Purpose

To define data management procedures for MTN-038

Scope

This procedure applies to all staff involved in data collection and/or data management for MTN-038.

Responsibilities

All site staff members delegated by the Investigator of Record to collect, record, enter, and/or review MTN-038 study data are responsible for understanding and following this SOP.

The [*site to insert appropriate staff job title*] is responsible for training study staff to collect and manage study data in accordance with this SOP and for day-to-day oversight of staff involved in data collection, data entry, quality control activities, and data management.

The MTN study Investigator of Recordhas ultimate responsibility for the quality of MTN-038 study data and for ensuring that all applicable staff members follow this SOP.

Procedures

1.0 Participant Identification Number (PTID) Assignment

Once a participant provides written informed consent for study screening and enrollment, she is eligible for PTID assignment. Site staff will assign a PTID to each participant by generating in the Medidata Rave study database a participant number (called “Subject ID” in Medidata Rave) within the electronic study and site folder. Specific instructions on generating a “Subject ID” are provided in the Medidata Rave Electronic Data Capture (EDC) Training Manual, which is posted on the MTN-038 SCHARP Atlas web page: <https://atlas.scharp.org/cpas/project/MTN/038/begin.view>?

Each PTID is unique. It will be assigned to a single participant only at a given site, and will not be assigned to any other participant at any site or in any study (e.g., MTN, HVTN, HPTN) for which SCHARP is the Statistical and Data Management Center (SDMC).

Site staff will maintain a PTID-Name Linkage Log document, which will be used to link a participant’s name with her assigned PTID. Site staff will complete one row of the log for each study participant, and will write the participant’s name and assigned PTID in the designated spaces on the log. For study purposes, the act of MTN-038 PTID assignment is defined as completion of an entry on the MTN-038 PTID-Name Linkage Log for a given participant.

To ensure participant confidentiality, the PTID-Name Linkage Log should be stored in a secure location, i.e., a locking file cabinet or drawer in a locking office/room, with limited staff access.

The table below designates the site staff member(s) responsible for the various tasks associated with PTID assignment and management of the associated logs.

|  |  |
| --- | --- |
| **Responsibility** | **Job Title(s) of Staff Member(s) Responsible** |
| Assignment of PTIDs (i.e., Subject IDs) in Medidata Rave |  |
| Maintenance and proper completion of the PTID-Name Linkage Log |  |
| Proper storage of the PTID-Name Linkage Log |  |

2.0 Participant Study Files

1. Paper Case Report Forms (CRFs)

Prior to study start, SCHARP will provide sites with a pdf file containing the full set of blank MTN-038 CRFs for on-site printing and data collection as needed. As documented in the site MTN-038 Source Documentation SOP, direct data entry into the study database will be maximized when feasible, followed by data entry based on non-CRF paper source documents (e.g., lab reports and chart notes). The use of paper CRFs will be avoided or minimized, to the extent possible. The site will assemble and maintain blank copies of all documents required during the screening and enrollment process, including but not limited to: informed consent forms; informed consent coversheets and comprehension assessments, locator forms, chart note sheets, visit/procedure/eligibility checklists, any required paper CRFs (if used by the site), counseling worksheets, contraceptive worksheets, and other site-specific documents as needed.

1. Screening/Enrollment Files

 In order to best protect participant confidentiality, all completed Screening visit documents bearing the participant’s name (and not the PTID) will be removed and used to create a Name File. All remaining documents bearing a PTID (but not the participant’s name) will make up the participant’s PTID (or Number) File.

 After completion of the Enrollment visit, if a participant is enrolled, all of her PTID File documents will be placed into an assigned hard-cover participant study notebook. If not enrolled (screened out), the PTID File will be stored (by PTID) in a file folder in a cabinet with PTID Files from other participants screened but not enrolled in the study.

 All screen-out files will contain chart notes and/or visit checklists that clearly document the procedures that were conducted up until the participant was determined to be ineligible. All source documents will be retained in these files. Electronic CRFs (eCRFs) will be completed in the Medidata Rave study database as stated in the Data Collection section of the Study-specific Procedures Manual (SSP).

 c. On-Study Files

Participant study notebooks (PTID Files) will contain all on-study paper documents bearing a PTID (and not a name) for the duration of the participant’s study participation. This includes, but is not limited to: completed prescriptions and study product request slips, participant chart note sheets, required follow-up visit checklists, procedure checklists, any required paper CRFs, (if used by the site) and other site-specific source and procedural documents as needed.

All files described above will be made available for review by authorized persons, including authorized study site staff and others as listed in the study protocol and informed consent forms.

d. Participant Study Files - Responsibilities

The table below designates the site staff member(s) responsible for the various tasks associated with participant study files.

|  |  |
| --- | --- |
| **Responsibility** | **Job Title(s) of Staff Member(s) Responsible** |
| Creation and storage of blank Screening/Enrollment Files |  |
| Storage and maintenance of Name Files |  |
| Storage of PTID Files for non-enrolled participants |  |
| Creation, maintenance, and storage of participant study notebooks |  |

3.0 Confidentiality

Participant study files will be stored as described above. The use of participant names to identify study documents will be minimized to the extent possible, and documents bearing participants’ names will be stored apart from documents bearing participants’ PTIDs. Logs and other documents linking PTIDs to participant names will be stored securely in a third location.

All files will be stored in locking cabinets in areas with access limited to study staff. During working hours, cabinets may remain unlocked if needed to allow staff access to files to conduct participant visits and perform other required data management functions.

No participant identifiers other than the PTID will be recorded on any CRFs, computerized questionnaires, or other transmitted documents. Written permission will be obtained from participants prior to release of any study-related information outside of the study site that personally identifies the participant.

4.0 Randomization

*Note: the Eligibility Checklist should be completed and all eligibility responses verified by designated site staff prior to initiating the randomization process.*

To begin the study treatment arm randomization process, site staff will first complete the Inclusion Exclusion Criteria eCRF with all responses indicating that the participant is eligible for study participation. Once this is done, the Randomization eCRF will appear in the participant’s Enrollment visit folder in the study database. Site staff will randomize a study participant by marking the “Yes” response box for the question “Is the participant ready to be randomized?” on the Randomization eCRF. Once this response is saved, the database (via the Medidata Balance module) will assign the participant to both treatment arm and biopsy schedule, and the Randomization Date and Time will appear automatically on the Randomization eCRF. As specified in Section 12-Data Collection of the SSP, a participant is considered officially enrolled in the study once this step takes place; that is, a randomization assignment is generated for the participant in Medidata Balance, as evidenced by the appearance of a Randomization Date and Time on the Randomization eCRF.

Participants will also be randomized to an IDI group. SCHARP will provide separate randomization listings for IDI assignment.

The table below designates the site staff member(s) responsible for the various tasks associated with participant study randomization.

|  |  |
| --- | --- |
| **Responsibility** | **Job Title(s) of Staff Member(s) Responsible** |
| Completion of the Inclusion Exclusion Criteria eCRF |  |
| Randomization of a participant to a treatment arm via completion of the Randomization eCRF |  |
| Randomization of a participant to an IDI group |  |

5.0 Site Data Entry – Medidata Rave Electronic Data Capture (EDC)

Site staff will enter study data electronically into the Medidata Rave study database as specified in the Data Collection section of the SSP. Designated site staff are granted access with specific user permissions to the study database, and are required to complete eLearning module(s) in Medidata, as assigned by SCHARP, before access is granted to the study database.

It is expected for MTN-038 that all required Medidata Rave eCRFs will be completed within 7 days of the completed study visit. Adverse Event Log (AE Log) eCRFs will be completed within 3 days. Exceptions to these guidelines are allowed for Screening Visit forms and certain forms that record local laboratory results that are not immediately available.

In the event that the study database cannot be accessed (e.g., due to a temporary internet outage, URL issues, or other unforeseen circumstances), paper CRFs will be completed and will serve as source (in lieu of eCRF completion via direct data entry) as a temporary solution until access to the study eCRFs is restored. Once access is restored, data from these paper CRFs should be entered into the Medidata Rave study database per section 6.0.Cof this SOP.

Once a participant has exited the study and all of her data QCs have been resolved, the site IoR/designee will complete a batch signature on all of the participant’s study eCRFs (i.e., the participant casebook) in the Medidata Rave study database.

The table below designates the site staff member(s) responsible for the various tasks associated with Medidata Rave EDC.

| **Responsibility** | **Job Title(s) of Staff Member(s) Responsible** |
| --- | --- |
| Designating initial site staff roles and requesting permissions to study database |  |
| Site Medidata Rave user account maintenance – requesting from SCHARP new accounts, permission updates, and account deactivations as needed throughout the study  |  |
| Data entry of Administrative CRFs * Screening Date of Visit
* Demographics
* Inclusion Exclusion Criteria
* Randomization
* Enrollment
* Follow-up Visit Y/N
* Follow-up Visit Summary
* Interim Visit Summary
* Missed Visit
* Discontinuation of Study Product
* Study Termination
* Additional Study Procedures
 |  |
| Data Entry of Pharmacy CRF* Pharmacy Dispensation

*Note: site permissions to enter/update data on this form are limited to site pharmacy staff.* |  |
| Data entry of Clinical CRFs* Vital Signs
* Physical Exam
* Pelvic Exam
* Pregnancy Report
* Pregnancy History
 |  |
| Data entry of Ring CRFs* Ring Insertion and Removal
* Ring Adherence YN
* Ring Adherence
 |  |
| Data entry of Lab CRFs* Hematology
* STI Test Results
* Chemistry Panel
* Pregnancy Test Results
* Specimen Storage
* Timed Specimen Storage
* Cervical Specimen Storage
* Timed Cervical Specimen Storage
* HIV Test Results
* HIV Confirmatory Results
 |  |
| Data entry of Log CRFs* Protocol Deviation – Y/N and log
* Adverse Event – Y/N and log
* Concomitant Medications – Y/N and log
* Medical History – Y/N and log
* Pregnancy Outcome Log
* Product Hold – Y/N and log
 |  |
| Data entry of Behavioral CRFs* Behavioral Summary
* CASI Tracking
 |  |
| Sign-off on all participant eCRFs (i.e., the participant’s casebook) in the Medidata Rave study database. | Investigator of Record/designee |

6.0 Site Data Quality Control (Data QC)

In addition to the guidance provided below and in the Data Collection section of the SSP, sites also should follow the detailed quality control processes as outlined in their Clinical Quality Management Plan (CQMP).

 a. During-Visit File Reviews (QC Review Step #1)

Review of participant files/documentation before the end of the visit is critical to ensure participant self-reported data are complete and accurate. This includes forms/documents that collect medical/symptoms history, product adherence, and interviewer-administered CRFs. It is also important to review applicable visit checklists to ensure all required study procedures have been completed. Documents such as these should be carefully reviewed (and updated as needed) before the participant leaves the study clinic.

The Data Collection section of each SSP Manual will specify the CRFs and other documents (e.g., visit checklists) that should be reviewed as part of the QC Review Step #1 process.

1. Post-Visit File Reviews (QC Review Step #2)

Review of participant paper files/documentation once the visit is completed is required so that errors and omissions in the paper CRF data (if applicable) and non-CRF paper source documents are corrected prior to being entered into the study database. Once entered into the study database, data inconsistencies and omissions will result in the creation of data queries, which require time and effort by site study staff to resolve. By identifying and correcting data errors and omissions prior to data entry, site staff will improve efficiency and reduce time needed to resolve queries.

QC Review Step #2 should be done by someone other than the person who originally completed the visit documentation, and should include all of the visit documentation that exists on paper. The person performing QC Review Step #2 can be a peer or another site staff member knowledgeable about the study and familiar with study documentation requirements. This may include site Study Nurses, a Data Manager, QC Officer, or other site members as appropriate.

The Data Collection section of each SSP manual specifies in detail the documents and items that should be reviewed as part of the QC #2 process.

* No additional QC #2 review steps are required for eCRFs that are source (i.e., the data is directly entered into the study database, rather than entered based on a separate paper CRF or other paper source document).
* Electronic CRFs that are completed based on other paper source documents (e.g., data entry of paper CRFs or lab reports) should be reviewed to ensure that the data entered matches the source documents.
1. Site Data Quality Control - Responsibilities

All paper documents, including any paper CRFs and non-CRF paper source documents identified as requiring completion or correction, will be revised prior to filing (during QC Step #1) and/or data entry (during QC Step #2).

The table below describes the site-specific QC Review Step #1 and QC Review Step #2 as they pertain to review of the CRF data. As listed below, each step may vary, depending on source documentation.

| **Responsibility** | **QC Review Step #1** | **QC Review Step #2** |
| --- | --- | --- |
| Data directly entered into the Medidata Rave study database (i.e., eCRF is source) | The staff member entering the data: * checks each eCRF for completeness and accuracy based on participant responses (see Data Collection section of SSP for list of targeted CRFs for review)
* checks to make sure all required eCRFs are completed for a given visit
* resolves any system queries that are triggered when the data is saved.
 | Not applicableThe study database (via system queries) will show which forms and fields are incomplete or inconsistent and require action by site staff. |
| Data entered from paper CRFs (if applicable) | The staff member completing the paper CRF:* checks each paper CRF s/he completes for completeness and accuracy based on participant responses (see Data Collection section of SSP for list of CRFs targeted for review)
* checks to make sure that all required paper CRFs are completed for a given visit.
 | The staff member reviewing the paper CRF:* checks for PTID and visit code accuracy
* checks to ensure no identifiers other than the PTID are present on the paper CRF
* performs targeted CRF review per the Data Collection section of the SSP
* checks to make sure all required items are completed, skip patterns have been followed, and responses are legible

The staff member entering the data:* checks the eCRF for completeness and accuracy
* ensures that an eCRF is completed for each paper CRF
* checks to make sure the data entered into the study database matches the paper CRF
* resolves any system queries that are triggered when the data is saved.
 |
| Data entered from other non-CRF source documents (e.g., chart notes, lab reports, testing logs, etc.) | The staff member entering the data: * checks each eCRF for completeness and accuracy based on participant responses (see Data Collection section of SSP for list of targeted CRFs for review)
* checks to make sure that all required eCRFs are completed for a given visit
* resolves any system queries that are triggered when the data is saved.
 | Another staff member checks designated eCRFs for completeness and accuracy, ensuring that the data entered into the study database is consistent with the source document.  |

The table below designates the site staff member(s) responsible for the various tasks associated with site data quality control.

|  |  |
| --- | --- |
| **Responsibility** | **Job Title(s) of Staff Member(s) Responsible** |
| Training of site staff on QC #1 process |  |
| Training of site staff on QC #2 process |  |
| QC #1 Review - Data directly entered into the Medidata Rave study database (i.e., eCRF is source) |  |
| QC #1 Review - Data entered from paper CRFs |  |
| QC #1 Review - Data entered from other non-CRF source documents (e.g., chart notes, lab reports, testing logs, etc.) |  |
| QC #2 Review - Data entered from paper CRFs |  |
| QC #2 Review - Data entered from other non-CRF source documents (e.g., chart notes, lab reports, testing logs, etc.) |  |
| Periodic evaluation of QC #1 process |  |
| Periodic evaluation of QC #2 process |  |
| Adequate documentation of QC #2 process |  |
| Compliance with site Clinical Quality Management Plan (CQMP) |  |

7.0 Timing of Data Entry and Management

The table below designates the site staff member(s) responsible for the various tasks associated with the timing of study data collection and management activities.

|  |  |
| --- | --- |
| **Responsibility** | **Job Title(s) of Staff Member(s) Responsible** |
| Ensure the proper QC reviews (i.e., QC #1 and QC #2) have occurred |  |
| Ensure data is entered into the study database within the time frames listed above |  |
| Re-file paper CRFs (if applicable) and other paper source documents in participant study notebooks after data entry |  |
| Ensure proper working condition of site data entry computers  |  |

1. Data Query Process

Within the Medidata Rave study database, two types of queries will be generated: system queries and manual queries. System queries are automatically generated at the time that data is entered and saved if the data entered does not conform to pre-programmed logic or edit checks, or a required field is left blank.

Manual queries are created in the study database by designated Rave users, such as the SCHARP Clinical Data Manager, SCHARP Clinical Safety Associate, and the study monitor (PPD). Designated site staff will be able to identify which eCRFs require query resolution by looking at the task bar on their study home page.

Detailed guidance on managing and resolving queries in the Rave environment is available in the Medidata Rave Electronic Data Capture (EDC) Training Manual, posted on the MTN-038 Atlas web site: [https://atlas.scharp.org/cpas/project/MTN/038/begin.view](https://atlas.scharp.org/cpas/project/MTN/036/begin.view)?. In cases where staff are not sure how to resolve a query, or when repeated attempts to address a query are unsuccessful, the site will contact the SCHARP Clinical Data Manager for further clarification and guidance.

To ensure data cleanliness, every effort should be made by the site to address all system queries at the time of data entry (i.e., as soon as they are generated), and resolve all manual queries no later than 7 days after the query is placed.

The table below designates the site staff member(s) responsible for the various tasks associated with the data QC process.

|  |  |
| --- | --- |
| **Responsibility** | **Job Title(s) of Staff Member(s) Responsible** |
| Review of queries in study database |  |
| Ensure queries are addressed in study database  |  |
| For paper CRFs, ensure data corrections/updates are made and consistent on both the paper CRF and eCRF  |  |
| Identification of data query patterns, and communicating these patterns and ways to address the errors to site staff (per the site’s CQMP) |  |

1. Computer Assisted Self-Interview (CASI)

As specified in the protocol and SSP, designated behavioral data will be captured directly from the participant into a computer or other electronic device via participant self-administered questionnaires.

Data collected electronically (and not via CRF) will be collected and submitted to SCHARP as described in the applicable SSP manual section.

The table below designates the site staff member(s) responsible for the various tasks associated with CASI data collection.

|  |  |
| --- | --- |
| **Responsibility** | **Job Title(s) of Staff Member(s) Responsible** |
| Adequate location and storage of equipment used to capture CASI data |  |
| Administration of CASI questionnaires |  |

10.0 Data Storage

All MTN study data — screening and on-study — will be stored securely as described in this SOP. All participant study files (paper) will be stored on-site and retained after the study per the specifications listed in the applicable study protocol.

**Abbreviations and Acronyms**

CASI Computer Assisted Self-Interview

CQMP Clinical Quality Management Plan

eCRF Electronic Case Report Form

EDC Electronic Data Capture

QC Quality Control

PTID Participant ID

SCHARP Statistical Center for HIV/AIDS Research and Prevention

SDMC Statistical Data Management Center

SSP Study-Specific Procedures Manual

SOP Standard Operating Procedure

[*List others as needed*]

**Attachments**

[*List all relevant attached materials here*]

**Reference Materials**

Study Protocol SSP Manual Site Clinical Quality Management Plan (CQMP) Applicable study SOP for Source Documentation

[*List other site SOPs and documents as applicable*]

**History**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Replaces** | **Review Date** | Change |
| 1.0 | dd MMM yyyy | N/A | dd MMM yyyy | Initial Release |

Approval

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|  | Author, Author’s Title |  |  | Date: |
|  |  |  |  |  |
|  | Approver’s Name, Approver’s Title |  |  | Date: |

[*Include Attachments here*]