Category: Regulatory – Work in Progress

Simplifying and Improving Training and Delegation Documentation

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1. Background

Training and delegation are a primary focus of the Code of Federal Regulations and good clinical practice guidelines. The Huntsman Cancer Institute (HCI) clinical trials office (CTO) process for documentation of training and delegation had several problems that needed to be addressed:

- Multiple signatures required from the principal investigator (PI)
- Frequent changes due to staff turnover
- Quality control issues
- No defined process for collecting electronic signatures
- Sponsor overreach due to too much flexibility in our standard operating procedure (SOP)

2. Goals

We identified four major goals for our new process:

- Decrease the signature burden on PIs
- Increase compliance
- Move from wet ink to an electronic platform
- Decrease ambiguity for sponsors

3. Solutions and Methods

One of our senior regulatory coordinators joined our team from another comprehensive cancer center and shared their process for training and delegation documentation. Three of the main components of the process used at this center that we chose to adopt were: 1) the creation of research personnel profile pages for each study role, 2) the creation of a protocol assignment and training log (PATL) to document protocol training, and 3) a principal investigator (PI) statement of oversight and delegation. As members of the AACI CRI listserv distribution list, we gleaned additional insight from other cancer centers in regard to SOP language to clarify sponsor expectations of our site. We used all of these components to develop a compliant, comprehensive process that would meet the goals outlined above.

The proposed process was shared with the HCI CTO physician leadership team to garner their support and approval of the new process. HCI CTO leadership drafted a comprehensive SOP and templates for research personnel profiles, PATL, and PI statement of oversight and delegation. We created work practice documents for the study teams to follow to initiate a new study using the revised SOP and how to transition a study that was initiated under our previous SOP to the new process. The new process is 100 percent electronic and compliant with 21 CFR Part 11.

Because the changes were so drastic, we decided to pilot the new process in one of our six research group teams.

4. Outcomes

The pilot began in January 2022 and has been going very well. The study teams have been able to identify and correct several errors in previous delegation and training records that have been transitioned indicating a large improvement in compliance. The study staff involved in the new process have found it to be straightforward and simple. Rather than requiring PI signature for each line on our former delegation of authority logs for every addition, the PI statement of oversight and delegation is signed annually. We are still getting feedback from sponsors on the new process as monitoring visits are occurring for the impacted studies.

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5. Lessons Learned and Future Directions

The value of insight gained from the community of cancer research programs cannot be overstated. We felt confident in our new SOP because of the success of other cancer center programs who shared with us. We look forward to making any adjustments to our process based on the feedback we receive as the new process begins to be scrutinized. Once these initial adjustments are made, we plan to implement gradually across the entire department.