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| **Study Stage:**  Start-up through Termination |



**Purpose:** To record assigned study related responsibilities.

**Useful to:** Principal Investigator (PIs), study coordinators, other study-site staff, and monitors

**Instructions:**

* Prior to delegating authority to a particular task, an individual’s training for each task must be documented on the Protocol Training Log.
* List the names of research team members and record the responsibilities that have been assigned to them using the letters in the Task Codes section on the Delegation of Authority Log.
* Revise the Task Codes list as needed to reflect study-specific needs. Task codes should be consistent with study’s eResearch application and protocol.
* Each study staff member listed should initial to indicate her/his understanding of the responsibilities assigned.
* The site PI should initial and date each line of the form as recorded as noted by the logs instructions. The PI’s signature at the bottom of each form is required at the conclusion of the study.
* Update the log following any change in site study personnel or delegated tasks of study personnel. If tasks are added or removed, make sure these are noted clearly and are initialed and dated.

**Best Practice Recommendation:** If a sponsor (Industry sponsor, coordinating site sponsor etc.) provides a Delegation of Authority Log (DOA), complete as instructed. Otherwise, the following is recommended:

* Number each page and maintain this log in the Regulatory Binder or system that may be used (eReg, etc.).
* Store pages in reverse chronological order, with the newest pages of the log placed at the front of the DOA section
* The Principal Investigator’s signature should be located on the bottom of each page

Study tasks should not be performed until the IRB has approved the study team member

* This form is recommended for interventional clinical research studies and can be used for observational studies.

**Template History:**

**Reference(s):**

* **FDA** – Investigator Responsibilities; Appropriate Delegation of Study-Related Tasks Pg. 3&4<https://www.fda.gov/media/77765/download>
* **ICH E6 GCP** 4.1.5 The investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

**Last updated**: 6/07/2022

**Version** 2.5

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| **Study Name:** | **IRB HUM #:** |
| **Principal Investigator:** |  |

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| **List (and update) all study site personnel and their study roles (Investigator, Co-investigators, study coordinators) involved in this protocol at any time during the conduct of the entire study** | | | | | | | | |
|  | | | |  |  |
| **Name (Please Print)** | **Initials1**  **(or signature)** | **Study Role** | | **Task(s)**  **(Use Task Codes Below)** | | **Dates of Work on Study** | | **Investigator Initials and Date\*** |
|  |  |  | |  | | Start:  End: | |  |
|  |  |  | |  | | Start:  End: | |  |
|  |  |  | |  | | Start:  End: | |  |
|  |  |  | |  | | Start:  End: | |  |
| Task Codes | | | | | | | | | |
| Study personnel, whose signatures and initials appear above, are authorized to perform the following study tasks indicated by the codes below as authorized by the Principal Investigator. The codes below are an example of responsibilities. Please update or include study specific requirements (i.e. insert more rows to add study team members) | | | | | | | | | |
| A= Obtain Valid Informed Consent  B= Recruit Subjects  C= Make eligibility decisions | | | E= Schedule visits/procedures  F= Make data entries/ corrections on CRFs  G= Evaluate AEs | | | | I= Regulatory work (IRB,FDA submissions, &  correspondence  J= Drug/device accountability | | |
| D= History and Physical Exams | | | H= Ongoing treatment and follow up AEs | | | | K= Other (describe and separate into as many additional codes as necessary; do not use “other” as a task code. Examples include, obtain lab samples blood/saliva, obtain vitals, list study specific testing, etc.). | | |

*\*The Principal Investigator should initial and date to indicate authorization of the staff member to perform the stated roles for this study.*

*\*\*The Principal Investigator signs the bottom of the Delegation of Authority Log on each page of the log after the study has been completed*

*1The individual must write their initials or provide signature (update form to specify), no other staff should do this for them.*

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\*\* Signature of the Principal Investigator Date