Heersink School of Medicine IRB Submission Process

Overview:

The purpose of this document is to describe the Heersink School of Medicine's internal review process that is required prior to submission of an application to the UAB Human Research Protection Program (HRPP)/IRB.

This process ensures that all initial IRB applications–whether for exemption determinations, expedited IRB reviews or fully convened IRB reviewed studies—undergo a scientific and quality review process, which is documented using the revised Protocol Oversight Review Form (PORF), before submission for IRB approval. For investigator-initiated studies, the review should confirm scientific merit (sound design, statistical plan, rigor and reproducibility). Studies that have undergone external peer review may rely on that review for scientific validity and rigor. However, all studies must be reviewed within the Heersink School of Medicine prior to IRB submission to verify completeness, accuracy, and consistency across the submission, completion of required training, conflict of interest disclosures, data/privacy plans, and feasibility (resources, team expertise, timelines). Information for completing this process is described below.

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/Biomedical, GCP) before initiating a protocol.
2. Protocol Preparation
    - Investigators (faculty or student + faculty advisor) prepare their IRB protocol in IRAP and, once implemented, in myUABResearch.
    - Investigators are supported by links to institutional tools that assist with determining the appropriate IRB submission pathway:
        - Quality Improvement (QI) Self-Determination Tool – Helps researchers determine whether a project qualifies as quality improvement (QI) or program evaluation rather than human subjects research under 45 CFR 46. If a project is deemed QI or program evaluation using this tool, no further action or submission to the IRB is required.
        - IRB Review Category Self-Determination Tool – A Microsoft Form that walks researchers through key questions to identify the correct IRB review category and directs them to the necessary fact sheet for application completion.
        - Not Human Subjects Research (NHSR) – Some studies may qualify as Not Human Subjects Research (NHSR) if they do not meet the federal definition of research or human subjects' involvement. Researchers must still apply to the IRB for an official determination before proceeding with their study.
3. Departmental Scientific & Quality Review
    - Investigators use the recently developed AI tool to conduct a quality and completeness check prior to submitting to their Departmental (or Division) signatory.

- Investigators submit IRB materials to a designated Departmental/Divisional contact(s) in each of the HSOM Departments (or Divisions) (see attached document).
- Departments (or Divisions) conduct internal review of IRB materials through a designated Departmental (or Divisions) signatory/ies ensuring that a quality and completeness check has occurred either through the AI tool or by manual review.
- Departmental (or Division) reviewers are provided with materials to support their scientific and quality review:
  - A standardized checklist developed based on IRB guidelines, institutional policies, and common protocol issues.
- Investigators receive detailed feedback from Departmental (or Division) signatories if revisions are needed prior to PORF approval.

4. Revisions (as needed) & Final Review
   - Investigators revise the protocol based on feedback and resubmit for final review.
   - Departmental or Divisional reviewer conducts a final review to confirm completeness and quality.
5. PORF Approval via Adobe Sign
   - The PORF is routed for electronic signature via Adobe Sign in the following order:
     1. Principal Investigator (PI) – faculty member (including advisor for students)
     2. Department (or Division) Research Signatory/ies
   - All signatures must be obtained before submission in IRAP or myUABResearch.
6. IRB Submission
   - Once the PORF is fully approved, the PI may proceed with submission.
   - The PI submits the final protocol in IRAP or myUABResearch.

Review Personnel and Signatories

- Department (or Division) Research Signatory/ies: (see attached document)

Expected Turnaround Times

- Internal Departmental (Division) Review: Within 10 business days.
- Revisions by Investigator (as needed): Varies based on responsiveness
- Final Review & PORF Initiation: Within 5 business days of final draft

- Adobe Sign Routing Completion: Within 5 business days, dependent on signatory availability
- Total Time to Submission: Usually 14-21 business days

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03/17/2026

Date