MATRIX-002 Study-Specific Procedures (SSP) Manual
Section 11 – Behavioral Measures

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Acronyms list

- CCG: Case Report Form Completion Guidelines
- CRF: Case Report Form
- D2D P2: Design to Delivery Pillar 2
- DR: Debrief Report

- IDI: In-Depth Interview
- IRB/IEC: Institutional Review Board/Independent Ethics Committee
- PUEV: Product Use End Visit
- QC: Quality Control
- REDCap: Research Electronic Data Capture
- SBR: Sociobehavioral Research
- SFTP: Secure File Transfer Protocol
- SMS: Short Message Service
- SOP: Standard Operating Procedure

11 Introduction

This section contains information on behavioral research procedures performed in MATRIX-002, including behavioral case report forms (CRFs) and in-depth interviews (IDIs))) guides. 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 coordinating unit. Any questions about behavioral data collection procedures, process, or management may be directed to matrixSBRdatamgmt@lists.matrix4prevention.org.

11.1 Overview

All behavioral case report forms (CRFs) will be administered by a trained interviewer and captured through REDCap. 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 for an IDI (either directly by study staff or through the participant, depending on site-specific SOP(s) and IRB/IEC guidance). This section provides general guidance on completion of behavioral CRFs, as well as instructions for all qualitative procedures.

A question-by-question guide for behavioral CRFs offers guidance for CRF administration. Detailed guidelines on how to access CRFs through REDCap and complete them are provided in Section 12 of this SSP Manual.

11.2 Data Collection Instruments

Table 1 outlines all behavioral data collection activities planned in MATRIX-002, indicating the form acronym, the assessment, how it will be administered, and when. All CRFs are intended to be administered electronically and will be programmed into REDCap for administration on tablet, laptop, or desktop computers. IDIs will be conducted through use of a ethics approved semi-structured interview guide that the interviewer will print out and may use for notetaking throughout the interview, though the source document for responses will be a transcription based on an audio recording.

All behavioral CRFs and IDI guides needed for MATRIX-002 will be provided by the Design to Delivery Pillar 2 (D2D P2) team, and current versions of all forms (English) will be available on the MATRIX-002 study webpage. All forms should be printed locally, as necessary and applicable. The current version of all forms (English) will be posted to the MATRIX-002 [https://www.matrix4prevention.org/activity-

hubs/clinical-trials/matrix-002/matrix-002-study-documents]. The site is responsible for translation of all CRFs, including behavioral questionnaires and IDI guides as outlined in Section 2 of this SSP. The site is responsible for maintaining an adequate printed supply of the current version 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 needed action by site teams. One copy of previous versions of CRFs and guides should be maintained in an archive, and all other hard copies destroyed.

Table 1: Behavioral Assessments – Timing and Mode of Administration

Form Acronym	Assessment	Mode of Administration	Visit
DEM	Baseline demographics	Electronic In-person	V1 *(Screening)*
BEH	Baseline behavioral assessment	Electronic In-person	V2 *(Enrollment)*
BL	Baseline acceptability	Electronic In-person	V2 *(Enrollment)*
FU1	Post-insertion acceptability assessment	Electronic In-person	V2, V6 *(Enrollment)*
CO	Clinician-completed observation	Electronic In-person	V2, V6 *(Enrollment)*
FU2	Brief behavioral assessment	Electronic Phone, SMS	V3, 4, 5, 7, & 8 *(24-72hr post-dose, 2 wk, and 6 wk contacts)*
FU3	Follow-up behavioral and acceptability questionnaire	Electronic In-person	V6 *(4wk visit)*
FU4	Final behavioral and acceptability questionnaire	Electronic In-person	V9 *(PUEV)*
SH	Social Harms	Electronic In-person or phone	*As needed*
IDI (P)	Participant in-depth interview (subset)	Discussion In-person or web conference	*V9 or prior to completing V10*
IDI (SP)	Sexual partner in-depth interview	Discussion In-person or web conference	*Within one month of V9*

11.2.1 Guidance on completion of Behavioral CRFs

- Whenever possible, behavioral assessments should be completed before counseling procedures. In the case of the post-insertion questionnaire scheduled for the enrollment visit, it is understood that it will happen 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 this should be documented in the participant chart notes.

- Behavioral CRFs should be administered by a staff person who is separate from the staff members who are 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, though 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 she hasn'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.
    - 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 the 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 directly to participant's safety and well-being—specifically, if violence/abuse, sexual assault, social harms, food insecurity, or adverse events (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. In cases where this is necessary, staff should take care to protect the participant's trust/rapport with the SBR interviewer as much as possible. See Section 11.3 of this SSP for further guidance related to management of AEs, social harms, intimate partner violence (IPV), or sexual assault. ap
    - If information reported during the interview reflects any other issue or misunderstanding (e.g., misunderstanding of efficacy/placebos, worries about the product, or unhealthy vaginal practices, lack of adherence to vaginal activity restrictions), the interviewer should seek verbal consent from the participant and refer the situation to the site study coordinator for management.
- Participant reports of expulsion (partial or full) of the study film should be documented on an FU2 form (if reported during administration of that form) or on the PRN Expulsion Log.
    - If expulsion of the film is reported by a participant at any visit other than a visit where the FU2 is administered (e.g., participant phone call, interim visit, V6/V9 during administration of the FU3 or FU4 forms), the PRN Expulsion Log should be used.
    - Existing questions in FU3 (#8a) and FU4 (#8a) ask about occurrences of partial/full expulsion. If a participant responds that they have had this experience, a prompt will appear in the REDCap platform to prompt the completion of the PRN expulsion log. However, if data collection is being done on a paper form, there is not a specific prompt

and interviewers should be made aware that they will need to flag this occurrence and independently initiate the PRN Expulsion Log as appropriate.
    - Each expulsion should only be captured once, on either the FU2 form OR the PRN Expulsion log. The question in the FU2 is phrased to ask about experiences "since your last visit/contact", which should indicate to the participant that we are asking about new reports. If multiple incidents are reported, please gather more information from the participant to be able to determine if a new report matches an expulsion that has already been documented.

11.2.2 Telephone check-ins

Telephone check-ins 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.

If the participant is not able to schedule and conduct the check-in via telephone or in-person within 48 hours of the Visit 2 and Visit 6 appointments, but is able to complete the questionnaire on a smartphone, a link to the participant-facing REDCap survey can be texted to them by study staff. Participants who are unable to complete the questionnaire via telephone call *or* via link sent to a smartphone will not complete that instance of the follow-up CRF. Staff will work diligently to assess why the visit was unable to completed during the designated visit window, and address that concern prior to the next visit window closing.

11.2.3 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).

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

- Overview: Up to 35 interviews with participants from the clinical study (target: 6-8 per site) and up to 30 sexual partners of participants (target: 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 35. All IDI participants must have agreed to participate in the IDI by providing appropriate written informed consent and agreed to be audio recorded before being selected as an IDI participant. All IDI participants will be selected purposively.
- Characteristics of clinical participants to be selected for IDIs: Clinical participants will be purposefully selected for IDIs with the intention of obtaining a qualitative sample balanced by Film

type (A and B). In addition to exploring women's experiences using the film over the two use periods, the team is interested in learning about the use of the vaginal film during sex. Thus, participants who report engaging in sexual activity during film use are anticipated to make up at least half of the qualitative sample for clinical participants.
    - In conversation with the sociobehavioral and/or clinical 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 film. If those are identified, the team will work together to update selection procedures as needed to ensure those perspectives are represented.
- Selection process: An IDI Selection Tool will be provided to each site to map out key characteristics of each participant selected for an IDI (e.g., randomization arm, sex during the study period, intravaginal practices, other characteristics of interest). Each site team will lead the process of selecting participants for IDIs and tracking that information. The site teams will collaborate with D2D P2 to discuss completed interviews and then make decisions about potential future participants to invite, based on the information gained through completed IDIs, and any emerging themes that the team wishes to further explore.
- Invitation of sexual partners: Sexual partners of participants will be invited per site specific SOP(s) if study participants have consented to this and later confirm willingness to have their partner enroll to complete an IDI. 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 the partner IDI target sample size, the team will seek to enroll sexual partners that represent a variety of different experiences engaging in sexual activity with the clinical study participant during the study period, with a goal to have a substantial representation from sexual partners who did engage in vaginal sexual activity with the participant while she was using study product.

11.2.3.1 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 film coming out, experiences with insertion, insightful film 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 site team may invite the participant during Visit 8 or 9, or soon thereafter. The interview must be scheduled and completed before completing Visit 10 (SEV).
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 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 of 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.

11.2.3.2 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.

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

11.2.3.3 Data Collection Considerations for Initiating and Conducting the Interview

- Qualitative visit checklists: These checklists should be used to guide the order of procedures for each IDI. The RTI team will provide a qualitative visit checklist template for each site to modify as needed.
- Rooms for conducting IDIs: 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.
- Informed consent: 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).
- Language of IDI: Confirm which language the participant would like to use when completing the IDI.
- 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.
- Length of qualitative activities: IDIs are anticipated to last approximately 45-60 minutes.
    a. For situations where the time available to conduct an IDI may be limited, *MATRIX-002 Operational Guidance- #01 SBR* provides additional guidance regarding which topic areas and questions are most important to cover during each IDI (for both participants and their sexual partners). If the cadence of the interview suggests that time limitations will not be an issue, interviewers should consider following the guide as-is, rather than the additional guidance provided in *MATRIX-002 Operational Guidance- #01 SBR*.
- 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. The management team should be contacted immediately following the IDI to inform them that the participant did not agree to the audio recording.
- 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.
- 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.

11.3 Safety Reporting

If any social harms (SH), AEs, protocol deviations (PDs), or other events that require mandatory reporting in the local legal context are reported by participants during administration of the SBR CRFs or during qualitative interviews, interview staff should refer the issue as shown in **Figure 1.**

- For most events, SBR 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, PD, or other reportable event. 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 as directed by the IoR/designee. The site-specific procedure for referring and documenting these occurrences should be outlined in the relevant site-specific SOP(s).
- Participant behaviors that are classified as PDs and reported during administration of an SBR CRF will not follow the same reporting process as other PDs.
    - SBR CRFs include questions about participant behaviors that, depending on participant response, may classify as a protocol deviation (e.g., sex or intravaginal product use during period when prohibited by protocol). When a participant behavior that is non-compliant with protocol is captured in an SBR CRF, no further action is required (i.e., no PD log will be completed, no CAPA will be created, and no change to counseling procedures should be done).
    - This may result in discrepancies between the clinical CRF data and SBR CRF data, which is anticipated and acceptable for these occurrences.

Although the interviewer is required to share information about many of 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. Study staff should prioritize protecting the trust between the interviewer and the participant, and should take care when acting on information shared when talking to the participant.

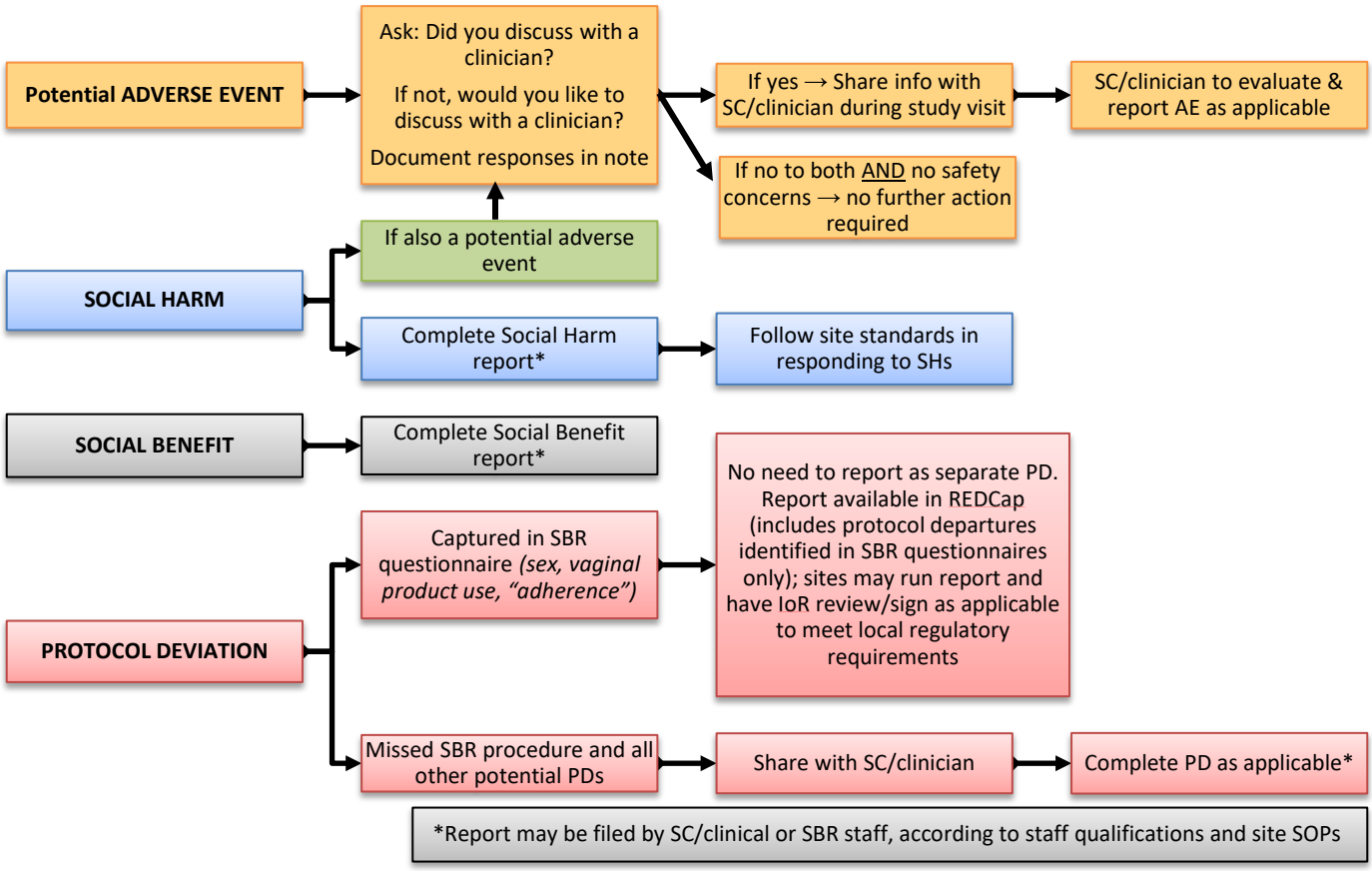
Some sample language for explaining referrals to participants is provided below:

- *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?*

Though sharing information learned during SBR interviews may be necessary for these types of circumstances, it has the potential to erode participants' trust and rapport with the SBR interviewers. Other

study staff (e.g., clinicians and coordinators) who learn of participant information from SBR staff should take care when acting on that information and when communicating with the participant. When possible, study staff should work to preserve the relationship between SBR interviewers and the participant, and mitigate the risk of introducing bias in future interactions.

Figure 2: Flow chart for reporting events identified by SBR staff during SBR CRF/IDI data collection activities



11.4 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 their site-specific SOP(s).

All documents listed below must be stored and managed according to the procedures outlined in this section and the site's relevant SOP(s).

Timeline for data storage and/or transfer to RTI after each qualitative activity:

- Same day as IDI:

    - Audio file(s) and back-up version(s) saved
    - Notes filed in participant records per site SOP
- Within one day:
    - Debriefing Report (DR) completed via REDCap by interviewer and sent to RTI.
    - RTI 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:
    - Transcript sent to RTI. See Appendix 11-2 for Secure File Transfer Protocol (SFTP) information.
    - RTI 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.

11.4.1 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. 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 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-002 Management Team.

11.4.2 Interview notes

Immediately following the IDI, all notes taken during the activity should be 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.

11.4.3 Debriefing reports

On the same day as the IDI (or within one business day), the interviewer should complete a Debriefing 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". 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.

11.4.4 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. When translating the audio files into English, 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.

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.

11.4.5 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, unless an alternate plan is developed (matrixSBRdatamgmt@lists.matrix4prevention.org). 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).

11.4.6 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
- Debriefing 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.

11.4.7 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 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.

11.4.8 Quality control procedures

Initial QC at Site

Initial QC of interviewing skills at site: An independent, senior socio-behavioral staff member with qualitative expertise or the qualitative lead should review the first 2 IDIs for each interviewer/facilitator 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/facilitator 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.

Initial QC of the transcript at site: 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

Sites will log the quality check process and send this QC log sheet to RTI monthly. These transcript reviews will be continued until the quality is deemed acceptable for each transcriber. Once this is determined, the site leadership will email D2D P2.

Ongoing quality control at site

Quality control of debrief reports at site: After initial completion, debrief report REDCap entries should undergo 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

Quality control of transcripts at site: After the quality of the first two transcripts (or more, if needed) has been deemed acceptable, quality checks will continue and include listening to at least three 5-minute spots in the audio file and comparing those 5 minutes spots to the transcript. 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.

Ongoing quality control with RTI:

For debriefing reports: After the site level QC process, the DR will be submitted via REDCap for RTI to review per SSP Section 11.3.3. Site teams should submit DRs to RTI as soon as they become available and within **24 hours** of when the IDI occurs. Site teams should communicate with RTI if delays are anticipated. DRs will not undergo a formal QC process, but RTI data 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, RTI 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 RTI 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 RTI to review per SSP Section 11.3.7. Site teams should send English language transcripts to RTI as soon as they become available and within **four weeks** of when the IDI occurs. Site teams should communicate with RTI if delays are anticipated. Transcripts will then undergo the following QC process:

1. Each transcript will be reviewed by a member of RTI's 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. RTI-reviewed transcripts will be emailed to the site 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.
5. Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles, and finalize the transcript. RTI will notify sites of this finalization status via email and upload final transcripts to SFTP site.

11.5 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.

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: "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?"
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 she/he has 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 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.
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 have been documented for follow-up, and provide the participant with their reimbursement.

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-002 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 RTI 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 RTI staff), and **Port number** (*22*). Follow these instructions:

1. Open **FileZilla**

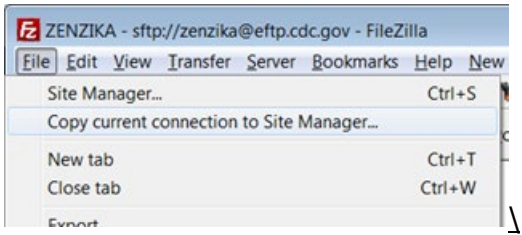
2. Enter the address of the server in the field **Host**, located in the **Quickconnect** bar.
3. Enter your username, password, and port number.
4. Click on **Quickconnect** or press **Enter** to connect to the server.
5. Click **OK** when you get a warning about an unknown host key. (The first time 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 their SFTP username sent to them by D2D P2 prior to the start of data collection.

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:

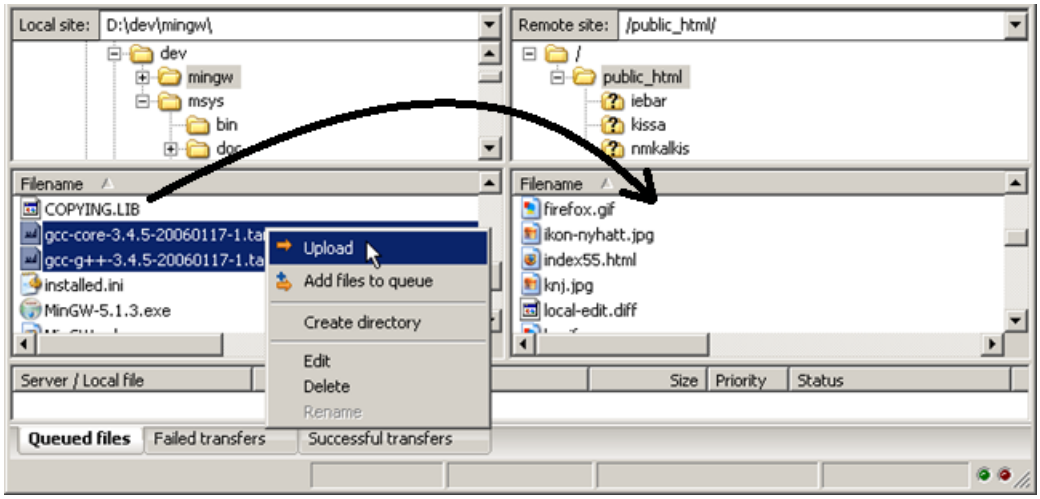
1. Appropriately name and save the file using the naming convention below to be copied to SFTP for transfer; please save all the files uploaded to SFTP on the original computer.
2. Upload the file via FileZilla (or other third-party program) to SFTP.
3. Inform a specific group of people that it has been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

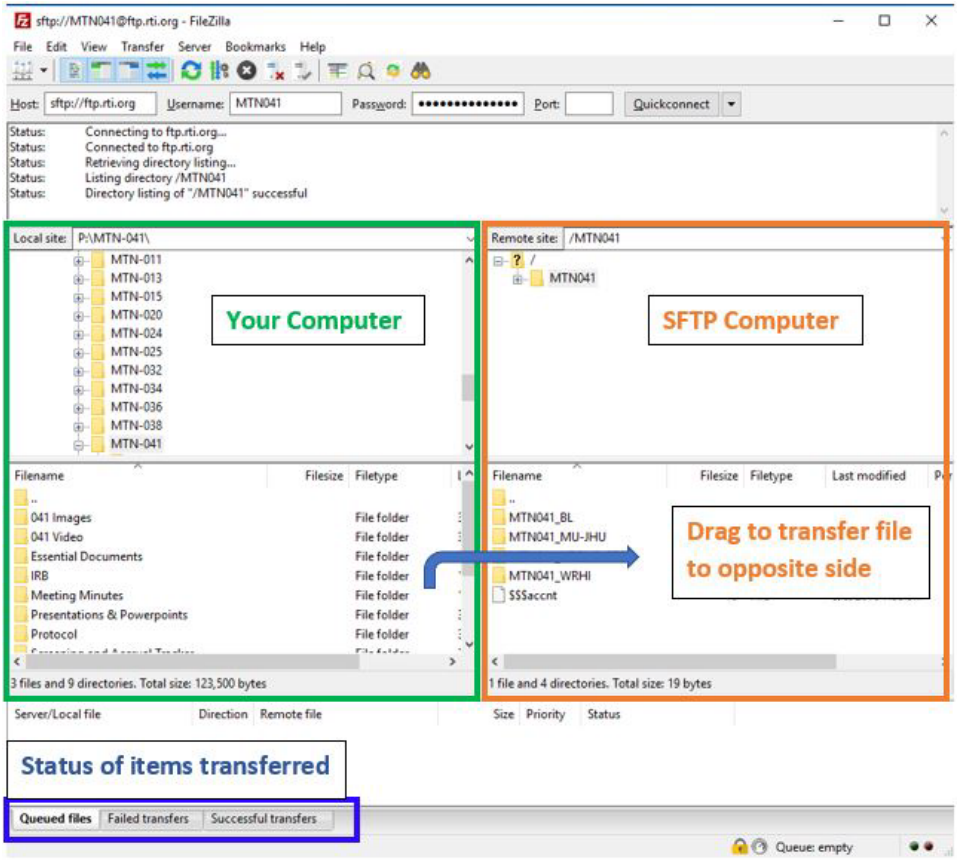
Name and Save the Files to be Transferred

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.

Example Email

"Hello [names of recipients],
I've just uploaded <name of file> to the <name of folder> on STFP. Please download the file within the next <time frame, ~24 hours> before <name of designated deleter> removes the file. Please let me know if you have any questions.

Thank you,
<name of sender>
<sender affiliation>"

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, RTI 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 RTI, **please delete those files from the SFTP folder**. Only documents that are newly uploaded and waiting for RTI should be in the appropriate folders at any given time.

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

Appendix 11-3: Example Formatted Transcript

Basic Transcript Information	
IDI Type:	☐ Participant IDI ☐ Sexual Partner IDI
Participant ID (PTID):	
Interview Date:	
Interviewer:	
Note taker (*if applicable*):	
Transcriber:	
Translator *(if applicable)*:	
Site Reviewer:	

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?