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| **DELEGATION OF RESPONSABILITIES LOG** |

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| Study Protocol title: | | |
| Clinical Trials Registry ID/number: | Site Name: | Investigator Name: |

\* THIS FORM IS TO BE COMPLETED BY ALL STUDY STAFF AND OTHERS TO WHOM THE INVESTIGATOR/INVESTIGATOR OF RECORD (IoR) HAS DELEGATED SIGNIFICANT RESEARCH-RELATED DUTIES, AFTER THEY HAVE BEEN TRAINED TO CONDUCT THE ACTIVITIES, AND PRIOR TO TAKING PART IN ANY STUDY ACTIVITIES.

**Investigator/Investigator of Record (IoR)**

By Signing, I confirm/acknowledge that the tasks listed below will only be delegated 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.

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| **Investigator /IoR Name** | **Investigator /IoR Signature** | **Initials** | **Start date**  **(dd/mm/yyyy)** | **End date**  **(dd/mm/yyyy)**  **(*complete only if prior to end of study)*** |
| <add as many rows as needed (one per investigator> |  |  |  |  |
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| **SIGNIFICANT RESEARCH- RELATED DUTIES KEY** | |
| 1. Perform participant selection/recruitment \* | 21- Signs off on CRFs/eCRFs |
| 1. Confirm eligibility (review inclusion/exclusion criteria) \* | 22- Evaluate study related test results \* |
| 1. Obtain and document informed consent \* | 23- Conducts QA/QC procedures |
| 1. Obtain and document medical history (source document) | 24- Resolve data queries |
| 1. Obtain re-consent | 25- Develop and maintain essential documents |
| 1. Perform counselling (HIV testing, adherence, etc) \* | 26- Manages Regulatory Documents/Submissions |
| 1. Perform and document physical exam \* | 27- Coordinates IRB/EC communications |
| 1. Prescribing study product \* | 28- Staff training |
| 1. Administers Study Drugs/Product | 29- Administrative management |
| 1. Study Product Management \* | 30- Financial management |
| 1. Directly observed therapy | 31- Internal monitoring |
| 1. Action code breaks for emergency | 32- Make study-related medical decisions \* |
| 1. Assess AEs/SAEs/EAEs \* | 33- Other (specify): |
| 1. Report SAEs/EAEs | 34- Other (specify): |
| 1. Lab/Sample collection | 35- Other (specify): |
| 1. Lab/Sample processing and/or shipment | 36- Other (specify): |
| 1. Perform significant study specific assessments \* | 37- Other (specify): |
| 1. Perform study specific procedures that require special training (lumbar puncture, leukapheresis, etc.) \* | 38- Other (specify): |
| 1. Data entry/management | 39- Other (specify): |
| 1. Make entries/corrections on (e)CRFs | 40- Other (specify): |

\*These 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.

Note: Ancillary clinical staff with only an occasional role in the conduct of the research (e.g., staff who intermittently provide a service or consultation such as a hospital radiologist) do not need to be included on the DoD Log.

| **Site Staff Information** | | | | | **Start Date and Investigator / IoR Delegation Approval / Date** | | **Stop Date and Investigator / IoR Delegation Approval / Date** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Site Staff Full Legal Name** | **Site Staff Signature** | **Site Staff Initials** | **Research Study Role** | **Key Study Task(s)**  ***(choose from duties key listt)*** | **Start date**  **(dd/mm/yyyy)** | **Investigator Initials** | **End date**  **(dd/mm/yyyy)** | **Investigator 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |