Category: Regulatory – Completed Project

How to Implement at Master Delegation of Authority Process across a Clinical Trials Office

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1. Background

Maintaining an accurate and complete list of staff participating on a clinical trial is an important part of study conduct. However, the documentation of staff delegation can be cumbersome and is often repetitive. Additionally, this documentation often differs across various types of trials, making consistency across multiple studies difficult. Developing a method to facilitate study document compliance and standardize delegation of study roles across the Clinical Trials Office (CTO) would be useful in minimizing regulatory burden.

2. Goals

- Establish a standardized method in which all studies conducted within the Clinical Trials Office (CTO) are delegated in the same manner
- Align personnel roles with tasks on protocols appropriate to duties and training
- Create documentation to support the Master Delegation of Authority initiative

3. Solutions and Methods

- Master Delegation of Authority (mDOA) process created to standardize staff delegation across all CTO new trials, with option to move over existing trials to the new process
- Staff roles assigned tasks on the mDOA as appropriate to their duties within role
    - Staff then assigned tasks by role on individual protocols as appropriate
- SOPs and templates created to explain the mDOA initiative and document delegation of authority appropriately with the CTO, as well as on individual protocols
    - Master Delegation Profiles created per role and completed by personnel upon start of role and maintained throughout time in role
    - Individual Protocol Delegation of Authority logs track staff assigned to specific protocols, along with dates active on the trial in role

4. Outcomes and Future Directions

Outcomes

- All new trials moving forward within the CTO have been opened utilizing the mDOA process (over 125 studies to date)
    - Significant number of existing number of trials have been transitioned over to new mDOA as well
- Regulatory burden has decreased across protocols managed by the CTO

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Lessons learned

- Maintaining clear communication with industry partners is important when not utilizing sponsor provided templates

Future directions

- Rolling out to teams outside of the CTO that operate under the Cancer Center