**Appendix A: Responsibilities of the Study Staff**

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| **Position** | **Responsibilities/Delegated duties** |
| **Principal Investigator** | * Overall responsibility for study at site * Medical care and supervision of patients * Delegation of study related duties * Ensuring all staff delegated to work on trial are adequately informed as to protocol requirements and trained in study procedures * Familiarity with Investigator Brochure (where available) * Patient recruitment strategy * Screening of patients * Informed consent * Signing of consent form (as appropriate to local policy & practice) * Administration of investigational product * Collection of trial related blood samples * Completion and return of Case Record Forms and providing responses to data queries * Prescriptions * Documentation of adverse events * Timely Serious Adverse Events reporting * Initiation of new trial personnel * Ethics committee approval/communications * Negotiation and completion of the financial agreement * Indemnity and compensation * Investigational Product accountability and monitoring of compliance * Available for audit and inspections * Archiving |
| **Co-investigator (s)**  (Delegated duties) | * Medical care of patients * Screening of participants for eligibility * Informed consent * Sign consent form * Responsible for administration of study drug * Responsible for collection of study specific blood samples * Completion and return of Case Report Forms and providing responses to data queries * Prescriptions * Assessment of adverse events * Timely SAE reporting * Ethics committee obligations |
| **Study Nurse, counsellors etc.** | * Screening of participants * Informed consent * Completion and return of Case Report Forms * Data queries * Documentation of adverse events in source data * Investigator/Study file set up and management * Support monitoring visits and audits and inspections * Preparation of paperwork for Ethics committee and Trust R&D Notification * Preparation of SAE reports for medical input and causality assessment * Sample handling |
| **Data manager /Officers** | * Data entry * Completion and return of Case Report Forms * Data queries * Support monitoring visits, audits and inspections |
| **Study Pharmacist/Pharmacy staff** | * Acknowledge receipt of trial supplies * Drug accountability and monitoring of compliance * Dispensing of Investigational Product to patients * Complete dispensing logs * Maintain Pharmacy file * Monitor storage of Investigational Product |

**Appendix B: Delegation of duties log template**

A Demonstration Project of Antiretroviral-based HIV-1 Prevention among High-risk HIV-1 Serodiscordant Couples in Nigeria (Nigeria PreP study)

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| --- | --- | --- | --- | --- | --- | --- |
| **Name**  **(please print)** | **Signature** | **Initials** | **Role1** | **Delegated Duties2**  **(Please circle all that apply)** | **Start Date**  **(mmm/dd/yyyy)** | **End Date**  **(mmm/dd/yyyy)** |
| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  | |  |  |  | **1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18**  **19 (specify):………………………** |  |  |
|  |  |  |  | **1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18**  **19 (specify):………………………** |  |  |
|  |  |  |  | **1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18**  **19 (specify):………………………** |  |  |

1 PI=Principal Investigator; SC=Site Coordinator; CI=Co Investigator; SN=Study Research Nurse; SP=Safety Physician; P=Pharmacist; MLS=Medical Laboratory Scientist; AC= Adherence Counsellor; HC=HIV Counsellor;

2 1=Confirm Eligibility; 2 Eligibility Screening; 3=Obtain Informed Consent; 4=Trial Related Medical Decisions; 5=Evaluation of Trial Lab Results; 6=Assess Adverse Events; 7=Review Study and Informed Consent with Subject; 8=CRF Signatures; 9=Perform Physical Exams; 11=; 11=CRF Completion/Corrections; 12=Query Resolution; 13=Study Drug Accountability; 14=Study Drug Dispensing; 15=Document Protocol Deviations; 16=Explain Correct Use of Investigational Product to Subject; 17= Analysis of Specimen; 18 =Other (please specify in Table above)

The above persons are working under my supervision and have permission appropriate to their level of expertise to perform study procedures as described.