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| DELEGATION OF RESPONSIBILITY LOG | | | | | | | |
| **Protocol Number** | **:** |  | | | | | |
| **Site Name** | **:** |  | **Site Number** | : | |  | |
| **Principal Investigator** | **:** |  |  |  | |  | |
| Sponsor | **:** |  |  | |  | |  |

| **Name** | **Role** | | **Key Study Task(s)** (choose from list below) | | | **Initials** | | **Signature** | **Start Date (dd/mmm/yyyy)** | **PI Initial** | **End Date**  **(dd/mmm/yyyy)**  **(If prior to EOS)** | **PI Initial** |
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|  | Principal Investigator | |  | | |  | |  |  |  |  |  |
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| **Investigator Signature:**  **Comments:** | | | | | | | **Date:** | | | | | |
| **Task Key:**  1 = Obtain Informed Consent  2 = Subject selection/recruitment  3 = Confirm eligibility (review inclusion/exclusion criteria)  4 = Obtain medical history (source documents) | | 5 = Perform physical exam  6 = Conduct study visit procedure as outlined in the protocol  7 = Make study related medical decisions  8 = Assess AEs/SAEs  9 = Dispense study drug | | 10 = Perform drug accountability  11 = Study drug storage and temperature monitoring  12 = Sample collection  13 = Sample processing and/or shipment  14 = Evaluate study related test results  15 = Use IWRS/IVRS | | | | | 16 = Make entries/corrections on CRFs 17 = Sign off CRF 18 = Maintain essential documents 19 = Perform study related assessments as per protocol 20 = Other (specify):       21 = Other (specify): | | | |
| **Name** | **Role** | | **Key Study Task(s)** (choose from list below) | | | **Initials** | | **Signature** | **Start Date (dd/mmm/yyyy)** | **PI Initial** | **End Date**  **(dd/mmm/yyyy)**  **(If prior to EOS)** | **PI Initial** |
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| **Investigator Signature:** | | | | | | | **Date:** | | | | | |
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| **End of Study Declaration:** I hereby 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:** | | | | | | | |

* It is the Principal Investigators’ (PI) responsibility to supervise the conduct of the clinical investigation and to protect the rights, safety and welfare of participants in clinical trials. Per ICH GCP, the PI should maintain a list of appropriately qualified and trained persons to whom the investigator has delegated significant trial related duties.
* To fulfil the requirements stated in ICH GCP all personnel performing study related procedures must be listed on the log.
* All staff delegated to study related duties must be able to show evidence of appropriate education and training to confirm they are qualified to perform the delegated task.
* The log should be updated as new personal are added or removed and/or study roles change. Changes must be approved by the PI before they are implemented.
* This log may be completed electronically; however the signature and initial columns are to be handwritten to validate signatures/initials used for consenting, source document completion and CRF entry.
* At the End of Study (EOS) the PI must strike through unused lines and sign the PI Declaration