FOUNDATION FOR PHYSICAL THERAPY RESEARCH

Welcome to the Foundation for Physical Therapy Research's (FPTR) online submission system!

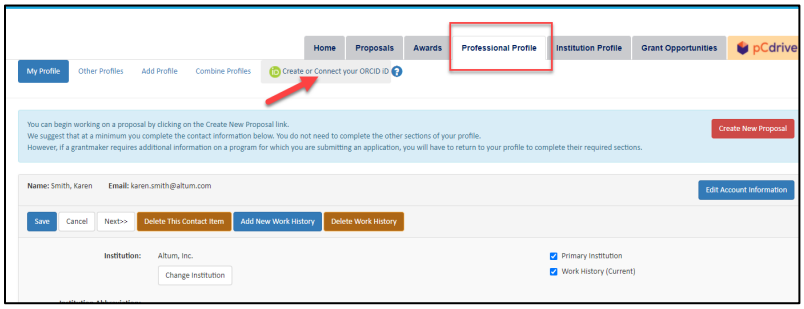
https://proposalcentral.com/

To start the application submission process, register by clicking on "need an account" At the registration screen, either create an account using your ORCID iD or create a username, submit your first and last name, email address, create a password and choose a challenge question and answer. Please record these details, to log into the system in the future.

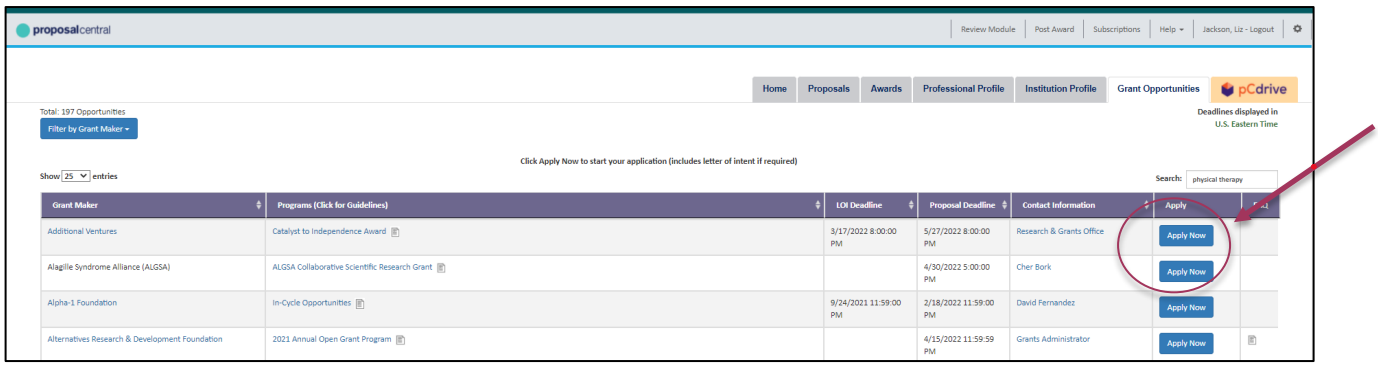
If you choose to create an ORCID iD (which will be required if you are awarded) click that link instead. Then follow the prompts behind, Don't have an ORCID iD yet? Register now

Per ORCID's terms of use, you may only register for an ORCID iD for yourself. Already have an ORCID iD? Sign In

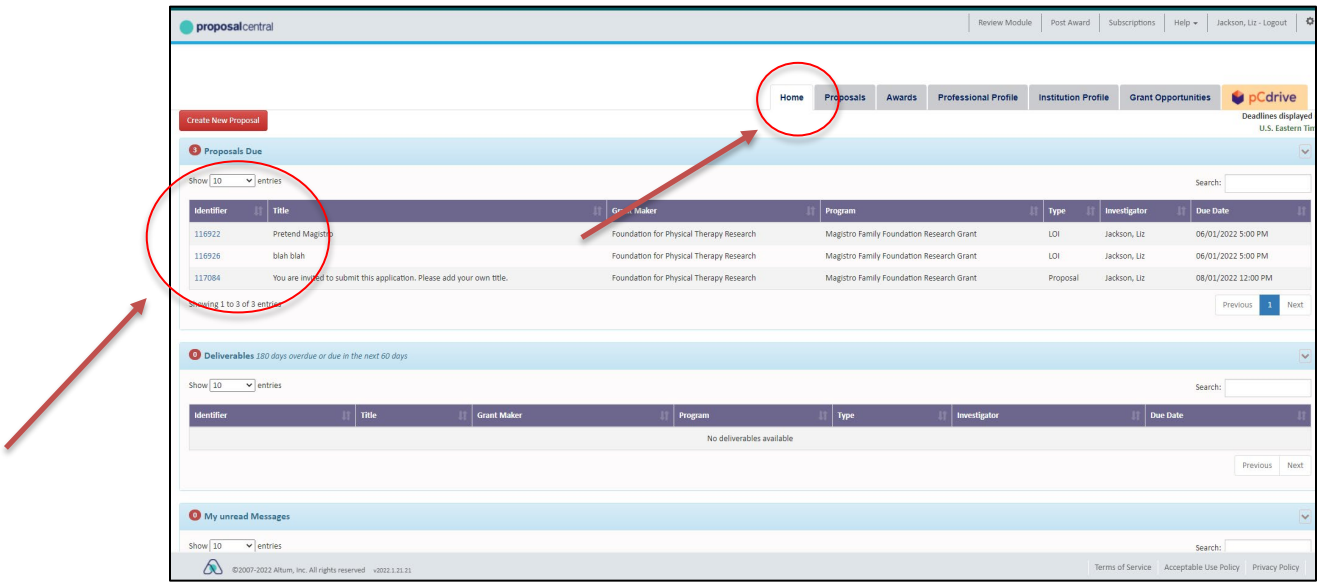
Once you have registered, return to the ProposalCentral main page. Click on the "Applicant or Awardee" tab and provide the credentials you created with ProposalCentral. Once you are logged into ProposalCentral, navigate to the Professional Profile tab. Here you will link your created ORCiD ID account with your ProposalCentral account.



After logging in and connecting your ORCiD ID, you will navigate to the "Home" or "Grant Opportunities" tab and search for "physical therapy" This will take you to all the open solicitations with physical therapy in the title. Be sure to choose awards from the Foundation for Physical Therapy Research. Click the "Apply Now" button next to the mechanism of your choice. Fill in the information working from the top down and click save. You will see steps along the left side of the website to follow.



To return to the list of open solicitations and/or submitted/pending applications, click on the Home icon located at the top of the screen. When working on an application, you are able to work on portions, save, and return to it an unlimited number of times until you submit it (by clicking "SUBMIT"). Even once it is finalized, you can modify and re-submit your application until the submission deadline, however, you must 'un-submit' your application first and re-validate to submit. Once the deadline passes, no changes can be made.



Important Points:

- Review this solicitation's corresponding Guidelines document before preparing an application. These are located both at foundation4pt.org and under the support links along the left side of the page within proposalCENTRAL.

- To ensure that you do not lose any information, save your work often (click "SAVE and/or Next"). You can return to your submission by clicking "the identifier" next to your application from the Home page (as shown above).

- No exceptions to the submission deadline will be made. FPTR will not be responsible for late applications or materials. It is your responsibility to ensure that your application is ready for submission in a timely manner. Plan to allow adequate time for technical assistance to resolve issues if needed.

- Read all instructions carefully and follow them closely.

Regarding Attachments:

- **Attachments must be submitted in Adobe PDF format**.

- **Note that, where applicable, the template or form to be used is located above the link where each attachment file is to be uploaded.** These files contain prompts for the information and also contain the desired formatting settings (e.g., margins should be set at ½ inch and font should only be Arial, size 11 or 12). **Label the start of each section with the appropriate heading title**. We strongly recommend that you download and use the form when completing your application. Word files should then be converted to Adobe PDF for uploading.

- **Please note** that page limits defined in each section are for the Adobe PDF, not the Microsoft Word document prior to conversion to Adobe PDF. When creating Adobe PDF files, do not alter default font and margins. Once you have uploaded Adobe PDF files, make certain that the information has uploaded, correctly and files are not corrupted.

Creating a Physical Therapy Education Research Grant (PTERG) Application

The **PTERG** Application consists of the following each section needs to be completed before your application is considered finished and officially submitted for consideration.

I. TITLE, GENERAL INFORMATION and Environment

Project Title: Provide a title for your project.

ENVIRONMENT
PRACTICE SETTINGS: Choose based on your project
Health System or Hospital-based Outpatient Facility or
clinic, Research Center
NUMBER OF PRACTICE SITES: Fill in the number of sites included in this project
NUMBER OF PATIENTS PER SITE: Fill in number of patients to be included in this project

II. DOWNLOAD TEMPLATES and INSTRUCTIONS

Application Instructions: These instructions for you to follow along to submit your application.
Research Plan: Templates for each part of the application required.
Cover Letter: Template to meet requirement for grant applicants.
Research Plan: Templates for each part of the application required.
Resources and Environment: Template for Facilities, Equipment, Resources, consortium/ contractual agreements.
Applicant Biosketch: Biosketch Template
Key Personnel Biosketch: Biosketch Template
Refer to https://grants.nih.gov/grants/forms/biosketch.htm for guidance on format, instructions, and samples
Inclusions-Risk and Protections Human Subjects and Animals: Template for description of Inclusions

III. ENABLE OTHER USERS to ACCESS this PROPOSAL
This screen allows you to give other users access to your grant application. If electronic signatures are required for submission, signatories will need at least Edit access on this screen. To facilitate the process, the system grants that access automatically when the contact is added to the Application. If any of your signatories have trouble accessing their signature, please confirm their access level on this page.

IV. Applicant/PI

The person who creates the application (letter of intent or proposal) is the default Applicant/Principal Investigator (PI). Contact information from this person's Professional Profile (My Profile), including primary institution affiliation, is pre-loaded to this section of the application. To change the Applicant/PI and the institution affiliation, choose from the list of available names. Note: if the required fields are incomplete or incorrect, changes must be made in the Applicant/PI's Professional Profile (Edit Professional Profile). You can go directly to the selected Applicant/PI's Professional Profile by clicking the button "Edit Profile." Alternatively, you may exit the Applicant/PI section and use the Professional Profile tab in your ProposalCentral management window (located in a different ProposalCentral browser window than the application).

Licenses, and Certifications Obtained and APTA Membership: List all licenses and certifications obtained using a comma to separate (degrees, including PT or PTA, currently held. List PT degree first, followed by other degrees. (Example: Jane Doe, PT, MPT, DPT, CSC) are all entered in your profile (Edit Professional Profile) to record or update.

APTA MEMBERSHIP:

- **Are you currently a member of the American Physical Therapy Association (APTA)?:** Select either YES/NO. *Please note that APTA membership is not required to apply.*
- **If yes, please provide your member number.**

- **If yes, please select from the following the Academy or Section(s) in which you are a member**:
  Acute Care, Aquatics, Cardiovascular/Pulmonary, Clinical Electrophysiology & Wound Management, Education, Federal, Geriatrics, Hand and Upper Extremity, Health Policy & Administration, Home Health, Neurology, Oncology, Orthopaedics, Pediatrics, Pelvic Health, Private Practice, Research, Sports

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V. DEMOGRAPIC INFORMATION (OPTIONAL*):

- **Race:** Please select **all** that apply: American Indian or Alaska Native, Asian, Black or African American (not of Hispanic origin) Native Hawaiian and Pacific Islander, White (not of Hispanic origin), Other, Prefer Not to Disclose
- **Primary Race:** Choose one from the drop-down menu
- **Ethnicity:** Do you consider your ethnicity to be Hispanic or Latino?

* *Information requested by FPTR is for statistical tracking only. Completion of this section is optional.*

VI. Institution Information & Contacts

The lead institution is the institution that will have primary contractual responsibility for the grant if awarded. The institution of the Principal Investigator was selected as the default Institution.

Institution information, from this institution's Institution Profile, is pre-loaded to this section of the application. Required fields are marked with a red asterisk *. To change the Institution, choose from the list of institutions and press the button "Change Institution." Initially, the list contains only the following: the current institution, the institutions that you listed in your Professional Profile, and any other institutions that include your UserID in their Access list. Use the Search option to search the other institution profiles available in proposalCENTRAL. Results of the Search will be added to the list of institutions. To change the Institution, choose from the new list of institutions and press the button "Change Institution." If, after changing the Institution, you need to update the contact information that appears below it, you can click "Edit Institution Profile" to go directly to that Institution Profile (button only available if you have Edit access to the selected Institution Profile). Note: Click Save before completing the sections below.

You will need to enter a signing official, director of sponsored programs, and department chair's email address to this section.

VII. Key Personnel

To add key personnel (i.e., co-investigators, consultants or any other individual involved in the project, and other individuals essential to the project), enter their email address and click the "Add" (icon below). Complete the contact form. (Note: If the person is already registered in ProposalCentral, some information will be pre-loaded into the contact form). To edit the person's contact information, click, 'Edit'(in the far right Action column). To delete a person from the table, click 'Del'. (Note: Changes that you make to the person's contact information will be for this proposal only. Permanent changes must be made in the person's Professional Profile).

Please note required key personnel below. You will need to upload a biosketch for each person added. You do not need to upload a biosketch for the Program Director.

For each Key personnel create a record including:

Role: Select the person's role
Other Role: For a role not listed above
Effort: % effort this individual will provide on the project
First: Enter first name
Middle: Enter middle initial or name
Last: Enter last name
Suffix: (Jr., Sr., III)
Email: entered on page prior
Degrees: enter if not reflected on existing profile
Title/Position: Enter current title/position
Institution: Search and Select or Enter manually current organizational affiliation/current employer
Department: Enter current organizational affiliation/current employer
Address Street: Enter full street address
City: enter city where current organizational affiliation/current employer
State/Province: Enter current organizational affiliation/current employer
Zip Code: Postal zip code

Country: Enter based on current organizational affiliation/current employer
Phone Work: Enter daytime phone number (format xxx-xxx-xxxx)

Key Personnel Biosketch: Attach completed biosketch

Click Save and Close window once complete. Repeat for each key personnel on the application

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VIII. Eligibility Questions

Review and complete general applicable RG eligibility information (e.g., regarding physical therapy license, citizenship, etc.). Number 7 under Proposal Sections:

- **Eligibility 1** – chose appropriate answer based on licensure
- **Eligibility 1.5** – enter PT/PTA License number or date of expected licensure
- **Eligibility 2** – Does your project address the APTA research Agenda see end of award guidelines? Or agenda appropriate for your section of research.
- **Eligibility 3** – See guidelines related to "Good Standing" with FPTR
- **Eligibility 4** – Residency status
- **Eligibility 5** – PI Has not Received large grants
- **Eligibility 6** – PI is not a student
- **Eligibility 7** – PI Submitting Application has Substantive Role

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IX. Project Abstracts/Keywords/Facilities/Equipment/Support/Administrative Arrangements

- **Lay Abstract:** Please describe your work as if are speaking to someone who has some knowledge of your work in simple understandable terms. This summary could be posted on the FPTR website and should not contain proprietary information. **This field has a character limit of 2,000 (approx. half page).**
- **Project Technical Abstract:** Describe where you are in the educational process and your proposed area of research concentration. Be as specific as possible given the current phase of your education. Include a description of how your research concentration relates to the science supporting physical therapist practice. Be as specific as possible while avoiding jargon or abbreviations. Do not include citations in this field. **This field has a character limit of 2,000 (approx. half page).**
- **Area(s) of Research:** Select area(s) of study for the RG project. You must select one area but no more than three. You may insert an unlisted sub-specialty in the field labeled "Other." Use the + sign to select.

X and XI. Budget Period Detail, Justification and Summary

Start Date: 1/1/20XX (Year start will be the following year after the application is submitted)

End Date: 12/31/20XX (Year-end will be either 1 or 2 full calendar year(s) from start) **Be sure if you are choosing 2 years to enter each budget period separately**.
Personnel Costs: Enter name, Role (PI, Co-I, Consultant etc.), % (i.e.,10, 20, 30 etc.) Effort, requested $ amt. of support (i.e., $10,000, $20,000, $30,000 etc.)
We are looking for a good estimate of the full budget breakdown to apply for the RG, if you already know what your costs will be you can add them under the Budget Period Detail, keep in mind this can be adjusted after awarded. All items entered in the detail section will populate to the summary.
Non-Personnel Costs: Costs associated with your project that do not fall into the other categories that are not salary and benefits to people working on the project.
Supplies/Materials: expendable items necessary to carry out the work of the project
Travel: Required travel expenses related to the project.
Patient Care Costs: the costs of routine and ancillary hospital services provided to individuals participating in research programs.
Other Expenses: A space for any expense related to the project that doesn't fall into the above categories.
Budget Justification: Explain items listed in budget above (2500 character limit).
Budget Summary: Summarizes entries on a separate page.

XII. Other Support

List active and pending support for all key personnel

Other Support includes all financial resources, whether Federal, non-Federal, commercial, or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

Overlap is not allowed. For each entry, any potential perceived overlap with this application and a description of the potential perceived overlap will be requested. Be sure to save any data required to submit a complete picture of the other support e3ntry for submission.

XIII. Assurances & Certifications
HUMAN SUBJECTS:
Does the proposed project involve Human Subjects? Y/N
If Yes, Status of IRB Approval - Indicate if the study has received IRB approval or a waiver. A copy of approval, if received, must be included in the attachments. IRB approval is not required at time of application submission. If award is made, payment will not be issued until IRB approval is received by the Foundation's Program Administrator.
Approved or Pending Date: mm/dd/yyyy
Human Subjects Assurance Number (OHRP) This assurance number cannot be entered on this screen – it will appear only if properly entered in the institutions profile (for the institution you selected in the institution section of the proposal). If no assurance number appears here, please contact your institution's grants and contracts office to have them add the assurance numbers to the institutions profile. If you need assistance, contact proposalCENTRAL customer support.

Approvals/Exemptions/Certifications: Upload Attachment
VERTEBRATE ANIMALS:
Does the proposed project involve Vertebrate Animals? Y/N
If Yes, status of IACUC approval - Indicate if the study has received IACUC approval or a waiver. A copy of approval, if received, must be included in the attachments. IACUC approval is not required at time of application submission. If award is made, payment will not be issued until IRB approval is received by the Foundation's Scientific Program Administrator.
Animal Welfare Assurance Number (OLAW) This assurance number cannot be entered on this screen – it will appear only if properly entered in the institution profile (for the institution you selected in the institution section of the proposal). If no assurance number appears here, please contact your institution's grants and contracts office to have them add the assurance numbers to the institution profile. If you need assistance, contact proposalCENTRAL customer support.
Approvals/Exemptions/Certifications: Upload Attachment
If "Yes", describe animals to be used: Provide details on species and numbers (1000 character limit).

XIV. Relevant Publications

Include and reference all publications applicable to this application.
To add your entries, please click the "+" link and all entries previously saved in your Professional Profile will show. Please select the applicable publications and save. If the program allows for Key Personnel and they have granted you at least View access to their profile, you can select Publications from their profile as well.

To add new Publication entries, click the "Create New Publication" button. By default, this entry will be added to your profile, unless the option "Add to Profile" is not selected. If you have Edit or Admin access to your Key Personnel's profile, you can add new Publication entries on their behalf to this application and update their profile as well.

Applicants can add up to three (3) of the following types of publications only:

- manuscripts and/or abstracts accepted for publication but not yet published;
- manuscripts and/or abstracts published, but a free, online, publicly available journal link is NOT available;
- and patents directly relevant to the project.

In addition to these three publication types, a full listing of peer-reviewed publications or abstracts also may be included. **Combine into one Adobe PDF file** and upload here.

XV. ATTACHMENTS

In this section, you will upload documents describing the details of your studies. Download all templates and instructions files located at the bottom portion of this page. Once you have completed each template, click the "Attach Files" button, and select the file to attach.

PTERG Cover Letter
PTERG Applicant Biosketch

XVI. Data Type/Plan

The Foundation for Physical Therapy Research is dedicated to the goal of improving the quality and delivery of patient care. The foundation accomplishes this by providing support to emerging 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 built upon in fulfillment of these goals, The Foundation for Physical Therapy Research encourages researchers to share data with the research community and expects it researchers to publish their findings, including but not limited to publication in peer reviewed journals.

The Foundation for Physical Therapy Research is aware of the need to provide flexibility in the assessment of Data Sharing Plans. The foundation recognizes that disciplines differ widely in their practices and expectations. The foundation encourages you to help shape effective implementation of this evolving issue.

In developing your plan, you may want to consult with university officials as many universities have explicit data sharing policies.

For additional guidance related to this topic please refer to: https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#ex

Please address the following questions:

- **1. What data will be generated by your research?** Examples include data (including sequencing and data), software, algorithms, curriculum materials and other materials that will be produced during the project.
- **2. What is your plan for sharing the data?** What will be your policies for access and sharing the data during the life of your award and after award closeout? What will be the format, mode of delivery and timetable for data distribution (e.g., posting data on institutional or personal websites, posting on a currently available national or public database such as (e.g., dbGaP, GEO, SRA, Genomics Hub or through a data archive)? Please include any provisions for appropriate protection of privacy, confidentiality, security, or intellectual property.
  This text box has a character limit of 4,000

Additional Guidance

A. PTERG Cover Letter

Submission of a cover letter is **required for grant and fellowship applications** (but is optional for scholarship applications) and it must be submitted on your institutional letterhead as a PDF or it may not be accepted.

The cover letter **must** include the following information at a **minimum:**

- **a.** Name, date, address, and signature of the applicant
- **b.** Project Title
- **c.** Status of IACUC and/or IRB approval
- **d.** Statement that all proposed research will be conducted according to the rules and regulations of the U.S. Department of Health and Human Services relevant to the ethical conduct of research on humans and/or animals.

You may choose to include any of the following information in your cover letter if it applies to you. These are just examples. This is not an exhaustive list. You may want to explain or clarify special circumstances, such as:

a. You have a pending proposal at another agency that includes some of the same aims;

b. You are considering moving institutions or have already begun planning to do so;

c. Your primary mentor (for mentored research projects) is at a different institution than the applicant (if the applicant is a student or postdoctoral fellow);

d. Some of your research equipment, tools, products, or other similar materials, are patent pending, or have already been issued a patent;

e. Your proposed research has received local or national media coverage;

f. Your proposed research has been written about in a recent lay publication, such as *Scientific American,* or has been published recently in a peer-reviewed journal, such as *PTJ*.

Please **do not** use the cover letter to summarize your project or to circumvent the page limit of the Application or Appendices. **The Cover Letter is limited to 2 pages; submit as one Adobe PDF file.**

B. PTERG Research Plan

Use the **PTERG** Application Template provided. It has been pre-formatted to the preferences of FPTR – please do not alter. The **PTERG** Application should have the following sections led by a

header for each: **Specific Aims, Significance, Innovation, Approach, and Citations**. Follow the instructions below as to the contents for each heading within the **PTERG** Application.

I. Specific Aims: State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s). List succinctly the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a new technology). **This section is limited to 1 page in Adobe PDF.**

II. Significance: Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses. Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice within the field to address the identified problem or barrier. Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved. **This section is limited to 1 page in Adobe PDF.**

III. Innovation: Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe any novel theoretical concepts, approaches or methodologies, instrumentation, or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions. **This section is limited to 1 page in Adobe PDF.**

IV. Approach: Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate. Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims. If the project is in the early stages of development, describe a strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work. Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. Discuss any Preliminary Studies, data, and/or experience to this application. **This section is limited to 8 pages in Adobe PDF.**

V. Scientific Rigor and Transparency: Describe how your experimental design and methods will achieve robust and unbiased results. For additional guidance related to this, please visit: https://grants.nih.gov/policy/reproducibility/index.htm **This section is limited to 1 page in Adobe PDF.**

VI. Publications: Cite published experimental details in the Approach. Provide full reference in the Bibliography and References Cited section**.** List all references. Each reference must include title, names of all authors, book, or journal, volume number, page numbers, and year of publication. References should be limited to relevant and current literature. It is important to be concise and to select only those literature references pertinent to proposed research. There is no page limit for citations.

Once completed, save the template, and submit the attachment as one Adobe PDF file.

C. PTERG Resources and Environment

Describe facilities, special equipment, consultative services, and other relevant resources available for the proposed project. This information is important in determining whether resources available can support successful completion of proposed project. If any of these are to be obtained through collaborative arrangements, letters confirming arrangements must be included in application. Some aspects to discuss are:

- **Facilities:** Briefly identify types of facilities available and indicate their capacity, proximity, and availability.
- **Equipment:** List special/important equipment already available for project.
- **Consultant and Secretarial Support Services:** Describe and list available consultant and secretarial support services available or planned for project.
- **Consortium/Contractual/Arrangements:** Explain programmatic, fiscal, and administrative arrangements to be made between applicant's organization and consortium organization(s). If consortium/ contractual activities represent a significant portion of overall project, explain why applicant organization, rather than ultimate performer of activities, should be grantee.

No page limit (be concise)

D. PTERG Biosketches

A biographical sketch must be provided for all key project personnel (**individuals with Person Records in Section III. PEOPLE except for the Institutional Official).**

Each biosketch is limited to 5 pages using the NIH format. Faculty should use the NIH biosketch form for non-fellowships. Use the biosketch templates here:
https://grants.nih.gov/grants/forms/biosketch.htm

In Addition to the PI's biosketch the following information is needed only for the PI – No page limit (separate page collated with applicant's biosketch):

- List all Pending, Current, and Completed (the last 3 years) Support; include all past or current support received from FPTR. If you list only the last 3 years of completed support, then you must include your top 10 highest dollar amount grants awarded regardless of agency, mechanism, or year (even if long ago).
- Each research support listing must include the following: Role, Agency, Mechanism, and Total Dollar Amount.

Scan PI's biosketch and key personnel biosketches (ordered together by person) into two separate Adobe PDF files.

E. PTERG Inclusions – Risk and Protections Human Subjects and Animals

Use the **PTERG** Human Subjects Vertebrate Animal Template provided. It has been pre-formatted to the preferences of FPTR – please do not alter. Address the Protection of Human Subjects Plan, along with Women, Minorities, and Children Inclusion OR Vertebrate Animals. Use section headers and follow the instructions below for contents of either.

STUDIES INVOLVING HUMAN SUBJECTS

I. Protection of Human Subjects Plan: If research involving human subjects is determined by your Institutional Review Board (IRB) to be NON-EXEMPT and your institution has determined that IRB Approval is necessary, then you must provide sufficient information for reviewers to determine that the proposed research meets: 1) the requirements of the DHHS regulations to protect human subjects from research risks; and 2) the requirements of Foundation policy on inclusion of women, minorities, and children. If no human subjects are involved and your research has been determined to be EXEMPT, please state so. The Foundation does not provide IRB review or make a determination regarding whether IRB Approval is necessary. Address each item within your Protection of Human Subjects Plan.

A. Risks to Human Subjects

1. Human Subjects Involvement, Characteristics, and Design: Describe the proposed involvement of human subjects outlined in the Application section. Describe and justify the characteristics of the subject populations, including their anticipated numbers, age range, and health status, if relevant. Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. Note that "prisoners" includes all subjects involuntarily incarcerated (for example, detention centers) as well as subjects who become incarcerated after the study begins. If relevant to the proposed research, describe procedures for assignment to a study group. As related to human subjects' protection, describe and justify the selection of an intervention's dose, frequency, and administration. List any collaborating sites where human subjects research will be performed and describe the role of those sites and collaborating investigators in performing the proposed research. Explain how data will be obtained, managed, and protected.

2. Sources of Materials: Describe the research material obtained from living individuals in the form of specimens, records, or data. Describe any data that will be collected from human subjects for the project(s) described in the application. Indicate who will have access to individually identifiable private information about human subjects. Provide information about how the specimen records, and/or data are collected, managed, and protected as well as whether material or data that include individually identifiable private information will be collected specifically for the proposed research project.

3. Potential Risks: Describe the potential risks to subjects (physical, psychological, financial, legal, or other) and assess their likelihood and seriousness to the human subjects. Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of alternative treatments and procedures, to participants in the proposed research.

b. Adequacy of Protection Against Risks

1. Recruitment and Informed Consent: Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed study will include children, describe the process for meeting requirements for parental permission and child assent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver. Informed consent documents need not be submitted unless requested.

2. Protections Against Risk: Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness. Research involving vulnerable populations must include additional protections. Where appropriate, discuss plans for ensuring necessary medical or professional intervention in case of adverse effects to the subjects. Studies that involve clinical trials must include a general description of the plan for data and safety monitoring of clinical trials and adverse event reporting to the IRB and others as appropriate to ensure safety of subjects.

3. Potential Benefits of the Proposed Research to Human Subjects and Others: Discuss the potential benefits of the research to research participants and others. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

4. Importance of Knowledge to Be Gained: Discuss the importance of the knowledge gained or to be gained because of the proposed research. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

5. Data and Safety Monitoring Plan: If the proposed research includes a clinical trial, include a Data and Safety Monitoring Plan. Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring. Describe the entity that will be responsible for monitoring and the process by which Adverse Events will be reported. Be succinct. The frequency of monitoring will depend on potential risks, complexity, and the nature of the trial; therefore, several options for monitoring trials are available. These can include, but are not limited to, monitoring by a: Primary Investigator (required); IRB (required); independent individual/safety officer; designated medical monitor; Internal Committee or Board with explicit guidelines; data and Safety Monitoring Board (see NIH requirements). A detailed Data and Safety Monitoring Plan must be submitted to the applicant's IRB and for approval prior to the

accrual of human subjects.

II. Inclusion of Women, Minorities, and Children:

a. Women and Minorities

Address, at a minimum, the following four (4) points:

1. The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups. If using existing specimens and/or data without access to information on the distribution of women and minorities, so state and explain the impact on the goals of the research as part of the rationale that inclusion cannot be described. Alternatively, describe the gender and minority composition of the population base from whom the specimens and/or data will be obtained.

2. A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design. The description may include, but is not limited to, information on the population characteristics of the disease or condition under study.

3. A compelling rationale for proposed outreach programs for recruiting sex/gender or racial/ethnic group.

4. A description of proposed outreach programs for equitable recruitment of members of sex/gender and racial/ethnic group as subjects.

b. Inclusion of Children

Address, at a minimum, the following four (4) points:

1. Provide either a description of the plans to include children, or, if children will be excluded from the proposed research, application, or proposal, present an acceptable justification for the exclusion.

2. If children are included, the description of the plan should include a rationale for selecting a specific age range of children. The plan must also include a description of the expertise of the investigative team in working with children, the ages included, the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

3. When children are involved in research, please address additional protections to children involved as subjects in research under Protections Against Risk.

4. Address any exclusion of any specific age group and justify the exclusion.

STUDIES INVOLVING ANIMAL RESEARCH

I. Vertebrate Animals: Research protocols on animal subjects must be reviewed by an Institutional Animal Care and Use Committee (IACUC). If vertebrate animals are involved in the project, address each of the five (5) points below. If all or part of the proposed research involving vertebrate

animals will take place at alternate sites, identify those sites, and describe the activities at those locations.

a. Provide a detailed description of the proposed use of the animals in the work outlined in the Application section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

b. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

c. Provide information on the veterinary care of the animals involved.

d. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

e. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations. If involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used.

There is no page limitation for this section but be succinct and do not use this section to circumvent the page limits of the **PTERG** Application. **Once completed, save the template, and submit the attachment as one Adobe PDF file.**

F. PTERG Support Letters

Applicants should provide letters of support and collaboration for the grant project.

Your institution must provide a Letter of Support for facilities, equipment, and personnel release time.

Letters from all consultants must be obtained confirming roles in project. Consultant letters should include rate/charge for consulting services.

Also, the consortium investigator and authorized official at consortium institution(s) must provide a signed statement or confirming letters that appropriate programmatic and administrative personnel of each organization are necessary to complete project.

Scan/combine all Support/ Collaboration/ Consortium/ Contractual/ Consultant(s) letters confirming role(s) in project and submit as one Adobe PDF file they will be uploaded to the attachments section of the application. Choose Letters of Support from the Attachment Type dropdown menu.

G. PTERG Budget/Budget Justification

Use the **PTERG** Budget Form/Budget Justification Template provided. It has been pre-formatted to the preferences of FPTR – please do not alter. **Complete the Budget template for each year of your grant project (i.e., for 2-year projects complete the template twice, convert to PDF, and combine the files together).** Follow the instructions below as to the contents for each item.

FPTR grant funding follows current NIH policies on investigator salaries caps. Please check with your Institutional Official to be sure your requests follow current limits. For reference, please see: https://grants.nih.gov/grants/policy/salcap_summary.htm

Budget: Insert all project expenses (in US dollars) into appropriate categories. Insert numbers only, no characters (i.e., dollars signs, percent signs, commas).

Personnel: List all individuals who will be participating in research project regardless of whether salary support has been requested. Indicate percentage of effort each will spend working directly on this research project. In all categories, indicate support requested from FPTR and total anticipated cost associated with project. Describe specific role each individual will have on project in the Budget Justification.

Consultant(s): Related costs should not exceed 10% of total amount of Grant request. Regardless of whether costs are involved, provide information on all consultants involved with project. Briefly describe services to be performed and related costs in the Budget Justification.

Equipment: Observe limitation for use of funds (support for purchase of major pieces of permanent equipment is limited to 20% or less of the total award). Itemize equipment to be purchased and justify purchase in the Budget Justification. Requests for computers and major software packages must have a detailed justification clearly showing that such items are essential to project and not otherwise available.

Supplies: Itemize supplies in categories, not individually (i.e., software, copying supplies, office supplies, etc.). If animals are involved, state species, number, unit cost, cost of care, etc.

Travel: All requests for support of travel must be justified thoroughly in the Budget Justification. Requests may include reasonable travel in the 48 continental United States to present research results during period of funding. No funds may be used for travel to foreign countries unless it is specifically and directly related to conduct of proposed project.

Patient Costs: Indicate number of patients, number of treatments, and cost per treatment anticipated; indicate what charge is for (e.g., equipment use). In the Budget Justification, provide names of facilities to be used and amount requested for each location. Indicate basis for estimating costs in this category.

Other: Itemize by category. Section may include cost of publication, computer charges, rentals and leases, equipment maintenance, etc. Explain in the Budget Justification.

Budget Justification: Describe specific functions of personnel, consultants, equipment purchases, etc. Identify individuals with appointments of less than full-time. Provide detail for all categories of expenditure. If other proposals for funding this project are pending, describe in detail how the research plan, budget, and time allocation will be adjusted if both proposals are funded. **There is no page limitation for this section** but be succinct and do not use this section to circumvent the page limits of the **PTERG** Application.

Once completed, "Save" / Next to view the Budget Summary and confirm entry is correct.

H. PTERG Approvals/Exemptions/Certifications

Please review the below and provide information regarding:

- Institutional Review Board (IRB) review **and** Human Subjects Research Training Certification.
- **AND/OR** Institutional Animal Care Use Committee (IACUC) review, as appropriate.

PLEASE NOTE: IRB/IACUC Approval is not required at time of application submission, but a description of plans is needed if not obtained yet. If approval or exemption has been received at time of application, include the letter/approval as described below**.** If an award is made, payment will not be issued until IRB/IACUC approval is received by the FPTR Scientific Program Administrator. **If approval or exemption has not been received at time of application, include a description of plans for obtaining it.**

For Human Subjects Research include:

Human Subjects: Institutional Review Board (IRB) Approval: If data is collected on human subjects or if data
used in the project contains identifiable private information that can be linked to human subjects, a copy of IRB Approval or exemption (if already obtained) should be scanned into a PDF file and attached**. If IRB Approval is needed but not currently obtained it must be before the start of the grant. Include a description of plans for obtaining approval/exemption if this is the case**. Should an awarded project have IRB approval that will expire in September or later, re-approval must be received by the Foundation 30 days prior to the date of expiration. If the proposed project has more than one site, IRB approval or exemption must be obtained for every site in the project before funding. Finally, 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.

Human Subjects: Research Training Certification/Evidence: ALL project personnel contributing to the execution of the project (i.e., anyone with a Person Record) must provide evidence demonstrating completion of human subject protections training. A certificate from a recognized credentialing agency (e.g., HPPERT, CITI) must be provided

for **all individuals named in Key Personnel** (except the Institutional Official) or it will be considered INCOMPLETE, which could result in administrative disqualification. The documentation must also provide the period of validity for the training and the training must be valid according to the dates listed on the certificate/evidence of completion. If you do not provide the period of validity for training or the dates on the certificate/evidence of completion do not fall within the period of validity, your application will be considered INCOMPLETE, which could result in administrative disqualification. If evidence is unsatisfactory, the application will be subject to administrative disqualification.

For Vertebrate Animal Research include:

Vertebrate Animals: Institutional Animal Care Use Committee (IACUC) Approval: If vertebrate experimental animals are involved in the study, attach the institution's Animal Care Use Committee (IACUC) approval if currently obtained. Projects including animal subjects must follow APTA's Position on Biomedical Research.

Scan relevant approval/exemption/certificate documents together and submit as one Adobe PDF file.

I. PTERG Relevant Publications

Include and reference all publications applicable to this application.

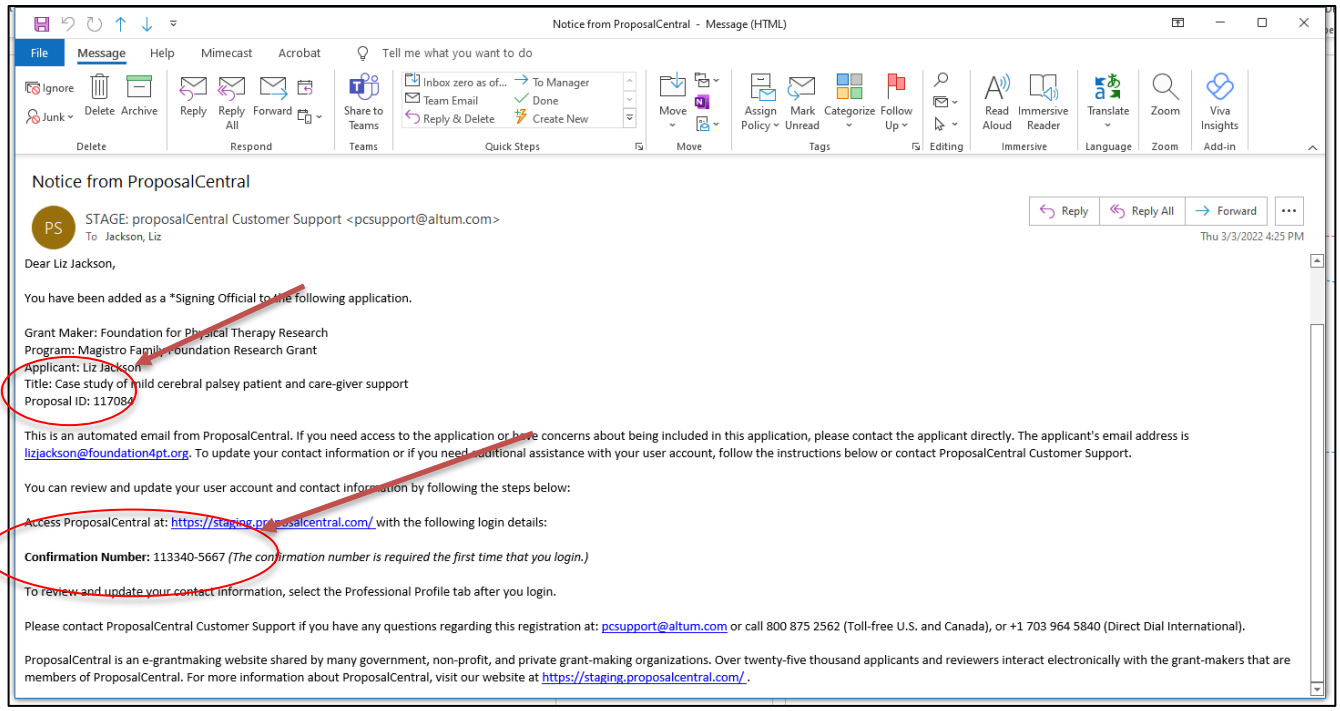
J. PTERG Appendix 1: Project Supplements

Applicants can scan surveys, questionnaires, data collection instruments, and clinical protocols into **one Adobe PDF file** and upload here.

APPROVALS

Required Signature(s) and Print, Validate and Submit

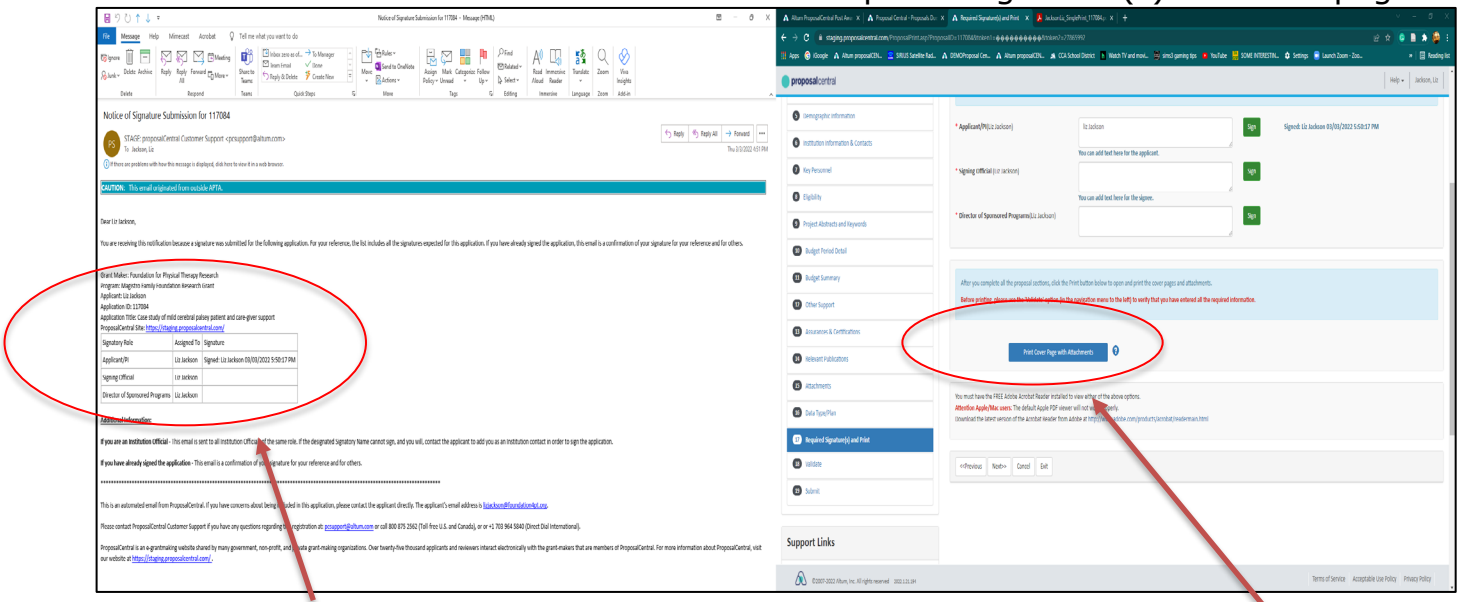
An authorized administrative official must approve your **PTERG** Application. This should be done after all your Letters of Support are submitted. To initiate the institutional approval and submission process, the Signing Official was added in the **Institution Information & Contacts** section at step 6 of your application entry. They each were sent an email at that time (or within a few minutes) that includes the proposalID and confirmation number to be entered to grant them access to sign off on your application.



After the electronic signatures have been entered "VALIDATE," your application. Be sure to review, and correct any missing items, and submit your **PTERG** Application. **Only click "SUBMIT" after you have reviewed your submission and are ready to submit your PTERG Application to FPTR. Before clicking, make sure all your attachments are complete, include all requested information, and are in the correct format.** (For example, including all needed human subjects training evidence/certificates (as appropriate for your institution); or appropriately addressing IRB status or plans to obtain in your submitted content.) **Be sure to check that all attachments are your final versions as well.**

Confirmation email

Required Signature(s) and Print page



The box in your confirmation email will show who has signed off with a time stamp. The cover page and attachments can be printed from the required signature(s) and print page.

If you are missing any required information or attachments, a message will appear with a list of requirements needed. If all components are present/uploaded, the submission will be finalized, and content cannot be changed (unless the institutional official declines approval). It is recommended that you locally save all the components of your submission.

The Signing Official must have administrative rights to the proposal in Section 3 – Enable Other Users to Access this Proposal in order to submit the application to FPTR. Otherwise, the applicant will need to click submit after they have entered their signature. It is the Applicant's responsibility to make sure the Signing Official **has enough time to review and approve (per your institution's requirements) the application before the submission deadline. APPROVAL OF YOUR APPLICATION MUST OCCUR BEFORE THE SUBMISSION DEADLINE (it is not considered fully submitted until approval is received)**.

You will receive an email confirming approval once it is done. You can also check the status by logging onto the submission system and going to the mechanism and clicking on your submission link.

QUESTIONS?

For content questions and guidance, please contact: **info@foundation4pt.org** or by phone **800-875-1378**

For any technical assistance in using the submission site, please contact: **pcsupport@altum.com** or by phone **800-872-2562** or **703-964-5840**