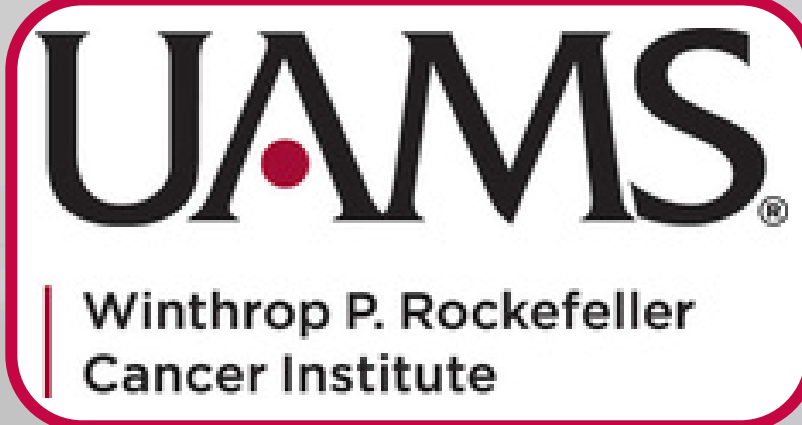


# Streamlining External Institutional Review Board (IRB) Submission Workflow

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## 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.

## Outcomes

- ✓ Improved clinical staff performance in treatment plan development
- ✓ Increased efficiency in implementation timelines and re-consent and new enrollment metrics
- ✓ Increased collaboration and understanding of clinical and regulatory staff leading to more efficient efforts and reduced delays.

## Goals

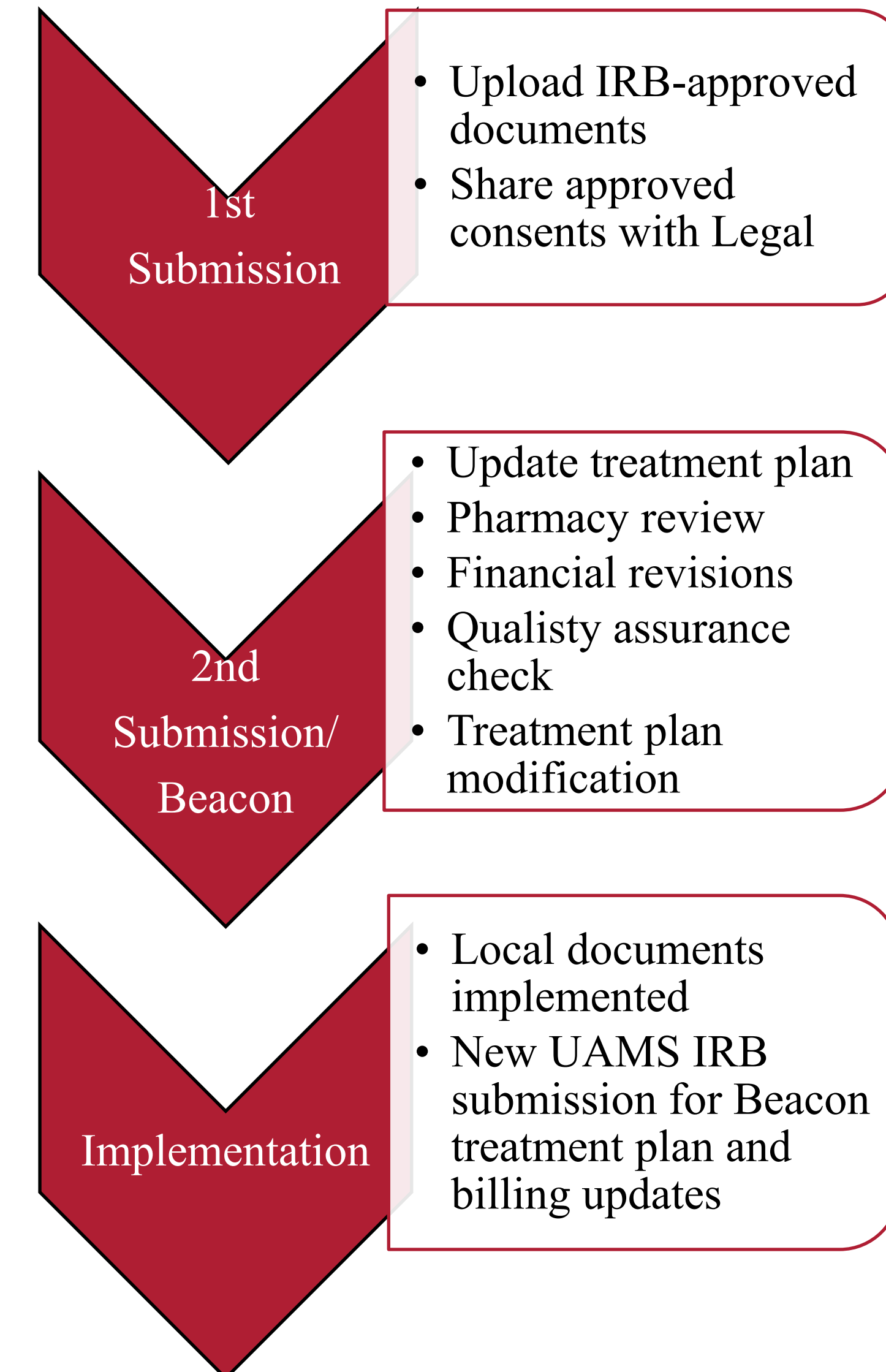
- Reduce study implementation timelines.
- Ensure documentation compliance by enrolling subjects according to the most current protocol.
- Maximize cross-functional collaboration across study teams and study sponsor/Contract Research Organization (CRO)

## Future Directions

- Potential for dual modification submissions for added flexibility.
- Continuing fostering better communication among various teams within CTO and sponsors
- Further workflow development to outline overall processes and automate notification system.

## 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.



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