Masonic Cancer Center, University of Minnesota
Comprehensive Cancer Center designated by the National Cancer Institute

Redesigning the Delegation of Authority Log for the Modern Cancer Center

NCI Designated Comprehensive Cancer Center

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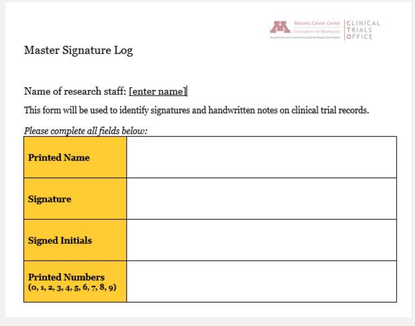
Background: For a large cancer center with a multidisciplinary team of clinical and research staff, the traditional format of delegation of authority log (DOA) poses limitations. These limitations include: obtaining signatures from 20+ staff members in a timely fashion; the need to send pages of the log throughout campus, leading to missing documentation; and lack of consistency in capturing the workflow of clinical research staff.

Goals

Goal: Reduce the time needed to obtain a completed delegation of authority (DOA) log after a study's site initiation visit (SIV). When reviewing the process, the step that took the greatest amount of time was collecting each research staff's signatures, with collection times varying over several weeks.

Approach: Only require the Principal Investigator's (PI) initials and eliminate the need for research staff to sign the DOA log for each study. The purpose of signature collection is to verify who the work is attributable to. Instead of completing the signatures for each log, a master signature log was created for each research staff member and made electronically accessible for all studies. See figure below.

Result: With the elimination of research staff signatures for individual studies, only the PI signature is required to be collected for DOA log completion. With the PI available at nearly all SIVs, DOA logs were able to be signed and uploaded to Oncore CTMS same day or next day from SIV.



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Master Signature Log

Name of research staff: [enter name]

This form will be used to identify signatures and handwritten notes on clinical trial records.

Please complete all fields below:

Printed Name	
Signature	
Signed Initials	
Printed Numbers (0, 1, 2, 3, 4, 5, 6, 7, 8, 9)	

Goal: Reduce opportunities to misplace individual pages of the delegation of authority (DOA) log. With multiple research staff signature requests circulating, many pages were out for signature at a time instead of on file in the investigator's regulatory file, leading to monitor findings for pending signatures.

Approach: As noted in the previous approach, only require Principal Investigator (PI) signature and eliminate the need for research staff to sign a DOA log for each study. See figures below.

Result: With the elimination of staff signatures, the log only had to be circulated to one individual (the PI) instead of multiple.

Original DOA Log Columns:

NAME (printed)	SIGNATURE	ROLE	STUDY RESPONSIBILITY (CODE)	DATE STARTED WITH TRIAL	DATE ENDED WITH TRIAL	PI INITIALS

Updated DOA Log Columns:

NAME (printed)	START DATE*	STOP DATE	ROLE	STUDY RESPONSIBILITY (codes)	PI Initials

Goal: Reduce the variability of delegated tasks.

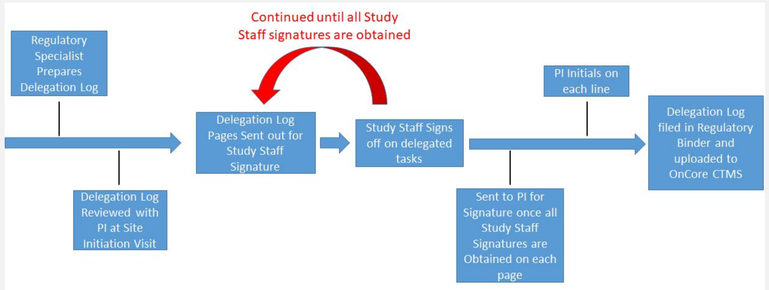
Approach: Customize set delegated tasks and determine which tasks are typical per role (PI, Sub-Investigator, Clinical Research Coordinator Nurse (CRC-RN), Clinical Research Coordinator (CRC), Advanced Practice Providers (APP), Treating Providers (TP), Investigational Drug Services (IDS), and Regulatory Specialist (RS)). See figure below.

Result: Created a policy to require use of our own site delegation of authority log template whenever possible, which included customized tasks as well as an option to add other tasks. Using our own template eliminated the variability from using Sponsor logs. Created a key with suggested tasks for each study role.

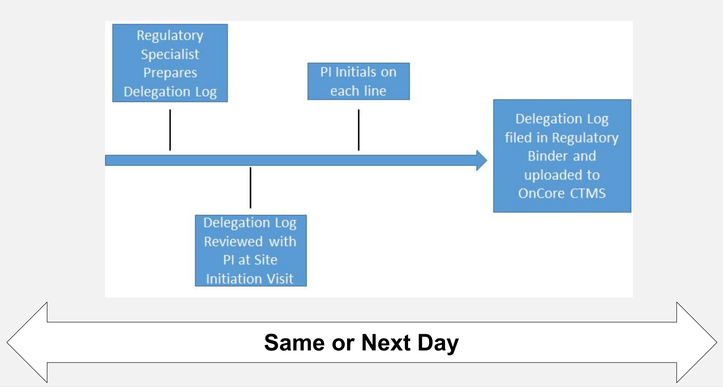
The following delegated tasks are typically linked to the responsible roles listed:

Delegated Task	Responsible Role
A. Determine subject eligibility	Sub-I
B. Obtain subject informed consent	Sub-I, CRC-RN, TP
C. Perform Physical Exam	Sub-I, TP, APP
D. Perform Drug Accountability	IDS, CRC-RN, CRC
E. Prepare and dispense study drug	IDS
F. Instruct subject on study drug administration	CRC-RN, Sub-I, TP, APP
G. Disease assessment evaluation	Sub-I, TP*
H. AE/SAE attributions	Sub-I
I. Safety/deviation reporting	CRC-RN, CRC, RS
J. CRF completion/query resolution	CRC-RN, CRC
K. Provide regulatory support	RS
L. Handle/ship research laboratory samples	CRC
M. Signing treatment plans	Sub-I, APP (non-CTEP studies), TP
N. Initial Protocol Training	Sub-I, CRC-RN, CRC, PM
O. Other (specify, if applicable)	[see below examples]

Previous Flow Summary



Current Flow Summary



Limitations and Future Directions

- Uncertain if individual research staff know they have been delegated to work on the study if they do not sign the DOA log.
- Differences between delegated start date and initial protocol training date.
- Balancing Sponsors' desire for consistency of DOA logs between sites vs. our site's requirement to use internal DOA log.

University of Minnesota research teams will transition to an electronic regulatory system in summer 2020. Masonic Cancer Center Clinical Trials Office is collaborating with the larger research community, using the lessons learned during this project to implement an electronic DOA system that meets the needs of not only our program, but also the University's research community at large.