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| **Tasks**1. Obtain informed consent
2. Confirm eligibility
3. Obtain medical history
4. Physical Exam
 | 1. Study product accountability
2. Study product administration
3. Sample collection
4. Sample processing
5. Adverse event assessment
 | 1. Regulatory submissions
2. Statistical Analysis
3. IRB Submission Preparation
4. Administer QOL Questionnaire
5. Administer SCID
 |

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| --- | --- | --- | --- | --- | --- | --- |
| **Name** | **Study Role** | **Task(s)** | **Signature** | **Initials** | **Dates of Involvement** | **PI Approval** |
| **Start**  | **End**  | **Initials** |  **Date** |
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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 Signature and Delegation of Authority Log**

The purpose of a Signature and 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.”*

This Signature and Delegation of Authority Log is provided as a template; it should be modified according to the specific tasks of your study. The log is used to maintain signatures and initials of individuals collecting and recording study data so that study documentation can be attributed to specific staff members.

The log should include research staff who have been delegated significant trial-related tasks.

The Principal Investigator (PI) and research staff should record the same signature and initials on the log as is done when signing and initialing research records.

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 tasks and is confirming that the individual is qualified to perform the work associated with the assigned task.

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 or 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.