

## Department of Health Services Administration (HSA) — IRB Scientific and Quality Review SOP

### Overview

The Department of Health Services Administration (HSA) has implemented a unified internal review process for all IRB submissions—whether initiated by students 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 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 or student + advisor) prepare their IRB protocol in IRAP.
- Consult with comprehensive **departmental resources** curated by Paria, 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 must complete a **Qualtrics intake form** to formally initiate the departmental review.
- The survey collects basic protocol information and triggers the review workflow.
- The form requires investigators to choose **one of the following options** to share protocol materials:

- Upload a PDF version of the draft
- Provide a Box/Google Drive link
- Enter the IRB number (if protocol is already created in IRAP)

#### 4. **Internal Scientific & Quality Review**

- Upon receipt of the intake form, Paria conducts the internal review using a standardized **checklist** developed based on IRB guidelines, institutional policies, and common protocol issues.
- Investigators receive detailed feedback for revision.
- Paria is available throughout the process to answer any questions and provide individualized support to both faculty and 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, Paria fills in appropriate parts of the PORF and sends to the PI to initiate the PORF approval process.
- The PORF is routed for electronic signature via **Adobe Sign** in the following order:
  1. **Principal Investigator (PI)** – faculty advisor (for students) or faculty member
  2. **Department Research Director**
  3. **SHP IRB liaison**
- All signatures must be obtained before submission in IRAP.

#### 7. **IRB Submission**

- Once the PORF is fully signed, PI can download the form and may proceed with submission

- The PI submits the final protocol in IRAP and uploads fully-signed PORF as an attachment
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### **Review Personnel and Signatories**

- **Department IRB Coordinator & Reviewer:** Paria Y Jami
  - **Department Research Director:** Larry R. Hearld
  - **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 Paria:** Within **5 business days** of receiving intake form and documents
- **Revisions by Investigator:** Varies based on responsiveness
- **Final Review & PORF Initiation:** Within **3 business days** of final draft
- **Adobe Sign Routing Completion:** Typically, **3–5 business days**, dependent on signatory responsiveness
- **Total Time to Submission:** Usually **7–14 business days**

### **Additional Notes**

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

