

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-009.

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-009. Because MTN-009 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-009:

- Financial Disclosure
- 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-009 and should be followed for MTN-009.

Section Appendix 3-1 presents a suggested essential documents filing structure for MTN-009. 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-009. 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 17 and 18 in Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories.
- For files maintained in separate location from the main essential documents files, add a note-to-file to direct the reviewer as to where the files can be located.
- The suggested filing structure assumes that MTN-009 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-009 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-009 for each study participant.

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

- Basic participant identifiers (e.g. PTID, names, initials)
- Documentation that the participant provided written informed consent for the study prior to conducting 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., lab findings)
 - Data obtained from non-study sources, if needed

In addition to the above, DAIDS requires that all protocol departures/deviations/violations be documented in participant records, along with reasons for the departures/deviations/violations and efforts made to correct or prevent the departures/deviations/violations. MTN-009 study sites also must report reportable protocol deviations per Section 15.4 of the MTN Manual of Operations (MOP).

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-009, participant case history records consist of the following types of source documents:

- Narrative chart notes
- Visit checklists
- 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)

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. Detailed information on proper completion of DataFax and Non-DataFax forms provided by the MTN SDMC is provided in Section 12 of this manual. Provided below is supplemental information on the use of three types of source documents to capture MTN-009 study data: chart notes, visit checklists, and forms provided by the MTN SDMC.

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

Chart notes are required to document the following:

- The study informed consent process (see also Section 4.4)
- Procedures performed that are not recorded on other source documents
- Pertinent data about the participant that are not recorded on other source documents
- Protocol departures/deviations/violations 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. Further information on the SOAP note format and several sample notes in SOAP format are provided in Section Appendix 3-3.

Visit Checklists: The checklists in Section 7 (Visit Checklists)) of this manual 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.

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. The SDMC will provide these forms to each site. The SDMC also will provide several study-specific non-DataFax forms to each site. See Section Appendix 3-4 for a listing of all DataFax and non-DataFax forms provided for this study.

As shown in Section Appendices 3-5 and 3-6, several of the DataFax and non-DataFax forms provided by the SDMC could 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 on 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 independently of their HIV status to ensure participant confidentiality, 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 and securely store all records.

All documents contained in participant case history records must bear a participant identifier (PTID or name). However, 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; the participant name should never be used.

Documents for participants that do not enrolled in the study will be labeled using participant's name. These documents must be filed separately in a secure location with other name files for the study.

Regardless of whether the identifier on a particular document consists of the participant name or PTID, the original identifier may never 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 participants, 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
- Data collection and transmission procedures for data collected via Audio Computer Assisted Self Interview (ACASI)
- 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 Record Retention Requirements

All study records must be maintained for at least two 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. Study records must be maintained on site for the entire period of study implementation. Thereafter, instructions for record storage will be provided by DAIDS. No study records may be moved to an off-site location or destroyed prior to receiving approval from DAIDS. .

Section Appendix 3-1
Suggested Filing Structure for MTN-009 Essential Documents

<p>File/Binder #1: MTN-009 Protocol and Current Informed Consent Forms</p> <ol style="list-style-type: none"> 1. MTN-009 protocol: Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments 2. Currently-approved MTN-009 informed consent form and all subsequent updates.
<p>File/Binder #2: IRB/EC Documentation</p> <ol style="list-style-type: none"> 3. FWA documentation for IRB/EC 4. Roster of IRB/EC (if available) 5. Relevant IRB/EC submission requirements/guidelines/SOPs 6. IRB correspondence for IRB/EC: 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.
<p>File/Binder #3: MTN-009 Study-Specific Procedures (SSP) Manual</p> <ol style="list-style-type: none"> 7. Final version 1.0 and any subsequent updates <p>Notes:</p> <ul style="list-style-type: none"> • 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.
<p>File/Binder #4: MTN-009 Study-Specific Standard Operating Procedures</p> <ol style="list-style-type: none"> 8. Final approved version of each SOP, and any subsequent updates to each
<p>File/Binder #5: MTN-009 Staffing Documentation</p> <ol style="list-style-type: none"> 9. DAIDS Investigator of Record Agreement (copy of form submitted for Protocol Registration, and any subsequent updates) 10. MTN-009 Investigator of Record CV (copy of CV submitted for Protocol Registration; ensure that the CV is current prior to initiating MTN-009; it is recommended that CVs be signed and dated to document at least annual updating) 11. Study staff roster (original version submitted for study activation, and any subsequent updates) 12. Study staff identification and signature sheet (if not combined with staff roster; original and any subsequent updates) 13. Study staff delegation of duties (if not combined with staff roster; original and any subsequent updates) 14. CVs for study staff other than the Investigator of Record (ensure that all CVs are current prior to initiating MTN-009; it is recommended that CVs be signed and dated to document at least annual updating) 15. Study staff job descriptions 16. Documentation of study staff training
<p>File/Binder #6: Local Laboratory Documentation</p> <ol style="list-style-type: none"> 17. Local laboratory certification(s), accreditation(s) and/or validation(s): file documentation current at time of study activation and all subsequent updates 18. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #5) <p>Note:</p> <ul style="list-style-type: none"> • 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).
<p>File/Binder #7: Monitoring Visit Documentation</p> <ol style="list-style-type: none"> 19. Monitoring visit log 20. Monitoring visit reports and documentation of response to visit findings
<p>File/Binder #8: Documentation of Other (Non-Monitoring) Site Visits</p> <ol style="list-style-type: none"> 21. (Non-monitoring) Site visit log 22. MTN CORE site visit reports and documentation of response to visit findings 23. MTN SDMC site visit reports and documentation of response to visit findings 24. MTN Network Laboratory site visit reports and documentation of response to visit findings 25. Other site visit reports and documentation of response to visit findings

Section Appendix 3-1
Suggested Filing Structure for MTN-009 Essential Documents

<p>File/Binder #9: Study-Related Sponsor (DAIDS) Communications</p> <p>26. Study-related communications to and from DAIDS, including but not limited to all submissions to and responses received from the DAIDS Protocol Registration Office</p> <p>Notes:</p> <ul style="list-style-type: none"> • 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.
<p>File/Binder #10: Other Study-Related Communications</p> <p>27. Study-Related Communications to and from MTN CORE</p> <p>28. Study-Related Communications to and from MTN SDMC</p> <p>29. Study-Related Communications to and from MTN Network Laboratory</p> <p>30. Other Study-Related Communications</p> <p>Notes:</p> <ul style="list-style-type: none"> • 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.
<p>File/Binder #11: Study Site Staff Meeting Documentation</p> <p>31. MTN-009 staff meeting documentation (agendas, attendee lists or sign-in sheets, and summaries)</p> <p>Note:</p> <ul style="list-style-type: none"> • Meeting documentation should be filed beginning from the date of the site-specific study activation notice.
<p>File/Binder #12: Conference Call Documentation</p> <p>32. MTN-009 Protocol Team and other study conference call summaries</p> <p>Note:</p> <ul style="list-style-type: none"> • Call summaries should be filed beginning from the date of the site-specific study activation notice.
<p>File/Binder #13: DAIDS and Other Reference Documentation</p> <p>33. DAIDS <i>Protocol Registration Policy and Procedures Manual</i></p> <p>34. US Regulations Applicable to Conduct of MTN-009 (45 CFR 46)</p> <p>35. Any other relevant manuals or reference documents</p>
<p>File/Binder #14: Site-Specific Study Activation Documentation</p> <p>36. Site-specific study activation notice and supporting documentation</p>

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN-009

Required Case History Element	Source Documents*
Basic participant identifiers	Site-specific locator form, Demographics CRF.
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, Eligibility Assessment CRF, 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, ACASI data, Screening and Enrollment HIV Test Results CRF, Other Trial Participation CRF, Laboratory Test Results CRF, local lab logs and result reports [§] ; Network Lab CRFs and result reports; other source documents pertinent to the study obtained from non-study sources ^{§§} ; signed and dated chart notes.
A record of all site deviations from protocol-specified procedures	Site memos-to-file and completed protocol deviation forms

*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, if applicable.

Section Appendix 3-3 Guidelines and Examples on the SOAP Format for Chart Notes

Guidelines

The SOAP Format: The benefits of the SOAP format are that it can be tailored to any type of study or study visit and that, if done properly, will satisfy both the medical record needs for the continuing care of the participant and the source documentation requirements for the study. Below is a broad definition of the components of the SOAP format and then three examples of how it might be used in specific scenarios.

- **S (SUBJECTIVE):** The subjective component is the participant’s report of how he or she has been doing including the current visit. Subjective comments made by participant may range from no complaints (“I feel great”) to specific current complaints (“I’ve had a headache for 3 days”) to complaints that took place in the interim but have resolved (“3 weeks ago I had diarrhea for a couple of days”). The participant should be asked directed questions about any complaints – current or reportedly resolved -- and ask appropriate follow-up questions and document all responses.

Reports of compliance with specific treatment regimens – whether study-related or not – should also be included here: “How much of your study medication did you take since your last visit? Did you miss any doses? Why?” or “At the last visit, you were given antibiotics for pneumonia. Do you have any pills left?”

- **O (OBJECTIVE):** The objective component is straightforward and includes vital signs (temperature, blood pressure, pulse, respiration), documentation of the physical examination that was done, and results of laboratory or other studies that may be done during the course of this visit. For a participant with no complaints, the physical exam may be limited to meet study specific needs. For a participant with a complaint, an appropriate focused physical exam should be completed in addition to or instead of the study-specific exam.

- **A (ASSESSMENT):** For this component, the clinician pulls together the subjective information gathered during the interview with the participant and the objective findings of the physical exam (and, possibly, laboratory or other study results) and consolidates them into a short assessment: “This is a 26-year old woman here for a routine MTN 009 study visit; there are no clinical problems today”.

- **P (PLAN):** The plan should include anything that will be done as a consequence of the assessment and could include:
 - The collection of study-specific labs or special studies
 - The collection of labs or special studies to address an acute complaint
 - Intention to admit to the hospital
 - Study-specific medications dispensed (name of drug, amount dispensed and dosing instructions)
 - Non-study medications prescribed or dispensed for a specific acute or chronic complaint (name of drug, amount dispensed and dosing instructions)
 - Follow-up instructions to the participant (for example: “return to the clinic if this problem does not resolve”)
 - Date of next appointment

Section Appendix 3-3
Sample Chart Notes for MTN 009 in Subjective-Objective-Assessment-Plan (SOAP) Format

Sample Chart Note for Screening and Enrollment:

13 OCT 2010: Participant presented for MTN 009 screening and enrollment visit. Obtained written informed consent for screening and enrollment before initiating any procedures. Procedures were completed per protocol, visit checklist and SOPs.

S: Participant reported no current health problems.

O: Behavioral assessment done, HIV test positive, additional laboratory tests done per protocol

A: Participant is eligible to continue in MTN 009.

P: Follow-up visit scheduled for 17 November 2010.

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Sample Chart Note for Screening:

13 OCT 2010: Participant presented for MTN 009 screening and enrollment. Obtained written informed consent for screening and enrollment before initiating any procedures. Procedures were completed per protocol, SOPs and visit checklist, with the additions listed here.

S: Participant reported no current health problems.

O: Behavioral assessment done, HIV test negative

A: Participant will be referred to VOICE

P: Participant HIV negative, no further MTN 009 procedures required

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Sample Chart Note for Follow-up Visit:

4 NOV 2010: Participant presented for MTN 009 first follow-up visit. Pretest counseling and CD 4 counts provided per protocol and site SOPs.

S: No issues/problems reported since last visit.

O: Participant understands counseling messages and meaning of CD4 test results.

A: No issues of concern.

P: Second follow-up visit scheduled on 5 January 2011 for counseling and disclosure of test results.

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Section Appendix 3-4
MTN-009 DataFax and Non-DataFax Forms

MTN-009 DataFax Forms
Demographics
Eligibility Assessment
Screening and Enrollment HIV Test Results
Other Trial Participation
Laboratory Test Results

MTN-009 Non-DataFax Forms
LDMS Specimen Tracking Sheet

Section Appendix 3-5
Use of MTN-009 DataFax Forms as Source Documents

MTN-009 DataFax Forms	Form as Source?	Comments
Demographics	Mixed	Items 1-17 are interviewer-administered; participant responses are recorded directly onto the form. The form may be source for item 18; alternately, sites may choose one of the following as source: recruitment logs, chart notes, or the visit checklist. The form may be source for items 19-19a; alternately sites may choose either chart notes or the visit checklist as source for these items.
Eligibility Assessment	Mixed	The form may be source for items 1, 1a, and 6. Alternately, the visit checklist or chart notes may be source for item 1, and the chart notes may be source for items 1a and 6. The site-specific MTN009 Screening and Enrollment Log is source for item 2. Source for item 3 may be one of the following: site locator form, visit checklist, or chart notes. The signed and dated MTN009 informed consent form is source for items 4-5a. The site MTN009 PTID-Name Link Log is source for items 7-7a.
Screening and Enrollment HIV Test Results	Mixed	Form may be source for item 2. All other items should be completed based on laboratory source documents.
Other Trial Participation	No	All items should be completed based on source data recorded on other source documents.
Laboratory Test Results	Mixed	Form may be source for item 3. All other items should be completed based on laboratory source documents.

Section Appendix 3-6
Use of MTN-009 Non-DataFax Forms as Source Documents

MTN- 009 Non-DataFax Forms	Form as Source?	Comments
LDMS Specimen Tracking Sheet	No	All items are based on source data recorded on other source documents.