicated to the goal of improving the quality and delivery of patient care. The Foundation accomplishes this by providing support to emerging and established investigators to promote scientifically based and clinically relevant research related to the effectiveness of physical therapy practice. The main output of research is new knowledge.

To ensure this knowledge can be accessed, read, applied, and elaborated in fulfillment of these goals, the Foundation for Physical Therapy Research encourages funded researchers to share data with the research community and with further expectations to publish their findings, including but not limited to publication in peer reviewed journals. For guidance refer to: https://grants.nih.gov/grants/policy/data_sharing_guidance.htm#ex

All clinical trials must be registered.

FPTR Credit Acknowledgement

To ensure that support provided by **FPTR** is adequately reflected, all publications, presentations, and press releases prepared in connection with the research program must include an appropriate credit line as follows:

" This research has been supported in full/part with a Pelvic Health Research Grant by the "Foundation for Physical Therapy Research".

Posters must display the **FPTR** logo and presentations must use the **FPTR** funding acknowledgement slide provided at time of award.

The Letter of Agreement will specify the endowment or group responsible for funding the **Pelvic Health Research Grant** which should be added to the acknowledgement as well.

FPTR may not consider future funding requests from the Sponsoring Organization/Institution and will deny future funding to the grantee if credit acknowledgment is not included.

Publications Resulting from Pelvic Health Research Grant

- Publications are not subject to **FPTR** approval.
- The Sponsoring Organization/Institution or grantee shall notify **FPTR** of the intention to release for publication the results of **FPTR**-funded research.
- Add the DOI, Pubmed ID, Title, Authors, Work Type, and relation to your award (at minimum) of all submitted papers to your award file located at proposalcentral.com. Choose + add deliverable and the date submitted to the file at the time of submission.
- Return to proposalcentral.com and update all publications, conference submissions, or other items when status changes immediately upon publication.
- For a period of five (5) years following the completion of the project and submission of the Final Report, upon
 request, the grantee is required to submit information to FPTR electronically regarding all submitted, in press or
 published papers; and submitted or accepted abstracts related to the Pelvic Health Research Grant.

Presentations Resulting from Pelvic Health Research Grant

- Presentations are not subject to FPTR approval.
- The Sponsoring Organization/Institution or grantee shall notify **FPTR** of the intention to present the results of **FPTR**-funded research.
- The grantee is required to submit results from the completed project to a national or international conference (preferably APTA) for a poster of platform presentation within two (2) years after completion of the Pelvic Health Research Grant.
- One (1) copy of all poster presentations and exhibits relating to the funded study are required to be uploaded to your award file located at proposalcentral.com immediately following presentation.
- For a period of five (5) years following the completion of the Pelvic Health Research Grant and submission of the
 Final Report, the grantee is required to submit summary information to FPTR through the award file located at
 proposalcentral.com at least annually regarding each poster presentation and/or exhibit presentation related to the
 Pelvic Health Research Grant project.

Press Releases Concerning Pelvic Health Research Grant

The Foundation may use Institution's name for the limited purposes of identifying and describing the award and making factual statements about the funding awardee at the Institution.

- Press releases prepared by the grantee are not subject to FPTR's approval.
- For a period of three (3) years following completion of the Pelvic Health Research Grant and submission of the Final Report, the grantee shall provide FPTR with an electronic informational copy of all announcements to the media related to the grantee and/or the work to be done or work accomplished under the Pelvic Health Research Grant.
- **FPTR** may use the abstract from the original grant proposal and information contained in the electronic abstract and the Progress and Final Reports in preparing announcements to the media and other efforts to promote public awareness and appraise potential **FPTR** funding sources of work in progress.

Royalties/Patent Policy

Any invention that has been accorded **FPTR** support shall herein be referred to as a **FPTR** Invention. **The grantee shall notify FPTR in writing within thirty (30) days of the filing by the Sponsoring Organization/Institution or grantee of any application for a patent, and of any invention first introduced into practice with the financial support, in whole or in part, of FPTR.**

<u>Title</u>: Title to any **FPTR** Invention shall belong to the Sponsoring Organization/Institution or grantee and not to **FPTR**.

<u>Patent Abandonment</u>: No patent application or patent shall be abandoned by the Sponsoring Organization/Institution or grantee without first notifying FPTR in writing and affording FPTR the opportunity to take title to FPTR Invention and pursue the patent process at FPTR's expense.

<u>Revenue Sharing</u>: It is expressly understood that **FPTR** shall share 50/50 in the Net Royalty Income derived from a **FPTR** Invention. Net Royalty Income is defined as gross royalty income generated by **FPTR** Invention less the direct, out-of-pocket patent costs of the Sponsoring Organization/Institution or grantee. **FPTR** shall have the right to accounting with respect to the determination of Net Royalty Income.

Upon notification of the filing of a patent application, the Sponsoring Organization/Institution or grantee shall enter into a written agreement (the Revenue Sharing Agreement) with **FPTR** wherein the sum certain, method of payment, and duration of **FPTR**'s participation shall be scheduled. Any disputes between the parties related to the Revenue Sharing Agreement shall be settled in arbitration by a majority of three arbitrators.

FPTR and the Sponsoring Organization/Institution or grantee shall each designate one arbitrator, and the two so selected shall select the third arbitrator. Any such arbitration proceeding shall be conducted in accordance with the rules of the American Arbitration Association.

Patent Assignment: In the event the Sponsoring Organization/ Institution or grantee or licensee, if any, has not taken effective steps to bring **FPTR** Invention to practical application within three (3) years after the issuance of a United States patent on such a **FPTR** Invention, the Sponsoring Organization/Institution or grantee agrees to assign said patent to **FPTR**. Notice of such right of assignment to **FPTR** shall be included and agreed to in any licensing agreement entered into between the Sponsoring Organization/Institution or grantee and third-party licensee. **FPTR** shall have the right to cancel any licenses issued under said patent upon exercising the right of assignment.

<u>Government Agencies</u>: Notwithstanding the foregoing, if any FPTR Invention is made with joint support of FPTR and any agency or department of the United States Government, FPTR may defer to the patent policy of that agency or department if such deference is a required condition of support provided by the agency or department.

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CRITERIA FOR EVALUATION OF APPLICATION

FPTR's SRC has responsibility for reviewing applications for the **Pelvic Health Research Grant**. The SRC, in evaluating applications, will consider the following:

Overall Impact: The project's overall impact on the field will be considered, weighting the review criteria and addressing the strengths and weaknesses of the application in terms of the five review criteria. An application does not need to be strong in all categories to be judged likely to have a major scientific impact, and thus, deserve a high merit rating. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward or improve clinical decision or outcome.

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 a Research Agenda question? If so, which questions? Does the proposed methodology enable the investigator to answer the Research Agenda question?

Approach: 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? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? Is the sample size appropriate? Are the recruitment and retention plans well thought out? Are the assessment and outcome measures to be used appropriate? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children justified in terms of the scientific goals and research strategy proposed? Does the study carry greater than minimal risk? Does the study have the likelihood of IRB Approval?

Investigators: Is/are the Primary Investigator, collaborators, and other researchers well-suited to the project? Do they have appropriate experience and training? If established, 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 work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

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AMERICAN PHYSICAL THERAPY ASSOCIATION RESEARCH AGENDA

Adopted and promulgated by APTA's Board of Directors (BOD), the Clinical Research Agenda (CRA) was the result of a series of conferences and editorial review processes in which large numbers of physical therapists participated. The Agenda was published in May 2000 (Clinical Research Agenda for Physical Therapy. *Phys Ther.* 2000; 80:499–513).

The CRA underwent extensive review and revision based upon input from all APTA Sections to produce the new Research Agenda, published in March 2011. The term "clinical" was removed from the title in recognition of a "more comprehensive perspective of physical therapy research than the manner in which the Clinical Research Agenda was perceived" (Goldstein et al., 2011, p. 1). The new Research Agenda reflects the changes in rehabilitation practices as well as expands upon the scope of rehabilitation research (Goldstein et al., 2011, p. 5).

APTA supports research that is conducted across all points on the continuum of health-related research. The BOD recognizes that the domains along this continuum should not be perceived as mutually exclusive areas of knowledge and that research across the continuum is vital to the profession of physical therapy. In March 2005, the BOD passed P03-05-18-49, Continuum of Research in Physical Therapy:

The profession of physical therapy is committed to understanding and participating in basic science, mechanistic, translational, clinical, and health services research, in order to provide patients/clients with the most current, appropriate, and effective management. The American Physical Therapy Association (APTA) has an obligation to foster leadership and participation in all research efforts related to the science of physical therapist practice. The science is inherently transdisciplinary and encompasses a seamless continuum of research from basic underlying mechanisms and theory to clinical application. The key questions confronting physical therapy require employment of the full range of methodological designs and approaches.

The CRA, and now the Research Agenda, should be read in this context. The Research Agenda describes prototypical questions that are relevant to clinical practice—and that are answerable in the near-term—within the broad array of questions along the continuum of research germane to physical therapy. Additional specific questions, including basic and applied scientific inquiries, also could provide new knowledge that would enhance physical therapist practice. If the answers to additional research questions can be applied to clinical practice, those questions would then be consistent with the intent of the Research Agenda and can be legitimately included as part of the Research Agenda.

More information regarding the review and revision of the Research Agenda may be found at:

Goldstein MS, Scalzitti DA, Craik RL, Dunn SL, Irion JM, Irrgang J, Kolobe THA, McDonough CM, Shields RK. The Revised Research Agenda for Physical Therapy. *Physical Therapy*. 2011;91(2):1-10.

I. Basic Science Research

- 1. Identify how genetic, anatomical, biomechanical, physiological, or environmental factors contribute to excessive stress, injury, or abnormal development of body tissues and systems.
- 2. Determine if modifiable genetic, anatomical, biomechanical, physiological, or environmental factors can decrease risk of excessive stress, injury, or abnormal development of body tissues and systems.
- 3. Examine the effects of physical therapy interventions that are provided independently or in combination on cellular structural properties and physiological responses of healthy, injured, or diseased body tissues.
- 4. Investigate the factors that modify the response to physical therapy intervention and positive tissue adaptation (eg, genetic, functional, structural, psychosocial, and physiological factors).
- 5. Determine the optimal dose of physical therapy interventions (frequency, duration, intensity) to achieve optimal cellular and physiological adaptation/response of body tissues and systems.
- 6. Examine skill acquisition and motor development in individuals with movement disorders.
- 7. Examine the relationship between biomarkers and impairments in body structure and function, limitations in activity, and restrictions in participation. (Biomarkers are any tools used to identify and quantify biologic responses).
- 8. Define the role for physical therapy in the maturation and modeling of genetically engineered tissues.
- 9. Determine the mechanisms by which physical therapy interventions modify disease and age-related or injury induced changes in normal cellular structure and function using appropriate human and animal models.
- 10. Develop new physical therapy interventions to promote tissue growth and adaptation.

II. Clinical Research

- 1. Determine the relationships among levels of functioning and disability, health conditions, and contextual factors for conditions commonly managed by physical therapists (eg, International Classification of Functioning, Disability and Health).
- 2. Develop and evaluate models of health and disability to guide the investigation, prevention, and treatment of health conditions relevant to physical therapy.
- 3. Identify factors that predict the risks of, or protection from, health conditions (injury, disorders, and disease).
- 4. Examine the impact of health promotion interventions that include the involvement of physical therapists on activity and participation of individuals with movement disorders.
- 5. Evaluate of develop effective interventions to prevent or reduce the risk of disability associated with common health conditions.
- 6. Determine the effects of interventions provided by physical therapists to address secondary prevention in patients/clients with chronic diseases (eq, diabetes, obesity, arthritis, neurological, other disorders).
- Determine the physical therapist's role and impact in contemporary delivery models on prevention of diseases and their secondary side effects.
- 8. Identify technologies to assist physical therapists in developing prevention approaches that optimize outcome.
- 9. Develop and evaluate effective patient/client classification methods to optimize clinical decision making for physical therapist management of patients/clients.
- 10. Identify criteria for progression in levels of care, activity, or participation of the patient/client.
- 11. Identify thresholds for adequate physical function to optimize outcomes and prevent injury.
- 12. Identify contextual factors (eg, personal and environmental) that affect prognosis.
- 13. Identify technologies to assist physical therapists in determining patient/client classification.
- 14. Determine predictors of recovery from adverse effects associated with medical or surgical treatment.
- 15. Determine the effectiveness and efficacy of interventions provided by physical therapists across relevant domains of health.
- 16. Determine interactions among interventions provided by physical therapists.
- 17. Determine the effectiveness and efficacy of interventions provided by physical therapists delivered in combination with other interventions (eg, medical, surgical, or biobehavioral interventions).
- 18. Determine the effects of frequency, duration, intensity, and timing of interventions provided by the physical therapist.
- 19. Develop and test the effectiveness of physical therapist interventions for primary and secondary conditions or disability.
- 20. Develop and test the effectiveness of physical therapist interventions to optimize treatment outcomes for specific subgroups of patients/clients.
- 21. Develop and test the effectiveness of decision support tools to facilitate evidence-based physical therapist decision making.
- 22. Develop and test the effectiveness of methods to improve patient/client adherence to the plan of care and selfmanagement.

III. Education/Professional Development

- 1. Evaluate the effect of physical therapist post-professional specialty training on clinical decision making and patient/client outcomes.
- 2. Determine the best methods to foster career development and leadership in physical therapy.
- 3. Determine the optimal criteria for board certification.
- 4. Evaluate the effect of clinical education models on clinical outcomes, passing rates on the National Physical Therapy Examination, and employment settings after graduation.
- 5. Determine the impact of professional-level physical therapist education on professional behaviors.
- 6. Assess the effectiveness of models of professional education on clinical performance.
- 7. Determine the relationship between student cultural competency and clinical decision making.
- 8. Evaluate the effectiveness of different methods used to improve cultural competence.
- 9. Develop and evaluate the most effective methods for facilitating physical therapist acquisition and use of available information resources for evidence-based practice.
- 10. Evaluate the skills needed by practitioners to provide optimal patient/client care, patient/client advocacy, and costeffective care.

IV. Epidemiology

1. Examine the incidence, prevalence, and natural course of health conditions (disorders, diseases, and injuries) commonly managed by physical therapists.

- 2. Examine the incidence, prevalence, and natural course of impairments of body functions and structure activity limitations, and participation restrictions associated with health conditions commonly managed by physical therapists.
- 3. Investigate the effects of contextual factors (eg, personal and environmental) on the effectiveness of interventions provided by physical therapists.

V. Health Services Research/Policy

- 1. Perform economic evaluation of specific physical therapy interventions.
- 2. Evaluate the effect of physical therapy service delivery models on economic and patient/client outcomes and consumer choice.
- 3. Determine the relationship between documentation and payment.
- 4. Evaluate the comparative cost and/or cost-effectiveness of specific physical therapy interventions compared with or in combination with other interventions.
- 5. Investigate factors that influence patient/client choices when selecting a health care provider or making treatment decisions.
- 6. Develop and evaluate new methods for incorporating patient/client values and expectations into the decisionmaking process.
- 7. Evaluate the effectiveness of shared clinical decision-making schemes between the patient/client and therapist on clinical outcomes and costs.
- 8. Establish the extent to which physical therapists deliver services in accordance with recommended guidelines for specific conditions and its impact on outcomes.
- 9. Determine disparities in the access to and provision of physical therapy and their impact on outcomes.
- 10. Examine the interaction among access, culture, and health literacy on physical therapy outcomes.
- 11. Examine the cultural competence of physical therapists and physical therapist assistants and its impact on intervention.
- 12. Develop innovative medical informatics applications for physical therapy and assess their impact on clinical decision making.
- 13. Investigate the influence of health policies on practice patterns and outcomes.
- 14. Evaluate methods to enhance adherence to recommended practice guidelines.
- 15. Assess the impact of continuity of physical therapy services on outcomes.
- 16. Describe patterns of physical therapy use and identify factors that contribute to variation in utilization.

VI. Workforce

- 1. Examine the effects of staffing patterns on the outcomes of physical therapy.
- 2. Assess productivity of physical therapists in various settings and identify factors (eg, use of extenders, mandates) that contribute to variations in productivity.
- 3. Identify and test the best methods to assess past, current, and future demand and unmet needs for physical therapy.
- 4. Identify the demand for services among populations underserved by physical therapists.
- 5. Determine factors that contribute to the retention of physical therapists across various settings and geographic regions.
- 6. Determine factors that contribute to the retention of physical therapists across various settings and geographic regions.
- 7. Determine the effectiveness of recruitment and retention initiatives in reducing the gap between supply and demand in various practice settings.
- 8. Identify variables that influence the decision of whether or not to enter the physical therapy profession.
- 9. Assess the impact of expanded scope of practice on supply and demand.
- 10. Investigate the relationship between the distribution of physical therapists and population health outcomes.
- 11. Examine the effects of workforce issues on career pathways (eg, participation in residency, fellowship, research training).
- 12. Examine the effects of participation in extended clinical training experiences on workforce.

VII. Measurement Development and Validation

- 1. Develop or adapt measures of effectiveness and impact of physical therapy at the community level.
- 2. Develop new tools or refine existing tools to measure the impact of physical therapy on activity, participation, and quality of life.
- 3. Provide evidence to guide selection and interpretation of measurement tools for specific purposes, conditions, and populations.

- 4. Develop and test a minimum set of measures to evaluate the process and clinical outcomes for specific conditions and populations.
- 5. Develop reliable and valid measures of cultural competence of physical therapy providers and students.
- 6. Determine how contemporary technology (eg, ultrasound, gen array, magnetic resonance) can be used to measure the effects of injury/disease and physical therapy intervention on body structure and function.
- 7. Determine optimal measurement methods to enhance clinical decision making for specific conditions and populations.