

POLICY
Delegation of Duties Log Policy

Effective Date: 03/14/19

Document No.: **POL-A15-OPC-002.00**

1.0 PURPOSE

- 1.1 This policy describes the requirements for creating and maintaining a research study-specific delegation of duties log for National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) supported and/or sponsored clinical research.

2.0 SCOPE

- 2.1 This policy applies to all NIAID (DAIDS) supported and/or sponsored clinical research.

3.0 BACKGROUND

- 3.1 It is customary practice for investigators/investigators of record (IoR) to delegate select research study-related duties/tasks to site staff and other individuals, if this practice is permitted per local laws, regulations, and institutional policies. The International Conference of Harmonization (ICH) Guidance for Industry, E6 Good Clinical Practice (GCP) (R2), lists the investigator's/IoR's responsibilities when delegating research study-related tasks. These considerations include maintaining a list of persons to whom significant research study-related duties have been delegated, investigators'/IoRs' responsibilities for supervising individuals who perform these duties and ensuring that individuals are qualified and trained to perform the duties.

Consistent with ICH E6 (R2) and FDA Guidance, DAIDS mandates that investigators/IoR maintain a research study-specific Delegation of Duties log for each DAIDS clinical research study. Note that delegation of duty logs are also commonly called delegation of authority logs and delegation of responsibilities logs.

4.0 DEFINITIONS

For additional definitions, see [DAIDS glossary](#).

- 4.1 **Significant study-related duties:** Any duty or task that could impact significantly on participant safety, protocol compliance, quality and the integrity of the study data. (*Definition adapted from [TransCelerate Information and Guidance Sheet for Site Signature and Delegation of responsibilities Log](#)*)

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5.0 RESPONSIBILITIES

- 5.1 Investigator/Investigator of Record (IoR)
The investigator/IoR is responsible for maintaining a research study-specific delegation of duties log, which lists the site staff and other individuals to whom the investigator/IoR has delegated significant research study-related duties. The investigator/IoR must ensure that these staff and others are permitted to perform the delegated duties per local laws, applicable regulations, and institutional policies.
- 5.2 Site Staff and Other Individuals
Site staff and other individuals (i.e., Individuals or entities not under the direct supervision of the investigator/IoR, such as a study coordinator employed by a site management organization, who is delegated significant study-related duties) are responsible for signing and dating the delegation of duties log. In addition, individuals delegated significant research study-related duties will limit their duties to remain within the scope of their professional licensure.
- 5.3 Site Monitor
The Site Monitor is responsible for verifying that there is an up to date research study-specific delegation of duties log for the research study(ies), including verifying that individuals performing the duties/tasks have been properly trained .

6.0 POLICY

- 6.1 Create and maintain a research study-specific delegation of duties (DoD) log using the DAIDS DOD templated for each DAIDS clinical research study. The DoD log lists all site staff and other individuals to whom significant research study-related duties are delegated.
- 6.2 The investigator/IoR ensures that each individual to whom a duty/task is delegated is qualified by education, training, experience, and additional credentialing/ licensing/certification, when relevant, to perform the delegated duty(ies)task(s) prior to the duty/task being delegated to the individual. The investigator/IoR retains records that demonstrate the individual's qualifications (e.g., signed and dated CV, training records for the individual with dates which are prior to the date of delegation). The investigator/IoR and the site staff or other individual must sign, initial, and

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date the DoD log before the site staff or other individual performs the delegated duties/tasks.

6.2.1 Prior to duty/task delegation, the investigator/loR ensures that site staff and other individuals participating in the conduct of the research study receive protocol training appropriate to the role and duties/tasks and ensures that documentation (e.g., training logs, CV) supports the delegated duties/tasks. The investigator/loR ensures that staff and other individuals:

1. Are familiar with the protocol, purpose of the research study and understand the specific details of the protocol;
2. Are trained on the applicable regulatory requirements, including human subject protections, and acceptable standards for the conduct of the research study (e.g., ICH E6 R2);
3. Are trained and competent to perform the delegated duty(ies)/task(s); and
4. Are informed of any pertinent changes during the conduct of the clinical research study and receive additional training as appropriate.
5. All protocol-mandated qualifications for tasks must be delegated to staff with the required qualifications and follow the [FDA Guidance for Industry, Investigator Responsibilities](#).

6.3 The investigator/loR personally provides adequate supervision of those staff and individuals to whom duties/tasks are delegated and is accountable for regulatory violations that result from the investigators/loRs failure to adequately supervise the conduct of the research study. The investigator/loR retains overall responsibility for the conduct of the clinical research.

6.4 The investigator/loR and individual site staff/other individuals personally sign (i.e., handwritten signature), initial and date the delegated duties/tasks in the relevant initials and date column of the DoD log at the time the delegation is made.

6.5 The investigator/loR ensures that the DoD log is updated in real time as new site staff are added or removed and/or research study-related roles and responsibilities change. The investigator/loR personally initials and dates the applicable row(s) for each entry.

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- 6.6 If there is a change in the investigator/loR, the new investigator/loR reviews the DoD log, initials beside all the previous investigators/loRs initials on the log indicating agreement with each individual duty/task delegation. Any changes to the delegated duties/tasks are specified on a new line. In addition, the new investigator/loR writes a note in the comments section stating that he/she reviewed the log and is in agreement with tasks delegated by the previous investigator/loR or clarifies any changes in delegated tasks. The note in the comments section is personally signed and dated by the investigator/loR. Alternatively, the new investigator/loR completes a new DoD log.
- 6.7 At the end of the clinical research study, the investigator/loR reviews the DoD log entries and updates as needed. The investigator/loR personally signs and dates the log in the End of Study Declaration section, attesting to the accuracy and completion of the log and that each study-related task listed in the log was delegated by the investigator/loR to the individuals.
- 6.8 Similar to clinical research records and other essential documents, the current DoD log and all previous versions are retained and accessible for inspection and copying at reasonable times and in a reasonable manner by authorized representatives of the sponsor(s) (including site monitors), DAIDS staff, and regulatory agency staff.

7.0 REFERENCES

- 7.1 [FDA regulations on Investigational New Drug Application at 21 CFR 312](#)
- 7.2 [FDA regulations on Devices at 21 CFR 800-892](#)
- 7.3 [E6 \(R2\) Good Clinical Practice: Integrated Addendum to International Conference of Harmonization \(ICH\) E6 \(R1\)](#)
- 7.4 [FDA Guidance for Industry, Investigator Responsibilities- Protecting the Rights, Safety, and Welfare of Study Subjects](#)
- 7.5 [TransCelerate Information and Guidance Sheet for Site Signature and Delegation of Responsibilities Log](#)

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- 7.6 TEMP-A15-OPC-001, DAIDS Delegation of Duties Log Template
- 7.7 WI-A15-OPC-001, DAIDS Delegation of Duties Log Instructions
- 8.0 APPENDICES**
Not applicable
- 9.0 REVISION HISTORY**
 - 9.1 POL-A15-OPC-002.00 is the original version of this Policy.

EFFECTIVE