



CT-206 DELEGATION LOG

EFFECTIVE DATE: January 2024

Purpose

The purpose of this policy and procedure is to outline which Investigator(s) and research personnel are required to be listed on the Delegation of Authority (DOA) log and in which instances delegation logs are required. This policy and procedure satisfies the requirements set forth in Good Clinical Practice.

Scope

This SOP applies to all research performed under the Clinical Trial Office. All clinical trials, regardless of the funding source, are required to complete and maintain a delegation log. USA recognizes that some external sponsors, networks, and funders may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the site to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts with this SOP, then approvadi ite ice. then a p8 (, a.c5c)-3 (e-a)-3 (o1/(e-a)-3 (o1homes it)3 (it)na6 (etoey

All studies requiring a DOA log will use our site-specific document. The site-specific document may be a physical paper log or an electronic log using the site's CTMS. Sponsor specific DOA logs will

- 4.4. Physical Exam
- 4.5. Adverse Event reporting and/or assessment
- 4.6. Unblinding
- 4.7. Preparing and/or dispensing Study intervention

- 5. All staff delegated to significant study related duties must show evidence of appropriate education and training to confirm they are qualified to perform the delegated task.
- 6. USA non-research personnel who perform trial related tasks are not required to be on the delegation log if the research task is within their normal scope of practice and/or duties. The non-research personnel must still be properly trained per SOP 205 Training Records.
- 7. The delegation log must be updated throughout the study to account for changes in delegated tasks, the addition of new personnel, and the removal of personnel who no longer work on the study.
- 8. Changes to the delegation log must be approved by the Principal Investigator.

Principal Investigator Change

- 1. There are two options for updating the delegation log for a change in PI. Either option is acceptable; however, Option A is preferred.

OPTION 1 - Preferred (start a new log)

Outgoing PI will sign and date the PI signature line on the bottom of page 1.
Enter a statement in the comment section of the form to indicate there was a change in PI.
The new PI will start a new DOA form by signing and dating a new page 1.
Delegation by the new PI for all site staff is documented on the new form. Date listed should be the date the new PI signed the new form.

OPTION 2 (keep existing delegations and start a new log)

Enter a statement in the comment section of the form to indicate there was a change in PI.
The new PI will start a new DOA form by signing and dating the top section of a new page 1
The new PI will enter a statement in the comments section of the original DOA form agreeing with the existing delegations.
Changes or new additions to the DOA that occur after a new PI begins will be made on the new DOA log.

Roles or Key Study Tasks Changes

1. If the role of a staff member changes during the course of the trial, an end date should be entered at the time the role is no longer being completed by the individual (e.g. Sub-I, becomes the new PI).
2. If there are any changes to study tasks for an individual, the current delegation line should be