

Streamlining External Institutional Review Board Submission Workflow

R. Perry, B. Scanlan, M. Kovak, A. Holley

UAMS Winthrop P Rockefeller Cancer Institute

1. Background

Implementing external Institutional Review Board (IRB) submissions has been a complex challenge for the Clinical Trials Office (CTO), involving collaboration with multiple campus teams and consistent communication between sponsor and site. Previous methods caused delays due to combining external IRB documents, budget updates, and local IRB approvals into a single submission. To expedite study implementation, a segmented approach was required.

2. Goals

Our objectives were to:

- Reduce study implementation timelines.
- Ensure documentation compliance by enrolling subjects according to the most current protocol.
- Maximize cross-functional collaboration across study teams and study sponsor/Contract Research Organization

3. Solutions and Methods

CTO introduced a new workflow to address external IRB implementation issues. The Regulatory Specialist (RS) now uploads external IRB-approved documents in the initial submission, including approval letter, protocol, consent, investigator brochure, and patient-facing documents. The RS shares approved consents with legal, but no immediate approval is needed. Once the local IRB approves the initial modification, the RS initiates a second submission to update the treatment plan. Pharmacy reviews and adjusts as needed financial revisions are made. After completion, clinical staff conducts a quality assurance check. The financial team alerts the RS when the modification is ready for submission. Concurrently, the beacon team works on internal treatment plan modifications, ensuring subjects enroll with the updated approved protocol. Local document implementation occurs, and if necessary, a new UAMS IRB submission opens for Beacon treatment plan and billing updates associated with amendments.

4. Outcomes

The external IRB Amendment Workflow implementation has streamlined collaboration across CTO teams. Feedback indicates improved clinical staff performance and reduced confusion between clinical documents and the treatment plan. Implementation timelines have shortened, leading to subjects enrolling in the most up-to-date protocol. Consent to outdated protocols has decreased, enabling research nurses to focus on enrolling new subjects. Any treatment plan issues can be rectified through additional modifications while ensuring subjects receive optimal care.

5. Lessons Learned and Future Directions

To further enhance the external IRB Amendment Workflow, future directions include:

- Implementing dual modification submissions for added flexibility.
- Continuing to foster better communication among various teams within CTO and sponsor as a whole.

Category: Trial Start-up, Activation, and Protocol Development – Work in progress

- This improved workflow has not only expedited the implementation of clinical trials but also improved the overall research process at our institution.