

Implementation of Protocol Amendment Project Manager to Improve Protocol Implementation Timeline

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1. Background

Clinical trial amendments frequently address safety concerns, incorporate emerging scientific understanding, or modify study design. At University of Florida (UF) Health Cancer Center, processing protocol amendments received during study startup are generally deferred until after study activation, often resulting in back-to-back budget and contract negotiations, along with sequential institutional reviews. However, even once active, protocol amendment processing impacts multiple units across the research office.

Commensurate with increasingly complex protocols, we have observed an increased volume of amendments, averaging 182 annually between 2022-2024. This volume is attributed to an increase in multi-stage study designs for new therapeutics, which commonly require multiple updates over the life of the trial to address emerging safety and efficacy signals. While these updates are essential for clinical trials to remain safe, and effective, site level implementation is labor and time intensive, representing increased workloads for teams dedicated to managing study start-up and ongoing study conduct.

2. Goals

- Improve amendment workflow, as measured by time to implementation.
- Identify high-impact activities within the amendment process for improvement.
- Benchmark staff effort at key points within the amendment process to facilitate cost recovery efforts.

3. Solutions and Methods

In 2024, 172 protocol amendments were received across 98 trials, 32 of which required calendar and budget updates. Days from receipt to activation were highly variable, revealing an inconsistent process that could be a key target for improvement.

A workflow tracker was created to identify key players, identify activities which must occur sequentially vs. in-tandem, and established target timelines for each step in the process.

We identified up to 11 discrete tasks, spanning across 5 divisions with 7 points of hand-off, requiring engagement of 10+ independent contributors to process an amendment. Recognizing the multimodal nature of this process without a single point of authority to maintain accountability and deadlines, a Project Manager was assigned to centralize updated tracking, facilitate communication and hand-off between teams, and escalate lagging updates. A bi-weekly inter-departmental meeting was adapted to allocate time for amendment updates and facilitate movement among teams, while harnessing collective expertise to problem-solve difficult and one-off scenarios.

4. Outcomes

Since December 2024, 13 amendments have been fully activated utilizing this new process, with an additional 19 in progress. Sufficient data on activation time is not yet available to assess improvement, however preliminary data has indicated that delayed budget receipt from Sponsors, and hand-offs with

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Contracting and the Research Office are components causing the most significant delays, enabling more targeted process improvement efforts. Subjective feedback from stakeholders has been positive, noting improved transparency, more real-time status updates and enhanced collaboration.

5. Learned and Future Directions

Future directions include collecting data to quantify effort involved in managing protocol amendments, identifying true average time to activation as compared to stated goals, and thoughtfully troubleshooting areas leading to inefficient implementation of protocol updates including cross-training within divisions to minimize hand-offs and consolidate tasks with a single independent contributor. Effort data will be used to refine the existing tiered amendment fee schedule, which will improve cost recovery of effort.