

## Department of Occupational Therapy (OT) — IRB Scientific and Quality Review SOP

### Overview

The Department of Occupational Therapy (OT) has implemented a unified internal review process for all IRB submissions—whether initiated by students, postdoctoral fellows, or faculty. This process ensures that every submission meets the highest standards of scientific rigor, ethical compliance, and institutional requirements. Following a recent university IRB policy update, all protocols must include a completed **Protocol Oversight Review Form (PORF)**, approved via **Adobe Sign**, before submission in IRAP.

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### Workflow for Scientific and Quality Review

#### 1. Training Completion

- All investigators (faculty, postdoctoral fellows, or students) must complete/update (if needed) the required IRB training (e.g., CITI-Social/Behavioral) before initiating a protocol.

#### 2. Protocol Preparation

- Investigators (faculty, postdoctoral fellow + advisor, or student + advisor) prepare their IRB protocol in IRAP.
- Consult with comprehensive **departmental resources** curated by Dr. Megan Carpenter, available in a shared **Box folder**, which include:
  - Detailed instructions for each step of the IRB process
  - Submission category guidance (e.g., Exempt, Expedited)
  - Templates for consent and information forms
  - Sample applications and best practice documents

#### 3. Intake Form Submission

- Once a draft is ready, investigators will upload a PDF version of the draft to the shared Box folder (OTD capstone projects) or e-mail it to Dr. Hon Yuen (non-OTD capstone projects).

#### 4. Internal Scientific & Quality Review

- Upon receipt of the draft, Drs. Carpenter or Yuen conducts the internal review using a standardized **checklist** developed based on IRB guidelines,

institutional policies, and common protocol issues. Specifically, Dr. Carpenter will be responsible for all OTD students' capstone projects, whereas Dr. Yuen will be responsible for projects initiated by OT faculty, postdoctoral fellows, or PhD students.

- Investigators receive detailed feedback for revision.
- Dr. Carpenter and Yuen are available throughout the process to answer any questions and provide individualized support to both faculty and postdoctoral fellows/student investigators.

## **5. Revisions & Final Review**

- Investigators revise the protocol based on feedback and resubmit for final review.
- A follow-up review may be scheduled if needed to confirm completeness and quality.

## **6. PORF Approval via Adobe Sign**

- Once the protocol is complete and meets all requirements, the principal investigator (i.e., faculty advisor or faculty member) initiate the PORF approval process.
- The PORF is routed for electronic signature via **Adobe Sign** in the following order:
  1. **Drs Carpenter (for OTD capstone projects) or Yuen (for non-OTD capstone projects)**
  2. **SHP IRB Liaison – Dr. Aneja**
- All signatures must be obtained before submission in IRAP.

## **7. IRB Submission**

- Once the PORF is fully signed, the PI submits the final protocol in IRAP and uploads the fully signed PORF as an attachment.

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## **Review Personnel and Signatories**

- **Department Research Director or OTD capstone coordinator:** Megan Carpenter (for all OTD capstone projects) or Hon Yuen (for all non-OTD capstone projects)

- **SHP IRB liaison:** Ritu Aneja
  - **Additional Faculty Reviewers:** Engaged as needed for complex or full-board protocols
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### **Expected Turnaround Times**

- **Initial Review by Investigator:** Varies based on responsiveness
- **Final Review & PORF Initiation:** Within **1 week** of final draft
- **Adobe Sign Routing Completion:** Typically, **1-2 business days**, dependent on signatory responsiveness
- **Total Time to Submission:** Usually within **5-7 business days**

### **Additional Notes**

- There is **one unified process** for both faculty and student submissions.
- Protocols requiring **Full Board Review** (rare in OT) will be reviewed by a **departmental panel** with subject expertise.

1. Training Completion (CITI or required IRB training)



2. Protocol Preparation (Draft in IRAP)



3. Intake Form Submission (Upload PDF / Link / IRB #) for OTD capstone projects  
(or)  
Email Dr. Yuen for all other projects (non-OTD capstone)



4. Internal Review (Drs. Carpenter or Yuen review using departmental checklist)



5. Revisions & Final Review (Investigator revises)



6. PORF Approval (Adobe Sign: PI → Dept. Director → SHP IRB liaison)



7. IRB Submission (PI submits final protocol in IRAP)