Section 18. ASPIRE Qualitative Component

This section describes study-specific procedures for the ASPIRE qualitative component. This component will be conducted at the Emavundleni, WRHI, Isipingo, Spilhaus, Kampala, and Lilongwe sites. These sites must maintain this section of the Study-Specific Procedures (SSP) Manual in its entirety. All other ASPIRE sites not participating in the qualitative component are not required to maintain this section of the manual. For clarity of documentation, however, all sites should maintain a reference copy of Version 1.0 of this page (18-1), dated 11 December 2012, in their SSP manuals.

Table of Contents

18.1 Introduction

This section specifies the sources of procedural information available to ASPIRE qualitative staff, the responsibilities of ASPIRE Investigators of Record (IoRs), and the process by which each study site is approved to begin implementation of the ASPIRE qualitative component.

Study implementation questions regarding the qualitative component that are not answered by the protocol or this manual should be directed to the MTN-020 Qualitative Management Team (QMT). This group consists of representatives of the MTN Coordinating and Operations Center (CORE-FHI 360), RTI International (which acts as the qualitative data center), and the Protocol Chairs. This group can be reached using the following email address: mtn020qmt@mtnstopshiv.org

There is not a separate activation process for the qualitative component of ASPIRE. However, prior to undertaking any study procedures, each site must receive notification of completion of all items on the ASPIRE Qualitative Component Readiness Checklist from FHI 360. Note that the qualitative component of ASPIRE was added as part of Letter of Amendment #2 (LoA#2); as such, no qualitative interviews should be conducted prior to receiving full regulatory approval of this amendment.

18.2 Documentation Requirements

Essential documents pertaining to the qualitative component, e.g. IRB correspondence, should be filed in accordance with site specific procedures for other ASPIRE Essential Documents. Study sites must maintain adequate and accurate participant file records containing all information pertinent to participation in the ASPIRE qualitative component, for each study participant.

18.2.1 Participant File Contents

In addition to the file elements outlined in Section 3, files for those participating in the qualitative component should contain:

- Documentation that the participant met the eligibility criteria to participate in the selected qualitative interview.
- Documentation that the participant provided written consent to participate in the qualitative component prior to the conduct of any study procedures.
  Note: At some sites there is a separate ICF for the qualitative component, and at other sites, informed consent for participation is contained within the ASPIRE enrollment informed consent form.
- A record of the participant's randomly pre-selected assignment, or purposive selection, to receive either single in-depth interview (IDI), serial IDIs or to participate in a focus group discussion (FGD). For purposive selection, documentation of approval from the QMT should be filed.
- If applicable: documentation of changes to assigned interview modality due to operational challenges or study design changes (and approval from the QMT).
- A record of all contacts, and attempted contacts, with the participant.
- A record of all qualitative research-related activities and interview transcripts that take place during the conduct of the study.

    - Notes recorded on interview guides, separate sheets, and/or additional materials used (e.g. body map templates) for in-depth interviews (IDIs; either single or serial) are filed in the participant file; separate files can be created to store all FGD group information such as checklists, notes and participant lists.
- Referrals made (including for social harms or adverse events reported) as a result of information gathered during qualitative interviewing.
- Reason for any deviation required from procedures outlined in the site Qualitative Component SOP.

18.2.2 Source Documentation

For the qualitative component of ASPIRE, participant files contain the following source documents:

- **Qualitative IDI and FGD notes, associated tools and transcripts:** IDI and FGD notes, taken during qualitative data collection, including those made on associated tools (e.g. body mapping template), are source documents and must be kept in the participant file per the site Qualitative Component SOP. Final versions of transcriptions and translations of audio files (i.e. in local language and the final translated version), and final debrief reports are also considered to be source documentation and must be kept in the participant file.
- **Visit Checklists:** The *Study Implementation Materials* section of the MTN-020 website contains examples of convenient tools to fulfill the requirement of documenting all study activities that take place at each IDI or FGD with study participants. Checklists used for IDI, or the Individual FGD Participant checklist, should be filed with the participant files. A Group visit checklist used for each FGD should also be filed with the corresponding FGD notes, per the site Qualitative Component SOP. Every item in the left column of each checklist should be initialed or marked 'NA'. If the visit procedures deviate from what is outlined in the checklist, documentation of this should be in the comments section at the bottom of the checklist or in chart notes.
- **Chart notes:** Chart notes should be used to document contact attempts (unless other site-specific tools exist for this), as well as any other visit information not otherwise captured through other sources.

18.2.3 Record Retention Requirements

Please refer to Section 3.5 of this manual. The documents for ASPIRE qualitative component must be maintained (at least) for the same timeframe as those for the ASPIRE study. No documents may be destroyed without written permission from DAIDS.

18.3 Participant Accrual

This section provides information on requirements and procedures for approaching participants for participation in the qualitative component. Informed consent considerations are provided in Section 18.5.

18.3.1 Study Accrual Plan and Site-Specific Accrual Targets

Approximately 35-40 participants per site are targeted to be included in the qualitative component, prior to the conclusion of the ASPIRE trial (Table 18-1). This is anticipated to take place over a period of approximately 2 years (about 24 months) but will ultimately depend on the overall schedule of the ASPIRE trial.

Table 18-1. Summary of Target Sample Size and Interviews, by Data Collection Type

Type of Qualitative Data Collection	# of Women per Site	# of Interviews/FGD per Site
Serial IDI	~12-14*	24-42
Single IDI	≥3**	≥3
FGD	~20***	2
Total	**~35**	**~29 - 47**

*12 of these should be recruited based on the randomization list with the other 1-2 should be purposively selected

**Up to all who discontinue with consideration for data saturation and the total target number of enrollees

***The target number of FGDs per site takes precedence over the approximate number of women enrolled in FGDs. However, the minimum number should be 4 participants per FGD.

Accrual Order & Timing

The majority of participants who will complete serial IDIs or FGDs will be randomly pre-selected by SCHARP, and will be approached for participation around their Month 3 ASPIRE visit (for serial IDIs) or around PUEV (for FGDs). While twelve of the serial IDI participants will be randomly selected, one to two additional serial IDI participants may be purposively selected for participation by the site , with approval by the QMT. These participants may be chosen based on unique or interesting situations, experiences, or events which occur during their study participation. Site staff should email the QMT and include a summary and rationale for purposeful selection of these cases prior to the first interview. Emails documenting approval for serial IDI selection from the QMT should be printed and filed in the participant file. SCHARP will overselect by approximately 100% at each site to account for participants who do not meet eligibility criteria, are lost-to-follow-up, or refuse to participate.

Additionally, at each site a minimum of three participants who discontinue product use prematurely or choose to withdraw consent from the study will be selected to participate in a single IDI. Sites are permitted to enroll up to all participants who discontinue early; however, data saturation, as well as the need to remain with the total site accrual targets (i.e. ~35-40) should be taken into consideration. These participants will be systematically selected, over the duration of the trial, after the event (e.g. incident HIV-infection and/or permanent product discontinuation) has been confirmed by the site team, in consultation with the QMT. These participants will be approached to participate in a single IDI on or after the visit on which they discontinue product use, and always prior to their termination from the study. Ideally, approval from the QMT should be obtained prior to conduct of any single IDI. In cases where this is not possible (e.g. a participant is withdrawing from the study and the interview needs to be scheduled quickly), notification of the QMT can occur after the interview.

Randomization

The randomization scheme is based on a 1:2 allocation to serial IDI and FGD, respectively. Prior to the start of the qualitative component, group assignment (not selected, serial IDI, Exit FGD) will be designated by SCHARP for the initial ASPIRE participants allocated to the site on the Qualitative Participant Tracking and Randomization List (Q-PTRL).

A sample template of this list is pasted below in Table 18-2. The site is responsible for updating the ASPIRE PTIDs on this list regularly. Because pre-selection for participation in the qualitative component is linked to the enrollment (randomization) sequence number into ASPIRE, and determined prior to the start of the study, it is critical that the corresponding ASPIRE-PTID is accurately recorded in the proper sequence order after the ASPIRE study starts. This should be done by referencing the ASPIRE Clinic Randomization Tracking Record.

Table 18-2: Sample Qualitative Participant Tracking & Randomization List

Enrollment sequence in ASPIRE	ASPIRE PTID		ASPIRE Qualitative Randomization Assignment	ASPIRE Enrollment Date	ASPIRE Month 3 Target Date (dd-MMM-yy)	Staff Initials	Date
1	325-		Not selected				
2	325-		Serial IDI				
3	325-		Not selected				
4	325-		Exit FGD				
5	325-		Not selected				
6	325-		Not selected				
7	325-		Not selected				

18.3.2 Eligibility Criteria

Eligibility for the specific interview type to which a person participates is contingent upon meeting the criteria described below.

Able and willing to provide informed consent for the qualitative component, as well as meeting the following criteria within their assigned group:

- Serial IDI: Participants who are enrolled in ASPIRE, HIV-negative, and had ever used study product in the past 3 months (per Ring Collection and Insertion (RCI) CRF, item 6) at the time of her first interview.
- Single IDI after premature product discontinuation: Participants who are enrolled in ASPIRE and who seroconvert and/or *permanently* discontinue product use prematurely and/or *withdraw* from study participation. This does not include those who temporarily discontinue product use (e.g. for pregnancy or other reasons).
- FGD after PUEV: HIV-negative participants who are enrolled in ASPIRE, have completed their PUEV, and have ever used study products in the 3 months prior to PUEV (per RCI, item 6).

Additionally, participants may be excluded from any type of qualitative interviews if they have any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives

Note: For serial IDI and FGD participants, the most recent study HIV test results can be used to determine HIV-negative status. For example, if the first serial IDI interview is scheduled before her ASPIRE Month 3 visit, the HIV test results from Month 2 can be used for eligibility determination. If the first interview is done on/after ASPIRE Month 3 visit, the Month 3 HIV test results should be used.

18.3.3 Qualitative Component Participation Logs

Data about participation in the qualitative component will not be recorded on the site's ASPIRE Screening and Enrollment Log. However, it is necessary for sites to maintain a comprehensive record of all participants who are pre-selected, those who participate in the qualitative component, and reasons for non-participation. This should be recorded on the Qualitative Participation Log (QPL).

An entry in the QPL should be completed for each participant pre-selected or purposively identified by site staff to participate in the qualitative component. This log will include ASPIRE PTID, Interview Modality, whether participant was eligible, whether she agreed to participate, Interview 1 Date; Interview 2 Date (for serial IDIs); Interview 3 Date (for serial IDIs), Reason for refusal (if applicable).

Table 18-3: Sample Qualitative Component Participation Log (QPL)

ASPIRE PTID		I&D	Eligible or reason for ineligibility	Agreed to participate or reason for refusal	Interview 1 Date	I&D	Interview 2 Date	I&D	Interview 3 Date	I&D	Comments
SERIAL IDIs											
325-											
325-											
325-											
325-											
….											
SINGLE IDIs											
325-											
325-											
325-											
….											
FGD											
325-											
325-											
….											

18.3.4 Qualitative Component Progress Reports

Upon request by the QMT, sites should begin reporting the cumulative number of participants interviewed through the 15th of each month to the QMT, along with other key progress indicators. The person responsible for this report should be described in the site Qualitative Component SOP. The template for reporting these statistics is available on the ASPIRE website under *MTN-020 Qualitative.*

18.4 Informed Consent

Informed Consent for participation in the Qualitative Component follows the same guidelines and procedures as for ASPIRE. Please refer to Section 5 of this manual.

At some sites, consent for participation in the qualitative component is provided as part of the ASPIRE Enrollment consent process. For these sites, key elements of the qualitative informed consent should be reviewed with participants prior to the first interview, and willingness to continue should be confirmed. This review/confirmation can be documented on visit checklists (and chart notes as needed).

At other sites there is a separate informed consent for the qualitative component. At these sites, only participants selected for an interview (serial IDI, single IDI, or FGD) will be approached for informed consent for the qualitative component. This consent should be done

prior to the start of the interview for single IDIs and FGD, and prior to the start of the first interview for serial IDIs.

Additional guidelines for undertaking written informed consent for FGD participants follow.

18.4.1 Informed Consent Procedures for a Group Setting (FGD)

Note that this section is only relevant for sites with separate informed consent forms for the qualitative component. For FGDs the site may choose to administer the ICFs individually, or during the FGD (as a group process). Sites should outline any plans for group IC in their site Qualitative SOP.

18.5 Visit Procedures

This section provides information on requirements and procedures for single and serial IDIs and FGD in ASPIRE.

18.5.1 Visit Scheduling

Serial In-Depth Interviews (IDIs)

Participants preselected to participate in serial IDIs may have the first IDI conducted on the same day as the Month 3 visit for ASPIRE, or scheduled for a more convenient time close to the Month 3 visit. It is recommended that the first IDI be held within 14 days of the Month 3 visit. If the Month 3 ASPIRE visit is missed, the IDI should be conducted on or around the time of her next clinic visit. If the participant has still not been interviewed and her Month 4 visit window has closed, sites should seek QMT guidance on whether or not to interview these participants. The target time for the second IDI should be on or around the Month 12 ASPIRE visit. A third serial IDI may be conducted and scheduled around PUEV, provided that at least three months have passed since the second interview.

The schedule of serial interviews for participants purposively selected will be determined in collaboration with the QMT on a case-by-case basis (not to exceed three interviews).

Note that eligibility criteria outlined in section 18.3.2 must be met before proceeding with a participant's first serial interview. Generally, subsequent interviews (2^{nd}, 3^{rd}) may proceed even if the participant is on product hold or declining product; but the QMT may be consulted for guidance if unique circumstances arise. If a serial IDI participant is permanently discontinued from study product and/or chooses to withdraw consent from the study, guidelines in section 18.5.2 below should be followed.

It is recommended that, if possible, the same ASPIRE interviewer be used for all serial IDIs in order to encourage greater rapport with the participant. Prior to the scheduled interview, study staff should contact the participant to remind them of the visit. The process for doing this should be described in the site Qualitative Component SOP. Participants who miss scheduled IDIs may reschedule their visit.

Single IDI

Participants who discontinue product use early and are selected for a single IDI should be scheduled for an interview to occur around the time that study product discontinuation is confirmed or soon thereafter.

Participants who decide to withdraw consent from ASPIRE should be approached before the participant is terminated about willingness to participate in a single IDI. If the participant agrees, it should be documented clearly in the chart notes that the participant is withdrawing consent, but is agreeing to participate in one final interview and when this interview will occur. If the participant declines, this should be documented and she should not be pursued further. The interview itself must be completed prior to termination from the study.

Focus Group Discussion (FGD)

Participants randomized to one-time-only FGDs will have the FGD occur around their PUEV, ideally after completing their PUEV visit and always prior to their study exit visit. Each qualitative site is targeted to conduct a total of two FGDs. At or before their ASPIRE PUEV visits, qualitative staff should contact selected FGD participants to discuss scheduling options for the FGD. At sites with a separate consent form for qualitative participation, the informed consent process may be done at or before the PUEV visit, or on the day of the FGD, prior to the interview. The site Qualitative Component SOP should describe the process for identifying, communicating with, and scheduling participants preselected for FGD.

Participants who miss the FGD may join a later FGD if there is one scheduled in the participant's language. If a FGD is scheduled and not enough (i.e. less than four) participants present to the FGD, participants should be re-scheduled to complete the FGD on another date. To avoid a situation whereby there is low turnout for a group discussion, site staff should aim to invite 12-20 participants to ensure adequately sized groups turn up the day of the discussion. If the site experiences difficulty or is concerned about recruiting adequate numbers of participants for an FGD (e.g. there are insufficient numbers of pre-selected FGD participants who are still eligible at the time of PUEV), this should be immediately reported to the IoR and QMT. The QMT will provide guidance on a case-by-case basis to ensure target numbers for FGDs are met, which may include selection of additional participants for FGDs.

18.5.2 Participants who Permanently Discontinue Study Product or Withdraw Consent and are Randomized to Serial IDI or FGD

Participants randomized to serial IDI or FGD may choose to withdraw consent or may permanently discontinue study product use for clinical reasons at some point during the trial. If a participant randomized to serial IDI permanently discontinues product or withdraws consent *after participating in her first interview*, she will continue to be considered a serial IDI participant; however the next IDI should be the final serial IDI. Guidelines outlined in section 18.5.1 under the section "Single IDI" should be followed regarding timing and documentation of this final interview.

If a participant randomized to serial IDI or FGD permanently discontinues product or withdraws consent *prior to her first interview*, she may be selected for a single IDI.

18.5.3 Preparing for the Interview

Before each data collection visit (interview or focus group discussion) the following should occur:

- Ensure the correct version of the informed consent form is ready for use (at sites with a separate consent for qualitative interviewing only).

- Ensure the correct version of the guide and other supplemental tools (e.g. body map template, HIV prevention product formulation) are ready for use.
- Ensure the audio-recorder and interviewing space are ready.
- For second and third serial IDIs: review the debriefing report, notes and/ or transcripts from the previous IDI(s).
- Contact the participant(s) to remind them of the visit.

18.5.4 Data Collection Procedures

All interviewer-administered guides should be administered in the preferred language of the participant. This may be different than the language she provided informed consent in, as long as fluency is confirmed/documented in both languages (e.g. on the IC coversheet and/or chart notes). Any deviation from this should be documented in the participant chart notes. Visit checklists should be used to guide the order of procedures for each IDI and FGD.

To maintain neutrality and promote an open/free environment, interviewers should be independent from (i.e. not involved in) any study procedures that will be discussed during the IDI or FGD.

In-Depth Interview Procedures

The IDIs will be conducted in private meeting rooms that are quiet enough for audio-recording. The IDIs should be located in a confidential private location that allows for neutrality, which may be at the clinic, or another venue preferred by the participant. If requested or preferred by the participant, the IDI can be arranged at the participant's home, or at a different outside location if she has provided consent for off-site visits. If conducted at the clinic, it is recommended that use of exam rooms be avoided to allow for a more comfortable discussion space. Please refer to Section 18.4 for the informed consent procedures for IDI.

The IDI will follow an IDI guide, but will allow for iteration, probing and digression on relevant themes. The interviewer may start the discussion with an ice-breaker to increase rapport as well as understanding of the context of participants' lives (e.g. asking about her home life, work, activities, family, friends). IDIs will be audio-recorded and later transcribed and translated by site staff or outsourced to a transcription/ translation agency. Ideally a note-taker will be present to take notes during the session, but if only a facilitator is available, the IDI may still go on, and the facilitator will take brief notes as the interview is ongoing (these will be immediately expanded by the facilitator, after completing the IDI).

Immediately following each IDI, the facilitator should expand their notes and complete a debriefing report. At this time, comments should be documented on the body mapping template to describe all markings made during the interview.

Further description of the management of the audio-files, interview notes, body maps, debriefing reports, visit checklists and transcripts of the IDIs is described in Section 18.9.

Focus Group Discussion Procedures

FGD visits will take approximately 2-3 hours, including provision of informed consent (as needed) and conduct of the FGD discussion (which will take about one hour). The FGDs should be scheduled to ensure a common language is spoken by all participants and conducted in an appropriate meeting room that is conducive to the number of participants, privacy, and the need to audio-record the session. Please refer to Section 18.4 for the informed consent procedures for FGD.

The participant should choose a pseudonym and write it on a sticker placed on her chest or on a card to place in front of herself during the discussion. If the participant cannot write, study staff can do this for the participant. The pseudonyms, linked to PTID, should be documented on the FGD Group Participant Checklist and FGD Debriefing Report.

The facilitator should initiate the FGD by first explaining that the session will be audio-recorded and later transcribed and translated. Ground rules for conduct should be described. These include a review of confidentiality requirements (use pseudonyms, do not share information outside the FGD), etiquette (do not interrupt or disrespect others opinions, turn off cell phones), and operational issues (no right or wrong answers, speak one-at-a-time, state your pseudonym before you speak).

The facilitator should then start the audio-recorder and begin the session. The facilitator may start with an ice breaker. The ice-breaker should be any light topic of interest to the participants (current events, weather, sports, favorite color, favorite dish, etc.) and not one that is controversial, too sensitive or related to the study topic as it may negatively affect the rest of the discussion. After the ice breaker the discussion should follow the FGD guide. FGD guides are structured, but will allow opportunity for probing and exploration of spontaneously generated themes. Participants should be encouraged to state their pseudonym prior to making any comments. This will ensure accurate attribution of statements during the transcription process.

The note-taker should take notes during the session as a back-up to the audio-recording, and to record non-verbal information. A FGD Group Participant Checklist should be completed to link participant pseudonyms to PTIDs, capture the version number of the guide used, procedures completed, the date, and staff initials. This group checklist should be stored with the FGD notes/transcript/translation. Additionally, an Individual FGD checklist should be completed for each participant to document eligibility for participation in the FGD. This individual checklist will be filed in each participant file.

Immediately following each FGD the facilitator and note-takers should expand their notes and complete a FGD debriefing report. The debriefing report will request some basic statistics about the session (i.e. duration, mood of interview, number of participants, people present, etc.) as well as a summary notes related to questions in the guide. This information and any other comments by the note-taker and facilitator should be hand-written and later typed into the debriefing report template. Each debriefing report should thus represent a summary and extraction of the full data that can be used in "real-time" to inform the entire QMT. This will allow access to pertinent findings while the data goes through the longer process of QA, coding and more formal qualitative analysis.

Further description of the management of the audio-files, interview notes, debriefing reports, visit checklists and transcripts of the FGDs is described in Section 18.9.

18.5.5 IDI and Qualitative Interview Techniques*

- **Maintain Confidentiality.** Respect confidentiality at all times. Be careful not to comment to other family members or neighbors about anything that you learned

* The Qualitative Interview Techniques section is adapted from the following reference: Mack, Natasha, Cynthia Woodsong, Kathleen MacQueen, Greg Guest and Emily Namey. Qualitative Research Methods: A Data Collector's Field Guide. RTP, NC: Family Health International, 2005.

during the interview. This is especially important when interviewing participants about their sexual behaviors and intimate relationships.

- **Remaining Neutral.** It is especially important to be on guard against asking leading questions and influencing responses. Leading questions are those that imply a value judgment on your part. This can bias the responses that you will obtain because if the participant disagrees with you, they may be reluctant to state it.
    - *Biased question: "I know that most smart people in this community always use condoms, don't they?"*
    - *Better phrasing: "I have heard some people in this community say that most smart people use a condom, and others say that they know smart people who don't use condoms. What do you think?"*

- **Probe for Depth.** As much as possible ask follow up questions and probe for a deeper understanding of what the participant is saying. Examples of probing phrases might be: "Why?" "How did you feel when that happened?" "What did you do next?" "What do you think?" "What happened then?" "Can you tell me more?" "Could you describe X? I'm not sure I understand." Such probing also may require extra patience on the part of the interviewer.
    - *Example: Can you tell me more about why you didn't feel you could ask him to use a condom?*

- **If Uncertain, Verify Responses.** When you want to be sure that you have heard clearly what the participant said or that the information is accurate. You may ask them to repeat their response, or sometimes better, you can reflect the answer back to the participant.
    - *Example of reflecting back: So you told him that you think it's a sign of being responsible if you avoid sex while drinking?*

- **Do Not Respond to Questions.** If the participant asks you questions that are the focus of the interview, do not answer them. Your answers might influence how the participant will answer the rest of the questions. Instead, turn the question around and ask them what they think.
    - *Example: Well, I was hoping you could help me understand what people in this community say about how you get infected with the HIV virus.*

- **Be Patient.** It is not necessary to be asking questions every minute. Creating pauses and allowing silence can permit the participant to think more deeply about the topic. Don't be afraid to wait quietly while they think about a response or further probe, but be reassuring in your body language so the participant knows are genuinely interested in what she/he has to say.

- **Do Not Interrupt Participant's Work.** The participant is doing a favor to answer the questions. If the participant must interrupt the interview to attend to a child, a customer, a neighbor, use this time productively to review your notes and think about what else you would like to ask and probe further upon.

- **Handle Time Wisely.** Always note the time when the interview begins and ends. As you begin the interview, evaluate how much time you may have with this participant and what are realistic goals for asking questions from the interview guide. Ideally, the interview will flow like a conversation rather than a series of questions and answers.

- **Be Truthful.** In obtaining informed consent or in responding to questions from participants during the interview, provide brief, truthful answers about the objectives of the study, the likely benefit to her or the community.

- **Moderate Tone of Voice.** During the interview, use a calm, moderate, friendly tone of voice.

- **Monitor Body Language.** Be sensitive to your participant's body language and aware of your own. Avoid body language that may send the signal that participants are giving "correct" answers, or that you approve of, or reciprocally, that you are wasting your time.

18.6 Visit Checklists

The qualitative section of the MTN-020 website contains examples of checklists detailing the protocol-specified procedures that must be completed at ASPIRE qualitative study visits. These checklists should be modified as needed, then reviewed by the MTN CORE (FHI 360) for approval prior to implementation.

18.7 Reporting of Social Harms, Adverse Events, or Protocol Deviations

If any social harms (SH), adverse events (AEs), or protocol deviations (PDs) are reported by participants during qualitative interviews, interview staff should refer the issue to ASPIRE clinic/counseling staff as soon as possible and not more than 24 hours later to document and handle the AE, SH, or PD. If the issue is ongoing, ideally follow-up should occur after the interview is complete. However, if the issue is historical/resolved at the time of the interview, follow-up may occur at the next scheduled visit, per the discretion of the IoR. The site specific procedure for referring and documenting these occurrences should be outlined in the site Qualitative Component SOP.

Although the interviewer is required to share information about these events with other appropriate ASPIRE staff, she should aim to maintain a sense of trust, discretion and rapport with the participant by explaining this referral. Some sample language is provided below:

- *Thank you for sharing that issue with me. I want to reassure you that our conversations today will be kept private, but since this relates to your health, I need to pass this information along to [the nurse/doctor] so that they can follow-up with you [after our interview, during your next visit] and ensure you're okay. Are you okay with that?*
- *I appreciate your willingness to open up to me about that. I'm going to make a note for [the nurse/doctor, the counselor] to check in with you about that [after our interview, during your next visit] to make sure you're okay and all the necessary information is captured. This is the only part of our conversation I will share with them. Are you okay with that?*

Interviewers may also identify misunderstanding of key concepts that relate to study participant/informed consent during the interview (e.g. not understanding placebo, randomization, required study procedures, confidentiality). While interviewers should probe to fully understand the issue, they should avoid departures into counseling or health education during the interview. Instead, it is recommended that interviewers summarize any concerns on the debrief report, so that designated staff may determine appropriate follow-up—for example, general review of key concepts may be addressed as part of ongoing informed consent (see section 5.11), or during group/waiting room education sessions.

18.8 Data Collection

Only data collection issues unique to the qualitative data are covered in this section. For more information on ASPIRE data collection procedures, see Section 14 of this manual.

For questions about this section or about general data collection policies, procedures, or materials for the ASPIRE qualitative component, please email the data management team at RTI (MTN020@rti.org).

18.8.1 Study Visit Timing

Participants selected to participate in Serial IDIs will complete two to three IDIs, per the timeframe referenced in section 18.6.1. Those selected for single IDIs and FGDs will complete one interview each.

If a serial or single IDI participant is not able to complete an interview in one day, she may be rescheduled to come back and complete the rest of the interview on another day. In the event that this occurs, the circumstances should be noted in the chart notes, the interview debriefing report and a comment included on the QPL. If an individual is unable to complete participation in an FGD, this should be documented in the debriefing report for the FGD as well as on her individual FGD checklist. She will not rejoin another FGD unless determined necessary by the QMT.

If a Serial IDI participant misses a scheduled interview, study staff should document this in the participant chart notes and reschedule this visit as soon as possible. In instances of missed visits for one-time interviews (single IDI, one-time FGD) every effort should be made to reschedule the IDI for a convenient time for the participant or reschedule the participant into the remaining FGDs (if applicable).

18.8.2 Visit Codes

Visit codes will not be used for ASPIRE qualitative data collection activities. If a participant comes for her interview as an interim visit, an ASPIRE visit code will not be assigned unless a CRF is completed and faxed to SCHARP for other reasons (e.g. an AE or SH is reported).

18.8.3 Interview Guides and Materials: Supply and Storage

All guides and supplemental materials (e.g. checklists, body map templates) needed for the qualitative component of ASPIRE will be electronically supplied by RTI and should be printed locally. These materials will also be posted to the ASPIRE website under *Study Implementation Materials.* The site is responsible for maintaining an adequate supply of the current version of these documents in all languages. One copy of previous versions of guides and materials should be maintained in an archive, and all other copies destroyed. Procedures for form storage should be detailed in each site's Qualitative Component SOP.

18.9 Qualitative Data Management

As a condition for initiation of the qualitative component, each study site must establish procedures for data management that should be described in the Qualitative Component SOP. The SOP minimally should contain the following elements:

- Data collection, data back-up, transcription/translation procedures, and transmission procedures. This section should also include timeframes, and mechanisms for identifying when documents have been transmitted
- Procedures and timeline for resolving data quality control notes from RTI on both debriefing reports and transcripts
- Storage locations for blank guides
- Storage locations for documents identified by participant names or other personal identifiers
- Confidentiality protections, including the procedure for destroying audio files
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

ASPIRE qualitative data will be captured from the IDI or FGD given at the site through audio recording and note-taking.

Audio Files

Following the interview or discussion, the audio file should be copied onto a password protected hard drive, and uploaded onto the study's secure FTP server[†] for back-up. See Appendix 18-1 for FTP instructions. Audio files of IDIs and FGDs will be destroyed following finalization of transcripts (transcript finalization process described below), only after notification by RTI. The destruction process will be the responsibility of the IoR or his/her designee and should be specified in the site Qualitative Component SOP. If required, sites may invite members of their community/CAB to observe the destruction. Once complete, destruction should be documented in the study files and confirmed via email with the data center (RTI).

Interview Notes

When an IDI or FGD is conducted, notes should be taken during each session to supplement the audio recording (or replace, if recording doesn't work or is refused (IDI only)). Immediately following the IDI or FGD, the Facilitator (and/or Note-Taker if involved) reviews the guide, and adds or expands on notes and comments as needed. Interview notes will be maintained by the sites, filed in the participant files.

Debriefing Reports and Body Mapping Templates

On the same day as the IDI or FGD, the Facilitator should complete a Debriefing Report (DR) which will list basic information about the session and provide a summary report of the interview or discussion that can be used in "real time." After initial completion, DRs should undergo a site level quality review during which, at a minimum, all staff members who were present at the interview review the report for accuracy and completeness. A DR template will be provided by RTI, and is also available on the ASPIRE website under *MTN-020*

[†] An encrypted FTP is set by RTI's IT department. FTP use is account, username, and password protected with only designated team members from RTI and the site given access. The encrypted FTP site tracks user activity and file uploads making it easy to manage precisely by whom and when new files are updated, what changes are made, and what versions are most current.

Qualitative. As part of the DR process, the body mapping template, used during the first serial IDI and single IDIs with participants discontinuing product use early, should be reviewed for readability and comprehensibility and scanned and emailed to RTI (MTN020@rti.org) along with the DR. Body mapping templates should be filed in the participant binder. Debriefing reports may be maintained electronically until final versions are provided by RTI as described below. The DR and body mapping template, if applicable, should be emailed to RTI (MTN020@rti.org) within **one week** of the interview. RTI will then conduct a QC review of the DR, and body mapping template, which will include the following process:

- At RTI, the report will be read and reviewed by data team members and queries will be made on the report using MS Word's comment feature within **one week** of receipt of the file. The following are examples of queries:
  - Problems such as typos that lead to ambiguous meaning (e.g. "sore the medication" vs. "store the medication"), confusing terms or missing /potentially incorrect data
  - Sentences that are unclear
  - Clarification of local terminology or context
- Within **one week**, the site is asked to correct or clarify any problems identified in the report directly in the report text using track changes and confirm the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query within the comment bubble.
- When the revised information is received by RTI, the Qualitative Data Manager or a designated data team member reviews the corrected areas and deems the issue resolved or further follows up with the site until all necessary changes are made on the report.
- Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles and email the final clean report to the Qualitative Team. This final version of the DR should be printed and filed in the participant chart.

Transcription-Translation

The site staff will conduct the transcription-translation process per their site Qualitative Component SOP. This may be done in-house or outsourced to an external agency. Regardless of whether this process is undertaken at the site or through an external agency, quality checks of the local language transcript and English translation should be performed at the site and involve checks against the audio file. While it is ideal to have a staff member different from the interviewer conduct the transcription/translation, it is recognized this may not be feasible. If the interviewer does conduct the transcription/translation, a separate staff member fluent in both languages must QC these documents. Sites should outline their QC process in their site SOP. Staff responsible for transcription must provide verification that the transcript is an accurate and complete representation of the original audio file through use of a coversheet. A template audio transcription certification coversheet is available on the ASPIRE website under *MTN-020 Qualitative*. The original certification should be filed with the final transcript.

After this site level QC process, the English language transcript will be emailed to RTI (MTN020@rti.org) for review within **one month** of the interview date where it will undergo a similar QC process to that of the DRs:

- Each transcript is reviewed by a member of RTI's data team and queries will be made on the transcript using comment bubbles. The QC may include the identification of the following:
  - Problems such as typos that lead to ambiguous meaning, confusing terms or missing/ potentially incorrect data
  - Sentences that are unclear
  - Clarification of local terminology or context
- RTI-reviewed transcripts will be emailed to the site within approximately **two weeks** of transcript receipt.

- The site then responds to all comments within **two weeks** of receipt of the reviewed transcript. Responses will be made either through changes directly in the transcript using track changes or through using the comment box in the reviewing mode of MS Word, when in-text changes are unable to be made. When changes in the text reflect content that was not spoken verbatim by the participant or interviewer, they will be inserted in [brackets].
- After the revised transcript is received by RTI, a designated staff member reviews the corrected areas and deems the issue resolved or further follows up with the site until all necessary changes are made.
- Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles, and finalize the transcript. Sites will be notified of this finalization status via email when a final version of the transcript is emailed to the site, which should be printed and filed in the participant chart.

During the transcript QC process (outlined above), issues identified by the protocol team requiring follow up, additional probing, or discussion in subsequent interviews (if applicable) should be noted on the debriefing form. This could include general findings related to IDI/FGD facilitation techniques or specific issues that should be teased apart further in future IDIs/FGDs.

File Naming Conventions:

Initial format: [Interview Mode]_[PTID]_[Data Type]_[Date of IDI]

Query format: [Interview Mode]_ [PTID]_[Data Type]_[Date of IDI]_[RTI Initials]

Query response format: [Interview Mode]_[PTID]_[Data Type]_[Date of IDI]_[RTI Initials]_[Site Initials]

Final format: [Interview Mode]_ [PTID]_[Data Type]_[Date of IDI]_FINAL

File Naming Conventions

All data files should be named according to a standard naming format. Each time a document is edited, the editor should add their initials to the filename without changing any other part of the filename. For the first iteration of the file that is sent to RTI for review, there is no need to include the editor's initials. It is only upon subsequent review (QCing) that this occurs. For example, when reviewed for the first time, the (second) serial IDI transcript ***"SIDI2_1001_Transcript_18NOV12"*** would become *"**SIDI2_1001_Transcript_18NOV12_CM**"* and *"**SIDI2_1001_Transcript_18NOV12_CM_NM"*** for the second revision. Once the document is finalized, RTI will remove all initials from the name and replace them with the word "FINAL."

Data Tracking

A Qualitative Data Tracking Log will be completed by RTI to maintain record of each audio file, debriefing report, body mapping template, and transcript that is submitted along with details regarding the submission date, query status, and finalization date. Sites will need to develop and outline their own tracking mechanism in the Qualitative Component SOP.

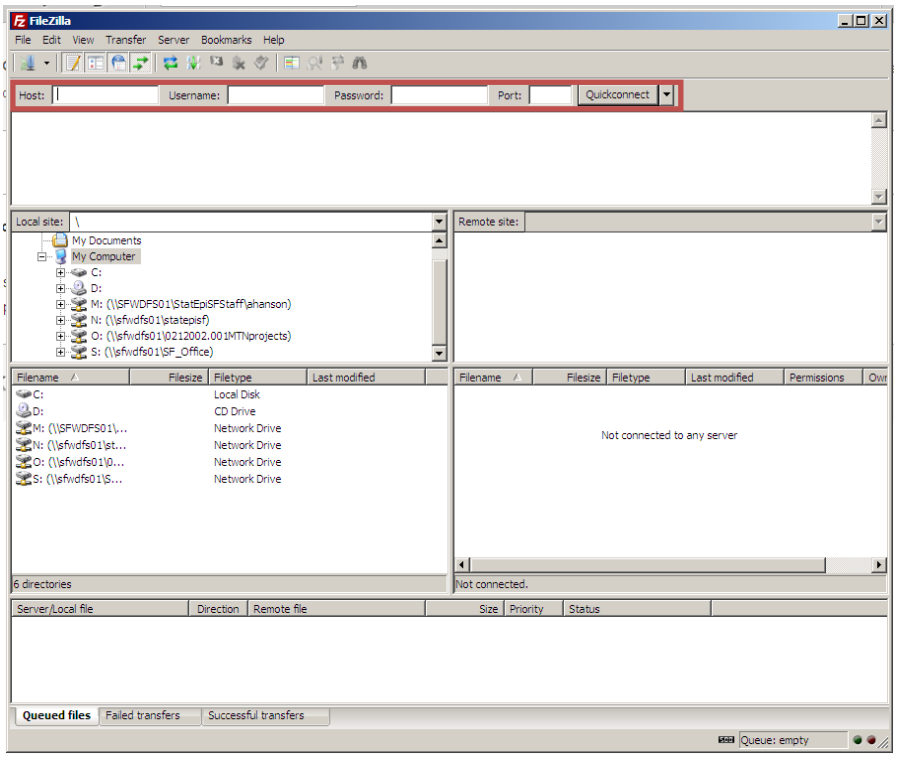
Appendix 18-1: File Transfer Protocol Instructions

Enter the FTP site through filezilla. If filezilla is downloaded, go to Start => Programs => FTP filezilla client => filezilla. If is not yet downloaded, download 'FileZilla Client' from the following link: http://filezilla-project.org/. Install the 'FileZilla Client' application by opening the ***.exe file*** which is downloaded from the site.

Once installed, open the application and connect to the site through entering the following information in section outlined below in red:

- Host: ftp.rti.org
- Username: To be provided separately
- Password: To be provided separately
- Port: 990

- Click on the QuickConnect button.



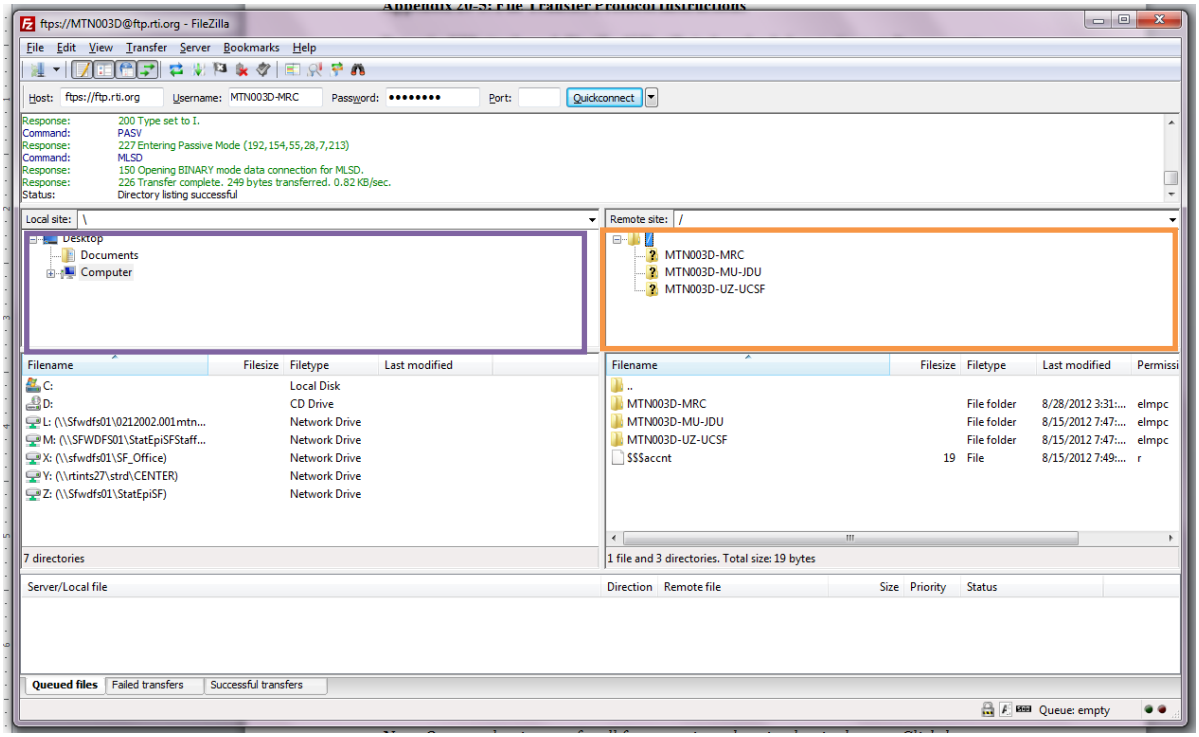
***Note**: Once you log-in once, for all future sessions, there is a log-in shortcut. Click the gray arrow to the right of the QuickConnect button and select the address listed. This will automatically connect you to the FTP site without having to enter all of the log-in information.*

The **left-hand side** of the screen, outlined in purple below, shows the 'local site' or the local drives on your computer.

The **right-hand side**, outlined in orange below, shows the 'remote site' or FTP site.

To transfer a file from one's local computer folders to the FTP site:
Using the left-hand side of the screen, navigate to the local drive on your computer where the file is saved that you wish to transfer. To navigate to sub-folders, you can either double-click the folder or click on the plus sign next to the folder you wish to expand.

Make sure the ‘Remote site’ on the right-hand side has the folder opened for the location in which you want to transfer the file to on the FTP server.



Once the left hand and right hand side are properly set-up, click on the file on the left side that you want to transfer and drag it to the right-hand side of the screen into the appropriate folder.

Alternatively, another way of transferring a file from the left-hand to the right-hand side of the screen is to double click on the file.

Note that when you transfer a file, it doesn’t become removed from your local files, but rather a copy of it is made on the FTP server.

To open a file on the FTP site: Open up the appropriate folder. Put your cursor on the file you wish to open. Right click and select “View/edit” and the file will open.

To save an updated file on the FTP site: when a file on the FTP site is opened and changes are made, the file must be saved to the user’s local computer and then be transferred onto the FTP site.

Appendix 18-2: Example Formatted Transcript

SIDI2_325-10001-5_Transcript_28Nov12

Participant ID: 325-10001-5/ **Interview Date**: 28 November 2012/ **Month in Study:** 6 / **Interview Mode:** Serial IDI 2/ **Clinical Site**: MRC/ **Audio File Name**: SIDI2_325-10001-5_Audio File_28NOV12.WMA/ **Audio Recording Length**: 45m:11s/ **Interviewer Name(s)**: Funeka Vilakazi/ **Transcriber**: Hlamalani Rikhotso / **Translator**: Khosi Mbuli/ **Interview Language**: IsiZulu & English

Interview Text:

1. I: How is living in the new house?
2. *R: It's alright, but it is boring.*
3. I: Why?
4. *R: Everything is far away.*
5. I: Like?
6. *R: The shops, and the ATM [automatic teller machine] and most of the things are far away. If you do not have money you suffer [Laughing].*
7. I: Do you take taxis when you go to withdraw?
8. *R: I do not have money for the taxi. If I have money I can buy bread because there is a spaza shop [an informal shop operating from home]. A car is a necessity and we need to have it. It is allright at least I have my own space and privacy [Laughing].*
9. I: It is better. I was thinking about you and how the situation is in your new home? Are the children still there?

Formatting Tips:

- Header of document (as in header/footer) should follow the filename as listed
- Header within documentincludes: Participant ID, Interview Date, Month in Study (for SIDI/IDI participants), Interview Mode, Clinical Site, Audio File Name, Audio Recording Length, Interviewer Name, Transcriber Name, Translator Name, Interview Language
- After header, label next section "**Interview Text**," insert a hard return and begin transcribing the content of the audio file verbatim.
- Use "I:" before Interviewer remarks and "R:" before respondent remarks. Italicize all respondent remarks.
- Auto-number the transcript by paragraph so that each time the Interviewer or Respondent begins a new response, this should be indicated by a new number
- Replace all references to individual names or other identifying data with pseudonyms
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets]
- Long pauses can be represented by use of an ellipsis "…"
- Insert a footer with page X of X on right-hand side
- Spell check the transcript for any spelling and grammar errors