**MTN-033 Delegation of Authorities Log**

**Site Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DAIDS Site #:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ IoR: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Instructions**: All personnel performing protocol procedures must be listed on this log. Start and end dates refer to the period during which staff is directly involved with conduct of study procedures. Start Date must be on or before the first date that any study activities were completed by the staff member, and after relevant training on delegated responsibilities is completed. Names should be printed legibly or typed; signatures and initials must be handwritten. The IoR should initial and date for each staff member in the ‘delegation approval’ column to confirm that s/he has determined that the staff member is trained and qualified, and has delegated the responsibilities listed. Maintain this roster with study Essential Documents and update as staffing changes occur. This log serves as a legal delegation of trial responsibilities; however, delegation assignment does not absolve the site IoR of any regulatory or contractual responsibilities for protocol management and oversight. Updates to staff responsibilities after study start (addition/removal of codes) may be handwritten by the IoR, initialed and dated. If staff undergo a *role* change, add an end date and IoR initials/date to the current line listing, and add the staff member to a new line and list their new role with all responsibilities with the new start date and IoR initial/date. In case of an IoR change, an end date should be completed for all entries on the original log, the original log should be archived, and a new DoA Log created to include all current staff. The new IoR should confirm the delegation of responsibilities to all staff by initialling and dating each row.

**Role Codes1:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PI** | Principal Investigator | **RN** | Research Nurse | **PoR** | Pharmacist of Record | **DM** | Data Manager |  |  |
| **IoR** | Investigator of Record | **C** | Counselor | **P** | Pharmacist | **DC** | Data Clerk |  |  |
| **SI** | Sub Investigator | **RA** | Research Assistant | **PT** | Pharmacy Technician | **QC** | QC Officer |  |  |
| **SC** | Study Coordinator | **LM** | Lab Manager | **CLO** | Community Liaison Officer | **QA** | QA Monitor |  |  |
| **MD**  | Medical Doctor | **LT** | Lab Technician | **CE** | Community Educator/Recruiter | **RC** | Regulatory Coordinator |  |  |

**Responsibility Codes2:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1** | Determines Eligibility | **12** | Obtains Locator Information/Confirms Participant Identity  | **23** | Performs Data Management Procedures and/or Responds/resolves QCs  |
| **2** | Conducts Randomization Procedures | **13** | Administers Behavior assessments (CRF/ CASI)  | **24** | Completes eCRF /Direct Data Entry Procedures in Medidata Rave |
| **3** | Makes Trial-Related Medical Decisions/Evaluates Lab Results/Assesses and Reports Adverse Events/Reviews AE CRF  | **14** | Provides Adherence Counseling | **25** | QA/QC |
| **4** | Reports SAE/EAEs  | **15** | Provides HIV Pre- and Post-Test Counseling | **26** | Manages Regulatory/Essential Documents  |
| **5** | Conducts Physical Exams  | **16** | Maintains Study Product Accountability | **27** | Documents Protocol Deviations |
| **6** | Conducts Rectal/Genital Exams | **17** | Dispenses Study Product  | **28** | Administers Qualitative Interviews |
| **7** | Obtains/Collects Medical/Medication History | **18** | Processes, Ships, or Transports Specimens | **29** | (site to include as needed) |
| **8** | Prescribes Study Product  | **19** | Conducts laboratory testing and/or releases lab results | **30** | (site to include as needed) |
| **9** | Authorized to sign Study Product Request Slip | **20** | Performs Laboratory QA/QC  | **31** | (site to include as needed) |
| **10** | Collects Specimens | **21** | Conducts Community Education/Outreach | **32** | (site to include as needed) |
| **11** | Obtains/Reviews Informed Consent | **22** | Tracks/Conducts Accrual and/or Retention Activities | **33** | (site to include as needed) |

The individuals listed on this log are properly qualified and have received appropriate training related to their respective task(s) for this protocol.

I assert that these duties were performed under my direct supervision.

IoR Signature (obtained at study close-out): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_ Total # of Log Pages: \_\_\_\_\_\_

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| --- | --- | --- |
| **Staff Information** | **Start Date and IoR Delegation Approval/Date**  | **Stop Date and IoR Confirm Delegation End/Date**  |
| **Name** **(print)** | **Signature** | **Initials** | **Project Role1**(List all that apply) | **Responsibilities2**(List all that apply) | **Start Date of Staff** | **IoR Initials and Date** | **Stop Date of Staff**  | **IoR Initials and Date** |
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