Section 2. Documentation Requirements

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-032.

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* specifies 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-032, 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-032 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-032 confidential participant files will be stored separately from other essential documents, including participant research files. Section 2.2 below provides information on the required contents of these files. The MTN-032 PTID-Name Linkage Log and Screening and Enrollment Log must be maintained in hard copy throughout the duration of the trial (and can be combined into one log). 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.
- Due to the nature of recruitment for MTN-032 i.e. selection from a pool of participants enrolled in ASPIRE and/or HOPE, site teams should take care to maintain documents containing HOPE and ASPIRE PTIDs separate from any MTN-032 pre-screening or screening information until after informed consent is obtained from MTN-032 participants.

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-032 study sites must maintain adequate and accurate participant research records containing all information pertinent to each study participant. See protocol Section 13 for further information regarding confidentiality of participant information; participant charts should be stored in locked file cabinets with access limited to authorized study staff. Phase 2 study documentation should be stored with a participant's Phase 1 study documentation.

2.2.1 Confidential Participant File Contents

Identifying information, such as participant identifiers, locator forms, and ICFs, should be kept in a locked area separate from study binders containing research information. The following items should be kept within participant files:

- Basic participant identifiers.
- For female participants: Documentation that the participant provided written permission to be contacted by ASPIRE and/or HOPE staff for future research studies.
- Documentation that the participant met the study's selection (eligibility) criteria.
- For male participants: Documentation that the former HOPE participant provided written consent to have this male partner contacted to participate in the study.
- Documentation that the participant provided written consent to participate in the study prior to the conduct of any study procedures.
    - 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. Documentation of referrals made (including for social harms or unexpected safety events reported)

2.2.2 Participant Research Files

Participant research files should contain all of the following elements:

- A record of all contacts, and attempted contacts, with the participant documented per Good Clinical Practices (GCP) and DAIDS source documentation guidelines.
- A record of all study activities that took place and interview data captured during the conduct of the study.
    - All notes recorded by study staff on interview guides and/ or separate sheets of paper and/ or tools for the in-depth interviews (IDI),
    - Audio files saved to a CD;
    - Final copies of the debrief report and transcript
- Chart notes or copies of referrals made (including for social harms or unexpected safety events reported).
- Reason for any deviation required from procedures outlined in the protocol, site SOPs or this SSP manual.

NOTE: Separate files can be created to store all focus group discussion (FGD) information such as checklists, notes, participant lists, and the CD of the group audio recording.

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with reasons for the deviations, efforts made to correct the deviations, and efforts made to prevent similar deviations in the future. Additional details regarding protocol deviation reporting requirements are found in Section 2.2.4 below.

2.2.3 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.

2.2.4 Required Source Documentation

For MTN-032, participant research files should consist of the following source documents:

- **Narrative participant file notes**: File notes should be used to document visit procedures (including verification of permission to contact and the IC process if not documented elsewhere), communicate any deviations from SOPs, any protocol deviations that are not recorded on other source documents, any referrals made that were not documented elsewhere, or contacts with all participants if the Participant Contact Log is not used for this purpose.
- **Case Report Forms (CRFs) and non-CRF forms:** The case report forms for this study are designed for use with the RTI data management system described in Section 7 of this 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 forms for this study. All CRFs and other forms used in this study can be found on the MTN-032 website.
- **Qualitative Guides for IDIs & FGDs**: Notes taken on IDI discussion guides, tools or separate pieces of paper during qualitative data collection are source documents and must be kept in the participant file. Separate files can be created to store all FGD group information such as checklists, notes, participant lists and annotated FGD discussion guides and tools.
- **Audio CD of IDI & FGDs**: Audio file recordings are also considered to be source documentation for these interviews and must be kept in the participant file, or FGD discussion file. Further details on the storage of these recordings is provided in Section 7.
- Other source documents (e.g., site-specific checklists, worksheets, debrief reports) as identified in the site Data Management SOP.

2.2.5 Protocol Deviations

Sites will follow the DAIDS requirements for 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 our study participants and to preserving the scientific integrity of research studies, while allowing the Network to meet its obligations to study sponsors. All deviations from the protocol will be reported centrally as soon as possible, but not 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 7 of this manual. Note that MTN-032 has a specific PD CRF for the RTI database, and this is available on the MTN-032 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 if something is a PD or not please contact the study management team, mtn032mgmt@mtnstopshiv.org, as well as mtnregulatory@mtnstopshiv.org for support. The 7-day window for reporting a PD will not start until a PD is confirmed by MTN Regulatory.

Some, but not all protocol deviations, may be considered Critical Events which are reportable directly to the DAIDS, per the DAIDS policy Identification and Classification of Critical Events. Sites are also to follow local requirements regarding reporting protocol deviations to local regulatory bodies.

Oversight

A central file of deviations will be maintained and will be available as requested by Network Leadership, DAIDS, OCSO, Protocol Teams, the Network Evaluation Committee, and other Network groups as needed.

The MTN Regulatory Department will review, track and maintain PDs, regardless of cause. The MTN Regulatory Department will, on a regular basis, distribute PD information to the Protocol Team and if further information is required, contact the site.

2.2.6 Document Organization and Participant Confidentiality

Study staff must make every effort to 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 some kind of 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 research files must bear a participant identifier, which generally will consist of the participant identification number (PTID). Participant files containing identifying information should be kept separately from participant research files to preserve 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 when people outside of the site are included.

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, 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' 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 otherwise accessible to study participants, other study clinic patients, or any other unauthorized persons.

2.3 Record Retention Requirements

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.

Table 2-1: Listing of MTN-032 Study Documents

Document Name	Name/ Initials only	MTN-032 PTID only	Name/Initials and/or MTN-032 PTID
Locator Form[1]	X		
Permission to Contact Form[1]			X
Recruitment Lists		X[2]	
Recruitment Checklist/Scripts		X[3]	
Screening and Enrollment Logs			X
Consent Forms	X		X
IC Comprehension Checklists		X	
Participant Contact Logs		X	
Case Report Forms (DEM, PSF & BA)		X	
Visit Checklists		X	
Discussion Guides, Notes and Tools		X	
CD of audio-recording		X	
IDI and FGD Debriefing Reports		X	

[1] The Locator Form and Permission to Contact Form are ASPIRE and/or HOPE forms that will be used for verifying eligibility and recruiting participants for MTN-032 Phase 1 and 2. If possible, a certified copy of these forms will be made for MTN-032 study files. Otherwise, a chart note will document this information in the MTN-032 file.

[2]This will be the HOPE PTID since it will be used prior to enrollment and the MTN-032 PTID once assigned. Note that the HOPE PTID should be removed prior to submitting the Recruitment List to RTI and the Obs # on the SCHARP Recruitment List will be used for communication with RTI for those who were considered but not enrolled.

[3] This will be the Obs # on the SCHARP Recruitment List since it will be used prior to enrollment.