### Purpose

To define procedures for implementation of the qualitative component of MTN-042.

### Scope

These procedures apply to all staff involved in the qualitative research-related study activities for MTN-042 (per responsibilities section below). Many procedures are already outlined in the Qualitative SSP. MTN-042 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

MTN-042 Investigator of Record has ultimate responsibility for ensuring that all applicable MTN-042 staff members follow this SOP.

MTN-042 [Study Coordinator or title of designee responsible for training on qualitative study components] is responsible for training study staff to conduct qualitative research-related study activities for MTN-042 in accordance with this SOP, and for day-to-day oversight of staff involved in qualitative visit scheduling, documentation, and procedures.

MTN-042 [staff members delegated by the IOR to collect, record, review, and/or transmit MTN-042 qualitative study data] to perform qualitative research-related study activities for MTN-042 are responsible for understanding and following this SOP.

### Procedures

MTN-042 SSP Section 14 specifies study requirements for qualitative research-related study activities. All staff responsible for conducting qualitative research-related study activities are required to read and understand the SSP section. This SOP supplements the SSP section, outlining site-specific procedures where applicable.

#### Documentation

[This section should designate documentation for qualitative visit procedures in a table below (or include as appendix). Review and modify the suggested documents currently listed in the table to reflect documents that will be used by your site.]

|  |  |
| --- | --- |
| **Procedure/Required Documentation** | **Document** |
| Documentation that the participant was selected to receive an IDI | Randomly-selected participants:  Qualitative Sampling List  Qualitative Participation Log (QPL)  Special case IDI participants: Email confirmation from QMT approving nomination  Special Case Qualitative Participation Log (SCQPL) |
| Documentation that the participant met the eligibility criteria to participate in the IDI | Qualitative Visit Checklist |
| Documentation of the outcome of IDI (whether it occurred, reason why it did not occur) | Qualitative Participation Log (QPL)  Chart Notes  Email notification from IoR for any randomized participants not invited per IOR discretion |
| A record of all contacts, and attempted contacts, with the participant | Chart Notes, Site-Specific Contact Log |
| A record of all qualitative research-related data that were captured during the conduct of the study | Interviewer notes  Final debrief reports  Final transcripts  Audio CDs |
| Documentation of referrals made (including for social harms, adverse events, or protocol deviations reported) as a result of information gathered during interviews | Chart Notes  Debrief reports |
| Documentation of reason for any deviation required from procedures outlined in the site Qualitative SOP | Chart Notes  Protocol Deviation form (if applicable) |

#### Qualitative Participant Accrual

[Outline responsibilities for maintenance and tracking all qualitative participants on the QPL and transmission of the updated QPL to the Qualitative Management Team (QMT) on a regular basis (e.g. weekly for cohort 1, fortnightly for cohorts 2-4). Responsibilities and approval procedures for purposive selection of interesting cases for special case IDIs should be described. Describe procedures for verifying participant eligibility to participate in the qualitative component.]

#### Flagging, Scheduling and Reminder Methods for IDIs

[This section is to outline the site’s procedures for flagging files/records for those selected for IDI, contacting the participant and scheduling the time and location of the qualitative visit, including the staff responsible for each task and communication to other key staff regarding the qualitative visit. Procedures to confirm eligibility (in particular the product use requirement), Visit reminder methods and procedures in the event of a missed visit should be specified (referenced to Retention SOP can be used as applicable).]

#### Confirmation of Identity and Agreement to Participate in IDI

[This section is to specify procedures and responsibilities for confirming participants’ identities (alternatively, reference to co-enrollment or other applicable SOPs can be included) and agreement to participate in the qualitative component prior to conduct of the IDI. Outline review and documentation of procedures either in chart notes, checklist, or other site specific document.]

#### Qualitative Training

[This section is to describe site specific procedures leading up to MTN-042 qualitative training, including:

* Which staff members will receive qualitative training
* Procedures that need to take place prior to qualitative data collection:
  + Review and signoff of Qualitative SOP and SSP Section 14
  + Procedure for conducting mock IDIs and those responsible for reviewing interviewers’ mock IDIs, as well as notifying OMT of interviewer approval or steps for corrective action if not approved]

#### Interview procedures

[This section should describe site specific procedures for conducting the interview, including:

* How and when participants’ IDIs will be scheduled, including how and when participants will be reminded of their IDI at least one day in advance
* Who will prepare for the interview
* Where interviews will be conducted
* Preparation of documents and materials for interviews, including ensuring audio recording devices are charged/working
* Procedures for conducting the interview (that are not addressed in the SSP)
* Procedures for expanding notes and compiling the debrief reports

#### Potential Social Harm (SH), Adverse Event (AE), and Protocol Deviation (PD) Reporting

[If any potential SHs, AEs or PDs are reported by participant during qualitative interviews, interview staff should refer participants to MTN-042 clinic/counseling staff as soon as possible and not more than 24 hours later to document and handle the SH, AE, or PD. The site specific procedure for referring and documenting these occurrences should be outlined in this section.]

The interviewer will be responsible for recording potential SHs, AEs or PDs in the debrief report, including actions that were taken for referrals, if applicable.

#### Qualitative Data Management

[This section should cover the following elements:

* Data back-up, translation-transcription procedures, internal review/quality control for translation-transcriptions, and transmission procedures. This section should also include timeframes and mechanisms for tracking when documents have been completed, internally reviewed and transmitted to RTI. The first three transcripts should be read in full and compared to the audio file by someone other than the transcriptionist fluent in the local language. All other transcripts and should be spot-checked with audio file for accuracy. Document procedures for corrective action if translation-transcription is not found adequate.
* Procedures and timeline for resolving data quality control notes (i.e. QC queries) from RTI on both debrief reports and transcripts.
* Storage locations for IDI guides and description of systems for version control and archiving previous versions of guides (when/if applicable)
* Storage locations for all documents, audio CDs, and other materials resulting from qualitative activities. Include what will be stored in individual participant files for qualitative component participants.
* Confidentiality protections, including the procedures for redacting/omitting protected health information (PHI) and personally identifiable information (PII) from transcripts and debrief reports.
* Procedure for logging file name and location of audio files on computer hard drive
* Other ethical and human subjects considerations
* Certification procedures for final paper copies of transcripts and audio CDs in accordance with MTN MOP certified source documentation
* Procedure for ensuring destruction of logged audio files when instructed to do so by RTI
* Staff responsibilities for all of the above (direct and supervisory)
* Quality control (QC) and quality assurance (QA) procedures (e.g. transcript-audio full reviews and continuous spot-checks) related to all of the above (if not specified elsewhere)

#### Attachments

Attachment X: [Insert as applicable]

#### References

SOP-MTN-042-XXX-XX, Obtaining Informed Consent for MTN-042

SOP-MTN-042-XXX-XX, Participant Retention Procedures for MTN-042

MTN-042 SSP Section 14

[Insert additional as applicable]

#### History

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Version | Effective Date | Supersedes | Review Date | Change |
| *1.0* | *DD MON YYYY* | NA | *DD MON YYYY* | Initial Release |

#### Approval

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