

Section 2: Documentation Requirements

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2. Documentation Requirements

Study staff members 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.

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.

Examples of essential documents specific to MTN-042B include (but may not be limited to):

- MTN-042B Protocol, v1.0
 - LoAs/CMs, as applicable
- MTN-042B SSP Manual
- Source Documentation-Case Report Forms (CRFs) (electronic)
- Delegation of Duties (DoD) Log
- Staff Training and Qualification Documentation (CVs, HSP/GCP, clinical licenses as applicable), HANC Financial Disclosures (as requested), MTN IoR Training
- DAIDS IoR Form, signed and dated Protocol Signature Page
- DAIDS Protocol Registration Approval
- Study Specific Training Documentation (i.e. agenda, materials, sign in sheets)
- Site Specific SOPs for MTN-042B (IRB/EC Communication, MTN-042B Implementation SOP) and SOP Training Logs
- MTN-042B PTID Linkage Log
- IRB Approvals and Communication, IRB roster(s)
- Study Activation Checklist and Notice
- Protocol Deviations and Deviation Reporting
- Key Correspondence/NTFs, as needed

When developing an ‘essential documents’ filing structure for MTN-042B, study sites are encouraged to consider their experiences implementing previous DAIDS network protocols. While taking into account these experiences, the structure should be tailored to meet the specific needs of MTN-042B and ensure that all required documents are properly filed. 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).
- Hard copies of the MTN-042B PTID Linkage Log must be maintained throughout the duration of the study. The suggested filing structure assumes that these logs will be stored in the data management area throughout the data abstraction period and not necessarily with the other essential documents. These documents must be stored securely with access limited to study staff to ensure patient confidentiality. Procedures for maintenance of the PTID Linkage Log must be addressed in each site’s MTN-042B Site Specific SOP.

2.2. Source Documentation and Patient Research Records

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. The DAIDS Source Doc SOP can be accessed on the MTN website: <http://www.mtnstopshiv.org/node/4537>.

It is assumed that MTN-042B Case Report Forms will be entered directly into the REDCap database, and that no PTID-specific paper CRFs or PTID binders will be maintained. However, should paper MTN-042B CRFs be used as a backup in the event electronic data capture is not accessible, completed forms should be stored securely in locked file cabinets with access limited to authorized study staff. Source documentation specifications, including back up procedures, must be outlined within each site’s MTN-042B Site Specific SOP.

Per section 2.3, Protocol Deviations will be reported using the paper MTN-042B Protocol Deviations Reporting Form. The final, signed copy must be stored with essential documents according to each site’s MTN-042B Site Specific SOP.

2.3. Protocol Deviations

Sites will follow requirements for reporting Protocol Deviations (PDs) as outlined in the DAIDS Policy on Source Documentation and the MTN MOP. DAIDS requires that all protocol deviations be documented in participant records, along with efforts made to correct and prevent similar deviations in the future. Note that the MTN MOP guidelines will be followed with the exception that paper-based PD reporting will be used for this protocol and oversight by the management team will be in real-time.

Reporting

All deviations from the protocol will be reported as soon as possible, but **no later than within 7 calendar days of site awareness**. Protocol Deviations will be reported in a paper-based system using the MTN-042B Protocol Deviation Reporting Form (available on the MTN-042B website under Study Implementation Materials). A draft of this form should be

submitted to and approved by the MTN-042B management team (mtn042b-mgmt@mtnstopshiv.org) prior to finalization and sign-off of the form by the IoR/designee.

Deviations that require reporting for MTN-042B include (but are not limited to) non-compliance with the MTN-042B protocol that results in breach of confidentiality, mishandling study data, conduct of a non-protocol procedure, staff performing procedures they are not qualified/delegated to perform, or use of non-IRB approved study materials. Note that missing data is expected given the nature of this chart abstraction study and therefore will not be considered a reportable PD. If there is a question about whether something is a PD, sites should contact the study management team, mtn042b-mgmt@mtnstopshiv.org, who will consult with MTN Regulatory mtnregulatory@mtnstopshiv.org as needed. 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.

Final signed, dated and certified PD forms should be kept among sites’ MTN-042B study essential documents. Final PD forms should be certified as per the MTN Good Documentation Policy (GDP) outlined in the MTN MOP. Only staff delegated the responsibility of reporting protocol deviations per the site’s MTN-042B DoD log should sign off on finalized PD forms. The final certified copy should also be scanned and emailed to the MTN-042B management team (mtn042-Bmgmt@mtnstopshiv.org).

Oversight

The MTN-042B management team will review all reported PDs in real time throughout study implementation as draft forms are submitted. If further information is required regarding any deviation or proposed corrective and preventative action, the MTN-042B management team will request this during review of the draft form. As needed, PDs may be discussed on management team calls and a summary of the discussion will be included in the minutes for the call.

2.4. Patient Confidentiality

MTN-042B is a multi-site, chart review, cross-sectional study. Study staff will have no interaction with women who have given birth and will not engage in direct conversations about the patient with health care providers. Interactions with hospital/clinic staff for logistical purposes of identification of charts or access to charts is permitted. Each patient record abstracted will be assigned a study patient identification number (PTID). No patient names will be recorded and only information that directly relates to the outcomes of interest (pregnancy outcomes and specific complications) will be collected. Given the nature of the study, each site that participates in MTN-042B will seek a waiver of informed consent from their IRB/EC. In the event this waiver is not granted, guidance from the IRB/EC regarding informed consent should be followed.

For the purposes of tracking and to ensure that records are not abstracted multiple times, a master log linking the study PTID to a facility or site assigned patient identifier, such as

medical record number, will be maintained by the site and kept in a secure location (e.g. locked cabinet/drawer) per site SOP. One PTID linkage log per facility will be provided to sites by the SDMC and maintained in hard copy for the duration of data collection activities (see SSP section 3.2 for further information regarding completion of the PTID linkage log).

Data will be abstracted from medical records and entered directly into REDCap using password-protected tablets. Tablets will be kept securely by study staff during abstraction activities and stored with access limited to authorized study staff only as specified in site SOPs. Study PTIDs will be used for all data collection and no patient identifiers (e.g. medical record numbers) will be collected in the study database.

Should paper records be generated during data abstraction (i.e. back-up system in the event tablets are not functioning), paper documents will bear only a study PTID to maximize patient confidentiality. Any paper records must be maintained securely per site SOPs. No copies of medical records will be maintained in study files.

Study records and/or equipment should not be left unattended or be otherwise accessible to unauthorized persons. Members of the study staff must have documented training in patient confidentiality (HSP/GCP) and well as study-specific training prior to conducting any study activities.

2.5. Record Retention Requirements

MTN-042B 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) and for at least seven years after final reporting or publication of the study's primary results per MTN policies. No MTN-042B 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.