Category: Regulatory – Completed Project

Delegation of Authority – A Simplified Process

B. Scanlan, A. Holley, M. Kovak, B. Lehman, P. Newman, R. Perry, D. Wade, M. Birrer

UAMS Winthrop P. Rockefeller Cancer Institute

1. Background

Collecting signatures and maintaining study-specific delegation of authority (DOA) logs has historically been a time-consuming process within our clinical trials office (CTO). With a CTO employing more than 60 staff and working with over 150 investigators, the process was burdensome for all involved. Further, there was no consistent process for DOA completion and maintenance across the approximately 300 research studies managed by the CTO. There were different requirements based on the type of study, whether initiated by a cooperative group, industry sponsor, or a local investigator. The processes were also made redundant due to DOA information required to be submitted in clinical research administration (CLARA), the UAMS electronic system for submission, review, and tracking of research. A simpler process to reduce administrative burden, streamline the procedure for all types of studies, and eliminate duplication of effort was imperative.

2. Goals

- Reduce administrative burden by eliminating requirement for wet-ink signatures on study-specific DOAs
- Streamline procedures by using the same process for all study types and eliminating use of sponsor provided DOAs
- Eliminate duplication of effort by integrating information that is already being captured in CLARA

3. Solutions and Methods

A new authority and delegations of responsibility standard operating procedure (SOP) was implemented to include completion of master signature pages (MSP) by all staff and investigators. At time of completion of the MSP, study staff reviews a central delegation key (CDK) that lists research roles and responsibilities based on credentials and job title. Signature on the MSP indicates agreement to perform delegated responsibilities as assigned based on role, education and training. The roles and responsibilities listed on the CDK are personalized to our site and mirror those listed in CLARA for each study. Staff and investigators are required to complete the MSP once, providing a wet-ink signature. The principal investigator is responsible for ensuring staff lists in CLARA are complete and updated at all times to provide an accurate account of the study specific DOA. Copies of completed MSPs and study specific staff lists are saved electronically for review by auditors and monitors.

4. Outcomes

- MSP completion and review of SOP is now part of our onboarding procedure for new staff and investigators
- Investigator involvement for tedious and redundant paperwork has been limited, allowing them to focus on more meaningful aspects of research
- Monitors have found the centralization of DOA information to be helpful and fewer monitor findings have been received
- Consistency in documentation of DOA across all types of studies has been established

5. Lessons Learned and Future Directions

Initial implementation of the revised process was time consuming for regulatory staff and led to many questions by staff and investigators. Additionally, although study monitors have been receptive to the process, many require additional documentation of our process in addition to the SOP. Overall, the

updated DOA SOP has been essential in helping our office meet goals of streamlining procedures and reducing administrative burden.