

Department of Clinical and Diagnostic Sciences (CDS)

IRB Scientific and Quality Review SOP

Overview

The Department of Clinical and Diagnostic Sciences (CDS) has implemented a standardized internal review process for all Institutional Review Board (IRB) submissions. This process ensures that each submission meets university standards for scientific rigor, ethical compliance, and safety.

Per School of Health Professions (SHP) policy:

- All IRB protocols **must include** a completed Protocol Oversight Review Form (PORF), approved via Adobe Sign, before submission in IRAP. For FORMS: <https://www.uab.edu/shp/home/office-of-research>
- **Only faculty may serve as Principal Investigators (PI)**; students may serve as co-investigators under faculty supervision. Faculty must review and approve all student-related protocols before departmental submission.

Workflow for Scientific and Quality Review

1. Training Completion

- All investigators (faculty and students) must complete or update all required IRB training (e.g., CITI: Social/Behavioral or Biomedical) before initiating a protocol. Faculty mentors are responsible for verifying that students have completed this requirement.

2. Protocol Preparation

- Investigators prepare their IRB submission in IRAP, following current UAB and SHP guidance. Faculty advisors should review and edit student drafts before departmental submission. Reference materials, including the PORF, helpful tools for IRB protocol category self-determination are available on the SHP Office of Research website: <https://www.uab.edu/shp/office-of-research>

3. Intake Form Submission (Qualtrics Portal): https://uab.col.qualtrics.com/jfe/form/SV_9um4UMvgbfnKW7c

- Once a draft is ready, investigators must complete the CDS IRB Intake Form (Qualtrics). The form collects basic information, including project title, PI, abstract, and submission type (Exempt, Expedited, or Unknown). The Qualtrics submission automatically notifies Dr. Keith McGregor (CDS Research Director) to initiate departmental review. You may upload the PDF of the IRAP form. Investigators may also provide a Box/Google Drive link to protocol materials.

4. Internal Scientific & Quality Review

- Dr. Keith McGregor conducts the initial review using a standardized checklist aligned with IRB and SHP quality standards. Feedback is provided via email with specific comments for revision and clarification. Faculty mentors should assist students in addressing feedback before resubmission.

5. Revisions & Final Review

- Investigators revise the protocol based on feedback and resubmit via email to Dr. McGregor for final review. A follow-up review may be conducted to confirm accuracy and completeness before PORF approval.

6. PORF Approval via Adobe Sign

- Once the protocol meets all quality and compliance standards, Dr. McGregor will notify 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 student-led protocols) or faculty PI; (2) CDS Research Director (Dr. Keith McGregor); (3) SHP Research Director (Dr. Ritu Aneja). All signatures must be obtained before submission in IRAP.

7. IRB Submission

- Once the PORF is fully signed, PI may proceed with submission. The PI is responsible for final submission through IRAP.

Review Personnel and Signatories

Role	Name / Title
Department IRB Coordinator & Reviewer	Keith M. McGregor, PhD
Department Research Director	Keith M. McGregor, PhD
SHP IRB Liaison (Associate Dean for Research)	Ritu Aneja, PhD
Additional Faculty Reviewers	Engaged as needed for complex, full-board, or radiation-related protocols

Expected Turnaround Times

Process Step	Expected Timeline
Initial Review by Dr. McGregor	Within 3 business days of intake form receipt
Investigator Revisions	Within 10 business days, depending on responsiveness
Final Review & PORF Initiation	7–15 business days, depending on protocol complexity
Adobe Sign Routing Completion	Typically, 3–5 business days, dependent on signatory responsiveness
Total Time to Submission	Usually 10–20 business days overall

Additional Notes

- Faculty mentors are responsible for reviewing and endorsing all student-led protocol drafts before departmental submission.
- All submissions must comply with UAB IRB and SHP Office of Research requirements.
- Protocols involving radiation or hazardous materials must coordinate with UAB Environmental Health and Safety prior to IRAP submission.
- There is one unified process for both faculty- and student-led protocols, with the distinction that only faculty may serve as PI.