Purpose

To define study implementation procedures, including data management, for MTN-042B.

Scope

This procedure applies to all site staff involved in study implementation procedures, including protocol deviation reporting, assigning PTIDs, and data collection and/or data management for MTN-042B.

Responsibilities

All site staff members delegated by the Investigator of Record (IoR) to report protocol deviations, assign PTIDs, or collect, record, enter, and/or review MTN-042B study data are responsible for understanding and following this SOP.

The [*site to insert appropriate staff job title*] is responsible for training study staff to collect and manage study data in accordance with this SOP and for day-to-day oversight of staff involved in data collection, data entry, quality control activities, and data management.

The MTN-042B study IoRhas ultimate responsibility for the quality of MTN-042B study data and for ensuring that all applicable staff members follow this SOP.

Procedures

1. **Healthcare Facilities Identified for MTN-042B**
   1. The following healthcare facilities have been identified for data abstraction activities for MTN-042B:
      1. *[Sites to Insert Facility Name #1 and Contact Information]*
      2. *[Sites to Insert Facility Name #2 and Contact Information]*
   2. Communication with Healthcare Facilities
      1. *[Sites to describe any established agreements for partnership with identified facilities for MTN-042B data abstraction activities, e.g. memorandum of understanding (MoU). Documentation can be referenced or attached to this SOP, as needed.]*
      2. *[Sites to outline procedures for ongoing communication with healthcare facilities for duration of data abstraction activities.]*
   3. Access to Facility Space, WiFi, and Patient Records
      1. Facility #1 *[enter institution name]*
         * + *[Sites to describe physical space where staff will conduct data abstraction activities and procedures for accessing patient records]*
           + *[Sites to describe if/how they will have access to facility-provided WiFi, or if alternative internet access (e.g. through use of WiFi dongles) will be used]*
           + *[Sites to describe procedures for identifying and accessing patient records to include in review and procedures for chart review tracking (i.e. use of stickers or other system to determine records reviewed/requiring review—note: may reference PTID assignment section below). Ideally, chart abstraction should occur soon after delivery (i.e. within one day) and before patient discharge to minimize missing data and avoid sampling bias. Acknowledging this may not always be possible, sites to outline facility-specific approaches and back up plans for abstraction of charts. This section should also address plans for deliveries that occur over the weekend.]*
      2. Facility #2 *[enter institution name]*
         * + *[Elements as outlined above to be described for facility #2]*
2. **Study Patient Identification Number (PTID) Assignment** 
   1. SCHARP will provide facility-specific PTID linkage logs pre-populated with lists of study-assigned maternal Patient IDs (PTIDs). Members of the research team will go to the participating facility and review birth registries, delivery and/or postpartum admission log entries since the last data abstraction. Each patient identified will be assigned a study PTID. The PTID linkage log instructions on the cover page of the log should be followed when completing the log.
   2. Staff delegated to PTID Assignment per the MTN-042B DoD Log are responsible for following all outlined instructions for PTID assignment, maintenance, and proper storage of the log.
   3. *[Sites to modify as needed:]* The linkage log linking PTIDs to patient medical record numbers will be maintained in paper and stored securely during non-working hours in locking cabinets in areas with access limited to authorized study staff. During working hours and transport to/from the health facilities, study staff should keep PTID logs securely in their possession such that unauthorized individuals do not have access to the logs, and to avoid loss.
3. **Site Data Entry – Research Electronic Data Capture (REDCap)**
   1. Site staff will enter study data electronically into the REDCap study database as specified in the Data Collection section of the MTN-042B SSP Manual and CRF Completion Guidelines. Designated site staff are granted access with specific user permissions to the study database.
      1. The *[sites to insert role, e.g. data manager or study coordinator]* is responsible for REDCap database account maintenance, including requesting initial user accounts and permissions, permission updates, and account deactivations.
      2. Staff delegated to data collection per the MTN-042B DoD Log are responsible for following all study guidance documents related to data entry (paper or electronic), quality control, and freezing study records.
   2. In the event that the study database cannot be accessed (e.g., due to a temporary internet outage, URL issues, or other unforeseen circumstances), a paper CRF will be completed and will serve as source in lieu of eCRF completion via direct data entry as a temporary solution until access to the study eCRF is restored. Once access is restored, data from these paper CRFs should be entered into the REDCap study database per the MTN-042B SSP Manual and Section 4.1 of this SOP.
4. **Patient Study Files** 
   1. Paper CRF
      1. Prior to study start, SCHARP will provide sites with a .pdf file containing the blank MTN-042B CRF for on-site printing and data collection in the rare event that the REDCap study database becomes unavailable due to internet outages or technical difficulties at the study site. The use of paper CRFs will be avoided or minimized, to the extent possible.
      2. In the rare cases that paper CRFs are used, completed forms will be stored securely in locked file cabinets with access limited to authorized study staff. Patient binders will not be used; instead, paper CRFs will be stored*[sites to specify where completed forms will be stored, e.g. in a centralized filing location/binder with other MTN-042B study essential documents]*. CRFs will be entered into the REDCap database when internet is restored, as detailed in Section 3 of the MTN-042B SSP Manual.
      3. *[Sites to insert details on how they will keep track of paper CRFs requiring entry into REDCap, in what timeframe this entry will occur, and system for tracking completion of this task. Sites are encouraged to consider filing systems that support tracking and organization of paper CRF entry – for example, paper CRFs requiring entry are stored in a certain binder/location until they have been entered and QCed, then moved to long term storage locations as indicated above.]*
   2. Protocol Deviation (PD) Form and Reporting
      1. Protocol Deviations will be reported in a paper-based system using the MTN-042B Protocol Deviation Reporting Form. Final signed and dated protocol deviation forms will be kept with the site’s MTN-042B study essential documents *[sites to specify further as needed regarding filing locations/plans].*
      2. Only staff delegated to report protocol deviations per the MTN-042B DoD Log should sign off on final PD Forms. See the MTN-042B SSP Manual for further information on reporting PDs for MTN-042B.
      3. *[Sites to insert local IRB policies for reporting PDs, including type of PDs that require reporting and frequency of reports (e.g. with annual IRB renewal). Can also refer to IRB Communication SOP if PD reporting procedures are summarized adequately in the IRB Communication SOP.]*
5. **Confidentiality and Data Storage**
   1. Study files and the PTID Linkage log will be stored as described above. Health information will only be captured by study PTID. No names, government issued numbers, or other identifiable information will be recorded into the REDCap database.
   2. *[Sites to describe how staff will ensure control of patient records and protection of patient confidentially during abstraction activities. As needed, include facility specific considerations.]*
   3. Security of Study Tablets: *[Sites to specify where tablets will be stored, who has access, and what procedures are in place to ensure they are not lost or stolen during transport or data collection activities]*
   4. All MTN-042B study data will be stored securely as described in this SOP. All patient study files (paper) will be stored on-site and retained after the study per the specifications listed in the study protocol.
6. **Site Data Quality Control (Data QC)**
   1. All records will undergo QC Review Step #1 and a subset of records will require QC Review Step #2. Records requiring QC Review Step #2 will be selected to represent approximately 10% of all charts reviewed, with no more than 5 charts requiring QC#2 each day. Charts requiring QC#2 review will be pre-selected on the PTID Linkage Log as every 10th PTID. If/when 5 PTIDs have been flagged for QC#2 for the day, sites may indicate “N/A” on the PTID Linkage Log to indicate the daily required QC targets have been met.
   2. Initial Review (QC Review Step #1, i.e. self QC)
      1. After entering data into the REDCap eCRF (or on the paper CRF), the person who entered the data will review the form to ensure data are complete and accurate. Any corrections should be made in real time. The “Form Status” item in REDCap will be used to track the status of each record:
      * If the data is incomplete and the data abstractor needs to review the chart again at a later date, the data abstractor will set the Form Status field to “Incomplete” (indicated by a red icon).
      * If the data is complete, and the PTID was not designated as requiring QC#2, the Form Status field will be set to “Complete” (indicated by a green icon).
      * If the data is complete and the PTID requires QC Review Step #2, the Form Status field will be set to “Unverified” (indicated by a yellow icon).
   3. Second Reviews (QC Review Step #2)
      1. Abstractors will flag records requiring QC#2 review by setting the form status item in REDCap to “Unverified”. *[Sites to modify the following to reflect site specific procedures for accomplishing QC#2 review:]* QC#2 will occur [*in real-time OR at the end of each day]* by a second staff member who has been delegated QC responsibilities on the MTN-042B DoD log. If QC#2 cannot be completed on the same day the original abstraction is completed, it will be done the following day. Weekly reviews will occur to identify any records marked as ‘unverified’ that are pending QC#2 review.
      2. QC Review Step #2 should be done by someone other than the person who originally completed the eCRF. The person performing QC Review Step #2 can be another site staff member knowledgeable about the study and familiar with study documentation requirements and delegated QC responsibilities on the MTN-042B DoD Log.
   4. Site Data Quality Control – Responsibilities
      1. The table below describes the site-specific QC Review Step #1 and QC Review Step #2 as they pertain to review of REDCap eCRF data. As listed below, each step may vary, depending on whether or not the paper CRF is used.

| **Responsibility** | **QC Review Step #1** | **QC Review Step #2** |
| --- | --- | --- |
| Data directly entered into the REDCap study database (i.e., eCRF is source) | The staff member entering the data:   * Checks the eCRF for completeness and accuracy based on information available in the patient chart. * Completes the “Form Status” item | If record was not identified as requiring QC #2, not applicable.  If record was identified as requiring QC #2 (Form Status=Unverified), the staff member performing QC #2:   1. Compares data entered on eCRF with patient chart 2. *[Sites to outline process for follow-up on any QC trends/issues – for example, this could be a real time discussion with original abstractor, and/or sites could choose to enter/track discrepancies on a QC#2 log]* 3. After consultation and agreement with original abstractor, makes updates, as needed, to eCRF 4. Updates the “Form Status” item 5. Indicates that QC#2 was completed by initialing and dating the QC2 columns on the PTID Linkage Log |
| BACK-UP DATA COLLECTION:  Data entered from paper CRF (if applicable) | The staff member completing the paper CRF:   * Checks the paper CRF for completeness and accuracy based on patient chart * Using the paper CRF, transcribes data from the paper CRF to the eCRF * Checks the eCRF for completeness and accuracy based on the paper CRF * Completes the “Form Status” item | If record was not identified as requiring QC #2, not applicable.  If record was identified as requiring QC #2 (Form Status=Unverified), the staff member performing QC #2:   1. Compares data entered on eCRF to paper CRF and original patient chart 2. *[Sites to outline process for follow-up on any QC trends/issues – for example, this could be a real time discussion with original abstractor, and/or sites could choose to enter/track discrepancies on a QC#2 log]* 3. After consultation and agreement with original abstractor, makes updates, as needed, to eCRF and/or paper CRF. Updates on paper CRF must be initialed and dated. 4. Updates the “Form Status” item 5. Indicates that QC#2 was completed by initialing and dating the QC2 column on the PTID Linkage Log |

1. **Mobile Data Download and Upload**
   1. [The MTN-042B Study Management Team is still working out the details of this section and will provide template text for sites to adapt, when available]

**Abbreviations and Acronyms**

eCRF Electronic Case Report Form

EDC Electronic Data Capture

IoR Investigator of Record

QC Quality Control

PTID Patient ID

SCHARP Statistical Center for HIV/AIDS Research and Prevention

SDMC Statistical Data Management Center

SSP Study-Specific Procedures Manual

SOP Standard Operating Procedure

[*List others as needed*]

**Attachments**

[*List all relevant attached materials here*]

**Reference Materials**

MTN-042B Study Protocol MTN-042B SSP Manual

[*List other site SOPs and documents as applicable*]

**History**

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| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Replaces** | **Review Date** | Change |
| 1.0 | dd MMM yyyy | N/A | dd MMM yyyy | Initial Release |

Approval

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|  | Author, Author’s Title |  |  | Signature and Date |
|  |  |  |  |  |
|  | Approver’s Name, Approver’s Title |  |  | Signature and Date |