

Section 2. Documentation Requirements

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2. Introduction

Study staff members are responsible for the 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 for MTN-041.

2.1 Essential Documents

The [DAIDS policy on Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials](#) and [E6 Good Clinical Practice: Consolidated Guidance](#) specify the essential documents that study sites must maintain. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location.

When developing an 'essential documents' filing structure for MTN-041, study sites are encouraged to consider their experiences implementing previous MTN protocols. While taking into account these experiences, the structure should be tailored to meet the specific needs of MTN-041 and ensure that all required documents are properly filed. Three tips for the suggested filing structure are provided below:

- Essential documents may be stored in files and/or in binders, which may be subdivided, consolidated, and/or re-organized.
- 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).
- It is assumed that MTN-041 participant files will be stored separately from the other essential documents. SSP Section 2.2 below provides information on the required contents of these files. Hard copies of the MTN-041 PTID-Name Linkage Log and Screening and Enrollment Log must be maintained throughout the duration of the study. The suggested filing structure assumes that these logs will be stored in the study clinic or data management area throughout the screening and accrual process and not necessarily with the other essential documents listed. These documents must be stored securely with access limited to study staff to ensure participant confidentiality.

Note: When required documents are modified or updated, the original and all modified or updated versions must be retained.

2.2 Participant Research Records

MTN-041 study sites must maintain adequate and accurate participant research records containing all information pertinent to each study participant. See Protocol Section 13.6 for further information regarding confidentiality of participant information; participant charts should be stored in locked file cabinets with access limited to authorized study staff.

2.2.1 Concept of Source Data and Source Documentation

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

The term **source data** refers to all information in original records and certified copies of original records related to clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the trial (including all screening and enrollment activities). Source data are contained in source documents (e.g., original records or certified copies).

The term **source document** refers to original documents, data, and records (e.g., hospital records; clinical and office charts; laboratory records and notes; memoranda; participants' diaries and/or evaluation checklists; pharmacy dispensing records; recorded data from automated instruments; copies of transcriptions certified after verification for accuracy and completeness; microfiche; photographic negatives; microfilm or magnetic media; x-rays; participant files; and records kept at the pharmacy, laboratories, and medico-technical departments involved in the study).

Source documents are commonly referred to as the documents—paper-based or electronic—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.

2.2.2 Required Source Documentation and Participant File Contents.

For MTN-041, participant files should contain all of the following elements which are considered **source data**:

1. **Basic participant identifiers.**
2. **Narrative participant file notes.** To document visit procedures including participant's provision of written consent* to participate in the study prior to the conduct of any study procedures (if not documented elsewhere).
 - * *Note: Any questions the participant asks during the written IC process (and responses to these questions) should be documented in file notes or on the informed consent cover sheet.*
 - a. Any deviations, including reason for deviation, from SOPs, procedures outlined in the protocol, or this SSP manual that are not recorded on other source documents. See section 2.2.3 below for more information on reporting protocol deviations.
 - b. A record of all contacts, both successful and attempted, with the participant and any referrals made (including for social harms or unexpected safety events reported) that were not recorded elsewhere documented per Good Clinical Practices (GCP) and DAIDS source documentation guidelines.
3. **Documentation that the participant met the eligibility criteria for the study** (i.e., completed MTN-041 Eligibility Worksheet and MTN-041 Eligibility Checklist).
 - a. For in-depth interviews, documentation of approval from the MTN-041 management team should be filed.

4. **Case Report Forms (CRFs) and non-CRF forms, and other source documents.** The case report forms for this study are designed for use with the RTI data management system described in Section 6 of this SSP manual. RTI will provide the master versions of these forms to the site, and printing will be coordinated locally. RTI will also provide several additional study-specific forms (non-CRFs) to the site. See Table 2-1 for a listing of all study forms, which can be found on the MTN-041 website. Additional source documents (e.g., charts notes, site-specific checklists, worksheets, debrief reports) will be identified in the site Data Management SOP.
5. **Qualitative Guides for IDIs & FGDs.** All notes will be recorded by study staff on interview guides and/ or separate sheets of paper and audio files will be saved to a CD. Focus group discussion (FGD) information such as checklists, notes, participant lists, and the CD of the group audio recording should be stored in separate files.
6. **Final English-Translated Transcripts, Audio Files & CD, and Debrief Reports.** Further details on the storage of these recordings is provided in SSP Section 6.

2.2.3 Protocol Deviations

Sites will follow the DAIDS requirements for reporting Protocol Deviations. DAIDS requires that all protocol deviations be documented in participant records, along with efforts made to correct and prevent similar deviations in the future. The MTN Manual of Operational Procedures should be referenced for complete guidance on protocol deviations.

Reporting

Centralized reporting and tracking of PDs is imperative to both ensuring the safety of study participants and to preserving the scientific integrity of research studies, while allowing the MTN to meet its obligations to study sponsors. All deviations from the protocol will be reported as soon as possible, but **no later than within 7 days of site awareness**.

Once a PD is identified at the site, the PD CRF is completed and submitted to RTI within 7 days, per CRF submission instructions in Section 6 (Data Management) of this manual. Note that MTN-041 has a specific PD CRF for the RTI database, and this is available on the MTN-041 website.

If a PD involves multiple PTIDs a separate PD form should be filled out for each PTID involved.

If there is a question about whether something is a PD or not, please contact the study management team, mtn041mgmt@mtnstopshiv.org, as well as MTN Regulatory at mtnregulatory@mtnstopshiv.org for support. In these cases, the 7-day window for reporting a PD will not start until a PD is confirmed by MTN Regulatory.

Some protocol deviations may be considered Critical Events, which are reportable directly to DAIDS per the DAIDS policy Identification and Classification of Critical Events. Sites must also follow local requirements regarding reporting protocol deviations to local regulatory bodies.

Oversight

A record of all deviations will be maintained in the study database and will be available as requested by MTN leadership, DAIDS, OCSO, the MTN-041 management team, the Network Evaluation Committee, and other MTN groups as needed.

The MTN-041 management team will review all PDs reported on a routine basis during team calls throughout study implementation. A summary of the discussion will be included in the minutes for the call. If further information is required regarding any deviation or proposed corrective and preventative action, the MTN-041 management team will follow up with the site.

2.2.4 Document Organization and Participant Confidentiality

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

Study-related documentation collected during the screening process should be stored in a file folder/binder for each potential participant. All screening documentation — for potential participants who eventually enroll in the study as well as for those who do not enroll or “screen out” — must be maintained and available for monitoring throughout the study. Flat files may be maintained for participants who enroll, if the files have a secure mechanism (i.e. rings, clasps) to hold papers. Otherwise, documentation should be transferred to files that have secure mechanisms for holding papers. Pocket files are not adequate as loose papers may still fall out.

All documents contained in participant files must bear a participant identifier, which will consist of either the participant identification number (PTID) or the participant name. Please refer to Table 2-1 below for guidance on which identifier to include on each study document. The PTID should be used where possible to maximize participant confidentiality. **Any documents transferred or transmitted to a non-study site location — including RTI or a local data management center — must be identified by PTID only. Care should also be taken to only refer to participants by PTID in email communication.**

Note: 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, if a copy of the original documents is made, the PTID can be entered onto the copies, and then the participant name can be obliterated from the copies. Copies handled in this way could then be stored in participants’ files.

All on-site databases must be secured with password-protected access systems. Any lists, appointment books, or other documents that link PTIDs to other participant identifiers should be stored securely (locked cabinet/drawer if hard copy; password protected if electronic). When in use, documents that link PTIDs to other participant identifiers should not be left unattended or be otherwise accessible to study participants, other study clinic patients, or any other unauthorized persons.

Table 2-1: Listing of MTN-041 Study Documents

Document Name	Name only	PTID only	Name and PTID
Locator Form	X		
PTID Name Link Log			X
Screening and Enrollment Logs		X	
Consent Forms	X		
IC Comprehension Checklists, IC Coversheet	X ¹	X ¹	
Case Report Forms (DEM, PSF, BA, PD, & SH)		X	
Visit Checklists, Behavioral Eligibility Worksheet, Eligibility Checklist		X	
Permission to Contact (PTC) Form/ Log ²	X ¹	X ¹	
Discussion Guides and Notes		X	
Interview Transcripts		X	
CD of audio-recording		X	
IDI and FGD Debriefing Reports		X	

¹ As stated above, study documents should contain participant name or PTID, but not both. Documents tracked by name should be stored separately from those tracked by PTID.

² PTC Forms/Logs are not required for MTN-041. However, follow guidance above if these will be used.

2.3 Record Retention Requirements

Study records must be maintained on site for the entire period of study implementation and in accordance with the [DAIDS policy on Storage and Retention of Clinical Research Records](#). Records relating to research and IRB/EC records will be retained for at least three years after completion of the research, as required by US Department of Health and Human Services (HHS) regulations 45 CFR 46.115(b). No study records may be moved to an off-site location or destroyed prior to receiving approval from DAIDS. Investigators and others retaining records covered under this policy will seek guidance from their institution on whether records are subject to any limitations on their disposal.