**MTN-035 Delegation of Authorities Log**

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

**Instructions**: All personnel performing protocol procedures must be listed on this log. Start and Stop dates refer to the period during which staff are directly involved with conduct of study procedures. Start Date must be on or before the first date that any study activities are undertaken 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 ‘IoR Delegation Approval’ column to confirm that s/he has determined the staff member to be duly 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 a stop date and IoR initials/date to the current line listing, and add the staff member to a new line and list his/her new role with all responsibilities as well as the new start date and IoR initials/date. In case of an IoR change, a stop 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 Codes:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PI** | Principal Investigator | **RN** | Research Nurse | **PoR** | Pharmacist of Record | **DM** | Data Manager | **QI** | Qualitative Interviewer |
| **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 Codes:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1** | Determines Eligibility | **12** | Obtains Locator Information/Confirms Identity | **23** | QA/QC |
| **2** | Conducts Randomization Procedures | **13** | Administers Behavioral assessments (CASI) | **24** | Completes eCRF /Direct Data Entry in Medidata Rave |
| **3** | Makes Trial-Related Medical Decisions/Evaluates Lab Results/Assesses and Reports AEs/Reviews AE CRF | **14** | Provides Adherence Counseling | **25** | Performs Data Management Procedures and/or Responds to/Resolves QCs |
| **4** | Reports SAEs | **15** | Provides HIV/Risk Reduction Counseling | **26** | Manages Regulatory/Essential Documents |
| **5** | Performs Physical Exams | **16** | Maintains Study Product Accountability | **27** | Documents Protocol Deviations |
| **6** | Performs Rectal/Genital/Pelvic Exams | **17** | Dispenses Study Product | **28** | Translates Study Materials |
| **7** | Obtains/Collects Medical/Medication History | **18** | Processes, Ships, or Transports Specimens | **29** | Provides Contraceptive Counseling |
| **8** | Prescribes Study Product | **19** | Conducts lab testing and/or releases lab results | **30** | *(site to include as needed)* |
| **9** | Signs 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** |  |

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 Role**  (List all that apply) | **Responsibilities**  (List all that apply) | **Start Date** | **IoR Initials/Date** | **Stop Date** | **IoR Initials/Date** |
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