Purpose

To define data management and source documentation procedures for MTN-045. This SOP provides additional, site-specific details for how procedures outlined in the SSP will be operationalized.

Scope

This procedure applies to all site staff involved in data collection and/or data management for MTN-045 (per Responsibilities section below). Many procedures are already outlined in the SSP. MTN-045 study staff are responsible for following all procedures as outlined in the SSP, and procedures in this document are in addition to those in the SSP (not contradicting, repeating, or overlapping).

**Responsibilities**

1. *[MTN-045 staff members delegated by the Investigator of Record to collect, record, review, and/or transmit MTN-045 study data]* are responsible for understanding and following this SOP.
2. *[Insert job title of the staff member responsible for training on Data Management]* 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, quality control activities, and data management.
3. MTN-045 Investigator of Record has ultimate responsibility for ensuring that all applicable MTN-045 staff members follow this SOP and for the quality of the data.

**Procedures**

1. **Participant Study Files** *[Sections 2.3, 2.4 and 6.5 of the MTN-045 SSP outline the documents that will be considered “source” in MTN-045, considerations for storage, and record retention requirements. Site-specific source documents and procedures for filing, storage, or retention should be documented here. This could include considerations such as: additional documents that the site considers to be “source”, how contact attempts and referrals are recorded, any specific format or guidelines for visit note documentation, and specifics of using the visit checklists not already listed in the SSP.]*
   1. Source Data and Source Documentation
      * *[The table below should designate the specific source documentation for all visit procedures listed in the left-hand column. Documents in italics on the right are suggestions: please add/edit as necessary.]*

|  |  |
| --- | --- |
| **Procedure/Required documentation** | **Source Document** |
| Provision of written informed to consent | *ICF, IC Comprehension Checklist, IC Coversheet* |
| Documentation that participant met study’s eligibility criteria | *Eligibility Checklist, Eligibility Confirmation* |
| Record of all contacts (attempted and successful) | *Contact log* |
| Record of all procedures performed by study staff during the study | *Visit notes, Visit checklists* |
| Record of all referrals made | *Visit notes, SH CRF,* |
| All data collection activities | *Paper CRFs (CO Tool, IPA).*  *Completion of eCRFs (DCEs, BDQ): documented on the weekly enrollment tracker.* |
| Documentation of any deviations from SOPs or other non-protocol study procedures | *Visit notes* |
| Notes taken during Couples Observation or In-Depth Interviews | *CO CRF, IDI Guide, Visit notes* |
| Documentation of In-Depth Interview content | *Audio recording (CD), Final English Transcript* |
| Termination from study | *PSF* |

* + - *[Include here any additional information about source data and documentation beyond that outlined in the SSP and above]*
  1. Participant file documentation
     + *[Include here any internal instructions or procedures about documentation processes used for participant files. If outlined in another SOP, reference to that SOP may be cited here.]*
  2. Confidential participant file contents
     + *[Section 2.34 of the MTN-045 SSP outlines the need for storing identifying information separately from study data. Please outline here where those storage locations will be, who will have access, security measures used to keep participant data and identities confidential, and who is responsible for maintaining document storage in such a way that maximizes protection of participant information.]*
  3. Participant data retention requirements
     + *[The MTN-045 SSP contains study-wide requirements for data retention, described in section 2.4, and specific information about audio file retention in 6.8. Please describe who is responsible for ensuring these are adhered to, any additional site-specific data retention requirements, and how any decisions or key actions about data retention will be documented and communicated.]*

1. **Storage**
   1. Management team correspondence
      * *[MTN-045 SSP Section 6.17 specifies that “A record of all correspondence with decisions from the MTN-045 Management Team should be saved and stored in the sites’ Essential Documents file, as outlined in the Data Management SOP.” Please describe who will be responsible for storing management team correspondence, and where it will be stored.]*
   2. Tablets: charging, storage, and security
      * *[Provide details as to where the 5 study tablets will be stored when not in use, security measures, and procedures for ensuring tablets have sufficient charge for each study visit that occurs (who is responsible, when/where will it be done).]*
   3. Paper forms and files
      * Storage *[Form and Guide Supply is briefly described in SSP Section 6.3. Please include here any additional information about who is responsible for maintaining a proper supply of blank, printed forms, where they will be stored, and how they will be accessed by site staff conducting MTN-045 visits)*
      * Archiving prior versions of forms *[SSP Section 6.3 also requires that “One copy of previous versions of CRFs and guides should be maintained in an archive, and all other copies destroyed.” Please mention who will be responsible for the process of archiving the single previous version, destroying additional previous copies, and where this archived prior version will be stored.]*
   4. Record Retention Requirements for records other than participant data
      * *[Please outline any considerations, roles, responsibilities, or procedures for retention of study documentation (not participant data, as that should be outlined above in DM SOP Section 1.4).]*
2. **PTID Assignment**
   1. Tracking
      * *[As outlined in MTN-045 SSP Section 3.6, participant IDs will be documented on the PTID/Name Link Log. These will also be documented on the Screening & Enrollment Log and then Weekly Tracker for purposes of tracking accrual. Please document specifics as to how the team will ensure correct assignment of PTIDs during the screening portion of the visit and any QC procedures to be used to ensure the correct PTID is assigned before proceeding with the visit.]*
   2. Responsibilities
      * *[If not included above, please describe who will be responsible for assigning PTIDs, who will be responsible for storing the PTID/Name Link Log in a secure location, and who will be responsible for ensuring that correct PTIDs have been assigned before proceeding with the visit.]*
3. **Quality Control (General)**
   1. Internal
      * Prior to participant leaving the study site: *[SSP section 6.8 outlines a “QC Review Step #1” process that is to be conducted before the participant leaves the site. Please outline any additional information about how this will be done or who will be responsible for conducting this process.]*
      * Same day as study visit, once visit has ended: *[Describe any additional internal quality control procedures that the site may conduct once the participants have finished their visit.]*
      * QC Review #2: *[Before paper CRFs are double data entered by site staff and before debrief reports are uploaded to the SFTP site, a second QC review (QC Review #2) should occur, as described in SSP section 6.8. Please outline any additional information about how this will be done or who will be responsible for conducting the QC#2 process.]*
      * Timing: *[Provide information about expectations and timeline, particularly with respect to “QC Review Step #2” as outlined in SSP section 6.8.]*
      * Responsibilities *[Provide any additional information about roles and responsibilities in the internal QC process, if not described above.]*
   2. External
      * Timing: *[SSP section 6.10 specifies that queries on REDCap data received from RTI should be addressed within 1 week. During that week at the site, what will the process be?]*
      * Responsibilities: *[Who will be responsible for managing the responses to the external QC process, and who will be responsible for addressing the queries with corrections to the REDCap data?]*
4. **eCRF Data Collection Procedures** *[See section 6.1.1 of MTN-045 SSP for relevant procedures already outlined]*
   1. Before and during study visit
      * Ensuring tablet readiness: *[Describe process for retrieving tablets from storage, ensuring they are sufficiently charged and Wi-Fi access is functional.]*
      * During data collection: *[Describe how staff will determine whether or not participant is able to self-administer portions of the individual DCE. If any technical difficulties are encountered (error messages, Wi-Fi connectivity issues, tablet system issues), describe how staff will proceed.]*
   2. After study visit
      * *[SSP Section 6.1.1 specifies that “Each site’s study coordinator or designee will log eCRFs (by PTID) that are completed on tablet computers each day. This will be logged in an Excel document (“Enrolled” tab of the Screening and Enrollment Tracker), saved with the current date in the filename each time it is updated, and sent weekly on a Friday (or other date as specified in the SOP) to the RTI data management team (*[*MTN045datamgmt@mtnstopshiv.org)*](mailto:MTN045datamgmt@mtnstopshiv.org))*.” Describe how the study coordinator/designee will be made aware of which eCRFs were completed that day and any other details about updating the Screening and Enrollment Tracker.]*
   3. Weekly tracking
      * *[Who will be responsible for sending the weekly tracker to the above email address, and on which day of the week it will be sent.]*
   4. eCRF specific QC
      * *[Who will be responsible for checking the Qualtrics online real-time report to confirm receipt of completed eCRFs? Where will this be documented.]*
5. **Paper CRF Data Collection Procedures**
   1. During study visit
      * *[Any additional procedures for paper CRF completion beyond what is described in SSP section 6.1.2 and appendix 6-6 should be detailed here. The SSP states that a primary individual will be responsible for each paper CRF, though other staff may fill in information and initial those additions. How will the primary responsible individual be decided?]*
   2. After study visit
      * Paper form QC: *[Include any additional procedures here that are not described above in section 4.1 of this SOP template.]*
   3. REDCap Data Entry
      * REDCap QC (double data entry and reconciliation): *[Describe where it will be documented, who is Data Entry 1 and who is Data Entry 2. How will the first enterer know when there are paper CRFs ready for them to enter? When they are done, how will they notify the second enterer that they are ready? (TBD whether reconciliation will be done on-site or at RTI.) Once queries are received from the data reconciliation process or the RTI QC process, how will they be communicated to the data entry team?]*
   4. Responsibilities
      * *[If not outlined above, who are the responsible parties, and where will this be documented?* *Indicate who is responsible for REDCap database account maintenance, including requesting initial user accounts and permissions, permission updates, and account deactivations.]*
   5. Timing
      * *[If not outlined above, what will the process be to ensure that double-data entry happens within a timely manner and reconciliation/RTI QCs are responded to promptly?]*
6. **Qualitative data collection procedures**
   1. Selecting IDI participants
      * *[Describe the step-by-step procedure that staff members will follow to select IDI participants, and how this selection process will be documented. An option worksheet provided by RTI can be used in combination with other documentation procedures, or sites can propose another system.]*
   2. Preparing for IDIs
      * *[A brief description of general procedures to begin an IDI is listed in SSP section 6.2. Describe site-specific processes around what will be done to prepare for an IDI. Consider the different procedures that may be in place if the IDI is conducted on the same day as the DCE data collection, or if it is a different day. Also consider the different procedures you may use if the couple is to be interviewed together, if the couple is to be interviewed separately, or if only one member of the couple is to be interviewed.]*
   3. Conducting IDIs: *[Describe any site processes/procedures to be followed, regardless of whether the IDI will be with 1 member of a couple of both members of the couple together.]*
      * Individual: *[Describe any site processes/procedures to be followed unique to an IDI conducted with one member of the couple.]*
      * Joint: *[Describe any site processes/procedures to be followed unique to an IDI conducted with both members of the couple together.]*
   4. After IDIs
      * Documentation: *[Describe the procedures to be followed after an IDI is complete to ensure the audio recording functioned properly, flesh out notes as necessary, and document completion of the IDI on logs, trackers, and checklists as appropriate.]*
      * Debrief reports: *[Describe who is responsible for ensuring the debrief report is drafted within the specified 24-hour time period, and who will be notified that it is ready for internal QC.]*
   5. Transcription and translation
      * *[Per SSP Section 6.8, “Following the IDI session, the audio file should be used to transcribe and translate the discussion per the process described in the Data Management SOP. All transcripts will be simultaneously translated (when conducted in a local language) and transcribed in English unless there are unique local language sayings that should be preserved.” Describe the process to be used to produce an English transcript ready for external QC within one month of completion of the IDI. How will the transcriber be notified that the audio file is ready for transcription? When will the initial transcript be completed to allow for internal review before transmitting to RTI?]*
   6. Transmission: *[Who will be responsible for uploading DRs (within 1 week) and Transcripts (within 1 month) to the SFTP when they are ready for external QC? How will they know when these are ready to be transmitted? Who will be responsible for ensuring this step occurs within the required time frame after the IDI occurs?]*
   7. Qualitative specific QC *[Qualitative QC procedures and process are outlined in the SSP in sections 6.8 (initial drafts of DR and transcript), 6.9 (internal transcript QC process), 6.11 (external DR QC process), 6.12 (external transcript QC process), and appendix 6-5 (general QC conventions).*
      * *[Provide additional information about the processes at site for internal QC of a DR before it is transmitted to RTI, and processes for addressing queries once received from RTI.]*
      * *[Provide additional information about the processes at site for internal QC of a transcript before it is transmitted to RTI, and processes for addressing queries once received from RTI.]*

**List of Abbreviations and Acronyms**

**Attachments**

**References**

MTN-045 SSP Manual Section …

MTN-045 SSP Manual Section …

Site SOP for …

[List any additional as needed]

**History**

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| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Supersedes** | **Review Date** | Change |
| 1.0 | *Xx Mon YR* | NA | *Xx Mon YR* | Initial Release |

Approval

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|  | Reviewer, Reviewer’s Title |  |  | Date |