**PURPOSE**

The purpose of this standard operating procedure (SOP) is to define source documentation requirements and procedures for MTN-039.

**SCOPE**

This SOP applies to all MTN-039 study staff at *[Insert site name]* that conduct study visits and/or complete source documents and Case Report Forms (CRFs).

**RESPONSIBILITIES**

MTN-039 staff members who complete study visits and/or complete MTN-039 study documentation are responsible for understanding and following this SOP.

MTN-039 *[Insert responsible staff]* is responsible for training study staff to collect and manage MTN-039 study data in accordance with this SOP, and for day-to-day oversight of staff involved in data collection and management.

MTN-039 QA/QC Manager is responsible for overseeing quality control (QC) and quality assurance (QA) procedures related to this SOP.

MTN-039 Site Leader/Investigator of Record has ultimate responsibility for ensuring that all applicable study staff follows this SOP.

PROCEDURES

Source documentation for MTN-039 will be completed in accordance with the DAIDS Standard Operating Procedure (SOP) for Source Documentation. This policy can be accessed at: <https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations>

*If applicable, include here the text “Source documentation for MTN-039 will also be completed in accordance with the [list applicable national, local, or facility-specific documentation regulations and guidelines] (see Attachment x).”]*

Table A provided in Appendix 1 lists all the MTN-039 study procedures and associated source documents. Table B provided in Appendix 1 designates the MTN-039 CRFs that will and will not be used as source documents.

Questions related to adherence to the DAIDS SOP for Source Documentation, the specifications of Appendix 1, and/or other aspects of this SOP will be directed to [*Insert responsible staff*].

Queries that cannot be resolved locally will be directed to MTN LOC (FHI 360) Clinical Research Managers and SCHARP Clinical Data Manager.

Definitions:

* **Source data:** All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies). [Source: ICH Consolidated Guidance for Good Clinical Practice (ICH-E6)].
* **Source documents:** Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participants’ diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies of transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the trial). [Source: ICH Consolidated Guidance for Good Clinical Practice (ICH-E6)].

Source documents are commonly referred to as the documents —paper

-based or electronic — upon which source data are first recorded.

* **Certified copies:** See pages 11 and 12 of Appendix 1 of the DAIDS SOP for Source Documentation.

**ABBREVIATIONS AND ACRONYMS**

DAIDS Division of AIDS

ICH International Conference on Harmonization

MTN Microbicide Trials Network

SCHARP Statistical Center for HIV/AIDS Research & Prevention

SOP Standard Operating Procedure

**APPENDICES**

Appendix 1 Part A, Listing of MTN-039 Procedures and Source Documents

Part B, MTN-039 CRFs and Source Documents

Part C, MTN-039 Site-Specific Forms Used as Source Documents

**REFERENCES**

ICH Consolidated Guidance for Good Clinical Practice (ICH-E6)

DAIDS SOP for Source Documentation (Version 2.0; 20 Dec 06)

FDA Guidance for Industry, Electronic Source Data in Clinical Investigations (Sep, 2013)

**REVISION HISTORY**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Supersedes** | **Review Date** | Change |
|  | DD MMMYYY | N/A (initial version) | DD MMMYYY | Initial Release |

APPROVAL

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | |  |  |  |
|  | Author, Author’s Title | |  |  | Date |
|  |  | |  |  |  |
|  | Approver’s Name, Approver’s Title | |  |  | Date |
| **Appendix 1: Part A**  **MTN-039 Source Documentation of Study Procedures**  \*\*Note that items in **bold** are required source documents for listed study procedure/evaluation\*\* | | | | | | |
| **Evaluation/Procedure** | | **Source Document(s)** | | | | |
| **ADMINISTRATIVE AND REGULATORY** | | | | | | |
| Obtain Informed consent(s) | | **Signed and Dated Informed Consent form** Informed Consent Coversheet (and/or chart notes) | | | | |
| Assess informed consent comprehension | | Informed Consent Comprehension Assessment tool | | | | |
| Confirm participant willingness to participate in study | | Chart notes (or other site-specific tool) | | | | |
| Assign a unique Participant Identification (PTID) number | | **MTN-039 PTID-Name Linkage Log (assigned within Medidata Rave)** | | | | |
| Assign a unique computer-assisted self-interview identification number (CASI ID) | | **MTN-039 CASI ID Log** | | | | |
| Collect or review/update locator information | | Site-specific locator tool (collect/update) Visit checklist (review) | | | | |
| Obtain demographic information | | **Demographics CRF** | | | | |
| Assess and/or confirm eligibility | | **Screening and Enrollment Behavioral Eligibility Worksheets**  Inclusion Exclusion Criteria CRF  **Eligibility Checklist** (signatures) | | | | |
| Randomization | | **Randomization CRF** | | | | |
| Reimbursement | | Visit checklist, site-specific reimbursement log, and/or chart note | | | | |
| Schedule next visit | | Visit checklist (and/or chart notes) | | | | |
| **BEHAVIORAL** | | | | | | |
| HIV pre- and post- test counseling/ HIV/STI risk reduction counseling | | HIV Pre/Post Test and STI Risk Reduction Counseling Worksheet, site specific tool and/or chart notes | | | | |
| Protocol requirements counseling | | Protocol Counseling Worksheet, site specific tool and/or chart notes | | | | |
| Behavioral assessment (CASI/In depth Interview (IDI) interview) | | **Baseline and Follow-up Questionnaires**  CASI completion documented on: CASI Tracking CRF  IDI completion documented on: Behavioral Assessment/ CASI Tracking CRF  Visit checklist and/or chart notes | | | | |
| **CLINICAL** | | | | | | |
| Medical history | | **Medical History Log CRF** (all baseline conditions including clinical evaluations and participant reported medical history will be summarized here)  Adverse Event Log CRF (all follow-up conditions including abnormal findings from clinical evaluations will be documented on this CRF)  Chart notes | | | | |
| Concomitant medications | | **Concomitant Medications Log CRF** | | | | |
| Physical examination (full or targeted) | | **Physical Exam CRF**  **Vital Signs CRF** | | | | |
| Pelvic examination | | Pelvic Exam CRF  Pelvic Exam Diagrams Form | | | | |
| Rectal examination | | Anorectal Exam CRF | | | | |
| Male genital examination | | Physical Exam CRF | | | | |
| Provide available test results | | Visit checklist (and/or chart notes) | | | | |
| Record/ update AEs | | **Adverse Event Log CRF** and/or chart notes | | | | |
| Treat or prescribe treatment for UTI/RTI/STIs or refer | | Chart notes, prescription and/or referral documentation | | | | |
| **LABORATORY** | | | | | | |
| *Pharynegeal* | | | | | | |
| NAAT for GC/CT | | Lab result report (or other required site-specific form) | | | | |
| *Urine* | | | | | | |
| hCG | | Site-specific lab requisition form  Site specific testing logs | | | | |
| Dipstick UA | | Site-specific lab requisition form  Site specific testing logs | | | | |
| Urine culture | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| NAAT for GC/CT | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| *Blood Samples* | | | | | | |
| CBC with differential and platelets | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| Chemistries (Creatinine, AST, ALT) | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| Hepatitis B surface antigen | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| Plasma archive | | Site-specific lab requisition form  Specimen Collection and Storage CRF  LDMS Tracking Sheet | | | | |
| Blood PK | | Site-specific lab requisition form  Specimen Storage CRF  LDMS Tracking Sheet | | | | |
| Syphilis serology | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| HIV-1/2 serology | | Site-specific lab requisition form  Lab result report (or other required site-specific form)  Site testing log/results report (rapids, Geenius confirmatory testing)  Lab result report (HIV RNA) | | | | |
| PT/INR | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| *Pelvic Samples* | | | | | | |
| Vaginal NAAT for GC/CT/TV | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| Cervicovaginal fluid for PK, microflora and PD | | Specimen Collection and Storage CRF  LDMS Tracking Sheet | | | | |
| *Anorectal Samples* | | | | | | |
| Rectal NAAT for GC/CT | | Site-specific lab requisition form  Lab result report (or other required site-specific form) | | | | |
| Rectal fluid for PK, microbiome and PD | | Specimen Collection and Storage CRF  LDMS Tracking Sheet | | | | |
| Rectal tissue for PD, PK and biomarkers | | Specimen Collection and Storage CRF  LDMS Tracking Sheet | | | | |
| **STUDY PRODUCT/ SUPPLIES** | | | | | | |
| Provision of study product | | **Study Prescription** (initial product request to pharmacy)  **Dose Administration CRF**  MTN-039 Study Product Request Slip  Site-specific Pharmacy Dispensing Log (source for dispensations from pharmacy)  Pharmacy Dispensation CRF (pharmacy staff only) | | | | |
| Provision of at-home enema kit | | **MTN-039 Home Saline Enema Kit Request Slip** | | | | |
| Offer/provide condoms | | Visit checklist or chart notes | | | | |
| **OTHER** | | | | | | |
| Protocol deviations | | **Protocol Deviation Log CRF** (and/or chart notes) | | | | |
| A record of all contacts, and attempted contacts, with the participant | | Missed Visit CRF  Site-specific contact/outreach/retention logs and/or chart notes | | | | |
| A record of all procedures performed by study staff during the study | | Visit checklists, chart notes, and/or other site-specific flow sheets | | | | |
| Staff-initiated study product holds or discontinuation | | **Product Hold CRF**  **Discontinuation of Study Product CRF**  Chart notes | | | | |
| A record of participant’s exit from the study | | **Study Termination CRF**  Chart notes | | | | |

**Appendix 1: Part B**

**MTN-039 Case Report Forms**

|  |  |  |
| --- | --- | --- |
| **CRF Name** | **Is eCRF Source?** | **Comments**  *(Unless otherwise noted in the Comments column, the CRF is source for all form items.)* |
| Additional Study Procedures | Yes | Form is administrative only. |
| Adverse Event Log | Mixed | Form is source for participant reported AEs.  Non-CRF documents are source for Laboratory and Clinical AEs. |
| Adverse Event Summary | Yes | Form is administrative only. |
| Anorectal Exam | No |  |
| Behavior Assessment | Yes |  |
| CASI Tracking | Yes |  |
| Chemistry Panel | No | Local lab report is source for other items. |
| Concomitant Medications Log | Yes | Form is source for all items. |
| Concomitant Medications Summary | Yes | Form is administrative only. |
| Demographics | Yes | Form is source for all items as participant responses are entered directly into the form. |
| Dose Administration | Yes |  |
| Enrollment | Mixed | Consent form is source for consent form date and long-term storage. Participant Replacement Assessment eCRF is source for PTID of participant being replaced. Form is source for sample collection schedule assignment (assigned from Medidata Balance) and is source for item “Is this a replacement participant”. |
| Follow-up Visit Summary | Mixed | Form is source for Visit date. All other items should be completed based on source data recorded on source documents. |
| Follow-up Visit Yes/No | Yes | Form is administrative only. |
| Hematology | Mixed | Form may be source for all non-lab value items (i.e., severity grade, etc.). |
| HIV Confirmatory Tests | Mixed | Form is source for final HIV status. Local lab report is source for other items. |
| HIV Test Results | No | Non-CRF lab source document (report or testing log) is source for all items. |
| Inclusion Exclusion Criteria | No | Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet, Eligibility checklist and/or Screening and Enrollment Log is source for all items. |
| Interim Visit Summary | Yes | Form is administrative only. |
| Medical History Log | Yes |  |
| Medical History Summary | Yes | Form is administrative only. |
| Missed Visit | Mixed | Chart notes and contact log will be source for reason visit was missed and corrective action taken. Form is source for all other items. |
| Participant Replacement Assessment | Yes |  |
| Pelvic Exam | No |  |
| Pharmacy Dispensation | No | Pharmacy dispensing records are source. |
| Physical Exam | No |  |
| Pregnancy History | Yes |  |
| Pregnancy Outcome Log | Yes |  |
| Pregnancy Report | Yes |  |
| Pregnancy Test Results | No | Local lab report is source for all items. |
| Product Discontinuation | Yes | Form will be source for reason for product use discontinuation. |
| Product Hold Log | Mixed | AE and CM logs are source for AEs and concomitant medications. |
| Product Hold Summary | Yes | Form is administrative only. |
| Protocol Deviations Log | Yes | Form is source for all items. Supplemental information may also be recorded in the visit checklist and chart notes. |
| Protocol Deviations Summary | Yes | Form is administrative only. |
| Randomization | Mixed | Form is source for “Is the participant ready to be randomized?” Medidata Balance is source for “Randomization Date and Time”. |
| Screening Date of Visit | Yes |  |
| Specimen Collection and Storage | Mixed | Form may be source for “If not stored, specify reason.”  LDMS Specimen Tracking Sheet or local lab form may be source for other items. |
| Specimen Collection and Storage (Group 1) | Mixed | Form may be source for “If not stored, specify reason.”  LDMS Specimen Tracking Sheet or local lab form may be source for other items. |
| Specimen Collection and Storage (Group 2) | Mixed | Form may be source for “If not stored, specify reason.”  LDMS Specimen Tracking Sheet or local lab form may be source for other items. |
| STI Test Results | No | Local lab report is source for all items. |
| Study Termination | Yes |  |
| Vital Signs | Yes |  |

*\*In cases where it is specified that initial form completion will be done using an eCRF, but the eCRF cannot be accessed due to temporary internet outage, off-site visits or other unforeseen circumstances, paper CRF completion is acceptable as a temporary solution until eCRF access can be restored. Data from these paper CRFs should be entered into Medidata Rave once database access is restored.*

| **Appendix 1, Part C:**  **MTN-039 Site-Specific Forms Used as Source Documents** | | | |
| --- | --- | --- | --- |
| **Form Name** | | **Is Form Source?** | **Comments** |
| Eligibility Checklist | | Mixed | All items are based on source data recorded on other documents. Form is source for signature items. |
| Behavioral Eligibility Worksheets (Screening and Enrollment) | | Yes | Form is source for all items as participant responses are entered directly into the form. |
| LDMS Specimen Tracking Sheets | | Yes | The LDMS sheets serves as source to document which specimens were collected, at what time, and on what date. The sheet is also source for specimen weights. |
| Local Site-Specific Testing Logs (HIV, pregnancy) | | Mixed | Local lab testing logs for test results (HIV rapids, pregnancy) |
| Pelvic Exam Diagrams | | Yes | Form is source for all items |
| Site-specific visit and Genital Exam Checklists | | Yes | Forms are source for the completed procedures. |
| Counseling Checklists (HIV Pre/Post Test and Risk Reduction Counseling Worksheet, Protocol Counseling Worksheet) | | Yes | Forms are source for protocol specified counseling |