|  |  |  |
| --- | --- | --- |
| **Tasks**1. <insert study specific task>
2. <insert study specific task>
3. <insert study specific task>
4. <insert study specific task>
 | 1. <insert study specific task>
2. <insert study specific task>
3. <insert study specific task>
4. <insert study specific task>
 | 1. <insert study specific task>
2. <insert study specific task>
3. <insert study specific task>
4. <insert study specific task>
 |

| **Name** | **Study Role** | **Task(s)** | **Signature** | **Initials** | **Dates of Involvement** | **PI Acknowledgment of Assigned Task(s)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Start**  | **End**  | **Initials** | **Date** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |

***To be signed at study closure: I confirm that the above information is accurate and complete and that I authorized the delegation of study-related tasks to each individual as listed above.***

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Instructions for the completion of the Delegation of Authority Log**

* The purpose of a Delegation of Authority Log is to fulfill the requirement outlined in E6 Good Clinical Practice: Consolidated Guidance, Section 4.1.5, *“The Investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.”*
* The Principal Investigator should initial and date entries on the log prior to the commencement of the assigned tasks. By initialing an entry, the Principal Investigator is acknowledging the delegation of the task(s) and is confirming that the individual is qualified to perform the work associated with the assigned task(s).
* As outlined in Chapter 4 of the University of Pittsburgh Human Research Protection Office (HRPO) policies and procedures, “*Although the PI may delegate tasks to members of his/her research team, s/he retains the ultimate responsibility for the conduct of the study.”*
* This Delegation of Authority Log is provided as a template; it should be modified according to the specific tasks of your study.
* The log should include research staff who have been delegated significant trial-related tasks. (*examples: Obtain Informed Consent, Obtain Medical History, Confirm Eligibility, Perform Physical Exam, Adverse Event Assessment, Regulatory Submissions, Administer Questionnaires, Sample Collection, Sample Processing, etc.*)
* **The log may be used to also maintain wet-ink signatures and initials** of individuals collecting and recording study data so that study documentation can be attributed to specific staff members. **If electronic signatures are obtained on this form, a Wet-Ink Signature Log should also be maintained** and filed with the study regulatory records.
* The information entered into all sections of the log should be legible.
* The log should be updated in a timely manner as new research staff are added, removed, and/or roles or tasks change.
* The log should be signed and dated by the Principal Investigator at the conclusion of the study.
* The log should be maintained with the regulatory documents for the study.