Guidelines for Completion of the CCR Delegation of Activities Log

Version 11/14/2023

The Delegation of Activities (DOA) log should provide a comprehensive list of study staff members and the duties that have been delegated to them by the Principal Investigator throughout the study. It is required for both observational and interventional clinical research studies. The DOA log fulfills the requirements stated in ICH GCP E6 R2:

- Section 4.1.5 "the Investigator should maintain a list of appropriately qualified and trained persons to whom the Investigator has delegated significant study –related duties."

Principal Investigator Responsibilities

- The Principal Investigator (PI) is responsible for the conduct of all study activities.
- The PI is responsible for assigning study activities to medically qualified/licensed staff in accordance with country specific regulations.
    - The evaluation of whether study staff are performing functions within the scope of their professional licensure depends not only on the scope of their licensure, but also on local regulations.
    - Final determination of what can be delegation will be based on professional licensing authority.
    - Each PI must be aware of their local regulations.
- All personnel who have been delegated **significant** study related duties or activities, which the PI would otherwise do, must be listed on the log and CITI training certificates provided to the PSO staff.

Completing the CCR DOA Log

General Instructions:

- Individuals listed on the DOA log, must have completed the CITI Biomedical 101 and US GCP Focus training.
- Information entered in all sections of the log should be legible and accurate.
- The Study Coordinator can begin the log by typing in the names and study role for delegated individuals.
- The PI should complete (i.e., check off) the delegated activities.
- The PI must meet with each of the individuals and review the activities being delegated. Once this review is completed:
    - the study staff member should sign the log which indicates their understanding of the responsibilities assigned, and
    - the PI will add the start date of responsibilities and their signature.
- All signatures are to be completed by PIV card only.
- The log must be updated in a timely manner as personnel are added or removed and/or study roles and activities change. Changes must be approved by PI before they are implemented (i.e., as indicated by PI signature and date).
    - The protocol's PSO Manager is responsible for maintaining the regulatory file so needs to know about any changes in the DOA log.

- Activities may not be performed by the staff member without or prior to the PI signature and date.
- Number each page with page x of y. Page numbering should be done sequentially with the final number of pages (i.e., the "y" of page x of y) added manually or via Adobe pdf edit with the completion of the log.
- If any page has a blank row(s) that will not be used, please strike through the blank row(s).
- Change of Principal Investigator: If during the study, there is a change in the PI, a new DOA log will be completed. The PI who is leaving would initial the end date for all delegated individuals and the incoming PI would initial the start date for all delegated individuals once the IRB has approved the PI change. The start date of delegated activities will be the date that the new PI assigned the tasks which should correspond to the end date on the old PI log.
- Role or study specific activities change: If there are any changes to the role and/or study activities for an individual, the current delegation line should be updated with an end date. A new line is then started with the updated delegated study activities. The new line must be signed and dated by the PI and individual.
- Name changes during the study: Staff will sign a new line on the log to reflect the signature used in the study records.

Protocol Number, Site Name and Branch Name:

The Protocol Number, site name (e.g., CCR) and branch name should be added into the header of the document on each page.

Staff Name and Credentials, if applicable:

All staff who have been delegated any activity related to the protocol should be listed on this log. This includes all Investigators listed as study team members in PROTECT, all Investigators listed on the FDA Form 1572 if applicable; Research Nurses, Study Coordinators, Data Manager(s), Protocol Support Office Manager. Changes must be approved by the PI before they are implemented. When applicable, include credentials (e.g., MD, PhD, RN, ANP-BC).

Study Role

Indicate the role for this study – select all that apply (e.g., a Research Nurse may be both an Investigator and Study Coordinator).

Task Codes

This section should identify the responsibilities as listed in the table found on the first page of the form. Additional activities may be added as required for the protocol.

Staff Signature

Each staff member signs the log which indicates their understanding of the responsibilities assigned. The signature will be captured via PIV card.

Start Date of Responsibilities

The Start Date refers to the date that the individual has been delegated the activity by the PI. The PI will add the start date of responsibilities and their signature once they have met with the staff member.

End Date of Responsibilities

The End Date is completed when the individual is:

- No longer working on the protocol
- When delegated activities have changed or ended
- When there is a name change for a staff member
- The end date must be signed by the PI

Principal Investigator Signature

At the end of the study, when the protocol and log are complete, the log will be updated with page numbers and must be signed by the PI via PIV card . This may occur at the time the study is closed with the IRB.