* THIS FORM IS TO BE COMPLETED FOR SITE PERSONNEL INVOLVED IN THE STUDY TO WHOM THE INVESTIGATOR HAS DELEGATED SIGNIFICANT STUDY-RELATED DUTIES. THE FORM IS TO BE **COMPLETED PRIOR TO CONDUCTING STUDY RELATED TASKS**.
* THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE FOR ALL TASKS CONDUCTED AT THE STUDY SITE, THEREFORE THE PI COMPLETES THE SECTIONS INDICATED BUT THE PI IS NOT DELEGATED SPECIFIC TASKS IN THE TASK SECTION OF THE LOG.
* THE PRINCIPAL INVESTIGATOR CONFIRMS TRAINING APPROPRIATE TO THE ROLE AND TASK IS COMPLETED BY SITE PERSONNEL.
* THE STUDY SITE IS REQUIRED TO MAINTAIN AN UP TO DATE VERSION OF THIS FORM IN ACCORDANCE WITH SPONSOR REQUIREMENTS.

**START OF STUDY DECLARATION:** (to be completed at the start of the study)

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| **Name of Principal Investigator** | **Principal Investigator’s Signature\*** | **Principal Investigator’s Initials** | **Date****(dd/mmm/yyyy)** |
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\*My signature confirms/acknowledges that the information contained here is accurate and that:

* I will remain responsible for the overall study conduct and reported data.
* I will ensure study oversight.
* I will authorize the delegation of study-related tasks to each individual as listed.
* The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.
* I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated study-related tasks prior to appropriate delegation and completion of study training appropriate to the role.
* I will ensure that site staff receives, in a timely manner, the appropriate information and training for delegated tasks.
* I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.

END OF STUDY DECLARATION: I confirm that the information contained in this document is accurate and complete.

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| **Name of Principal Investigator** | **Principal Investigator’s Signature\*** | **Principal Investigator’s Initials** | **Date****(dd/mmm/yyyy)** |
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**SPONSOR COMMENTS (optional):**

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**STUDY TASKS:**

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| **Medically Qualified/Trained/Licensed Staff** | **Trained/Qualified Staff** | **Trained/Qualified Staff Continued** |
| 1. Determine eligibility criteria (inclusion/exclusion)
 | 10. Manage IRB/EC communications & submissions | 24. Report SAEs  |
| 1. Perform Physical Exam
 | 11. Maintain essential documents | ***\*other – please specify*** |
| 1. Make study-related medical decisions
 | 12. Collect/process biological samples  | 29. Other |
| 1. Evaluate study related test results
 | 13. Ship biological samples | 30. Other |
| 1. Assess AE/SAE causality
 | 14. Make (e)CRF entries, corrections and queries | 31. Other |
| 1. Assess Safety notifications
 | 15. Recruit study subjects | 32. Other |
| 1. Sign off on (e)CRF visit data
 | 16. Use IWRS/IVRS/IRT |  |
| 1. Unblind/Unmask
 | 17. Manage Investigational Product (IP) receipt/storage/ temperature monitor |  |
| 1. Discuss medical content of Informed Consent
 | 18. Prepare/Dispense IP |  |
| ***\*other – please specify*** | 19. Perform IP accountability |  |
| 25. Other | 20. Administer IP |  |
| 26. Other | 21. Perform vital signs, ECGs |  |
| 27. Other | 22. Obtain medical/medication history |  |
| 28. Other | 23. Perform study activities |  |

| **Complete upon assignment of site staff** | **To complete when staff exit****the study** |
| --- | --- |
| **Name** | **Signature**My signature below indicates that I accept the study task. | **Initials** | **Study Role** | **Study Task(s)(Select from key)** | **Start Date****(dd/mmm/yyyy)** | **PI Signature** | **End Date****(dd/mmm/yyyy)** | **PI Signature** |
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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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**INVESTIGATOR SITE COMMENTS (optional):** *(all Comments must be signed and dated)*

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