

[SiteVault's Digital Delegation feature](#) provides a digital record of a principal investigator's (PI) decision to allow specific site staff members to perform one or more of the PI's study activities. Instead of having to manually manage this with a paper-based delegation log, which is prone to errors, this feature allows delegations to be recorded in a digital format which cannot become lost or damaged, with a process that updates the delegation log automatically to eliminate potential for human error. SiteVault's electronic DOA is designed to align with all ICH GCP E6(R3) principles and complies with established FDA and EU regulations.

- **Responsibilities are delegated, accepted and approved directly in SiteVault** saving sites the hassle of trying to pass around a manual log which can be confusing to read, maintain and update over time
- **Staff member delegation acceptance and PI approval dates are system generated**, removing ambiguity on dates by eliminating human error
- **The delegation log is a living document that updates as delegations are updated or changed**, SiteVault updates the log over time with clear and accurate data on a secure digital log which cannot become lost or damaged

## Common Questions

### Is there a section for activities delegated to the PI for completion?

To align with ICH E6(R3) Annex 1 (2.3 Responsibilities), the function of a delegation log is to record activities which the PI has delegated to other study team members. As the principal investigator is ultimately responsible for all tasks performed on a study, as stated in ICH E6(R3) (Principle 10), the SiteVault digital delegation log does not include a section for tasks delegated to the PI.

### Why are there no signatures or initials on the delegation log?

The purpose of a wet-ink signature on a paper log is to provide evidence of user acceptance and PI approval of delegated activities. The digital delegation feature replaces this paper process by having the applicable staff member perform a "review and acceptance" task for their delegated activities. Once these tasks are completed, the PI performs a "review and approval" task to approve these delegations within SiteVault. This data is then auto populated by the system into the delegation log, in a digital process that eliminates the need for a paper-based signature and initial process, while complying with regulatory requirements for documenting delegation of PI activities.

*(Note: Some sites have utilized their paper DOA as a reference for examples of site staff signatures to help attribute any handwritten records, however, in SiteVault these are documented under the "Signature & Initials" document type for formalized record keeping with less ambiguity.)*

### Is there an end of study declaration page?

Some paper-based DOA templates include an end of study declaration page for the PI to attest the delegation and training of staff throughout the trial. Per ICH E6(R3) Annex 1 (2.3.2), however, the PI should always ensure that only staff who are appropriately qualified and adequately trained, are delegated trial related activities. This erroneous confirmation is not included as part of the SiteVault digital delegation log, as such a practice is redundant and not in line with the ICH GCP principles.

## SiteVault's Delegation of Authority Log

### When/how is the Delegation of Authority Log generated?

When the PI approves delegations, SiteVault generates a new or updated version of the Delegation of Authority document and files it to the PI Oversight section of the study eBinder.

### What information is included in the Delegation of Authority Log?

The delegation of authority log is divided into two sections, the first section is a "Summary Page" section which includes study identifiers, a list of study team members with study start and end dates, and an outline of all study responsibilities with information on if the responsibility is delegated and to whom.

|                              |               |                               |                      |
|------------------------------|---------------|-------------------------------|----------------------|
| <b>Study Sponsor</b>         | Verte         | <b>Site Study Identifier</b>  | AVEG-027             |
| <b>Protocol Study Number</b> | Alpha-236-127 | <b>Site</b>                   | Site Solutions Unit  |
| <b>Study Site Number</b>     | Site 0023A    | <b>Principal Investigator</b> | Larry Bird (VeevalD) |

#### Study Team

| Study Staff      | Study Role                    | Start Date<br>Date Staff Member made Active on the Study | End Date<br>Date Staff Member made Inactive on the Study | Notes |
|------------------|-------------------------------|--|--|-------|
| Allie Regulatory | Regulatory Coordinator        | 17.Apr.2023  |  |       |
| Larry Bird       | Principal Investigator        | 12.Apr.2023  |  |       |
| Meredith Grey    | Subinvestigator               | 17.Apr.2023  |  |       |
| Oliver Davis     | Clinical Research Coordinator | 09.Sep.2023  | 01.Nov.2023  |       |
| Emma Brown       | Data Coordinator              | 18.Apr.2023  | 01.Nov.2023  |       |

#### Study Responsibilities

| Study Responsibility               | Delegated? | Delegated to                      |
|------------------------------------|------------|-----------------------------------|
| Administer Study Intervention (SI) | Yes        | Meredith Grey<br>Allie Regulatory |

The second section of the delegation of authority log consists of "Study Staff Member Pages" which also has study identifiers, study start and stop dates for each study team member, and a break down of each of the staff member's delegated activities, with staff acceptance dates, PI approval dates, and start/end dates for each delegated activity.

|                              |               |                               |                      |
|------------------------------|---------------|-------------------------------|----------------------|
| <b>Study Sponsor</b>         | Verte         | <b>Site Study Identifier</b>  | AVEG-027             |
| <b>Protocol Study Number</b> | Alpha-236-127 | <b>Site</b>                   | Site Solutions Unit  |
| <b>Study Site Number</b>     | Site 0023A    | <b>Principal Investigator</b> | Larry Bird (VeevalD) |

| Study Staff      | Study Role             | Start Date<br>Date Staff Member made Active on the Study | End Date<br>Date Staff Member made Inactive on the Study | Notes |
|------------------|------------------------|--|--|-------|
| Allie Regulatory | Regulatory Coordinator | 17.Apr.2023  |  |       |

#### Delegated Responsibilities

| Delegated Responsibility                   | Staff Member Accepted Date | PI Approval Date | Start Date<br>Start Date of the Delegation | End Date<br>End Date of the Delegation |
|--|----------------------------|------------------|--|--|
| Maintain essential documents               | 17.Apr.2023                | 17.Apr.2023      | 17.Apr.2023                                |  |
| Manage IRB/EC communications & submissions | 17.Apr.2023                | 17.Apr.2023      | 17.Apr.2023                                |  |
| Obtain/Conduct Informed Consent            | 17.Apr.2023                | 17.Apr.2023      | 17.Apr.2023                                |  |