# MATRIX-003 Study-Specific Procedures (SSP) Manual
## Section 11 – Behavioral Measures

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## Introduction

This section contains information on behavioral measures and research procedures performed in MATRIX-003; including those pertaining to implementation of behavioral case report forms (CRFs) and in-depth interviews (IDIs). All staff involved in administering behavioral assessments must read and understand the sub-sections that pertain to their responsibilities. The Data Management & Statistical Support team for this

study is part of the MATRIX Clinical Trials Hub (CTH) located at Magee Women's Research Institute, and RTI International's Women's Global Health Imperative (RTI) serves as the qualitative data management center (QDMC). Any questions about behavioral data collection procedures, process, or management may be directed to matrixSBRdatamgmt@lists.matrix4prevention.org.

## Overview

All behavioral case report forms (CRFs) will be administered by an interviewer or appropriately trained data collector and captured through REDCap according to the schedule shown below in Table 1. A subset of participants will be invited for an in-depth interview (IDI), and participants who provide permission to contact their sexual partners may also have their sexual partners invited (either directly by study staff or through the participant, depending on site SOP for Obtaining Informed Consent and IRB/IEC guidance) for an IDI. This section provides general guidance on completion of behavioral CRFs (where it may differ from the guidance provided for non-behavioral CRFs in SSP section 12), as well as instructions for all qualitative procedures.

A question-by-question guide for behavioral CRFs that offers guidance for CRF administration will be provided by the D2D Pillar 2 (D2D P2) team. Detailed guidelines on how to access CRFs through REDCap and complete them are provided in Section 12 of this SSP Manual.

## Data Collection Instruments

Table 1 outlines all behavioral data collection activities planned in MATRIX-003, indicating the form acronym, the assessment, the administration mode, and the visit timing. All CRFs are intended to be administered electronically and will be programmed into REDCap for administration on tablet, laptop, or desktop computers. Sites may administer paper forms and later transfer the data to REDCap if necessary (i.e., in cases of power outages/Wi-Fi outages and REDCap not being accessible).  In these cases, staff will need to take extra care for manually following skip patterns and other instructions to interviewers and apply all GCP practices to these forms. In-depth interviews will be administered through use of an interview guide that the interviewer will print out and may use for notetaking throughout the interview.

All behavioral CRFs and guides needed for MATRIX-003 will be supplied by D2D P2 and should be printed locally, as applicable. The current version of all forms (English) will be posted to the MATRIX-003 study webpage (https://www.matrix4prevention.org/) and may be provided to site leadership via email as a back-up to the webpage. The site is responsible for translation of all CRFs, including behavioral surveys and IDI guides as outlined in SSP Section 02 Documentation Requirements. The site is responsible for maintaining an adequate printed supply of the current versions of blank CRFs and guides in all relevant languages (in case of technical issues with REDCap). Should there be any updates to the CRFs, a Data Communique will be sent out via email indicating the updates that were made, and any  actions requested from  site teams. One hard copy of previous versions of CRFs and guides should be maintained in the site Master File of Essential Documents, and all other copies destroyed.

**Table 1:** Behavioral Assessments – Timing and Mode of Administration

| Form Acronym | Assessment | Primary Mode(s) of Administration | Visit |
|---|---|---|---|
| DEM | Baseline demographics | In-person | V1 |
| BEH | Baseline behavioral assessment | In-person | V2 |
| BL | Baseline acceptability | In-person | V2 |
| FU1 | Post-insertion acceptability assessment | In-person | V2 & V6 |
| COI | Clinician-completed observation: insertion | In-person | V2 & V6 |
| COR | Clinician-completed observation: removal | In-person | V5 & V9 |
| FU2 | Brief acceptability assessment | Phone | V3 & V7 |
| FU3 | Follow-up behavioral and acceptability assessment | In-person | V4 & V8 |
| FU4 | Final behavioral and acceptability assessment | In-person | V5 & V9 |
| SH | Social Harms | In-person, phone | *As needed* |
| IDI (P) | Participant in-depth interview (subset) | In-person, web conference | *Ideally within 1 week following V9 but no later than 3 weeks after V9.* |
| IDI (SP) | Sexual partner in-depth interview | In-person, web conference | *Within one month of V9* |
| SP DEM | Sexual partner demographics | In-person | *Within one month of V9* |

## Guidance on completion of Behavioral CRFs

- Whenever possible, behavioral assessments should be administered and completed before counseling procedures. In the case of the post-insertion questionnaire (FU1) scheduled for the enrollment visit, it is understood that this CRF will be administered after study counseling occurs.
- All behavioral CRFs should be administered in private rooms where the participant and interviewer will not be interrupted or overheard.
- All interviewer administered behavioral CRFs should be administered using the CRF in the preferred language of the participant. This may be different than the language they 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 the preferred languages should be documented in the participant chart notes.
- Behavioral CRFs should be administered by a staff member who is separate from the staff completing the clinical and counseling procedures in this study. Having separate staff member(s) designated to administer behavioral CRFs allows for tailored training on skills for sociobehavioral data collection and helps prevent the participant from providing answers that could be biased or influenced by clinical or counseling guidance provided.
  - In cases where a trained sociobehavioral CRF data collector is not available, other trained study staff may step in. Consideration should be made about which staff the participant may be *least* likely to feel obligated to provide "correct" answers perceived to be socially desirable (e.g., a staff member who they haven't seen at that visit, or who provided a brief clinical exam but not extensive interaction).
  - When possible, Behavioral CRFs should be completed by a staff person of the gender that the participant is comfortable with, to allow participants to feel more comfortable sharing their experience. If a staff member of the same gender is not available, comfortability with a staff member of the opposite gender must be confirmed first with the participant prior to completing the CRFs.

- o D2D P2 will provide training to all staff involved in administering Behavioral CRFs, and all staff authorized to administer behavioral CRFs should be indicated on the Delegation of Duties (DoD) log.
- To standardize behavioral data collection from site to site and to maximize quality, it is critical that behavioral CRFs be administered with a non-biased, non-judgmental approach. Study staff should help a participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.
- No counseling or correction of misinformation should ever be provided during the interview/data collection process. However, it is recognized that some information reported during the interview may prompt further action, in which case the guidance below should be followed:

If information reported during an interview relates or may be related directly to participant's safety and well-being—specifically, if potential or actual violence/abuse, sexual assault, social harms, food insecurity, or AEs are reported—the participant should be followed up on an individual level to collect additional information as needed and to provide referrals for the well-being of the participant. This should be done after the interview and by a separate staff member. See also SSP section 08 for further management of AEs, social harms, IPV, or sexual assault.

## Telephone check-ins

Telephone check-ins may be scheduled for Visits 3 and 7 for this protocol and should be administered at a time and place when the participant and interviewer will not be overheard or interrupted. When possible, telephone check-ins should be scheduled in advance to ensure that the participant is available at the agreed upon date and time. Interviewers administering the telephone check-in should ensure that the participant is ready and able to conduct the interview at the start of the check-in and should reschedule if the participant is unable to speak openly during the call. The site team and participant may agree to complete the visit as an in-person visit instead if preferred. In addition, the site team can choose to send questions to the participant via SMS, as long as the participant agrees and SMS contact is approved by the site's appropriate IRB or ethics committee.

If the participant is not able to schedule and conduct the check-in via telephone or in-person within 48 hours of the Visit 3 and Visit 7 appointments, the visit will be considered missed (see SSP Section 5.5.1.1 Study Procedures for details on missed visits). Staff will complete a Missed Visit form and work diligently to assess why the visit was unable to be completed during the designated visit window, and address that concern prior to the next visit window closing.

## In-Depth Interviews (IDIs)

The IDIs for this study will be conducted in a semi-structured format that follows a discussion guide (provided by D2D P2), allowing for iteration, probing, and reflections on relevant themes. IDIs will be audio-recorded, transcribed, and translated into English (if conducted in a language other than English). See section 11.3.4 for further information on translation and transcription process.

In communication with D2D P2, each site must complete an IDI Readiness Checklist before conducting any qualitative interviews, and this may be completed after the site is activated. D2D P2 will provide the readiness checklist to each site.

**Selection of IDI participants**

1. Up to 30 interviews with participants from the clinical study (approximately 6 per site) and up to 30 sexual partners of participants (approximately 6 per site) will complete in-depth interviews. A site may conduct more than 6 in-depth interviews with consultation from the D2D P2 team, as long as the total number of interviews across all sites does not exceed 30. All IDI participants must have agreed to participate in the IDI and be audio recorded during their written informed consent process before being selected as an IDI participant. All IDI participants meeting these criteria will subsequently be eligible to be selected purposively by study staff.

    a. We do not anticipate participants declining to be audio recorded at the time of the IDI since they will have agreed to audio recording during the informed consent process at enrollment. The allowance for declining audio recording at the time of the interview is to accommodate the rare circumstance in which a participant originally consents to audio recording but declines at the moment of the IDI.

- <u>Characteristics of clinical participants to be selected for IDIs:</u> Using data collected in CRFs during the study, clinical participants will be selected for IDIs with the intention of obtaining a qualitative sample balanced by the IVR type (A and B) to which they were randomly assigned. In addition to exploring women's experiences using the ring over the two IVR use periods, the team is interested in learning about the use of the vaginal ring during sex. Thus, participants who report engaging in sexual activity are anticipated to make up at least half of the qualitative sample for clinical participants. In conversation with the sociobehavioral team at each site, the management team will also seek to understand if there are unique circumstances or emerging themes that seem to impact how participants use and experience the vaginal ring. If those are identified, the team will update selection procedures as needed to ensure those perspectives are represented.

    o An IDI Selection tool will be provided to each site by D2D P2 to map out key characteristics of each participant selected for an IDI (e.g., randomization arm, sex during product use, intravaginal practices, other characteristics of interest). The management team and each site will collaboratively track and make decisions about potential future participants based on participant characteristics and any emerging themes that the team wishes to further explore.

- <u>Invitation of sexual partners:</u> Sexual partners of participants will be invited to participate in an IDI if study participants provide initial consent and later confirmation of consent to have their partner contacted for IDI enrollment. Sexual partner contact will follow site SOPs. It is anticipated that sexual partners may be difficult to enroll, in which case additional selection criteria may not be applied. In the case where more sexual partners are available for participation than anticipated, the team will seek to enroll sexual partners that represent a variety of different experiences engaging in sexual activity with the clinical participant while they were using the IVR, with a goal to have a substantial representation from sexual partners who engaged in vaginal sexual activity with the participant while using study product.

Staff involved in inviting sexual partners should be attentive to any indication that the sexual partner may not be fully aware of the clinical trial participant's involvement with the study, or use of study product. Investigator discretion should be used in inviting sexual partners who may not be fully informed about the study and study product as this could pose challenges to conducting a high-quality interview, as well as the possibility of disclosing information about the participant's involvement to their sexual

partner through the interview context. Site-specific SOPs may provide further details about assessing this risk during the Sexual Partner invitation process, and how to manage if it emerges during the IDI itself.

**Scheduling the Interview**

*Clinical participant IDI scheduling:*

D2D P2 will provide each site an IDI Selection Tool that a designated site member will be responsible for updating using participant data collected over the study period. The IDI selection tool will include all participants who provide consent for an IDI at study enrollment and any who later provide consent, if this occurs. The IDI selection tool will be updated to reflect key pieces of information for IDI selection (e.g., vaginal sex, experiences with IVR coming out, experiences with insertion, insightful IVR experiences and attitudes during study participation). This information will be obtained from a data summary report, from flags integrated into REDCap and/or communication among study team members.

1. A point person at each site will be responsible for updating the IDI Selection Tool. Site-specific SOPs will detail the responsible staff, cadence, and process for this.
2. D2D P2 will train staff involved in IDI selections specifically around relevant considerations and decision points for inviting participants to an IDI.
   a. The sociobehavioral team at each site may work collaboratively with clinic staff to assess personal experiences with, and research records of participants who may be a good fit for IDIs as the study end visit at Visit 9 (SEV) approaches. Once the Visit 8 behavioral assessment is complete, the interviewer should take note of the relevant participant responses, particularly related to sexual activity during Stage 2 and any other salient topics. Using this CRF information, combined with an assessment of the participant's capacity to be a responsive interviewee, the site sociobehavioral team will determine whether the participant should be invited for an interview. The site team may invite the participant during Visit 8, or soon thereafter. The interview must be scheduled and completed ideally within 1 week following V9 but no later than 3 weeks after V9.
3. For sites where the qualitative interviewers are off-site: The qualitative interviewing team will work closely with the on-site study team to communicate about potential interviewees, decisions about invitations, and scheduling.

*Sexual partner (SP) IDI scheduling:*
1. During each participant's V9 procedures (and/or earlier, per site SOPs), site staff will review and confirm whether the participant has provided permission to contact their sexual partner.
   a. Discussion with participants about the sexual partner interviews at earlier study visits may facilitate the confirmation of permission to contact at Visit 9.
2. Invitations should be prioritized for sexual partners of participants who report sexual activity during the study period and for whom permission to contact has been provided.
3. Sexual partners may be invited immediately following V9 procedures, as per site SOP and as approved by IRB/IEC.
4. The IDI with sexual partners must occur within 1 month after the participant's V9 date.
5. D2D P2 will have regular communication with site teams to understand the frequency of sexual activity and provision of permission to contact. Based on the frequency of these situations and

emerging information through other data collection activities, the D2D P2 team will work with sites to update and tailor sexual partner invitation processes as needed.

6. Site staff will conduct informed consent procedures with sexual partners prior to administering the SP DEM CRF. After the ICF and SP DEM are completed, the SP IDI can occur.

## Preparing for the Interview

Before each IDI, the following should occur (see Appendix 11.1 for Quick Tips for In-Depth Interview):

1. A consent form must be signed prior to the IDI. For clinical participants this will have been done during enrollment. For sexual partners, this should be the first step at the SP IDI visit. Contact the participant to remind them of the visit at least one day before the interview: inform them of the time and location of the IDI (for IDIs completed virtually, ensure access to video software (e.g. Zoom) .
2. Ensure the audio-recorder(s) are ready: functioning, charged or has extra batteries, memory card has sufficient space.
3. Ensure interviewing space has been reserved and is ready for use.
4. Ensure the correct version of the IDI guide and any other supplemental tools are ready for use, in the participant's preferred language. Gather needed supplies, e.g., pen and stationery for notetaking, IDI guide, visual probes, refreshments (if applicable), and reimbursement (if applicable).
5. Upon participant's arrival for the IDI, confirm participant identity per site-specific SOPs.

Roles, responsibilities, procedures, and timing for these steps will be outlined in site-specific SOPs.

## Conducting the interview

Procedures for conducting the interview are outlined in the **Qualitative Visit checklists**, which are available on the study website as templates, and modifiable by each site as needed.

- These checklists should be used to guide the order of procedures for each IDI.
- Separate qualitative visit checklists exist for the participant and sexual partner visits.
- Sections 11.2.3.5 (Qualitative interview techniques) and 11.2.3.6 (Safety reporting) provide additional information about key components of the procedures outlined in the visit checklists.

## Qualitative interview techniques

2. <u>Rooms for conducting IDIs:</u> The IDIs will be conducted in private meeting rooms that are quiet enough for audio-recording. It is recommended to avoid the use of exam rooms to allow for a more comfortable discussion space.
   a. Conducting virtual IDIs: The IDIs may be alternatively conducted remotely over a secure digital platform if informed consent has been provided according to site procedures.
3. <u>Informed consent:</u> Key elements of informed consent should be reviewed with participants, as needed. Confirm willingness to participate in the IDI. This review/confirmation must be documented on qualitative visit checklists (and chart notes as needed).
4. <u>Language of IDI:</u> Confirm which language the participant would like to use when completing the IDI.

5.  Interviewer expectations: All interviews will be conducted by a trained qualitative interviewer. 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.

6.  Length of qualitative activities: IDIs are anticipated to last approximately 45-60 minutes.

7.  Audio recording: IDIs will be audio-recorded. The use of two or more audio recorders is recommended in case of malfunction or differing audio quality. The expectation is that all participants agree to being audio recorded, given that it is incorporated in the study informed consent. All IDI participants should confirm that they agree to be audio recorded before being selected as an IDI participant.

    a.  While uncommon, in cases where an IDI participant declines to be audio recorded at the time of the interview, a separate note-taker must be present during the interview. The interviewer will inform the participant of this requirement and ask for their permission to have a note-taker present. If the participant also declines to have a note-taker present, the IDI should not proceed and sites should follow site-specific guidelines for reimbursement in these scenarios. The management team should be contacted immediately following the IDI to inform them that the participant did not agree to the audio recording and/or to the notetaker.

8.  Note-taking: When an IDI is conducted, notes should be taken to capture non-verbal communication and supplement the audio recording (or replace, if recording doesn't work or is refused). The interviewer will take brief notes as the interview is ongoing. The PTID may be recorded on the notes, but no other personally identifying information (including the participant's name) should be on the notes.

9.  Misunderstandings of key concepts raised during IDIs: Interviewers may also identify misunderstanding of key concepts that relate to study participant/informed consent during the interview (e.g., 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, or during group/waiting room education sessions.

## Safety Reporting

If any potential or actual social harms (SH), adverse events (AEs), or protocol deviations (PDs) are reported by participants during qualitative interviews, interview staff should refer the issue to study 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 as soon as the interview is complete. However, if the issue is historical/resolved at the time of the interview, follow-up may occur at a later date, per the discretion of the IoR. The site-specific procedure for referring and documenting these occurrences should be outlined in the relevant site-specific SOP(s).

Although the interviewer is required to share information about these events with other appropriate study staff, they should aim to maintain a sense of trust, discretion and rapport with the participant during the interview 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. Do you have any questions about 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. Do you have any questions about that?*

## Qualitative Data Management

As a condition for site specific study activation, each study site must establish procedures for data management that should be described in the Qualitative Component SOP.

All documents listed below must be stored and managed according to the procedures outlined in this section of this SSP and the site's relevant SOPs.

Timeline for data storage and/or transfer to the QDMC after each qualitative activity:
- Same day as IDI:
  o Audio file(s) and back-up version(s) saved
  o Notes filed in participant records per site SOP
- Within one working day:
  o Debrief Report (DR) completed via REDCap by interviewer.
- Within three working days:
  o DR undergoes internal QC and is ready for review by the QDMC
  o The QDMC will respond within one week with queries. All further iterations of the DR with queries and responses to queries should happen within one week of the date of receipt.
- Within four weeks:
  o Transcript sent to the QDMC. See Appendix 11-2 for Secure File Transfer Protocol (SFTP) information.
  o The QDMC will respond within two weeks with queries. All further iterations of the transcript with queries and responses to queries should happen within two weeks of the date of receipt.

## Audio Files

Following the IDI and before the end of the day, the audio file(s) should be copied onto a password protected hard drive of a computer at the site and saved onto a password-protected external hard drive as source documentation of the interview. The computers should be stored in a locked room. If any site prefers a different method to save audio files, they must confer first with the D2D P2 team for guidance. Audio files do not need to be sent to RTI, except in cases where requested specifically for training or quality control (QC) purposes.

Computer audio files of IDIs 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/designee and should be specified in the site's relevant SOP(s). If required, sites may invite members of their community/CAB to observe the destruction. Once complete, destruction should be documented in the study files with signatures from the staff member responsible for the destruction and

a witness, and confirmed via email with the data center (RTI). Copies of the audio files saved on password-protected external hard drives must be kept along with all other study records according to the study protocol and/or SOPs. No external hard drive or other documentation should be destroyed without prior approval from the MATRIX-003 Management Team.

### Interview notes

Immediately following the IDI, all notes taken during the activity should be numbered and stapled together (if more than one page), with PTID and date of IDI listed on each page and filed per the site-specific SOP(s), along with any written/visual materials produced during the course of the activity.

If the audio recording did not work, the interviewer will review the guide and expand the notes they have taken during the discussion to serve as an alternate transcript, and a protocol deviation should be reported via a PD Log CRF.

### Debrief reports

On the same day as the IDI (or within one working day), the interviewer should enter a Debrief Report (DR) entry in the Debrief Report form on REDCap, which will list basic information about the IDI and provide a summary report of the interview that can be used in "real time." The DR will then undergo quality control at site level before being sent to the QDMC  (see 11.3.8 Quality Control Procedures).

- In rare cases where the REDCap form is unable to be accessed within the time period specified, a .docx version of the Debrief Report template will be made available. In these situations, the interviewer should complete the .docx version of the debrief report, and then copy/paste the responses into the REDCap form as soon as it is available

After these reports are reviewed and approved by RTI, they will be circulated to relevant members of the site and study management teams for review. Once any queries are addressed, the reports will be finalized.

### Transcription

IDIs should be translated and transcribed verbatim by someone other than the person who conducted the interview to ensure data integrity. 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. While transcribing, staff should follow their site's relevant SOP(s) that include how the interview notes will be incorporated in the transcripts.

- Transcripts can be simultaneously transcribed and translated (when conducted in a local language) and written up in English unless there are unique local language expressions that should be preserved. These expressions can be kept in the local language in italics, with explanatory notes provided in brackets to explain their meanings. All explanatory notes will be written in English.
- Transcription 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 English transcript should be performed at the site and involve checks against the audio file.

- In addition to audio files, transcripts will be treated as source documents, including original language transcripts if competed. If the participant declines to be recorded at the time of the interview, written notes are considered source documentation for the IDI.

Transcripts should be formatted as indicated in the example provided in Appendix 11-3. Qualitative transcripts must clearly document who was responsible for the translation by filling in the translation certification statement found in the transcript template at the top of the first page. This statement will be signed and dated by the transcriber once transcription is complete before undergoing QC procedures (see 11.3.8 Quality Control Procedures).

## Data Tracking

Data about participation in the qualitative component will be recorded in each site's IDI Selection Tool. See SSP Sections 11.2.3 and 11.2.3.1 for further information. The tool serves as a comprehensive record of all participants who are pre-selected, including tracking decisions regarding the participant's eligibility and participation.

Sites should share an up-to-date version of this tool on a weekly basis with D2D P2 via the SFTP, unless an alternate plan is developed. More frequent reporting requests may be made by D2D P2, if deemed necessary. The person responsible for this report should be described in the site-specific SOP(s) and the Delegation of Duty log.

## File naming conventions

All data files should be named according to a standard naming format. The name will include the study name, interview mode, followed by the PTID, data type (audio file, transcript), and the date the IDI was conducted.

Abbreviations for file naming:
- Interview mode: participant IDI = PIDI, sexual partner IDI = SPIDI
- Participant ID = PTID
- Data type abbreviation: Transcript = TR, Audio File = AF, Debrief Report = DR

Once the document is finalized, a final version will be created with the standard format of "v1.0" at the end of the file name. Any subsequent versions of the document will indicate a version change in the file name.

## Data transfer

The SFTP is a highly secure file directory used to transfer files from one computer to another computer. Because the qualitative documents could contain personally identifiable information, an SFTP will be used to transfer IDI selection tools and transcripts to RTI. Files with personally identified information MUST always be transferred in a secured way and should never be sent via email.

The purpose of SFTP is only for file transfer; files will not be stored for an indeterminate amount of time on SFTP and should be deleted typically after 24 hours. See Appendix 11-2 for details of the use of the SFTP.

### Quality control procedures

#### Initial QC at Site

<u>Initial QC of interviewing skills at site:</u> An independent, senior socio-behavioral staff member with qualitative expertise or the qualitative lead should review the first 2 IDIs for each interviewer to provide feedback on interviewing techniques (e.g., adequacy of probing, appropriate linking of topics, fidelity to the guide, etc.). This will be achieved through review of the audio file. The feedback will serve to provide additional training to the interviewers and to improve on the quality of the data collected. Once the first 2 IDIs have been completed and feedback has been given, the site leadership should decide whether an interviewer is ready to continue these interviews on their own. The decision as to whether the interviewer is ready to continue activities on their own, or whether they require further training, should be documented in an email to the D2D P2 team that specifies which IDI were observed.

<u>Initial QC of the transcript at site:</u> Quality checks of the transcription/translation should be performed at the site as described in the relevant site-specific SOP(s). This will include having a second staff member (i.e., one who did not translate the interview) who is fluent in the local language listen to the entire audio file while reading the English transcript. Preferably this will be the person who conducted the interview; if that person is not available, another staff member may review the audio and transcript together. The quality of at least the first two transcripts per transcriber/translator will be checked in this manner to determine that the quality of translation and transcription is sufficient. Specifically, the reviewer should ensure that:

- The translation accurately reflects the speakers' original words
- The translation is coherent and reflects the flow of the conversation in the original language
- Appropriate and sufficient punctuation is used throughout the transcript
- Formatting is consistent and conforms to the template in Appendix 11-3
- Pseudonyms are used in place of any names or other identifying information such as employers or schools

#### Ongoing quality control at site

<u>Quality control of debrief reports at site:</u> Once the interviewer has entered their debrief report into REDCap, they will use the Form Status feature to indicate where the DR is in the QC process. After a DR is created for a participant, the debrief report REDCap entry should be marked as "incomplete" before undergoing a site level quality review by the person who is managing the qualitative component of this study. If any other staff member were present in the IDI, they should also review the report for accuracy and completeness. Specifically, reviewers should ensure that:

- Summaries are provided for all main topics of interest as outlined in the DR template
- Information such as the context of the IDI, the demeanor/disposition of the respondent(s), and non-verbal cues that help the reader understand IDI responses are included
- Pseudonyms are used in place of any names or other identifying information

Once the Debrief Report has undergone site-level QC, the interviewer should change the form's status from "Incomplete" to "Unverified", within three working days of when the IDI occurred. Once the DRs have been reviewed and approved by RTI, the form's status will be changed to "Complete."

Quality control of transcripts at site: After the quality of the first two transcripts (or more, if needed per transcriber) has been deemed acceptable, quality checks to compare audio files against transcripts will proceed according to site SOPs. The text of each transcript will still be reviewed in its entirety even if the entire audio file is not reviewed. Sites will log the QC process (including which transcripts were reviewed in their entirety, and which were spot checked and by whom). This process and staff responsible for it should be described in the relevant site-specific SOP.

If at any time the site coordinator decides that the direct transcription from audio to English transcript is not consistently of high quality, they should consult the D2D P2 team to determine the corrective action, which may involve a temporary or permanent switch from a 1-step to a 2-step transcription/translation process for that translator/transcriber.

**Ongoing quality control with RTI:**

For debriefing reports: After the site level QC process, the DR will be submitted via REDCap for the QDMC to review per SSP Section 11.3.3. Site teams should submit DRs to the QDMC as soon as they become available and within **three working days** of when the IDI occurs. Site teams should communicate with the QDMC if delays are anticipated. DRs will not undergo a formal QC process, but the QDMC team members will read and review all DRs within one week of receipt. If there are any outstanding questions, such as clarification of local terminology or context, the QDMC will utilize the Field Comment Log feature to query the site. When all queries (if any) are answered and the DR is ready to be finalized, the QDMC team will change the Form Status on REDCap from "Unverified" to "Complete".

For transcripts: After the site level QC process, the English language transcript will be uploaded to the SFTP site for the QDMC to review per SSP Section 11.3.7. Site teams should send English language transcripts to the QDMC as soon as they become available and within **four weeks** of when the IDI occurs. Site teams should communicate with the QDMC if delays are anticipated. Transcripts will then undergo the following QC process:

1. Each transcript will be reviewed by a member of QDMC data team and queries will be made on the transcript using comment bubbles (or track changes for smaller/straightforward typos). The QC may include the identification of the following:
    a. Problems such as: typos that lead to ambiguous meaning, confusing terms or missing/potentially incorrect data, unclear sentences, clarification of terminology or context

     b.  Issues identified by the protocol team requiring follow up, additional probing, or discussion with the interviewers. This could include general findings related to discussion facilitation techniques or specific issues that should be teased apart further in future IDIs.

2. QDMC-reviewed transcripts will be sent back to the site using the sFTP within approximately two weeks of transcript receipt.
3. The site must then respond 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].
4. After the revised transcript is received by RTI, a designated staff member will review the corrected areas and deem the issue resolved or else will follow up with the site until all necessary changes are made.

Once the QDMC  finds no additional issues, the QDMC  will accept all changes, remove all comment bubbles, and finalize the transcript. the QDMC will notify sites of this finalization status via email and upload final transcripts to SFTP site.

## Staff Training

The D2D P2 team will design and conduct a study-specific behavioral training that covers the contents of this SSP, allows for practice and feedback with interviewing skills, and discusses site-specific needs, modifications, and considerations for sociobehavioral data collection. The sociobehavioral data collection training may be split up (quantitative and qualitative) if this better aligns with study schedule. This training will be completed before sociobehavioral data collection begins.

**Appendix 11-1: Quick Tips for In-Depth Interview**

**Preparing for the Interview**

Before each IDI, the following should occur:

1. Ensure a signed copy of the Screening/Enrollment Informed Consent Form with permission to participate in the IDI is on file.
2. Contact the participant to remind them of the visit at least one day before the interview: inform them of the time and location of the IDI (for IDIs completed virtually, ensure access to Zoom).
3. Ensure the audio-recorder(s) are ready: functioning, charged or has extra batteries, memory card has sufficient space.
4. Ensure interviewing space has been reserved and is ready for use.
5. Ensure the correct version of the IDI guide and any other supplemental tools are ready for use, in the participant's preferred language. Gather needed supplies, e.g., pen and stationery for notetaking, IDI guide, visual probes, refreshments (if applicable), and reimbursement (if applicable).
6. Upon participant's arrival for the IDI, confirm participant identity per site-specific SOPs. For Sexual Partner IDIs, complete the Informed Consent Process before administering any behavioral forms.

Roles, responsibilities, procedures, and timing for these steps will be outlined in site-specific SOPs.

**Conducting the Interview**

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.

1. **Maintain Confidentiality.** Respect confidentiality at all times. Be careful not to comment to other family members or neighbors about anything that you learned during the interview. This is especially important when interviewing participants about their sexual behaviors and intimate relationships.
2. **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: "What do you think are some qualities of someone that uses condoms? Of people that don't use condoms?"
3. **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?" "Why do you say that?" "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." "What do you mean by…?" 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? An experienced interviewer may also use other non-verbal probes such as the silence probe and the nodding probe.

4. **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. When reflecting back to the participant, try not to interrupt.
   - Example of reflecting back: So you told him that you think it's a sign of being responsible if you avoid sex while drinking?

5. **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.

6. **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 you are genuinely interested in what they have to say.

7. **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.

8. **Be Truthful.** In responding to questions from participants during the interview, provide brief, truthful answers. If a longer conversation or response is needed, or if the issue is complicated, let the participant know that it will be further discussed after the end of the interview.

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

10. **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. Maintain eye contact without staring. Be interested in what the participant is saying even if you have heard it in other interviews. **Master your guide!** This will be done through training and role plays.

## Ending the Interview

After each interview is complete, the interviewer should be sure to thank the participant, ensure that any questions that they had are documented for follow-up, and provide the participant with their reimbursement.

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**Appendix 11-2: Secure File Transfer Protocol (SFTP) Instructions**

**Overview**

Secure File Transfer Protocol (SFTP) is a highly secure file directory used to transfer manually files from one computer to another computer. MATRIX-003 will primarily use SFTP to transfer **files with potentially personally identifiable information (such as transcripts)**. Files with personally identified information MUST always be transferred in a secured way and should never be sent via email. The goal of SFTP is *only* for file **transfer**; files will not be stored for an indeterminate amount of time on SFTP and should be deleted typically after 24 hours.

Access to SFTP is based on folders, not individuals—a username and corresponding password will provide a connection to that folder, regardless of who is logging in. Because of this, username and password will be provided by the SFTP administrator to a specific individual and that individual shall not distribute that username and password to anyone beyond themselves. An individual wishing to receive access to a folder needs to send a request to the QDMC and may be granted access by the SFTP administrator through an email communication. **Any violation of this could be considered an ethics violation and a breach in study confidentiality.**

**Download FileZilla**

FileZilla is a free, third-party program that allows access to an SFTP site. You must have this or a similar program to access SFTP.

Download FileZilla here (https://filezilla-project.org/download.php) and ensure in your download process that you are not downloading additional programs, bloatware, or viruses.
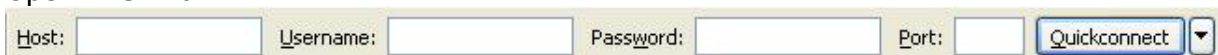
**Connect to SFTP with FileZilla**

Only connect to SFTP directories with the username and password provided to you by the SFTP administrator. Do not share your username or password information with **anyone**.

**Quick Connect**

To connect, you will need a **Host** (*sftp://ftp.rti.org*), **Username** and **Password** (provided via email from the QDMC staff), and **Port number** (*22*). Follow these instructions:

1. Open **FileZilla**



2. Enter the address of the server in the field **Host**, located in the **Quickconnect** bar.
3. Enter your username, password, and port number.
4. Click on **Quickconnect** or press **Enter** to connect to the server.
5. Click **OK** when you get a warning about an unknown host key. (The first time you connect to the FTP server you may be asked to verify that it is a trusted site. Check the "Always trust certificate in future sessions" box. Then click "OK" to continue.)

Each site will have a Username as follows:

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- **Pitt:** MATRIX003-PITT
- **HHRC/Zengeza:** MATRIX003-UZ
- **Wits RHI:** MATRIX003-WRHI
- **CAPRISA-Vulindlela:** MATRIX003-VULINDLELA
- **Aurum-Tembisa:** MATRIX003-TEMBISA

Passwords will be provided separately to the individual(s) at each site who are responsible for file transfer using SFTP.

## Save a Connection with Site Manager

1. Perform Quick Connect
2. Click **File** and **Copy current connection to Site Manager…**
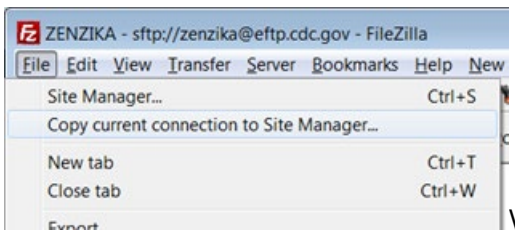


Now you are ready for file transfer!

## Transfer Files

Transferring files via SFTP requires administrative and technical actions. The process includes:

1. Appropriately name and save the file using the naming convention below to be copied to SFTP for transfer; please save all the files uploaded to SFTP on the original computer.
2. Upload the file via FileZilla (or other third-party program) to SFTP.
3. Inform a specific group of people that it has been uploaded by email.
4. Download the file via FileZilla (or other third-party program) to a secure location on another computer.
5. Delete the file on SFTP after a specific time frame.

## Name and Save the Files to be Transferred

Please keep a folder on your computer of all files uploaded to SFTP. This is very important. It provides a chronological history of your hard work, can be referenced by date, and these files can serve as backups, if needed.

## Upload the File

You can upload a file by double-clicking on it, by right-clicking one or more file and selecting Upload, or by dragging one or more files from one side and drop them on the other side. Whichever method, the files will be added to the transfer queue and the transfer starts automatically.
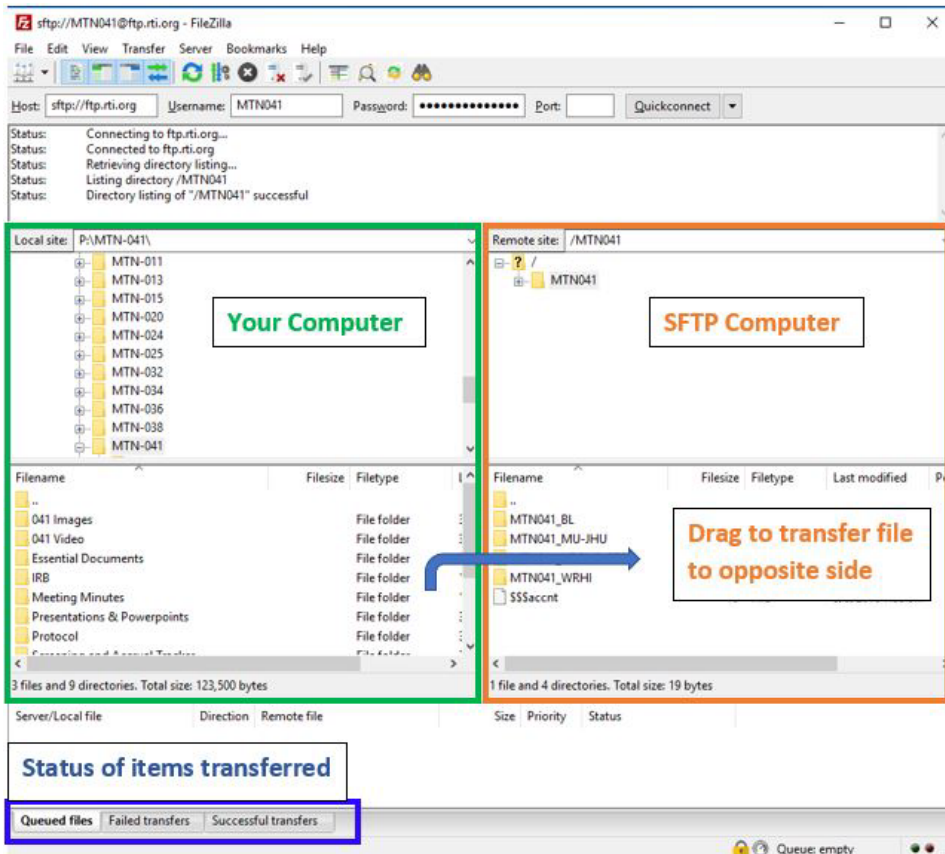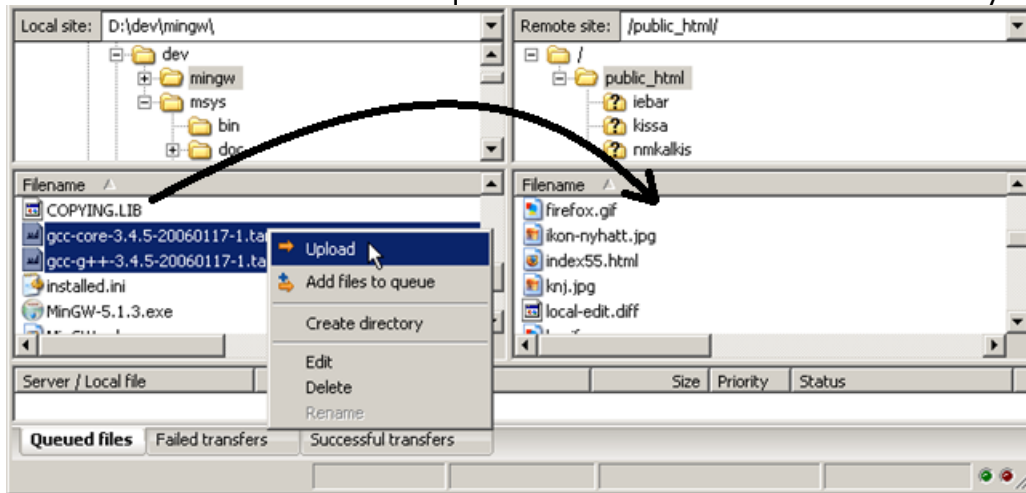




## Inform Recipient(s)

STFP is a manual process. There are no automatic alerts when a file is added to a folder. Because of this, the person uploading a file must alert the recipients that a file has been uploaded.

**Download the File**

Downloading a file is similar to uploading a file, only that the file is double-clicked, dragged, or right-clicked on the STFP side of the navigation pane (i.e., the file directory on the right) and moved to your computer's side. Ensure you know where you are saving a file when moving it to your computer; double-clicking will pick an automatic folder whereas dragging allows you to choose a folder with your mouse.

**Delete the File**

SFTP is designed for file transfer, *not* for file storage. It is important that files uploaded are deleted (do **not** delete the original file from your computer, instead leave this in the Uploads folder you created above) after an adequate amount of time (typically, 24 hours). Because of this, the QDMC and each site will have one person who is the designated "deleter". It is the responsibility of the deleter to ensure the people who need the file have received and downloaded the file before they delete.

> **REMINDER**: Once you receive files from  the QDMC , **please delete those files from the SFTP folder**. Only documents that are newly uploaded and waiting for the QDMC should be in the appropriate folders at any given time.

Please contact the QDMC  (matrixSBRdatamgmt@lists.matrix4prevention.org) with any questions about this process.

**Appendix 11-3: Example Formatted Transcript**

| Basic Transcript Information | |
|---|---|
| **IDI Type:** | ☐ Participant IDI<br>☐ Sexual Partner IDI |
| **Participant ID (PTID):** | |
| **Interview Date:** | |
| **Interviewer:** | |
| **Note taker (*if applicable*):** | |
| **Transcriber:** | |
| **Translator (*if applicable*):** | |
| **Site Reviewer:** | |
| **Transcript QC'd alongside audio** | ☐ Yes, by whom: _____<br>☐ No |

I, [*translator/transcriber*], certify on [*date of transcription*] that this transcript is an accurate and complete representation of the original audio file.

**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 alright 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?