

Department of Physical Therapy (PT) – IRB Scientific and Quality Review Standard Operating Procedure (SOP)

Director of Research & IRB Liaison: Jereme D. Wilroy, PhD

Overview

The Department of Physical Therapy (PT) requires an internal review process for all Institutional Review Board (IRB) submissions initiated by faculty, mentors, or student investigators within the Rehabilitation Science PhD Program. This process ensures that each submission meets scientific rigor, ethical standards, and institutional compliance prior to submission through the Institutional Review Application Portal (IRAP). All protocols must include a **completed and signed Protocol Oversight Review Form (PORF)** approved via Adobe Sign before IRAP submission.

Workflow for Scientific and Quality Review

1. Training Completion

All investigators (faculty, mentors, and student research personnel) must complete or update all required training prior to protocol preparation:

- **CITI Human Subjects Research Training** (Biomedical or Social/Behavioral)
- **Conflict of Interest (COI) disclosure**

Verification of completion will be conducted by the PT Director of Research prior to PORF approval.

2. Protocol Preparation

Investigators prepare the IRB protocol in **IRAP**, including all required study documents and attachments.

Faculty and mentors are encouraged to:

- Consult prior approved protocols within the department.
- Review IRB templates for consent, recruitment, and information sheets.
- Ensure all study personnel are listed in the ePersonnel Form within IRAP.

3. Departmental Submission to Director of Research

Once a draft is ready, investigators must:

- Export a **PDF of the full IRB e-Portfolio** and **ePersonnel Form**.
- Submit both to the **Director of Research (Jereme Wilroy, PhD)** via email or Box upload for internal review.

Submissions include:

- New protocols (Exempt, Expedited, Full Board)

4. Internal Review and Consultation

The **Director of Research** will review each submission to ensure:

- Scientific quality
- Completion of all required training
- Accuracy of listed study personnel
- Completeness of IRB documents and attachments

If the submission is incomplete or requires clarification:

- A brief meeting will be scheduled to discuss revisions.
- The Director of Research will return it to the PI/faculty mentor with comments.

5. Revision and Final Review

The investigator revises materials based on feedback and resubmits the updated PDF package.

Upon satisfactory completion:

- The Director of Research will confirm the protocol's readiness for submission.
- A **final review** will verify that all issues have been addressed.

6. PORF Approval and Routing

Once the internal review is complete:

- The PI initiates the PORF via Adobe Sign on the website:
<https://www.uab.edu/shp/home/office-of-research/porf>
- The **Director of Research (Jereme Wilroy)** signs the **PORF**.
- The form is routed via **Adobe Sign** to the **Associate Dean of Research (Ritu Aneja, PhD)** for review and signature.
- After all parties sign, the finalized PORF is available for download to all involved.

7. IRB Submission in IRAP

Following PORF completion:

- The investigator attaches the signed PORF to the IRB application within **IRAP**.

- The PI then submits the protocol for institutional review.

Review Personnel and Signatories

Role	Name	Responsibilities
Faculty Investigators / Mentors	—	Prepare IRB materials, complete revisions, and ensure compliance with departmental SOP.
Director of Research	Jereme D. Wilroy, PhD	Conduct internal scientific and quality review; verify training and personnel; sign PORF.
Associate Dean of Research & SHP IRB Liaison	Ritu Aneja, PhD	School-level signatory ensuring SHP compliance.

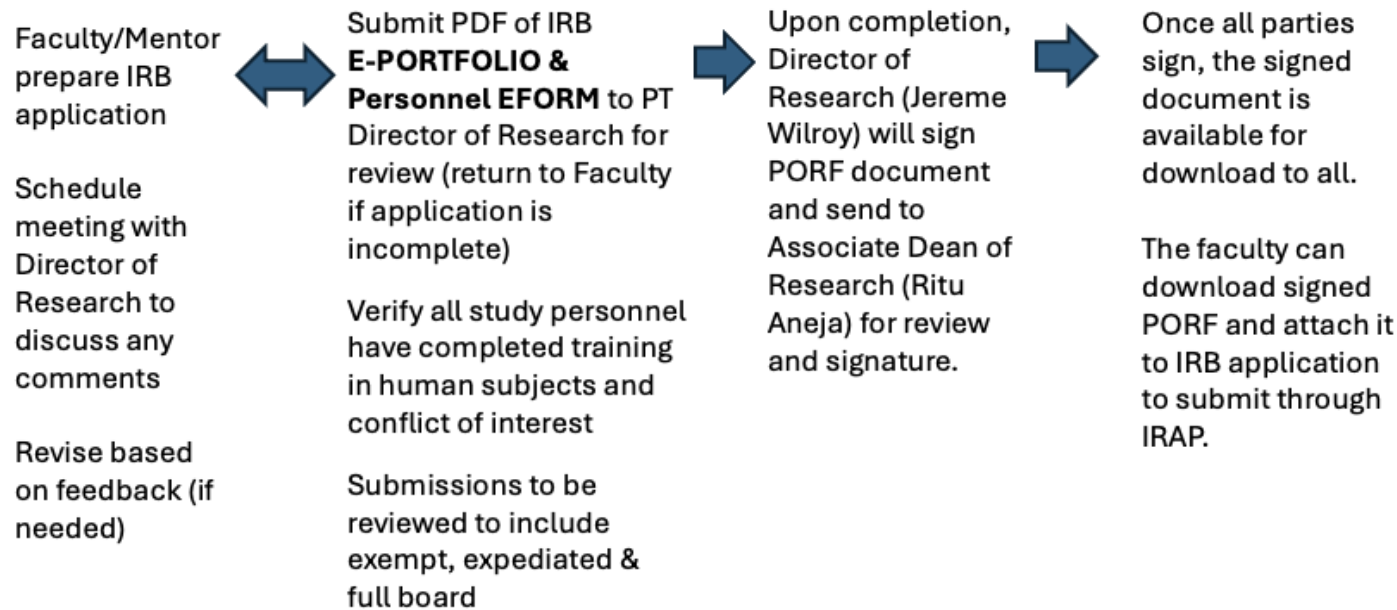
Expected Turnaround Times

Stage	Responsible Party	Expected Timeframe
Initial Review	Director of Research	Within 5 business days of receiving materials
Investigator Revisions	PI / Faculty Mentor	Variable, depending on responsiveness
Final Review & Signature	Director of Research	Within 3 business days of receiving revisions
Adobe Sign Routing	Automated Process	3–5 business days (dependent on signatories)
Total Estimated Time to IRB Submission	—	7–14 business days

Additional Notes

- One unified process applies for both faculty and PhD student submissions.
- The Director of Research is available for consultation on study design, recruitment strategies, and use of departmental resources.
- Full Board protocols may require additional faculty reviewers with relevant expertise.
- The department encourages timely submissions and early consultation to prevent delays in IRB processing.

PT Department IRB Review & Approval Workflow



Brief Description: All PT faculty (& PT Rehabilitation Science PhD Program mentors) will submit a completed PDF of the IRB E-PORTOFOLIO and the E-Personnel FORM to the Director of Research (Jereme Wilroy) to be reviewed for IRB application completeness, completed training in human subjects/COI, and scientific merit. Incomplete IRB applications will be returned to the PT faculty for revision. Set up brief meet with Director of Research to discuss feedback/comments and make necessary revisions. Upon completion, the Director of Research will sign the PORF form and forward it to the Associate Dean of Research to review and sign. Once all parties have signed, the PT Faculty member can download the PORF form to include with their IRB application to submit to IRB.