Category: Regulatory – Work In Progress

Redesigning the Delegation of Authority Log for the Modern Cancer Center

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1. Background

For a large cancer center with blended clinical and research staff, maintaining the traditional format of delegation of authority log (DOA) has proven difficult. Obtaining signatures from 20+ staff members in a timely fashion is nearly impossible, and the need to send pages to offices all over campus inevitably leads to missing documentation. Additionally, using the varied industry sponsor templates makes it hard to capture the workflow of our local clinical research staff accurately.

FDA auditors have pointed out this issue. Nearly 20% of all monitor findings over the last two years relate to the DOA. With these things in mind, the Masonic Cancer Center Clinical Trials Office regulatory staff and management set out to reimagine the DOA to simplify the process while still documenting all pertinent information needed to conduct a study under Good Clinical Practice.

2. Goals

- Reduce time needed to obtain a completed DOA during startup
- Reduce opportunities to misplace individual pages of the DOA
- Accurately reflect the delegations given to local staff members across studies

3. Solutions and Methods

- Only the principal investigator's signature is needed for each delegation. This satisfies our first two goals. It allows regulatory staff to obtain a complete DOA at the study initiation visit, and eliminates the need to send separate pages to individual staff members.
- All research staff completed Master Signature Log pages, which are available to all monitors and auditors via Box for handwriting comparisons.
- The delegation categories are tailored to our site, and are highly customizable to fit any type of study (e.g., therapeutic vs non-therapeutic, transplant vs chemotherapy, primary intervention vs supportive care).

4. Outcome

- Fewer monitor findings for missing pages or signatures.
- DOA can be uploaded to the research database prior to study opening for immediate study staff needs; i.e., investigational pharmacy staff verifying authorized drug prescribers.
- Study delegations are easier to comprehend, and it is easy to work with sponsors to add study-specific needs.

5. Lessons Learned

Results have been ultimately positive; however, some concerns have yet to be addressed, including:

- How do individual staff members know they have been delegated to work on the study if they do not sign the DOA?
- Differences between delegated start date and initial protocol training date.
- Balancing industry sponsors' desire for consistency between sites vs. MCC CTO's unique challenges.

MCC CTO will transition to an electronic regulatory system in late 2020. We will collaborate with the larger University of Minnesota research community, using the lessons learned during this project to implement an electronic DOA system that meets the needs of not only the MCC CTO, but also the university research community at large.