Section 3. Documentation Requirements

Study staff are responsible for proper collection, management, storage, quality control, and quality assurance of all study-related documentation. This section contains information on the essential documents that each study site must maintain throughout the study. It also contains information related to establishing adequate and accurate participant research records — commonly referred to as participant "case history records" — for MTN-015.

3.1 Essential Documents

The Division of AIDS (DAIDS) policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* specifies the essential documents that study sites must maintain for DAIDS-sponsored studies, including MTN-015. Because MTN-015 is an observational study that does not involve any investigational products, the following categories of documents listed in the DAIDS policy are not applicable to MTN-015:

- Investigator's Brochures
- Institutional Biosafety Committee
- Pharmacy Accountability Records
- Expedited/Serious Adverse Events and Safety Reports
- Unblinding

When required essential documents are modified or updated, the original and all modified or updated versions must be maintained.

Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location. In its policy on *Requirements for Manual of Operational Procedures*, DAIDS requires study sites to establish a standard operating procedure (SOP) for maintaining essential documents. This SOP should be established prior to activation of MTN-015 and should be followed for MTN-015.

Section Appendix 3-1 presents a suggested essential documents filing structure for MTN-015. The suggested structure incorporates guidance previously received from the DAIDS Prevention Sciences Branch and the DAIDS Clinical Site Monitoring Group. Study sites are not required to adopt the suggested structure, but are strongly encouraged to consider it when developing their filing approach for MTN-015. Further clarifications of the suggested filing structure are as follows:

- Essential documents may be stored in files and/or in binders. The files/binders listed in Section Appendix 3-1 may be further sub-divided or consolidated if desired.

- It is recommended that a contents sheet be maintained and inserted as the first page(s) of each file/binder. Within each file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).

- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders (see

items 21-23 in Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories.

- The suggested filing structure assumes that MTN-015 participant case history records will be stored separately from the other essential documents listed in Section Appendix 3-1. Section 3.2 below provides information on the required contents of these records. The suggested filing structure also assumes that the MTN-015 Screening and Enrollment Log and the Participant Name-ID Number Link Log (which are described in Section 4 of this manual) will be stored in the study clinic or data management area, and not necessarily with the other essential documents listed in Section Appendix 3-1.

3.2 Participant Case History Documentation

Study sites must maintain adequate and accurate participant case history records containing all information pertinent to MTN-015 for each study participant.

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

- Basic participant identifiers
- Documentation that the participant provided written informed consent for the study prior to the conduct of any study procedures
- Documentation that the participant met the study's selection (eligibility) criteria
- A record of all contacts, and attempted contacts, with the participant
- A record of all procedures performed by study staff
- Study-related information on the participant's condition before, during, and after the study, including:
  - Data obtained directly from the participant (e.g., interview responses and other self-reported information)
  - Data obtained by study staff (e.g., exam and lab findings)
  - Data obtained from non-study sources (e.g., non-study medical records)

3.2.2 Concept of Source Data and Source Documentation

The International Conference on Harmonization Consolidated Guidance for Good Clinical Practice (ICH-E6) defines the terms source data and source documentation as follows:

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 documents: Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' 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 documents are commonly referred to as the documents upon which source data are first recorded. All study sites must comply with the standards of source documentation specified in the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*. The DAIDS policy specifies both requirements and recommendations. Study sites must comply with all requirements and are encouraged, but not required, to comply with all recommendations.

For MTN-015, it is expected that participant case history records will consist of the following types of source documents:

- Narrative chart notes
- Visit checklists
- Certified copies of parent study source documents
- Local laboratory testing logs and result reports
- DataFax and Non-DataFax forms provided by the MTN Statistical and Data Management Center (SDMC)
- Other source documents (e.g., site-specific worksheets, non-study medical records)

As a condition for study activation, each study site must establish an SOP for source documentation that specifies the use of the above-listed documents as source documents. Although it is the responsibility of each site to determine the most appropriate source document for each required case history element, Section Appendix 3-2 provides a guide that sites may follow for this study. Supplemental information on the use of chart notes, visit checklists, certified copies, and forms provided by the MTN SDMC is provided below. Detailed information on proper completion of DataFax and Non-DataFax forms provided by the MTN SDMC is provided in Section 12 of this manual.

Chart Notes: Study staff must document every contact with a study participant in a signed and dated chart note specifying the date, type, purpose, and location of the contact, and the general status of the participant. The time at which a contact takes place, or at which particular procedures take place, also should be specified when necessary to document adherence to protocol requirements.

Chart notes also must be used to document the following:

- The study informed consent process (see also Section 4.5)
- Procedures performed that are not recorded on other source documents
- Pertinent data about the participant that are not recorded on other source documents
- Protocol deviations that are not recorded on other source documents

Study sites are strongly encouraged to adopt a common format — such as the Subjective-Objective-Assessment-Plan (SOAP) format — for all chart notes, to help ensure adequacy and consistency of note content and maximize adherence to GCP standards.

Visit Checklists: The checklists posted on the MTN-015 Study Implementation Materials webpage (http://www.mtnstopshiv.org/node/468) represent convenient tools to fulfill the requirement of documenting all study procedures performed with each study participant. Note, however, that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to document procedures performed at unscheduled study visits, and/or to explain why procedures in addition to those listed on a checklist may have been performed or why procedures listed on a checklist were not performed. Chart notes also may be required to document the content of counseling sessions and/or other in-depth discussions with participants.

Certified Copies of Parent Study Source Documents: Because all MTN-015 participants will have previously taken part in an MTN microbicide study (referred to as the "parent study"), certain source documents maintained for the parent study will be relevant to MTN-015. However, MTN-015 study records must comply with the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials* independent of parent study records. In order for MTN-015 records to independently comply with DAIDS policies, it is recommended that certified copies of certain parent study source documents be prepared and filed in MTN-015 records, as follows:

- The MTN-015 protocol requires updating of participant medical history information: for clinical reference, prepare a certified copy of the baseline medical history source document maintained in the parent study record and file the copy in the MTN-015 study record. Similarly prepare and file a certified copy of the last interval medical history source document completed for the parent study prior to enrollment in MTN-015.

- The MTN-015 Enrollment form (item 4) requires HIV testing data from the parent study: prepare certified copies of the relevant parent study source documents and file the copies in the MTN-015 study record.

- The MTN-015 HIV/AIDS Associated Events Log form captures medical history data that, for some participants, may have been source documented on parent study medical history documents. When applicable, prepare certified copies of the relevant parent study medical history source documents and file the copies in the MTN-015 study record.

- The MTN-015 Acute Seroconversion Assessment form requires HIV testing data from the parent study: prepare certified copies of the relevant parent study source documents and file the copies in the MTN-015 study record.

- The MTN-015 Acute Seroconversion Assessment form also captures historical HIV viral load and CD4+ cell count data, if available: if source documents related to such testing are available in the parent study record, prepare certified copies of the parent study source documents and file the copies in the MTN-015 study record.

- The MTN-015 Seroconversion Symptoms form requires medical history data from the parent study covering the three months prior to seroconversion: prepare certified copies

of the relevant parent study source documents and file the copies in the MTN-015 study record.

- The MTN-015 Antiretroviral Treatment Regimen Log form captures medication data that, for some participants, will have been source documented on parent study source documents: for such participants, prepare certified copies of the relevant parent study source documents and file the copies in the MTN-015 study record.

In addition to the above specifications, further recommendations related to use of certified copies for participants who remain co-enrolled in their parent study while also taking part in MTN-015 are provided in Section 7 of this manual. Because of the importance of certified copies as source documentation for MTN-015, an excerpt from the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials* related to certified copies is presented in Figure 3-1 (below).

Note that certified copies may be need to be made by photocopying paper records, or printing eCRFs from the parent protocol Medidata Rave clinical database, as appropriate. The process for certifying the photocopy or printout as a true copy of the original is identical (i.e. with a stamp/statement and staff initials and date on each page). Additional information for printing eCRFs from Medidata are as follows:

1. Site staff will need to have a Rave user account and have access to MTN-025 Rave database.
    a. Note: Coordinate with staff who have access to the parent protocol database (e.g., access to the MTN-025 database) to print eCRFs as needed.
2. Log onto Medidata and select the MTN-025 Rave database.
3. Navigate to the applicable eCRF and click the "View PDF" link at the bottom of the page (see screen shot below).
4. Print PDF of the completed eCRF(s) and associated audit trail.
5. Person who made the printout or person designated to verify the copy signs/initials and dates and writes statement (or stamps), "exact copy of the original information"
6. File certified copy of eCRF printout in MTN-015 binder.

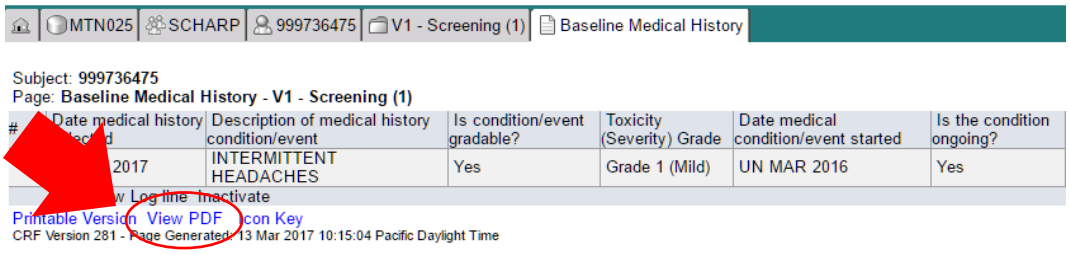

Figure 3-1
Excerpt from DAIDS Policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials* Related to Certified Copies

Certification of a copy may be indicated by any of the following methods:

1. A signed/initialed and dated statement on the copy that indicates it is *an exact copy of the original information.*
   - ➢ This is to be done by the person making the copy, or, the person verifying that the copy is the same as the original.
   - ➢ The statement may be in the form of a stamp as long as it is accompanied by an original signature/initials and date.
2. Signature/initials and date without a statement.
   - ➢ The dated signature/initials mean that the signer has verified that the copy is an exact copy of the original as per this (DAIDS) SOP.
3. Certification for copies received from an outside institution indicates it is an *unaltered copy as received.*

Documents received via fax are copies, and NOT originals.

Printouts retrieved from a computer system are copies and NOT originals.

Documents consisting of more than one page may be verified in a package as being one copy if the package of copies is to remain intact in the file.

1. For verification, the first page of the copy must have on it a signed and dated statement that indicates *the package consisting of X (specify) number of pages is an exact copy of the original information.*
2. Each page must then be initialed and dated to verify that it is part of the package.

A copy used as a source document should be certified that it was verified to be an exact copy of the original, having all of the same attributes and information as the original. This provides an audit trail in the event that the copy appears to have been altered. This is strongly recommended to comply with FDA guidance; however, it is not required by regulation.

DataFax and Non-DataFax Forms Provided by the MTN SDMC: The case report forms for this study are designed for use with the DataFax data management system described in Section 12 of this manual. Case report forms are posted on the MTN-015 SSP Manual webpage and available for downloading and printing via the ATLAS website. See Section Appendix 3-3 for a listing of all DataFax and non-DataFax forms provided for this study.

As shown in Section Appendices 3-4 and 3-5, several of the DataFax and non-DataFax forms provided by the SDMC may serve as source documents. Each study site must document the forms that routinely will be used as source documents in its SOP for source documentation, and must follow the specifications of this SOP consistently for all study participants. In the event that study staff are not able to record data directly forms designated as source documents, the following procedures should be undertaken:

- Record the data onto an alternative source document
- File the alternative source document in the participant’s study chart
- Transcribe the data from the alternative source document onto the appropriate form
- Enter a chart note stating the relevant visit date and the reason why an alternative source document was used

3.2.3 Document Organization

Study staff must make every effort to store all study records securely and confidentially. Case history records must be stored in the same manner for all participants, in areas with access limited to authorized study staff only. Study staff are responsible for purchasing file folders, binders, storage cabinets, and any other equipment or supplies needed to properly store all records.

All documents contained in participant case history records must bear a participant identifier, which generally will consist of either the participant identification number (PTID) or the participant name. To maximize participant confidentiality, the PTID should be used whenever possible. Any documents transferred or transmitted to a non-study site location — including DataFax forms — must be identified by PTID only.

Regardless of whether the identifier on a particular document consists of the participant name or PTID, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated on copies of original source documents. For example, if medical records obtained from a non-study health care provider bear the participant's name, the original documents bearing the name must be stored unaltered with other study documents bearing the name. However, a copy of the original documents could be made, the PTID could be entered onto the copies, and then the participant name could be obliterated from the copies. Copies handled in this way could then be stored in participants' study notebooks and/or transferred or transmitted to non-study site locations.

All on-site databases must be secured with password-protected access systems. Any lists, logbooks, appointment books, or other documents that link PTIDs to other participant identifiers should be stored securely at the study site. When in use, these documents should not be left unattended or otherwise accessible to study participants, other study clinic patients, or any other unauthorized persons.

As a condition for study activation, each study site must establish an SOP for data management. This SOP minimally should contain the following elements:

- Procedures for establishing participant files/charts/notebooks
- During-visit participant chart and case report form review procedures
- Post-visit participant chart and case report form review procedures and timeframes
- Data transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted
- Procedures for resolving data quality control notes from the SDMC
- Procedures for handling and filing field workers' logs, worksheets, etc.
- Storage locations for blank case report forms
- Storage locations for documents identified by participant names or other personal identifiers
- Storage locations for documents identified by PTID
- Handling of participant study records for off-site contacts (if applicable)
- Confidentiality protections
- Staff responsibilities for all of the above

3.3 Protocol Deviations

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with efforts made to correct the deviations, and efforts made to prevent similar deviations in the future. The MTN policy on protocol deviations and the MTN Manual of Operational Procedures should be referenced for complete guidance on protocol deviations.

For MTN-015 the Protocol Deviation Log CRF will be used to document each protocol deviation. The Protocol Deviation Log CRF is completed and faxed to the SDMC for each reportable deviation identified. Like all CRFs, completed Protocol Deviation Log CRFs will be filed in the participant's study binder. Missed visits are not considered protocol deviations for MTN-015.

If there is any question as to whether a deviation has occurred, or how it should be documented, MTN Regulatory (mtnregulatory@mtnstopshiv.org) and the MTN-015 Management team should be contacted. Once the potential protocol deviation has been confirmed, the site will be contacted with this confirmation and the 7-day reporting requirement will begin. Once the CRF is faxed, the MTN Regulatory department or the MTN-015 study management team will follow up with the site regarding any next steps as needed.

In addition to completing and faxing the PD Log CRF, it is recommended that sites report in an expedited manner to IRBs/ECs PDs that pose a potential safety risk to a participant(s) and those that could affect the integrity of the study according to the local IRBs/ECs' standard operating procedures and guidelines.

It is also recommended that a complete list of all PDs occurring at the site, including PDs not meeting immediate reporting standards noted above, be submitted to the local IRBs/ECs in accordance with their reporting policies. If a local IRB/EC does not have a specific reporting policy, MTN recommends that this be done at the time of IRB renewal submission, annually or semi-annually per local requirements. These listings will be provided by MTN to the sites on request. Sites should request these PD listings from SCHARP at least two weeks prior to the planned date of submission to their local IRBs/ECs by submitting a MTN Data Request Form to the study Clinical Data Manager

Note that some protocol deviations will also be considered critical events. Refer to the DAIDS Critical Event Policy and Critical Event Manual for detailed guidance on the definition of critical events and reporting process. These documents can be accessed on the MTN Website under *Resources and Links*: http://www.mtnstopshiv.org/node/4535.

3.4 Record Retention Requirements

All study records must be maintained for at least three years after study close-out. Records must be retained in accordance with protocol-specified protections of participant confidentiality and site IRB/EC policies and procedures. No records are permitted to be discarded or destroyed without prior authorization from DAIDS.

Section Appendix 3-1
Suggested Filing Structure for MTN-015 Essential Documents

Section Appendix 3-1
Suggested Filing Structure for MTN-015 Essential Documents

File/Binder #1: MTN-015 Protocol and Current Informed Consent Forms

1. MTN-015 protocol: Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments
2. Currently-approved MTN-015 informed consent form(s)

File/Binder #2A: IRB/EC Documentation for [IRB/EC A]

3. FWA documentation for IRB/EC A
4. Roster of IRB/EC A (if available)
5. Relevant IRB/EC A submission requirements/guidelines/SOPs
6. IRB correspondence for IRB/EC A: file complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all IRB/EC responses and all approval documentation.

File/Binder #2B: IRB/EC Documentation for [IRB/EC B]

7. FWA documentation for IRB/EC B
8. Roster of IRB/EC B (if available)
9. Relevant IRB/EC B submission requirements/guidelines/SOPs
10. IRB correspondence for IRB/EC B: file complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all IRB/EC responses and all approval documentation.

File/Binder #3: MTN-015 Study-Specific Procedures (SSP) Manual

11. Final version 1.0 and any subsequent updates

Notes:

- For this reference copy of the SSP Manual, do not discard out-dated pages or sections when updates are issued; retain all versions of all pages as a complete historical record.
- The SSP Manual contains reference versions of all study case report forms, therefore additional (blank) copies of the case report forms need not be stored elsewhere in the essential document files.

File/Binder #4: MTN-015 Study-Specific Standard Operating Procedures

12. Final approved version of each SOP, and any subsequent updates to each

File/Binder #5: MTN-015 Staffing Documentation

13. DAIDS Investigator of Record Agreement (copy of form submitted for Protocol Registration, and any subsequent updates)
14. Signed Investigator Signature Form from protocol
15. MTN-015 Investigator of Record CV (copy of CV submitted for Protocol Registration; ensure that the CV is current prior to initiating MTN-015; it is recommended that CVs be signed and dated to document at least annual updating)
16. Study staff roster (original version submitted for study activation, and any subsequent updates)
17. Study staff identification and signature sheet (if not combined with staff roster; original and any subsequent updates)
18. Study staff delegation of duties (if not combined with staff roster; original and any subsequent updates)
19. CVs for study staff other than the Investigator of Record (ensure that all CVs are current prior to initiating MTN-015; it is recommended that CVs be signed and dated to document at least annual updating)
20. Study staff job descriptions
21. Documentation of study staff training

File/Binder #6: Local Laboratory Documentation

22. Local laboratory certification(s), accreditation(s) and/or validation(s): file documentation current at time of study activation and all subsequent updates
23. Local laboratory normal ranges: file documentation of relevant normal ranges for all protocol-specified tests current at time of study activation and all subsequent updates
24. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #5)

Note:

- It is recommended that a cross-referencing list be included in this file/binder specifying the storage location(s) of other lab-related essential documents filed in the local lab(s).

Section Appendix 3-1
Suggested Filing Structure for MTN-015 Essential Documents

File/Binder #7: Monitoring Visit Documentation 25. Monitoring visit log 26. Monitoring visit reports and documentation of response to visit findings
File/Binder #8: Documentation of Other (Non-Monitoring) Site Visits 27. (Non-monitoring) site visit log 28. MTN LOC site visit reports and documentation of response to visit findings 29. MTN SDMC site visit reports and documentation of response to visit findings 30. MTN Laboratory Center site visit reports and documentation of response to visit findings 31. Other site visit reports and documentation of response to visit findings
File/Binder #9: Study-Related Sponsor Communications 32. Study-related communications to and from DAIDS, including but not limited to all submissions to and responses received from the DAIDS Protocol Registration Office Notes: • Communications should be filed beginning from the date of the site-specific study activation notice. • Any participant-specific communications should be filed in the relevant participant's study chart.
File/Binder #10: Other Study-Related Communications 33. Study-Related Communications to and from MTN LOC 34. Study-Related Communications to and from MTN SDMC 35. Study-Related Communications to and from MTN Laboratory Center 36. Other Study-Related Communications Notes: • Communications should be filed beginning from the date of the site-specific study activation notice. • Any participant-specific communications should be filed in the relevant participant's study chart.
File/Binder #11: Study Site Staff Meeting Documentation 37. MTN-015 staff meeting documentation (agendas, participant lists or sign-in sheets, and summaries) Note: • Meeting documentation should be filed beginning from the date of the site-specific study activation notice.
File/Binder #12: Conference Call Documentation 38. MTN-015 Protocol Team and other study conference call summaries Note: • Call summaries should be filed beginning from the date of the site-specific study activation notice.
File/Binder #13: DAIDS and Other Reference Documentation 39. DAIDS *Protocol Registration Policy and Procedures Manual* 40. US Regulations Applicable to Conduct of MTN-015 (45 CFR 46) 41. Any other relevant manuals or reference documents
File/Binder #14: Site-Specific Study Activation Documentation 41. Site-specific study activation notice and supporting documentation

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN-015

Required Case History Element	Source Documents*
Basic participant identifiers	Locator form, Demographics form.
Documentation that the participant provided written informed consent for the study	Signed and dated informed consent form, signed and dated chart note stating that informed consent was obtained prior to initiating study procedures.
Documentation that the participant met the study selection (eligibility) criteria	Screening and Enrollment visit checklist, certified copies of parent study HIV testing source documents, signed and dated chart notes.
A record of all contacts, and all attempted contacts, with the participant	Signed and dated chart notes, field worker logs and/or worksheets, other worksheets or site-specific documents if designated in site SOPs.
A record of all procedures performed by study staff	Completed visit checklists, signed and dated chart notes detailing (i) procedures performed in addition to those contained on the checklist and/or (ii) the reason why procedures contained on the checklist were not performed, other worksheets or site-specific documents if designated in site SOPs.
Information on the participant's condition before, during, and after the study	All above-listed documents, certified copies of relevant parent study source documents, Medical History Log form, Acute Seroconversion Assessment form, Seroconversion Symptoms form, HIV/AIDS Associated Events Log form, Physical Exam form, Pelvic Exam Diagrams form, Concomitant Medications Log form, Non-ART Concomitant Medications Log form, Baseline Behavioral Assessment form, Follow-up Behavioral Assessment form; Social Harms Assessment form, Antiretroviral Treatment Regimen Log form, Antiretorviral Adherence form, Pregnancy Report and History form, Pregnancy Outcome form, local lab logs and result reports[§]; other source documents pertinent to the study obtained from non-study sources[§§]; signed and dated chart notes.

*Other site-specific source documents also may be used.

[§]A clinician must review all local laboratory reports and document this review by signing and dating all reports.

[§§]A clinician must review all non-study medical records/reports and document this review by signing and dating all records/reports.

Section Appendix 3-3
MTN-015 DataFax and Non-DataFax Forms

MTN-015 DataFax Forms
Enrollment
Microbicide Trial Participation
Demographics
Non-ART Study Visit
ART Study Visit
Acute Seroconversion Assessment
Seroconversion Symptoms
HIV/AIDS Associated Events Log
Non-ART Concomitant Medications Log
Laboratory Results – Revised – Version 2
Microbicide Trial Participation
Sexually Transmitted Diseases Results
Specimen Storage
Baseline Behavioral Questionnaire – Version 2
Follow-up Behavioral Questionnaire – Version 2
Social Harms Assessment
ART Enrollment – Version 2
ART Initiation Information
Antiretroviral Treatment Regimen Log
ART Adherence Questionnaire
Pregnancy Report and History
Pregnancy Outcome
Interim Visit
Missed Visit
Participant Transfer
Participant Receipt
Termination
End of Study Inventory
Protocol Deviation Log
Family Planning
ACASI Tracking
PAP Test Result

MTN-015 Non-DataFax Forms
Medical History Log
Concomitant Medications Log
Physical Exam
Pelvic Exam Diagrams
LDMS Specimen Tracking Sheet

Section Appendix 3-4
MTN 015 DataFax Forms

[NOTE TO SITES: Sites must determine whether each form will serve as a source document and modify the chart accordingly.]

Form Name	Source?	Comments
Demographics	Yes	Form is interviewer-administered; participant's responses are recorded directly onto the form.
Acute Seroconversion Assessment	No	All items require parent study records as source.
Microbicide Trial Participation	Mixed	Form may be source for items 5 and 5a only.
Enrollment	Mixed	Form may be source for items 5 and 5a only
ART Enrollment – Version 2	Mixed	Form may be source for items 1 and 1a only.
ART Initiation Information - Revised	Mixed	Form may be source for item 1 only.
Baseline Behavioral Questionnaire – Version 2	Yes	Form is interviewer-administered; participant's responses are recorded directly onto the form.
Non-ART Study Visit	Yes	Form can be source for all items.
ART Study Visit	Yes	Form can be source for all items.
Seroconversion Symptoms	No	Certified copy of parent protocol records must be used as source.
Sexually Transmitted Disease Results	Mixed	Form can be source for items 1a-1b at all sites. Form may be used as source for items 1c-1f only at sites where wet preps are read in clinic by clinic staff. Local lab result reports will be source for items 2-4. For co-enrolled participants, may use certified copies of parent study source documents as source for all items.
Laboratory Results – Revised (Version 2)	No	Laboratory logs and/or result reports are source for all items. For co-enrolled participants, may use certified copies of parent study source documents as source for item 3.
Specimen Storage	Yes	Form may be used as source. Visit checklist/chart notes will be used as source to document specimen collection.
Antiretroviral Treatment Regimen Log	Yes	Form can be used as source for all items.
Interim Visit	Yes	Form can be used as source for all items.
ART Adherence Questionnaire	Yes	Form is interviewer-administered; participant's responses are recorded directly onto the form.
Follow-up Behavioral Questionnaire – Version 2	Yes	Form is interviewer-administered; participant's responses are recorded directly onto the form.
Social Harms Assessment	Yes	Form is interviewer-administered; participant's responses are recorded directly onto the form.
HIV/AIDS-associated Events Log	Yes	Form can be used as source for all items.
Non-ART Concomitant Medications Log	Yes	Form can be used as source for all items.
Pregnancy Report and History	Mixed	Form can be source for items 1 and 2 only. For co-enrolled participants, certified copy of parent protocol source documents may be used as source.
Protocol Deviation Log	Yes	Form may be source for all items

Section Appendix 3-4
MTN 015 DataFax Forms

[NOTE TO SITES: Sites must determine whether each form will serve as a source document and modify the chart accordingly.]

Form Name	Source?	Comments
Family Planning	Yes	Form may be source for all items
ACASI Tracking	Yes	Form may be source for all items
Pregnancy Outcome	Yes	Form can be source for all items when medical records are not able to be obtained. For co-enrolled participants, certified copy of parent protocol source documents may be used as source
Missed Visit	Yes	Form can be used as source for all items.
Participant Transfer	Mixed	Form can be source for items 1, 2, and 4 only.
Participant Receipt	Mixed	Form can be source for items 1 and 2 only.
End of Study Inventory	No	All data items come from other completed forms.
Termination	No	All items are based on source data recorded on other documents.
Pap Results CRF	No	Laboratory logs and/or result reports are source for all items.

Section Appendix 3-5
MTN 015 Non-DataFax Forms

[NOTE TO SITES: Sites must determine whether each form will serve as a source document and modify the chart accordingly.]

Form Name	Source?	Comments
Medical History Log	Yes	Form may be used as a source for all items. For co-enrolled participants, certified copies of parent study medical history source documents may be used source.
Physical Exam	Yes	Form may be used as a source for all items. For co-enrolled participants, if an exam is performed for the parent study within 30 days of an MTN-015 visit, certified copies of parent study source documents may be used in lieu of this form
Pelvic Exam Diagrams	Yes	Form may be used as a source for all items. For co-enrolled participants, if an exam is performed for the parent study within 30 days of an MTN-015 visit, certified copies of parent study source documents may be used in lieu of this form
Concomitant Medications Log	Yes	Form may used as source for all items. For co-enrolled participants, certified copies of parent protocol source documents may be used as source.
MTN 015 LDMS Specimen Tracking Sheet	No	Visit checklists/other documents are source for specimen collection.