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

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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.

Metrics & Goals to be Achieved

- 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

Solution or Methods Implemented

- 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

Figure 1. Example mDOA Role Profile

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DELEGATION OF AUTHORITY PROFILE

Proclamation: I hereby adhere to the following significant trial-related duties and understand that the overall responsibility for conduct of all trials remains with the designated investigator(s) for trials coordinated by the CTO.

Print Full Name:	
Title/Position:	Principal Investigator

Significant trial related duties:	☒ Review/Obtain Informed Consent	☒ Obtain and document Medical History/AEs/Medications
	☒ Determine Subject Eligibility	☒ Complete CRFs/Queries
	☒ Perform Physical Exams	☒ Prepare/Ship Lab Samples
	☒ Assess Lab/ECG/EKG/Medical Reports	☒ Essential Document Maintenance
	☒ Assess and document AEs/SAEs	☒ Administer study specific questionnaires, tools, diaries
	☒ Sign CRFs/Queries	☒ Perform IVRS/IWRS
	☒ SAE Reporting	☒ Central Imaging – Transmittals & Queries
	☒ Prepare/Dispense IP *(Blinded, as appropriate)*	☐ **Additional tasks - Manager Initials & Date**
	☒ Perform IP Accountability	☐

By signing this form I agree that I am performing delegated research responsibilities as assigned based on education and training.

Signature:		**Initials:**	
Start Date in Role:		**End Date in Role:**	

Please complete document in blue or black ink

Figure 2. Example mDOA Documentation for Individual Trial

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Log of Study Personnel

Protocol Number		**Principal Investigator**	
Staff Name	**Role***	**Start Date of Study Delegation**	**Stop Date of Study Delegation**

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PI Delegation of Authority Memo

Protocol Title:			
Protocol Number:		Sponsor:	
Principal Investigator:		Site Number:	

The section below is to be completed at study initiation.

I, the Principal Investigator for the above listed trial, have delegated study related duties to the individuals included on the Log of Study Personnel. Individuals with completed Delegation of Authority Profiles are working within the scope of their positions and delegated duties.

Please see the IUSCC CTO Master Delegation of Authority SOP for an explanation on the maintenance of these documents.

Start date of delegation time period: _____

Signature of Principal Investigator: _____ Date: _____

The section below is to be completed at study close-out.

I, the Principal Investigator for the above listed trial, have reviewed the Log(s) of Study Personnel and have deemed them to be a complete and accurate record of the delegated tasks during the course of this trial.

End date of delegation time period: _____

Signature of Principal Investigator: _____ Date: _____

Outcome

- All new trials moving forward within the CTO have been opened utilizing the mDOA process *(over 140 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

Lessons Learned & Future Directions

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