# DIVISION OF AIDS (DAIDS) DELEGATION OF DUTIES LOG TEMPLATE

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| **Protocol/Study Number:** | blank |
| **Principal Investigator (PI)/Investigator of Record (IoR) Name:** | blank |
| **Clinical Research Site (CRS) Name:** | blank |
| **Clinical Research Site Number:** | blank |

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

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## **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.**

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| **PI/IoR Name** | **PI/IoR Signature** | **Initials and Date** | **Start Date**  **(dd/mm/yyyy)** | **End Date**  **(dd/mm/yyyy)**  **(complete only if prior to end of study)** |
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## **SIGNIFICANT STUDY-RELATED DUTIES**

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| 1. Coordinates Institutional Review Board (IRB)/ Ethics Committee (EC) communications | 17. Conducts Quality Assurance (QA)/Quality Control (QC) Procedures |
| 1. Perform participant selection/recruitment\* | 18. Provides/Administers Study Drug/Product |
| 1. Confirm eligibility (review inclusion/exclusion criteria)\* | 19. Make study-related medical decisions\* |
| 1. Obtain and document medical history (source documents) | 20. Assess Adverse Event (AEs)/SAEs/EAEs\* |
| 1. Enters/Manages Data | 21. Study product management\* |
| 1. Manage Regulatory Documents/Submissions | 22. Laboratory/Sample processing and/or shipment |
| 1. Perform significant study specific assessments\* | 23. Make entries/corrections on (e)CRFs |
| 1. Evaluate study related test results\* | 24. Maintain Essential Documents |
| 1. Report Serious Adverse Events (SAEs)/Expedited Adverse Events (EAEs) | 25. Perform study-specific procedures that require special training (lumbar puncture, leukapheresis, etc)\* |
| 1. Laboratory /Sample collection | 26. Other (specify): |
| 1. Prescribing study product\* | 27. Other (specify): |
| 1. Resolve data queries | 28. Other (specify): |
| 1. Perform counseling (HIV testing, adherence, etc)\* | 29. Other (specify): |
| 1. Obtain and document informed consent\* | 30. Other (specify): |
| 1. Perform and document physical exam\* | 31. Other(specify): |
| 1. Sign-off on Case Report Forms (CRFs) | 32. 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.**

| **Site Staff Information** | | | | | **Start Date and PI/IoR Delegation Approval/Date** | | **Stop Date and PI/IoR Confirm Delegation End/Date** | |
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| **Site Staff Full Legal Name** | **Site Staff Signature** | **Site Staff Initials** | **Study Role** | **Key Study Task(s)**  **(choose from list)** | **Start Date**  **(dd/mm/yyyy)** | **PI/IoR Initials** | **End Date**  **(dd/mm/yyyy)** | **PI/IoR 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: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |