Task Delegation Log

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| PROTOCOL NUMBER:  | **PRINCIPAL INVESTIGATOR (PI):****QUALIFIED INVESTIGATOR (QI):** *(if different from PI)* | **SITE NUMBER :** |
| **FULL STUDY TITLE :** | **INSTITUTION:**  | **SPONSOR NAME:**  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name (N) and Role (R)****(PRINT CLEARLY)** | **Full Signature** | Initials | **Authorized Responsibilities, Write Numbers (see list)** | Dates of Study Involvement*(yyyy-mmm-dd)* | **PI/QI Signature to Authorize Delegation and affirmation of identity of individual** | **Date of Signature***(yyyy-mmm-dd)* | **PI/QI Signature for End of Study or End of Role** | **Date of Signature***(yyyy-mmm-dd)* |
| N  |  |  |  | **Start**  |  |  |  |  |
| R  | Stop |
| N  |  |  |  | **Start**  |  |  |  |  |
| R  | Stop |
| N  |  |  |  | **Start**  |  |  |  |  |
| R  | Stop |
| N  |  |  |  | **Start**  |  |  |  |  |
| R  | Stop |
| N  |  |  |  | **Start** |  |  |  |  |
| R  | Stop |
| N  |  |  |  | **Start** |  |  |  |  |
| R  | Stop |

**Instructions:**

Identification of study role includes but is not limited to sub-investigators, study nurses, clinical nurses, study coordinators, pharmacist (when appropriate, technicians, nurse practitioners, physician assistants, residents, and data recorders). List individual’s delegated study-related tasks (ICH GCP 4.1.5) as described in the Responsibility List. Signatures/Initials required for all persons authorized to make entries and/or corrections to Case Report Forms (ICH GCP 8.3.24). When tasks are delegated by the PI/QI, the PI/QI is responsible for providing adequate supervision and training of those to whom tasks are delegated. PI/QI affirmation and delegation, by means of signature and date above, must occur after individual has completed all required training and prior to conducting any study-related tasks. Note: If a research team members’ role changes, reassign remaining study-related tasks from the Responsibility List to a qualified site research team member by creating a new line and include the new start date.

**Task Delegation/Responsibility List:**

1 Subject identification, recruitment 7 Instruction on Investigational Product Administration 13 e-CRF Signature 19 Training Staff 25 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2 Obtain Informed Consent 8 Investigational Product Dispensing 14 Trial measurements (i.e. BP, HR, temp, weight , ECG) 20 Filing and Archiving Data 26 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3 Physical Examination 9 Review AEs/SAEs 15 Interpretation of Lab Data 21 Essential Document Management 27 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4 Medical History 10 Review, Assessment of AE/SAE Criteria (QI/Sub-I) 16 Administration of Questionnaire(s) 22 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_ 28 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5 Affirmation of inclusion/exclusion criteria 11 Reporting of Serious Adverse Events 17 Shipping Biological Samples 23 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_ 29 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

6 Medical Oversight 12 e-CRF Completion 18 Obtaining Biological Samples 24 Other: \_\_\_\_\_\_\_\_\_\_\_\_\_