**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)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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.