| **Study Information I** | | |
| --- | --- | --- |
| **Study Title:** | **Local Protocol No:** |  |
| **DCP Protocol No:** |  |

**A Separate Delegation of Tasks Log must be completed by each study staff member or by each study site.**

| **Study Information II** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Site Investigator Name** | | **Site** | | | **Site Investigator Signature** | | | | **Date** |
|  | |  | | |  | | | |  |
| **♦ I have delegated to the staff members below the authority to perform the task(s) indicated, under my supervision. As of the start date, the staff member was qualified to perform the delegated task(s) on the basis of education, training or experience.** | | | | | | | | | |
| **Delegations** | | | | | | | | | |
| **Staff Member Name** | **Staff Member Position** | | **Staff Member Task Code(s)** | **Staff Member Signature** | | **Staff Member Start Date** | **Staff Member End Date** | **Site Investigator Initials** | |
|  |  | |  |  | |  |  |  | |
|  |  | |  |  | |  |  |  | |
|  |  | |  |  | |  |  |  | |

**You can use a continuation page or add more rows to this table to accommodate all of the research team members**.

The Site Investigator will sign above at the beginning of study and sign below when study is complete. If the staff member’s position or tasks change during the study lifecycle, use additional lines to record new position/tasks. *(Reference: FDA Guidance for Industry Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects, 2009)*

| **Study Information III** | | | |
| --- | --- | --- | --- |
| **Site Investigator Signature at conclusion of the study:** |  | **Date:** |  |

Task Code

1. Obtain & Administer Informed Consent 5. Obtain/Prepare Lab Samples 9. Maintain Regulatory Documents 13. Instruct Patients on Study Procedures 17. Data Analysis

2. Perform Study Drug Accountability 6. Complete Source Documents 10. Obtain Medical History 14. Complete Case Report Forms 18. Research Analysis

3. Determine Patient Eligibility 7. Review & Correct Source Documents 11. Dispense Study Medication 15. Review & Correct Case Report Forms 19. Other (specify)

4. Recruit Patients 8. Perform Physical Examinations 12. Report SAEs 16. Sign/Approve Data Correction Forms 20. AE assessment/attribution

21. Site Investigator out of office coverage