Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) – Work in progress

The Evolution of IRB Submissions – Streamlining IRB Amendment Submission Workflows for Local Implementation Utilizing Oncore

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1. Background

Institutional Review Board (IRB) submissions have always been a complex challenge for the Clinical Trials Office (CTO), involving collaboration with multiple campus teams and consistent communication between sponsors and local staff. Fragmented workflows can lead to inconsistent documentation, delayed implementation, unclear re-consent communication, and audit vulnerabilities. To address these challenges, our academic cancer center developed a standardized, system-integrated workflow aligning protocol amendment processing within our IRB module (CLARA) with operational execution in OnCore, explicitly mapped to institutional Standard Operating Procedures (SOPs) governing re-consent and regulatory communication.

2. Goals

Our objectives were to:

- Reduce regulatory implementation timelines
- Ensure regulatory compliance by enrolling subjects according to the most current protocol
- Maximize cross-functional collaboration across study teams to ensure regulatory, clinical, and financial compliance despite segmented efforts
- Create a reproducible, auditable workflow for IRB protocol amendments without budget impact that clearly defines system ownership, standardizes re-consent determination and communication, and ensures synchronization between regulatory approval and operational implementation

3. Solutions and Methods

With the introduction of Oncore, the CTO introduced a structured workflow to address IRB submission delays. The workflow defines sequential decision points for document revision, sponsor and legal approvals, IRB submission, and post-approval execution.

The Regulatory Specialist (RS) uploads documents within the IRB submission portal, including approval letters, protocol, consents, investigator brochures, and patient-facing documents. The RS shares approved consent documents with legal, with no immediate approval needed. The RS notifies the financial team to address within Oncore while simultaneously submitting through the IRB submission portal for pharmacy review. The initial pharmacy review takes place within two to three business days and allows for the IRB submission to proceed after completion. The study goes directly to the IRB while the pharmacy team continues to modify and adjust dispensing and administrative timepoints as needed and financial revisions are made within Oncore. The RS will address IRB contingencies and approvals while the clinical staff conducts a quality assurance check surrounding the modified budget. At the time

of budget finalization, the EPIC beacon team works on internal treatment plan modifications to align with current documentation. At the time of local implementation, clinical staff are notified of the approved documentation as well as the status of the treatment plan to ensure all subjects are enrolled with the appropriate treatment plan in place**.**

4. Outcomes

With the separation of the financial and treatment plan aspects from the IRB submission portal, the updated Oncore Amendment Workflow indicates improved clinical staff performance, reduced confusion between clinical documents and the treatment plan, and drastic improvements in regulatory implementation timelines, version control, and quality assurance. Utilizing outdated consents has decreased, enabling research nurses to focus on enrolling new participants. Any treatment plan issues can now be resolved without additional modifications while ensuring subjects receive optimal care.

5. Lessons Learned and Future Directions

Future directions include:

- Implementing dual submission capability for added flexibility
- Clarifications regarding internal triggers leading to more effective workflow communication
- Improved workflow has not only expedited the implementation of clinical trials but also improved the overall research process at our institution as items are addressed more efficiently