**PURPOSE**

The purpose of this standard operating procedure (SOP) is to define source documentation requirements and procedures for MTN-035.

**SCOPE**

This procedure applies to all MTN-035 study staff at *[Insert site name]* that conduct study visits and/or complete source documents and Case Report Forms (CRFs)

**RESPONSIBILITIES**

MTN-035 staff that complete study visits and/or complete MTN-035 study documentation are responsible for understanding and following this SOP.

MTN-035 *[Insert responsible staff]* is responsible for training study staff to collect and manage MTN-035 study data in accordance with this SOP, and for day-to-day oversight of staff involved in data collection and management.

MTN-035 QA/QC Manager is responsible for overseeing quality control (QC) and quality assurance (QA) procedures related to this SOP.

MTN-035 Site Leader/Investigator of Record has ultimate responsibility for ensuring that all applicable study staff follow this SOP.

PROCEDURES

Source documentation for MTN-035 will be completed in accordance with the [DAIDS Standard Operating Procedure (SOP) on Source Documentation.](https://www.niaid.nih.gov/sites/default/files/sourcedocappndx.pdf) This

*[Note to sites: if applicable, include here the text “Source documentation for MTN-035 will also be completed in accordance with the [list applicable national, local, or facility-specific documentation regulations and guidelines] (see Attachment x).”]*

Appendix 1 Part A below lists all the MTN-035 study procedures and associated source documents. Appendix I, Part B designates the MTN-035 CRFs that will and will not serve as source documents. Appendix 1 Part C designates the MTN-035 Site-Specific Forms that will serve as source documents.

Questions related to adherence with the DAIDS SOP for Source Documentation, the specifications of Appendix 1, Parts A, B and C, and/or other aspects of this SOP should be directed to [*Insert responsible staff*]. Queries that cannot be resolved on-site should be directed to the MTN LOC (FHI 360) Clinical Research Manager(s) and the SCHARP Clinical Data Manager(s).

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 and complete, 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 page 11 of the DAIDS SOP for Source Documentation

**ABBREVIATIONS AND ACRONYMS**

DAIDS Division of AIDS

ICH International Conference on Harmonisation

MTN Microbicide Trials Network

SCHARP Statistical Center for HIV/AIDS Research & Prevention

SOP Standard Operating Procedure

CRF Case Report Form

**APPENDICES**

Appendix 1 Part A, Listing of MTN-035 Procedures and Source Documents

Part B, MTN-035 CRFs and Source Documents

Part C, MTN-035 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 |
| *1.0* | *Xx Mon Year* | NA | *Xx Mon Year* | Initial Release |

APPROVAL

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  | Author, Author’s Title |  |  | Date |
|  |  |  |  |  |
|  | Reviewer, Reviewer’s Title |  |  | Date |

**Appendix 1, Part A**

Listing of MTN-035 Procedures and Source Documents

| **Evaluation/Procedure** | **Suggested Source Document(s)** | | |
| --- | --- | --- | --- |
| ADMINISTRATIVE AND REGULATORY | | | |
| Informed consent (written) | **Signed and Dated Informed Consent Form** Informed Consent Coversheet (or chart note) | | |
| Consent Form comprehension | Informed Consent Comprehension Assessment tool | | |
| Informed consent review/confirm participant’s willingness to participate in study | Chart Notes or other site-specific tool | | |
| Participant Identification (PTID) number | Assigned within Medidata Rave; transcribed onto the MTN-035 PTID-Name Linkage Log | | |
| Participant CASI Identification (ID) number | **MTN-035 CASI ID-PTID Log** | | |
| Demographic information | **Demographics CRF** | | |
| Eligibility Assessment/confirmation | **Screening and Enrollment Behavioral Eligibility Worksheets**  Inclusion/Exclusion Criteria CRF  **Eligibility Checklist** (IoR/designee/verifier signatures) | | |
| Locator information | Site locator documents (collect/update) Visit checklist (review) | | |
| Randomization | **Randomization CRF** | | |
| Reimbursement | Visit checklist, site-specific reimbursement log, and/or chart note | | |
| Schedule next visit/contact | Visit checklist (and/or chart notes) | | |
| BEHAVIORAL/COUNSELING | | | |
| HIV pre- and post- test counseling | Chart note and/or site-specific counseling worksheet | | |
| HIV/STI risk reduction counseling | Chart note and/or site-specific counseling worksheet | | |
| Protocol counseling | Chart note and/or site-specific counseling worksheet | | |
| Training in SMS/IM Reporting System | Visit checklist (and/or chart notes) | | |
| Behavioral assessment (CASI/IDI) | **CASI Baseline, Rectal Insert PUEV, Rectal Suppository PUEV, and Rectal Enema PUEV Questionnaires; In-depth interview audio file recordings, interview notes and transcripts**  CASI and IDI completion documented on Behavioral Assessment Summary and CASI Tracking CRFs | | |
| CLINICAL | | | |
| Medical history (baseline and follow up) | **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 | | |
| Physical examination (full or targeted) | **Physical Exam CRF**  **Vital Signs CRF** | | |
| Rectal examination | Anorectal Exam CRF, Genital Exam Checklist | | |
| Genital Examination | Genital Exam checklist, Genital Exam CRF | | |
| Pelvic examination | Pelvic Exam CRF, Pelvic Exam Diagrams, Genital Exam Checklist | | |
| Concomitant medications | **Concomitant Medications Log CRF** | | |
| Treat or prescribe treatment for UTI/RTI/STIs or refer | Chart notes, prescription and/or referral documentation | | |
| Disclosure of available test results | Chart note and/or visit checklist | | |
| Adverse Events | **Adverse Event Log CRF** (and/or chart notes) | | |
| LABORATORY | | | |
| *Pharyngeal Sample* | | | |
| NAAT for Gonorrhea/Chlamydia (GC/CT) | | | Lab result report (or other required site-specific form) |
| *Urine Samples* | | | |
| hCG | | Site-specific testing logs | |
| Dipstick UA | | Site-specific testing logs | |
| Urine culture | | Lab result report (or other required site-specific form) | |
| NAAT for GC/CT/Trichomonas (TV) | | Lab result report (or other required site-specific form) | |
| *Blood Samples* | | | |
| Plasma for archive | | Specimen Storage CRF  LDMS Specimen Tracking Sheet | |
| Syphilis serology | | Lab result report (or other required site-specific form) | |
| HIV-1/2 test | | Lab result report (or other required site-specific form)  Site testing log/results report (rapids, confirmatory testing)  Lab result report (HIV RNA) | |
| *Pelvic Samples* | | | |
| NAAT for GC/CT/TV – Vaginal Swab | | Lab result report (or other required site-specific form) | |
| *Anorectal Samples* | | | |
| HSV 1/2 detection | | Lab result report (or other required site-specific form) | |
| NAAT for GC/CT – Rectal Swab | | Lab result report (or other required site-specific form) | |
| STUDY PRODUCT/SUPPLIES | | | |
| Study product provision | | **Study Prescription** (initial product request for each period to pharmacy)  Study Product Request Slip  Site-specific Pharmacy Dispensing Log (source for dispensations from pharmacy)  Pharmacy Dispensation CRF  Visit checklist | |
| Study product use counseling | | Chart note and/or site-specific counseling worksheet | |
| Study product application at the clinic | | Site-specific counseling worksheets, visit checklist, or chart notes | |
| Condom and/or lubricant provision | | Site-specific counseling worksheets, visit checklist, or chart notes, Concomitant Medications Log CRF, Pharmacy Dispensation CRF | |
| OTHER | | | |
| Protocol Deviations | | **Protocol Deviation log CRF** | |
| Missed visits (all contacts, and attempted contacts) | | 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 Hold/Discontinuations | | **Product Hold log CRF**  **Discontinuation of Study Product CRF**  Chart notes | |
| A record of participant’s exit from the study | | **Study Termination CRF**  Chart notes | |

**Appendix I, Part B**

**MTN-035 CRFs and Source Documents**

|  |  |  |
| --- | --- | --- |
| **CRF Name** | **Is CRF 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 Y/N | Yes | Form is administrative only. |
| Anorectal Exam | Mixed | AE Log CRF is source for item ‘any new genital findings AEs’. |
| Behavioral Assessment Summary | Yes |  |
| CASI Tracking | Yes |  |
| Concomitant Medications Log | Yes |  |
| Concomitant Medications Log Y/N | Yes | Form is administrative only. |
| Demographics | Yes | Form is source for all items as participant responses are entered directly onto the form. |
| Discontinuation of Study Product | Yes |  |
| Enrollment | Yes |  |
| Follow-up Visit Summary | Mixed | Form may be source for Visit date. All other items should be completed based on source data recorded on source documents. |
| Follow-up Visit Summary Y/N | Yes | Form is administrative only. |
| Genital Exam | Mixed | AE Log CRF is source for item ‘any new genital findings AEs’. |
| HIV Confirmatory Tests | Mixed | Form is source for final HIV status. Non-CRF lab source document (report or testing log) is source for other items. |
| HIV Tests Results | No | Non-CRF lab source document (report or testing log) is source for other items. |
| Inclusion/Exclusion Criteria | Mixed | Consent form is source for consent form date. Screening Behavioral Eligibility Worksheet, Enrollment Behavioral Eligibility Worksheet, Eligibility checklist and/or Screening and Enrollment Log is source for all items. |
| Interim Visit Summary | Mixed | Form may be source for Visit date, interim visit code, reason for interim visit, and study procedures completed at this visit. All other items should be completed based on source data recorded on source documents. |
| Medical History Log | Yes |  |
| Medical History Y/N | Yes | Form is administrative only. |
| Missed Visit | Yes |  |
| Participant Receipt | Mixed | Form may be source for study site names. Applicable informed consent form is source for the remaining items. |
| Participant Transfer | Yes |  |
| Participant Replacement Assessment | Yes |  |
| Pelvic Exam | Mixed | Pelvic Exam Diagrams is source for findings. AE Log CRF is source for item ‘any new pelvic findings AEs’. |
| Pharmacy Dispensation | No | Pharmacy dispensing records and randomization information from Medidata Balance are source. |
| Physical Exam | Yes |  |
| Pregnancy History | Yes | Form is source for all items. Supplemental information also may be recorded in chart notes. |
| Pregnancy Outcome Log | Mixed | Form may be source for all items or source may be medical records, if available. Supplemental information may also be recorded in chart notes. |
| Pregnancy Report | Yes | Form is source for all items. Supplemental information also may be recorded in chart notes. |
| Pregnancy Test Results | No | Site testing log and/or local lab report is source. |
| Product Hold | Yes |  |
| Product Hold Y/N | Yes | Form is administrative only. |
| Protocol Deviation Log | Yes | Form is source for all items. Supplemental information may also be recorded in the chart notes. |
| Protocol Deviations Y/N | 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 | Form is administrative only. |
| Social Impact Log | Yes |  |
| Social Impact Log Y/N | Yes | Form is administrative only. |
| Specimen Storage | Mixed | Form is source for “If not stored, specify reason”. LDMS Specimen Tracking Sheet or local lab form may be source for other items. |
| STI Tests Results | No | Local lab report is source for all items. |
| Study Discontinuation | Yes |  |
| Syphilis Serology | No | Local lab report is source for all items. |
| 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 CFR 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-035 Site-Specific Forms Used as Source Documents *(Forms listed in alphabetical order)* | | |
| --- | --- | --- |
| 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. |
| Screening Behavioral Eligibility Worksheet | | Yes | Form is source for all items as participant responses are entered directly into the form. |
| Enrollment Behavioral Eligibility Worksheet | | Yes | Form is source for all items as participant responses are entered directly into the form. |
| LDMS Specimen Tracking Sheet | | Yes | The LDMS Tracking Sheet serves as source to document which specimens were collected, at what time, and on what date. The sheet is also source for specimen weights. |
| Pelvic Exam Diagrams | | Yes | Form is source for all items. |
| Local Site-Specific Testing Logs (HIV, Pregnancy, Urinalysis, etc.) | | Yes | Form is source for all these test results |
| Site-Specific Visit and Genital Exam Checklists | | Yes | Forms are source for the completed procedures |
| Counseling Worksheets (HIV Pre/Post Test and Risk Reduction, Protocol Adherence | | Yes | Forms are source for protocol specified counseling |