## **Principal Investigator (PI)/Investigator of Record (IoR)**

**By signing, I confirm/acknowledge that the tasks listed below will only be delegated to appropriately trained, skilled, and qualified staff. I remain responsible for the overall study conduct and reported data and I will ensure study oversight. Any changes in staff or delegation in staff will be recorded in real time. New study staff will be reported to the OHRA with appropriate training documentation prior to their engagement in research activity.**

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| **PI/IoR Name** | **PI/IoR Signature** | **Initials and Date** | **Start Date** | **End Date**  (complete only for transfer of PI duties) |
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## **SIGNIFICANT STUDY-RELATED DUTIES**

*\*asterisk indicate tasks may only be performed by qualified individuals as permitted by local law, regulations, institutional policy, medical or standard of care practices, and applicable required training as per job description or designation. This list should be customized for the applicable study based on the protocol*

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| 1. Perform participant selection/recruitment\* | 1. Maintain Study Issues log (Deviations, Adverse events) |
| 1. Confirm eligibility (review inclusion/exclusion criteria)\* | 1. Assess Adverse events (AE, SAE)\* for reporting criteria |
| 1. Obtain and document medical history (source documents) | 1. Report SAE’s / Major Deviations |
| 1. Obtain and document Informed Consent\* | 1. Compliance/Quality Assurance/Quality Control Procedures |
| 1. Make study related medical decisions \* | 1. Coordinates Institutional Review Board (IRB) and ancillary communications |
| 1. Perform and document physical exam\* | 1. Enters/Manages Data |
| 1. Perform Counseling (study adherence, genetic counseling ) | 1. Maintain Essential Documents |
| 1. Perform significant study specific assessments\* | 1. Make entries/corrections on (e)CRFs |
| 1. Perform study specific procedures that require special training\* | 1. Manage Regulatory Documents/Submissions |
| 1. Evaluate study related tests results | 1. Resolve data queries |
| 1. Prescribe study product | 1. Study Staff Protocol training |
| 1. Provides/Administers Study Drug/Product |  |
| 1. Study product management\* |  |
| 1. Laboratory / Sample collection |  |
| 1. Laboratory/Sample processing and/or shipment |  |

| **Site Staff information** | | | | |  | |  | |
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| **Site Staff Full Legal Name** | **Site Staff Signature** | **Site Staff Initials** | **Study Role** | **Key Study Tasks**  (from list) | **Start Date** | **PI Initials** | **End Date** | **PI Initials** |
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### **Comments:**

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| **Principal Investigator’s/Investigator of Record’s 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.**  **PI’s/IoR’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |