

MTN-045 Study-Specific Procedures Manual Table of Contents - Current Sections

Section Number	Section Title	Version Number	Version Date
1	Introduction	Version 1.1	16JUL2020
2	Documentation Requirements	Version 1.0	12NOV2019
3	Accrual, Eligibility Determination and Study Procedures	Version 1.0	12NOV2019
4	Informed Consent	Version 1.0	12NOV2019
5	Safety and Counseling Considerations	Version 1.0	12NOV2019
6	Data Collection and Management	Version 1.0	12NOV2019
7	Data Communiqués	Version 1.0	12NOV2019

Section 1. Introduction

1. Introduction	1-1
1.1 Current Protocol Specifications	1-1
1.2 Procedural Information.....	1-1
1.3 Investigator of Record (IoR) Responsibilities	1-2
1.4 Study Activation Process	1-3
1.5 IRB/EC Submissions.....	1-3
Figure 1-1: IRB/EC Submissions Required for MTN-045.....	1-3

1. Introduction

This section specifies the sources of procedural information available to study staff, the responsibilities of the Investigator of Record (IoR) and the process by which each site will be approved to initiate implementation of MTN-045.

1.1 Current Protocol Specifications

The table below documents the version history of the MTN-045 protocol, along with any Clarification Memos and Letters of Amendment, if applicable, all of which are considered Essential Documents. To ensure this section reflects the current specifications of the protocol, upon issuance of any future protocol Clarification Memo (CM), Letter of Amendment (LoA), or Protocol Amendment, the table will be updated accordingly. These documents are available on the MTN-045 webpage (<https://mtnstopshiv.org/research/studies/mtn-045>).

Document	Date
MTN-045 Protocol, Version 1.0	25 February 2019
Clarification Memo #01 for Protocol Version 1.0	27 May 2020

Sites are expected to operate under the protocol version and associated Clarification Memos and/or Letters of Amendment that are currently approved by the local institutional review board/ethics committee (IRB/EC). A copy of each document should be available to staff and a copy should be maintained in site essential files. Further information on the content and required handling procedures for these documents is available in the Microbicide Trials Network (MTN) Manual of Operational Procedures (MOP), which is located on the MTN webpage (<http://www.mtnstopshiv.org/MOP>).

Note: In order to respond to the developing COVID-19 pandemic, sites may need to rapidly implement practices and procedures that are not in line with the protocol or SSP Manual (e.g., paused visit procedures in the interest of staff/participant safety, conduct of remote study activities such as transcription and QA/QC procedures, etc.). Sites should communicate with the MTN-045 Management Team about this and document contingency plans related to COVID-19 proactively, to the best of their ability (and retrospectively, as needed).

1.2 Procedural Information

This Study Specific Procedures (SSP) Manual serves to supplement the protocol. It does not replace or substitute the protocol or its contents. In the event this manual is inconsistent with the information and guidance provided in the protocol, the specifications in the protocol will take precedence. In the event study implementation questions are not adequately addressed by the study protocol or this manual, or if any inconsistencies between the two documents are identified, please notify the MTN-045 Study Management Team at mtn045mgmt@mtnstopshiv.org.

The MTN-045 Study Management Team consists of the Protocol Chairs and representatives

from the MTN Leadership and Operations Center (LOC)-University of Pittsburgh (Pitt) and FHI 360, Research Triangle International (RTI), the DAIDS Medical Officer, NIMH and the study sites. Sites should contact this group for general questions on protocol implementation or study procedures.

Contact details for the above-listed individuals are listed in the MTN-045 protocol and are also available in the MTN Directory, which is accessible via the MTN webpage (<http://www.mtnstopshiv.org/people/directory>).

1.3 Investigator of Record (IoR) Responsibilities

MTN-045 must be conducted in accordance with the United States (US) Code of Federal Regulations (CFR) and the International Conference on Harmonization Consolidated Guidance for Good Clinical Practice (GCP). In addition, MTN-045 must be implemented in accordance with all site-specific regulations, policies, and guidelines applicable to human subjects research in general and/or the conduct of study procedures in particular. Copies of all such regulations, policies, and guidelines should be maintained in on-site essential document files.

The Division of AIDS (DAIDS) policies '[Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials](#)' and '[Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials](#)' are useful for interpreting and operationalizing the applicable regulations and guidelines in accordance with DAIDS expectations. These resources are also available on the MTN website under 'Resources and Links' (<http://www.mtnstopshiv.org/resources>).

The IoR at each study site must sign an Investigator Signature Form (Protocol Signature Page [PSP]) and a DAIDS IoR Form to formally indicate his/her agreement to conduct MTN-045 in accordance with the provisions of the study protocol, applicable US regulations, and MTN policies. The obligations and responsibilities assumed by the IoR when signing the DAIDS IoR Form are listed on the form itself, which is available on the DAIDS Regulatory Support Center (RSC) website. Note that no staff member should fulfill the IoR role in the IoR's absence. Full responsibility and authority over the protocol by anyone other than the IoR may only take place if an additional DAIDS IoR Form is completed and submitted to DAIDS. A PSP must be signed by the IoR and uploaded to DPRS for all initial protocol versions, all full protocol amendments, and all LOAs.

An IoR may delegate his or her obligations and responsibilities for conducting MTN-045 procedures to other study staff members. However, in doing so, this delegation does not relieve the IoR of his/her ultimate responsibility for all study procedures performed and all study data collected. Delegation of IoR responsibilities must be formally documented throughout the period of study implementation on the site's Delegation of Duties (DoD) Log. DoD Logs must meet standards as outlined in the DAIDS **Delegation of Duties Log Policy**. Sites must employ the DAIDS-provided DoD [template](#) and should reference the related [instructions](#).

Consistent with the regulations, guidelines, and policies cited above, the site IoR must obtain and maintain IRB/EC approval of MTN-045 throughout the period of study implementation. Detailed information on IRB/EC submission, review, approval, and documentation requirements is located in the MTN MOP. All sites are encouraged to request acknowledgement of receipt for all documents submitted to their IRBs/ECs and to request that IRBs/ECs note the effective and expiry dates of all approvals. Documentation of all correspondence to and from all responsible IRBs/ECs (i.e., complete copies of all submissions, responses, and approvals) must be maintained in on-site essential document files. Documentation of all IRB/EC approvals may also be requested by the MTN Leadership and Operation Center (LOC).

Note: Guidance outlined in the current [DAIDS Protocol Registration Manual](#) regarding which staff should be included on the DAIDS IoR form as sub-investigators should be followed. The manual outlines that staff who make a "direct and significant contribution to the data" should be included as sub-investigators. This includes "site personnel who have more than minimal involvement with the conduct of the research (performing study evaluations or procedures or providing intervention) or more than minimal study conduct-related contact with study

participants or confidential study data, records, or specimens.” The CRS Leader should be included as a sub-investigator if this individual is not also the IoR at the site.

If there is a change in IoR after study activation, a revised DAIDS IoR Form and a new PSP should be submitted to the DAIDS Protocol Registration Office (PRO). Sites should follow guidance in the current DAIDS Protocol Registration Manual regarding procedures for a change in IoR with the DAIDS PRO. Incoming investigators should also complete IoR training and document the change in IoR on the study DoD log (per DAIDS’ instructions). In addition, they may need to complete an electronic financial disclosure form via the HANC system; investigators who need to complete a HANC financial disclosure will be contacted by MTN Regulatory with additional guidance. Outgoing investigators sign off all DoD Log entries. Additionally, sites should notify FHI 360, MTN Regulatory, and their OCSO PO of the change and complete any other documentation requested.

1.4 Study Activation Process

Prior to commencing active recruitment activities and undertaking any study procedures, each study site must complete the following:

- obtain approval to conduct MTN-045 from all required local regulatory authorities and IRBs/ECs,
- complete protocol registration procedures with the DAIDS RSC PRO, and
- complete study activation requirements, and be issued a Site-specific Study Activation Notice from MTN LOC.

Information on these procedures can be found in the MTN MOP. Detailed information on the requirements of pre-implementation steps are summarized in the MTN-045 Activation Checklist. FHI 360 will notify sites (on a site-by-site basis), when all activation requirements have been met by issuing a Site-Specific Study Activation Notice.

1.5 IRB/EC Submissions

Figure 1-1 lists IRB/EC submission and approval requirements pertinent to MTN-045. The study sites are encouraged to request that their IRBs/ECs acknowledge receipt for all documents submitted to them, and to request that the IRBs/ECs note both the effective date and the expiry dates of all approvals. Procedures for IRB/EC communication must be documented in site-specific Standard Operating Procedures (SOPs). Documentation of all correspondence to and from all responsible IRBs/ECs (i.e., complete copies of all submissions, responses, and approvals) must be maintained in on-site essential document files. Documentation of all IRB/EC approvals may also be requested by the MTN LOC.

Figure 1-1: IRB/EC Submissions Required for MTN-045

Documents to be submitted to IRB/EC	Written Approval Required*
Prior to study initiation:	
MTN-045 Protocol, Version 1.0	Yes
Informed Consent Forms: <ul style="list-style-type: none"> • Screening/Enrollment 	Yes
Investigator of Record current CV	No
Participant pre-screening, recruitment plans and materials (prior to use)	Yes
Other written information for study participants (prior to use)	Yes
Other documentation required/requested by the IRB/EC such as SOPs, CRFs, and interview questionnaires.	If required by IRB/EC

During and following conduct of the study:	
Study status reports/updates (at least annually)	Yes
Protocol clarification memos (submission encouraged but not required by DAIDS)	No
Protocol amendments (including full amendments (to a new protocol version) and letters of amendment)	Yes
Amended informed consent forms (including forms that are amended due to protocol amendments as well as forms that are amended for site-specific reasons, e.g., to update participant incentive information or to update site contact information)	Yes
Protocol departures/deviations/violations (per IRB/EC requirements and/or as directed by DAIDS)	No
New information that may adversely affect the safety of study participants or the conduct of the study	No
Investigator of Record current CV (if IoR changes during study)	No
Updated/additional participant recruitment plans and materials (prior to use)	Yes
Updated/additional written information for study participants (prior to use)	Yes
Other documentation required/requested by the IRB/EC	If required by IRB/EC
Final study report/closure report	No

*Denotes approvals required by US regulations and GCP guidelines.

Section 2: Documentation Requirements

2.	Introduction.....	2-1
2.1	Essential Documents	2-1
2.2	Participant Research Records	2-2
2.3	Required Source Documentation.....	2-3
	2.3.1 Visit Notes.....	2-3
	2.3.2 Visit Checklists.....	2-4
	2.3.3 Case Report Forms (CRFs).....	2-5
	2.3.4 Document Organization and Participant Confidentiality	2-5
2.4	Record Retention Requirements.....	2-6
2.5	Translation Procedures	2-6
2.6	Protocol Deviations.....	2-7

2. Introduction

Study staff are responsible for proper collection, management, storage, quality control and quality assurance of all study-related documentation. This section contains information on the essential documents that each study site must maintain throughout MTN-045. It also contains information related to establishing adequate and accurate participant research records for the study.

2.1 Essential Documents

The DAIDS policy on [Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials](#) and [E6 Good Clinical Practice: Consolidated Guidance](#) specify the essential documents that study sites must maintain. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location. Further information and recommendations related to essential document filing are as follows:

- Essential documents may be stored in files, binders, and/or electronically. The files/binders listed in essential documents filing structure may be further subdivided, consolidated, and/or re-organized.

NOTE: Sites that chose to file documents electronically must ensure computer systems are 21 CFR Part 11 compliant and are required to have documentation on file certifying that their systems meet such requirements. Refer to the MTN Manual of Operational Procedures, Section 9, for further details on the requirements that must be met when using electronic systems/software.

- It is recommended that a contents sheet be maintained and inserted as the first page(s) of each file/binder. Within each file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).
- It is assumed that MTN-045 participant research records will be stored separately from the other essential documents. Section 2.3 below provides information on the required contents of these records.

- The MTN-045 Participant Link Log and Screening and Enrollment Log must be maintained in hard-copy. It is assumed that these logs will be stored in the study clinic or data management area throughout the screening and accrual process and not necessarily with the other essential documents.
- All significant communications between the study sponsor and/or management team and study sites should be printed and filed with other essential documents.
 - All site responses to any priority emails (thereby indicating they were read and responded to)
 - All study management team and/or sponsor communications that document agreements or significant decisions involving study administration or conduct, protocol deviations, eligibility and informed consent, safety and/or study endpoints
 - Protocol Team call slides
 - Final training reports, including sign-in sheets
 - Final study activation notification memo and activation checklist
 - Emails from the study management team that specify to print and file

Note: When required documents are modified or updated, the original and all modified or updated versions must be retained in the files. Communications that are PTID-specific should be printed and filed in the participant binder. Communications that are overarching (i.e. are not PTID-specific) can be printed and filed with regulatory documentation.

2.2 Participant Research Records

Study sites must maintain adequate and accurate participant research records containing all information pertinent to MTN-045 for each study participant. See protocol sections 11.2 and 13.6 for further information regarding all participant information that should be stored securely with access limited to authorized study staff. Please note that all records that contain names or other personal identifiers, such as locator forms and informed consent forms, will be stored separately from study records identified by PTID.

As MTN-045 will enroll couples, sites have the option to organize participant documentation such that study records for both members of a couple are stored within a single binder or file.

The International Conference on Harmonisation Consolidated Guidance for Good Clinical Practice defines the terms *source data* and *source documentation* as follows:

The term **source data** refers to all information in original records and certified copies of original records related to clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the trial (including all screening, enrollment and randomization activities). Source data are contained in source documents (e.g., original records or certified copies).

The term **source document** refers to original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participants' diaries and/or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, participant files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the study).

Source documents are commonly referred to as the documents – paper-based or electronic – upon which source data are first recorded. All study sites must comply with the standards of source documentation specified in the [DAIDS policy on Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials](#). The DAIDS policy specifies both requirements and recommendations. Study sites must comply with all requirements and are encouraged, but not required, to comply with all recommendations.

2.3 Required Source Documentation

For MTN-045, participant research records should consist of the following source documents:

- Visit notes
- Documentation that the participant provided written informed consent to screen for and participate in the study prior to the conduct of any study procedures
- Documentation that the participant met the study's eligibility criteria
- A record of all contacts, and attempted contacts, with the participant
- A record of all procedures performed by study staff during the study (e.g., on visit checklists and/or other site-specific procedural flow sheets or visit notes)
- A record of any referrals made (including for social harms or unexpected safety events reported that were not recorded elsewhere), per Good Clinical Practice (GCP) and DAIDS source documentation guidelines
- Case Report Forms (CRFs) and other forms provided by RTI International or MTN LOC
 - The Behavioral and Demographic Questionnaire (BDQ) and Discrete Choice Experiment Survey (DCE) are “electronic” CRFs. The Couples Observation Tool, Ideal Product Activity (IPA), Protocol Deviations (PD) and Social Harms (SH) forms are “paper” CRFs.
- Documentation of any deviations from SOPs or procedures outlined in the protocol or this SSP Manual that are not recorded on other source documents. See Section 2.6 below for more information on reporting protocol deviations.
- IDI Guides. Data collected on and any notes taken on IDI discussion guides or separate pieces of paper during qualitative data collection are source documents and must be kept in the participant file.
- Final English and translated transcripts, audio files, CDs, and Debrief Reports. Details on the storage of these is provided in Section 6 (Data Collection and Management) of this SSP Manual.

2.3.1 Visit Notes

Study staff must document every contact with a study participant in a signed and dated visit note or contact log specifying the following information:

- Visit date at which a contact takes place or at which a particular procedure takes place
- Purpose of the visit and location of the contact if other than the research clinic
- General status of the participant at the time of the visit

Visit notes should also be used to document the following:

- The informed consent process (if an Informed Consent Coversheet is not used)
- Procedures performed that are not recorded on other source documents (e.g. visit reminder phone calls, emails etc.)
- Counseling sessions and/or other in-depth discussions with participants (e.g., related to social harms, if not documented on other worksheets)

- Other pertinent data about the participant that are not recorded on other source documents and/or any clarifications or information needed to supplement data recorded on a CRF
- Reason(s) why protocol-specified procedures were not performed
- Explanation of why procedures in addition to those listed on a checklist were performed
- Contact attempts to follow up on participants who missed a scheduled study visit

2.3.2 Visit Checklists

Visit checklists are convenient tools that may serve as source documentation if designed and completed appropriately. These checklists alone may not suffice for documenting all procedures but can be used to indicate that certain procedures were completed. Visit notes may be required to supplement this for any of the reasons mentioned above. Visit checklist templates are available on the MTN-045 website under Study Implementation Materials.

Instructions for completing visit checklists in accordance with these requirements are as follows:

- Document the participant identification number (PTID) and visit date on the top section of each checklist page.
- Complete staff initials next to procedures completed.
- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.
- If applicable, for items on the checklist that contain checkboxes, one set of initials is sufficient, even if multiple boxes are checked.
- Entering multiple sets of initials for one procedure should be avoided as much as possible. If this happens on a regular basis, the site should consider splitting the task into multiple items on the checklist so each procedure receives only one set of initials.
- If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why on the checklist or in visit notes; initial and date this entry.

The sequence of procedures presented on the visit checklist templates is a suggested ordering. In consultation with RTI International, sites may modify the checklists to maximize the efficiency of site-specific study operations. Visit checklists, and visit flow, should be monitored and updated as needed to ensure that study visits are completed as quickly as possible, with minimal delays for participants and study staff. Sites may alter the sequence of procedures to suit local staffing and logistical requirements, with the following exception:

- Written informed consent must be obtained before any study procedures are performed. Study visit procedures are listed in protocol section 7.

Note that the time of each study procedure does not need to be documented to demonstrate the order of visit procedures if this can be accomplished through other approaches. Acceptable alternatives include using a statement in the chart note or on visit checklists which verifies that the correct order was executed, or by documenting that procedures were conducted ‘per site SOPs’ which specify order. Deviations from SOPs should be explained in visit notes.

2.3.3 Case Report Forms (CRFs)

Case Report Forms (CRFs) for MTN-045 are designed for use with the RTI International data management system described in Section 6 (Data Collection and Management) of this manual. RTI International will provide the master versions of these forms to the sites, and printing will be coordinated locally. RTI International will also provide several additional study-specific forms (non-CRFs) to the sites. See Table 2-1 for a listing of all study forms, which can be found on the MTN-045 website. Additional source documents (e.g., visit notes, site-specific checklists, worksheets, debrief reports) will be identified in sites' Data Management SOPs.

2.3.4 Document Organization and Participant Confidentiality

Study staff must make every effort to store all study records securely and confidentially. Participant file records must be stored in the same manner for all participants, in areas with access limited to authorized study staff only. Study staff are responsible for purchasing file folders, binders, storage cabinets, and any other equipment or supplies needed to properly store all records.

Study-related documentation collected during the screening process should be stored in file folders/binders for each potential participant. All screening documentation – for potential participants who eventually enroll in the study as well as for those who do not enroll or “screen out” – must be maintained throughout the study. For participants who enroll in the study, screening documentation should be transferred to a separate file folder/binder that will serve as the participant's study notebook for the duration of their participation in the study.

All documents contained in participant files must bear a participant identifier, which generally will consist of either the participant identification number (PTID) or the participant name. Refer to Table 2-1 below for guidance on which identifier to include on each study document. The PTID should be used whenever possible to maximize participant confidentiality. As a best practice, it is recommended that records bearing names or other personal identifiers, such as locator forms and informed consent forms, be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location must be identified by PTID only. Care should also be taken to only refer to participants by PTID in email communications when people outside of the CRS are included. Regardless whether the identifier on a particular document consists of the participant name or PTID, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated on copies of original source documents. For example, if medical records obtained from a non-study health care provider bear the participant's name, the original documents bearing the name must be stored unaltered with other study documents bearing the name. However, a copy of the original documents could be made, the PTID could be entered onto the copies, and then the participant name could be obliterated from the copies. Copies handled in this way could then be stored in participant study notebooks and/or transferred or transmitted to non-study site locations.

All on-site databases must be secured with password-protected access systems. Any lists, appointment books, or other documents that link PTIDs to other participant identifiers should be stored securely (locked cabinet/drawer if hard copy; password protected if electronic) and in a location separate from records identified by participant name only and separate from records identified by PTID only. When in use, documents that link PTIDs to other participant identifiers should not be left unattended or otherwise accessible to study participants, other study clinic patients, or any other unauthorized persons.

Table 2-1: Identifier Requirements for MTN-045 Study Documents

Document Name	Mode	Name only	PTID only	Name and PTID
Locator Form	Paper	X		
Participant Link Log	Paper			X
Screening and Enrollment Log	Paper		X	
Informed Consent Forms	Paper	X		
IC Comprehension Checklist, IC Coversheet	Paper	X ¹	X ¹	
Case Report Forms (PSF, CO tool, IPA, PD, SH)	Paper		X	
Behavioral and Demographic Questionnaire	Electronic (tablet)		X	
Discrete Choice Experiment Survey	Electronic (tablet)		X	
Visit Checklists, Eligibility Checklists, Eligibility Confirmation Form	Paper		X	
Permission to Contact Form/ Log ²	Paper	X ¹	X ¹	
Discussion Guides and Notes	Paper		X	
Interview Transcripts	Electronic		X	
Audio-recording	CD		X	
IDI Debriefing Reports	Electronic		X	

¹ As stated above, study documents should contain participant name or PTID, but not both. Documents tracked by name should be stored separately from those tracked by PTID.

² PTC Forms/Logs are not required for MTN-045. However, follow guidance above if these will be used.

2.4 Record Retention Requirements

Study records must be maintained onsite for the entire period of study implementation. Thereafter, guidance for record storage will be provided by FHI 360 in consultation with DAIDS and the MTN Executive Committee. No study records may be moved to an off-site location, discarded or destroyed without prior written authorization from the protocol team. Refer to the MTN Manual of Operational Procedures (MOP; Section 18) for further requirements pertaining to record storage.

The IoR/designee will maintain all study documentation for a minimum of three years after submission of the site's final Financial Status Report to DAIDS, unless otherwise specified by DAIDS or the MTN LOC. However, documents may be stored for a longer period if required by applicable regulatory requirements or by an agreement with the sponsor.

2.5 Translation Procedures

Per MTN MOP Section 11, all study materials that are read verbatim or provided to the participant must be translated into local languages, back-translated, and reviewed by members of the study management and/or behavioral team as appropriate. Participant materials may include the informed consent forms and comprehension assessments, interview guides, questionnaires and other study materials developed for participant use. Site teams are responsible for establishing a Translation SOP that should, at minimum, contain the following elements:

- Description of the translation and back-translation process and the quality control of it
- Who is responsible for conducting each step of this process (and whether it is done by on-site staff or through a contracted group)

All staff involved in the translation and back-translation process should ensure that language fluency is documented on their CV on file at the research site and that this responsibility is assigned per the site Delegation of Duties Log. A standard *Certificate of Translation* should be issued for translations completed, indicating the specific documents that were translated (with version number/date as appropriate) as well as the individual conducting the translation. It is recommended that, as part of translation procedures, staff members who will be responsible for utilizing the translated study materials review and/or pilot use of the tool to confirm translations are understandable in the context they will be used.

2.6 Protocol Deviations

DAIDS requires that all protocol deviations be documented in participant records, along with efforts made to correct the deviations, and efforts made to prevent similar deviations in the future. The MTN MOP should be referenced for complete guidance on protocol deviations.

For MTN-045 the Protocol Deviation (PD) CRF will be used to document each protocol deviation identified. Corrective and preventive action (CAPA) plans are required components of protocol deviation documentation. Note that the corrective and preventive action plans documented on the PD CRF are not required to be completed in order to report the deviation. The PD CRF should be completed even if the action plans are pending or in progress.

If there is any question as to whether a deviation has occurred, or how it should be documented, the MTN Regulatory Department (mtnregulatory@mtnstopshiv.org) and MTN-045 Management Team (mtn045mgmt@mtnstopshiv.org) should be contacted. Once the potential protocol deviation has been confirmed, the site will be contacted with this confirmation and the 7-day reporting requirement will begin. Once the CRF is submitted, RTI International will follow up with the site if any clarifications or additional information on the CRF are needed. The study management team will follow up with the site regarding any next steps, as needed.

Note that some protocol deviations may also be considered critical events. Refer to the [DAIDS Critical Event Policy](#) and [Critical Event Manual](#) for detailed guidance on the definition of and process of reporting critical events. The site OCSO Program Officer (PO) should be contacted with any questions related to critical events, including reporting requirements and procedures, CAPAs, and critical events tracking questions. Site consultation with OCSO may be facilitated using the MTN Critical Event Reporting Form, available in the 'Resources' section of the MTN web page; however, use of this form is not mandatory. Sites that choose to use this document should email the completed form to their OCSO PO, who will work with other DAIDS staff to review available details about the event and determine if a critical event has occurred. If a critical event is confirmed, the OCSO PO will work with the site to develop, review and carry out any CAPAs associated with the reported critical event.

Sites are recommended to report to their IRBs/ECs any PDs that pose a potential safety risk to a participant(s) and those that could affect the integrity of the study according to the local IRBs'/ECs' standard operating procedures and guidelines. It is also recommended that a complete list of all PDs occurring at the site, including PDs not meeting immediate reporting standards noted above, be submitted to the local IRBs/ECs in accordance with their reporting policies. If a local IRB/EC does not have a specific reporting policy, MTN recommends that this be done at the time of IRB renewal submission, annually or semi-annually, per local requirements. These listings will be provided to the sites on request.

Section 3: Accrual, Eligibility Determination and Study Procedures

3.	Introduction	3-1
3.1	Study Accrual Plan and SOP	3-1
3.2	Site-Specific Accrual Targets and Timelines.....	3-2
3.3	Prescreening/Recruitment Activities.....	3-2
3.4	Visit Location.....	3-3
3.5	Screening and Enrollment Visit Procedures	3-3
3.5.1	Visit Checklists	3-4
3.5.2	Preparing for the Study Visit.....	3-4
3.6	Assignment of Participant ID Numbers (PTIDs)	3-5
3.7	Eligibility Determination and SOP	3-5
3.7.1	Study Inclusion and Exclusion Criteria	3-6
3.7.2	Eligibility Checklists (Male and Female) and Eligibility Confirmation Form	3-7
3.7.3	Evaluation of IPV Risk.....	3-7
3.7.4	Dummy Questions on Eligibility Checklists.....	3-9
3.8	Screening and Enrollment Logs	3-10
3.9	Weekly MTN-045 Progress Reports.....	3-10
3.10	In-Depth Interview	3-10
3.10.1	IDI Selection	3-10
3.10.2	Procedures for Selected Participants	3-12
3.10.3	After the IDI is Completed	3-12
	Appendix 1: Study Visit Flow Diagram.....	3-13

3. Introduction

MTN-045 will enroll heterosexual couples who have been in a relationship for ≥ 3 months (living together or not) and are interested in contraception and/or HIV prevention. The purpose of this SSP Manual section is twofold: 1) to provide information on requirements and procedures for recruiting participants and determining participant eligibility and 2) to outline study procedures for MTN-045.

3.1 Study Accrual Plan and SOP

Participants will be recruited from the communities served by the selected clinical research sites. Recruitment materials must be approved by site Institutional Review Boards/Ethics Committees (IRBs/ECs) prior to use. Site community representatives will advise on these materials before they are submitted to the IRB/EC for review. Community education strategies, including group sessions, may be employed as part of participant outreach. Site staff may work with community stakeholders, including community advisory board (CAB) members and voluntary health workers, to identify and recruit a community-based sample of couples.

Each site is responsible for developing its own accrual plan that should be described in the site SOP for Participant Accrual, Eligibility Determination, and Informed Consent. Note that sites may choose to separate these topics into standalone SOPs based on their preferences. SOPs should at minimum contain the following elements related to the site accrual plan:

- Site-specific accrual targets and timelines
- Description of any community sensitization plans
- Recruitment strategies relevant for accrual of couples, including:
 - Potential recruitment locations and venues
 - Plans for education about the study

- Description of prescreening activities (as applicable)
- Plans for referral to screening visits (and how ineligible participants will be handled)
- Plans for recruitment materials (as applicable)
- Methods for tracking targeted versus actual accrual, and implementation of back-up plans as needed
- Methods for maintaining participant confidentiality during the accrual process
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures (if not specified elsewhere)

Study staff are responsible for updating this SOP as needed to meet site-specific accrual goals.

3.2 Site-Specific Accrual Targets and Timelines

Approximately 400 couples are targeted to be enrolled in MTN-045. Per protocol, the total accrual time allotted for this study is 12-15 months for recruitment and enrollment at each site, however sites should make efforts to accelerate this timeline as needed and in consultation with the Management Team. A subset of up to 80 participants (i.e., one or both partners from up to 40 couples) will be selected to complete a single post-survey explanatory in-depth interview (IDI) to provide further insight into the participants' survey responses and any unexpected and/or interesting examples of experiences and behaviors relevant to the study endpoints. Achievement of site-level accrual goals will be based on the number of participants enrolled in the study, not the number of Participant IDs (PTIDs) assigned.

The site-specific enrollment targets are summarized in Table 3-01.

Table 3-01: Approximate Enrollment Targets per Site

Site	Target Enrollment	Target Number of IDIs	IDI Type/Number
MU-JHU CRS	200 couples	20 couples total, up to 40 participants	At each site: 2-3 couples will be selected from the following categories: <ol style="list-style-type: none"> 1. Male partner opinion dominated, newer relationship 2. Male partner opinion dominated, more established relationship 3. Female partner opinion dominated, newer relationship 4. Female partner opinion dominated, more established relationship 5. Equal contributions, newer relationship 6. Equal contributions, more established relationship 2-8 couples will be selected who represent interesting cases
Zengeza CRS	200 couples	20 couples total, up to 40 participants	

3.3 Prescreening/Recruitment Activities

Prescreening for this study primarily refers to recruitment procedures undertaken by site staff in the field, prior to scheduling potential participants for their MTN-045 screening and enrollment visit. Site teams should provide education about the MTN-045 study to potential participants as outlined in their site-specific SOPs. Potential participants may be asked about their interest in contraception and/or HIV prevention, or other study eligibility criteria, during pre-screening activities to ascertain presumptive eligibility to enroll in MTN-045. Study sites will take steps during pre-screening and screening activities to minimize the potential for partner coercion or for placing participants at increased risk of intimate partner violence (IPV). Prescreening checklists to evaluate presumptive eligibility may be implemented with appropriate approvals

from site IRBs. Should sites choose to develop these materials, their usage should be outlined in site-specific SOPs. After providing study education, potentially interested participants should be scheduled for an MTN-045 screening and enrollment visit for formal evaluation of study eligibility.

Recruitment activities should be tracked on site-specific logs to monitor progress towards accrual goals. These logs should include only summary level, non-identifiable information such as: recruitment venue, total number of potential participants contacted, number of potential participants booked for screening and enrollment visits, and date of scheduled visit.

3.4 Visit Location

It is important that study visits be conducted in a private location to maintain the confidentiality and safety of the participant(s). It is also important that locations for conduct of the IDIs be quiet enough for audio-recording. Typically, visits will be conducted at the study site. Per protocol, visits may also be conducted at an alternate location (such as the participant's home for an IDI), if agreed upon by the participant and if privacy can be maintained. In the event a visit is conducted anywhere other than the study site, staff should document participant agreement to the visit location in their participant binder.

3.5 Screening and Enrollment Visit Procedures

Sites should consider visit length and make efforts to minimize participant fatigue when scheduling participants for study visit procedures.

For each study visit, completion of the following procedures for each participant is required and should be documented on the applicable Study Visit Checklist (see Appendix 1 for the study flow diagram):

1. **Obtain written informed consent for screening and enrollment:** Written IC must be obtained from each member of the couple prior to conducting any protocol-specified study procedures. Details are outlined in SSP Manual Section 4 (Informed Consent).
2. **Assign a PTID Number:** See Section 3.6 below for details.
3. **Collect locator information:** Although "provision of adequate locator information" is not a required inclusion criterion for MTN-045, sufficient participant locator information should be collected to allow for participant contact in the case of visit rescheduling and/or visit reminders for completion of the IDI (if scheduled on a different day), necessary follow-up on safety issues/social harms (expected to be rare), and/or dissemination of study results. Each site may determine the appropriate type of locator information to collect for these purposes, and suitable approaches for capturing this information.
4. **Confirm eligibility:** Eligibility of each member of the couple must be confirmed by designated staff, after written IC is obtained, and prior to completion of any data collection procedures (survey questionnaires, Case Report Forms [CRFs], or IDI). All eligibility procedures, inclusive of eligibility determination and final confirmation, should occur on the same day and not across multiples days/visits. Both members of the couple must be eligible to be enrolled. Details are outlined in Section 3.7 below.
5. **Provide introduction to DPP products via standardized materials:** Placebo versions of four product forms and a study video will be provided to sites in local languages to facilitate introduction to dual purpose prevention (DPP) products. The video and placebo products should be shown to each member of the couple before any questionnaires are administered.

6. **Administer individual questionnaires:** All questionnaires should be administered to study participants in a location that ensures participant confidentiality. Survey questionnaires will be administered to each member of the couple separately. This will include a DCE and a questionnaire with demographic and behavioral questions, both of which will be administered using a tablet computer.
7. **Administer Couple's DCE and Ideal Product Activity:** The individual questionnaires will be followed by a joint couple decision task completed by the couple together. As the couple completes the joint DCE and the ideal product activity, the interviewer will complete the Couples Observation CRF. Procedures for survey administration are further described in Section 6 (Data Collection and Management) of this SSP Manual.
8. **Complete other study CRFs as needed:** The Protocol Deviation CRF and Social Harms CRF are completed on an as-needed basis only.
9. **Provide reimbursement:** Sites must establish, in consultation with their IRBs/ECs, appropriate reimbursement for participant time/travel to conduct MTN-045 study visit(s). Reimbursement amounts should be specified in site-specific Informed Consent Forms.
10. **Schedule next visit (if applicable):** Ideally couples enrolled into MTN-045 will complete their screening and enrollment procedures, individual survey questionnaires, and joint couple decision task on the same day. However, if that is not possible, visit procedures may be conducted over more than one day. Should this be necessary, the next visit should be scheduled. Separate visits may need to be scheduled for a subset of participants selected for an IDI (see below).
11. **Complete In-depth Interview (subset):** A subset of participants will be selected to complete an in-depth interview. Participants selected for an IDI may complete this procedure on the same day as screening and enrollment or at a separate visit scheduled **within 28 days** of their screening and enrollment visit. If the IDI is scheduled to occur on a different day, sites must also update locator information on the day of the IDI and provide reimbursement for time/travel to the clinic for the IDI. Site staff should consider the availability of all necessary interview staff (e.g., qualitative interviewers) when scheduling participants for their IDIs. Details regarding conduct of the IDIs is described in section 3.10 below.

3.5.1 Visit Checklists

Visit checklists will be used to document completion of all required study procedures and data collection forms for each visit and each type of participant in MTN-045. There are three types of visit checklists for MTN-045 (templates are available on the MTN-045 website):

1. Joint Visit Checklist (to be completed for all couples)
2. Individual Visit Checklist (to be completed individually for each member of the couple)
3. IDI Visit Checklist (to be completed for participants selected for an IDI)

Visit checklists should include, at minimum, the visit date, male and female PTIDs, a list of all required study procedures and a place for staff to indicate that each item has been completed and to write their initials and the date. Template visit checklists should be modified as needed to ensure they fit with systems at the site, then reviewed by RTI International for approval prior to implementation.

3.5.2 Preparing for the Study Visit

Site staff should do the following to prepare for MTN-045 study visits:

- Consult the Version Control Table for MTN-045 and ensure the correct versions (English and local language) of the following study materials and all necessary study equipment will be available, including:
 - MTN-045 Informed Consent Form

- Informed Consent Comprehension Checklist and Coversheet
- MTN-045 Screening and Enrollment Log
- Visit Checklist(s)
- Eligibility Checklists (male and female) and Eligibility Confirmation Form
- Study educational video (including equipment for showing the video) and placebo products
- MTN-045 CRFs
- Tablet computers to administer electronic CRFs (DCE and BDQ)
- As applicable, ensure couple has been reminded of their visit per site MTN-045 SOPs
- For IDIs (subset), also confirm:
 - IDI guide and associated IDI equipment (charged audio recorder, note taking materials, etc.) are available
 - Confirm the availability of the interview venue/room.

3.6 Assignment of Participant ID Numbers (PTIDs)

Sites should assign one PTID to each potential participant after informed consent for the study has been obtained. PTIDs are assigned in sequential order (within the applicable range) as potential participants complete informed consent. Staff should ensure that each PTID is assigned only once and should track this by using the MTN-045 Participant Link Log. To reduce the chance of error in writing/typing PTIDs throughout the visit, site teams should consider pre-populating the PTIDs on the Participant Link Log and pre-printing sticky labels that correspond to each couple's PTID assignments (Female ID, Male ID, Couple ID). When the PTIDs are assigned, a staff member would place the pre-printed sticky labels corresponding to assigned PTID on the appropriate visit checklist (Individual, Joint, IDI, respectively) at a minimum, and other paper forms if desired.

MTN-045 PTID boxes are located near the top of each CRF page. The PTIDs used for this study are five digits long and are formatted as "X-XXX-X". Note that male and female participant IDs of a couple are formatted such that the IDs are identical with a check digit that distinguishes the male and female member of the couple.

Table 3-02: PTID Breakdown

1 st Digit	2 nd - 4 th Digit	Last Digit
Site #	Sequential for couple identification	Male vs. Female Partner
MU-JHU = 2 Zengeza = 4	100-999	Female = 3 Male = 5

3.7 Eligibility Determination and SOP

It is the responsibility of the site Investigator of Record (IoR) and other designated staff to ensure that only couples who meet the study eligibility criteria be enrolled in the study. Each study site must describe how study staff will fulfill this responsibility within their SOP(s) for Accrual, Eligibility Determination, and Informed Consent. This SOP should contain at minimum the following elements related to eligibility determination:

- Eligibility determination procedures, including:
 - Eligibility assessment procedures, including how potential for coercion from either member of the couple for their partner to join will be minimized and how risk of IPV will be minimized and managed
 - Final confirmation and sign-off procedures prior to enrollment
 - Documentation of all eligibility criteria (met or not met)
- Ethical and human subject considerations
- Staff responsibilities for all of the above (direct and supervisory)

- QC/QA procedures (if not specified elsewhere)

Should study staff identify that an ineligible participant has inadvertently been enrolled in the study, the IoR or designee should contact the MTN-045 Management Team (mtn045mgmt@mtntstopshiv.org) immediately.

Formal eligibility determination for MTN-045 should occur only after each member of the couple has signed the informed consent form (see SSP Manual Section 4: Informed Consent).

3.7.1 Study Inclusion and Exclusion Criteria

Inclusion Criteria

Each member of the couple must meet all of the following criteria to be eligible for inclusion in the study, and both members of the couple must be willing and eligible for the couple to enroll:

1. Able and willing to provide written informed consent in one of the study languages.
2. Able and willing to complete the required study procedures.
3. Currently in a heterosexual relationship (living together or not) for at least 3 months (by self-report) with the other member of the couple.
4. At time of Enrollment, expressed interest in contraception and/or HIV prevention (by self-report).

For female partner:

5. Between the ages of 18 to 40 years (inclusive) at Enrollment, verified per site standard operating procedures (SOPs).
6. HIV negative (by self-report).*

* Females should report their HIV status to the best of their knowledge and site staff should use their discretion in assessing potential participants' self-reported HIV status. Site SOPs should describe processes for evaluating HIV status reports, including how to manage cases of "unknown" HIV status.

For male partner:

7. Aged 18 years or older at Enrollment, verified per site SOPs.

Exclusion Criteria

Potential participants who meet the following criteria will be excluded from the study along with their partner:

1. Has any significant medical condition or other condition that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe (including risk for IPV as a result of study participation), complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

3.7.2 Eligibility Checklists (Male and Female) and Eligibility Confirmation Form

The **MTN-045 Eligibility Checklists** should be used to evaluate inclusion and exclusion criteria that rely on participant self-report (questions in *italic* font) and serve to document that all eligibility criteria have been met. An individual Eligibility Checklist is available for each member of the couple (male and female). The eligibility checklists should be administered to each member of the couple privately, to allow them an opportunity to freely express if they do not want to join the study. Per the form instructions, questions in *italic font* should be translated into local languages and administered verbatim to participants in their preferred language. The checklists must also be administered in full, even if a participant is found ineligible prior to the form's completion. This is to allow for the potential use of the "dummy" questions as justification for a couple's exclusion from the study (see Section 3.7.4 below for more details). If required by local IRBs/ECs, eligibility checklists should be approved before use.

After the eligibility checklists have been completed for both members of the couple, designated staff must document the couple's final eligibility determination using the **MTN-045 Eligibility Confirmation Form**. The IoR/designee should check the appropriate boxes on the form indicating whether each member of the couple individually met all eligibility criteria and whether the couple as a whole is eligible or not for study participation. A signature, date and timestamp must also be recorded, regardless of eligibility status. For those eligible to enroll, the act of completing and signing this form is the act of enrolling the couple into MTN-045. Staff who sign off on participant eligibility must be delegated this responsibility on the MTN-045 delegation of duties (DoD) log. All eligibility forms and checklists are available on the MTN-045 website under *Study Implementation Materials*.

3.7.3 Evaluation of IPV Risk

Per protocol, the IoR should exclude any couples from enrollment in MTN-045 if, at their discretion, either member of the couple "*[h]as any significant medical condition or other condition that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe (including risk for IPV as a result of study participation), complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.*"

To facilitate evaluation of the potential risk of IPV as a result of study participation, the following two questions have been included on both the male and female Eligibility Checklists:

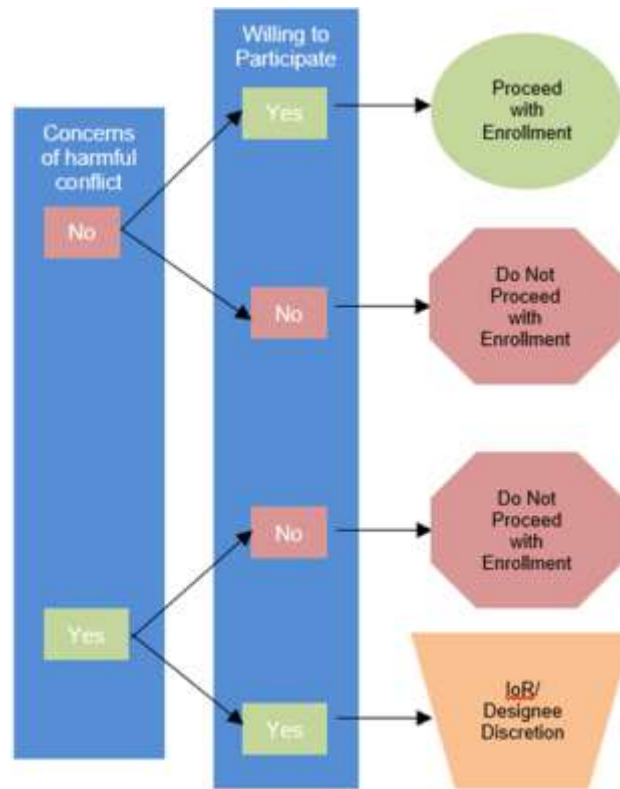
Table 3-03: Eligibility Checklist Questions to Evaluate Risk of IPV

<i>Based on what we said about the study, do you have any concerns that your participation could create or increase harmful conflict between you and your partner?</i>	Yes ..	No ..
<i>Are you still willing to participate in the study with your partner as a couple?</i>	Yes ..	No ..

Staff should administer both of these questions and then assess appropriate next steps before completing the final item on the eligibility checklist that documents if a participant should be excluded from the study per IoR discretion. See Figure 1-1 for actions based on participants' answers to these two questions, and written descriptions of actions based on answers below:

- If a participant answers "NO" to concerns of harmful conflict and "YES" they are willing to participate → OKAY to proceed with enrollment, assuming all other eligibility criteria are met
- If a participant answers "NO" to concerns of harmful conflict and "NO" they are (not) willing to participate → DO NOT PROCEED WITH ENROLLMENT → counsel and refer participant as needed
- If a participant answers "YES" to concerns of harmful conflict and "NO" they are (not) willing to participate → DO NOT PROCEED WITH ENROLLMENT → counsel and refer participant as needed to manage any IPV risk
- If a participant answers "YES" to concerns of harmful conflict and "YES" they are willing to participate → PROCEED WITH CAUTION → Appropriately trained staff should have a conversation with participant to elicit specific concerns about what harmful conflict they foresee the study could cause and their rationale for still being willing to enroll. Based on this conversation, the IoR/designee should determine whether enrollment would be unsafe for the participant. Ultimately, the IoR/designee can determine whether the participant is ineligible due to risk of harm, even if they still express willingness to participate. Counseling and referrals should be provided as needed to manage any IPV risk.

Figure 1-1: Harmful Conflict Decision Diagram



All conversations, counseling and referrals related to potential conflict and IPV should be fully documented in visit notes or other source documents. See also SSP Manual Section 5 (Safety and Counseling Considerations) regarding participant safety and IPV referrals.

3.7.4 Dummy Questions on Eligibility Checklists

Due to the small number of inclusion and exclusion criteria for MTN-045, and to minimize the potential risk of social harms and/or IPV, several dummy questions exist on the eligibility checklists, indicated by Yes/No response options with a hashed background. The dummy questions should also be read verbatim to participants but are ultimately not used in determining a participant’s eligibility. Should a participant express concern that participating in the study with their partner may cause harmful conflict in their relationship, staff may, at their discretion, rely on responses to the dummy questions to justify the participant’s non-enrollment in the study. Using this approach will help minimize social harms and/or IPV by providing a “benign” reason to the participant’s partner why the couple is ineligible for study participation. Alternatively, no specific reason needs to be provided to the couple regarding their ineligibility. Staff should use their discretion and discuss the preferred approach with the member of the couple who expresses that enrolling in the study could create harmful conflict and, because of this, are unwilling to enroll. The dummy questions on the male and female behavioral questionnaire are shown in Table 3-04:

Table 3-04: Dummy Questions on Female and Male Behavioral Eligibility Checklist

<i>Do you and your partner have children together?</i>	Yes	No
<i>Are you currently employed?</i>	Yes	No
<i>Are you and your partner married to each other?</i>	Yes	No

3.8 Screening and Enrollment Logs

The DAIDS policy on [Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials](#) requires that study sites document screening and enrollment activity on Screening and Enrollment Logs. These provide a comprehensive picture of all participants screened and enrolled in the study. This log must be maintained in hard copy. When recording the reason(s) for screen failure/discontinuation, staff should use the codes listed at the bottom of the sample log. In addition to the Screening and Enrollment Log, each participant that is screened for MTN-045 should have a completed Participant Status Form (PSF) CRF, which will indicate enrollment into MTN-045 or reasons for non-enrollment. Each couple that provides informed consent is provided with the next sequential PTID, with a designated “check” digit on the end which will be assigned based on sex (this structure indicates that the male and female participant are undergoing screening and enrollment as a couple). Couples in which the male and female partner both meet all eligibility criteria and whose final sign-off of enrollment status is documented on the **MTN-045 Eligibility Confirmation Form** are considered enrolled in the study.

There is no cap to the number of screening attempts allowed by potential participants; this is to be decided by the site IoR, using their discretion. If a potential participant rescreens for MTN-045, a new line should be used on the Screening and Enrollment Log documenting the new attempt, and the same PTID previously assigned to the participant should be used.

An example of a Screening and Enrollment Log can be found on the MTN-045 website. Sites are encouraged to modify this template as needed. This log must include, at minimum, the MTN-045 Male and Female PTIDs, screening date, screening attempt, enrollment date or reason for non-enrollment (if applicable), and staff initials and date.

3.9 Weekly MTN-045 Progress Reports

Once MTN-045 accrual is initiated, study staff will report the total number of couples screened and enrolled to RTI on a weekly basis, along with other key progress indicators, as necessary. RTI will send a Screening and Enrollment report to the MTN-045 Management Team prior to each scheduled management team call.

3.10 In-Depth Interview

3.10.1 IDI Selection

Summary of MTN-045/CUPID IDI Selection considerations

Per language in the protocol that describes the purpose of the IDIs, the impetus for the qualitative component of MTN-045 is to “provide further insight on the participants’ survey responses and on any unexpected and/or interesting examples of experiences and behaviors relevant to the study endpoints.” Additionally, the protocol specifies that, “Whenever possible, we will also compare study sites and explore differences or similarities related to product preferences due to different socioeconomic, cultural and geographical contexts.” With that in mind, the IDI selection criteria for MTN-045 take into consideration the following elements:

1. Preference
 - a. Notable differences or similarities between individuals’ preference and the couple’s preference
 - b. Preferences around product attributes (particularly with respect to any differences that may be related to sociodemographic factors)
2. Relationship dynamics: interpersonal factors and influence on decision-making
3. Site differences: any salient differences between preference at a site level

Selection Plan

The following plan is intended to respond to the three above-listed priorities for the IDI component of MTN-045. RTI will monitor incoming data (through Qualtrics, REDCap, and

debriefing reports) to identify potential needs to re-adjust this plan during the course of data collection.

1. To address the goal of gaining a better understanding of factors that impact preference, couples will be selected based on the response to Question #4 on the CO CRF, which asks “Which partner’s opinion contributed to the final product selections?” Couples will be selected to participate in IDIs from each of the three response options.
 - a. Male partner’s opinion dominated
 - b. Female partner’s opinion dominated
 - c. Equal contributions
2. To meet the goal of addressing how relationship dynamics within a couple may influence decision-making, 12-18 out of the 20 couples at each site should be selected based on the length of their relationship. Although length of relationship is only a small piece within the larger picture of the interpersonal factors of a relationship, it is related to many other factors of interest (age of members of the couple, cohabitation, having children together). This will be based on the response to Question #10 on the female partner’s BDQ CRF (“For how many years have you and your partner been in a sexual relationship? If you have been in a relationship for less than one year, how many months have you been together?”), and stratified into two categories, though site staff selecting couples should look for a range of relationship lengths within each of these categories:
 - a. Newer relationships: Responses to BDQ Question #10 that are marked as ≤ 3 years old
 - b. More established relationships: Responses to BDQ Question #10 that are marked as >3 years old
3. To address the goal of exploring any site level differences, the 40 couples to be recruited in this study will be split evenly between the two sites.

Site discretion

For the 20 couples to be recruited at each site, the MTN-045 Management Team accords the site teams significant autonomy in selecting couples or members of couples who can provide rich information to help further understand the three above-stated elements. This means that site teams should particularly look for individual participants or couples who:

1. Are able to articulate their rationale for preferences and decision-making
2. Are willing to complete an IDI the same day or will be willing to return to site within 28 days to do so
3. Fit within the selection plan:
 - a. Per selection criteria: As described above and outlined in Table 3-01, participants who fall into each of the three response options for Question #4 on the CO CRF *and* who represent a range of relationship durations, based on Question #10 on the BDQ CRF OR
 - b. Interesting cases: Represent a particularly interesting or impactful experience, (regardless of how they fall into the stratifications for relationship duration and dominance of opinion in Joint DCE).

Table 3-05: Selection Criteria and Target Numbers for MTN-045 IDI Selection

	Male partner's opinion dominated	Female partner's opinion dominated	Equal contributions
Newer Relationship	2-3	2-3	2-3
More established relationship	2-3	2-3	2-3
Subtotal			12-18
Interesting case			2-8
Total			20

3.10.2 Procedures for Selected Participants

For the subset of selected participants, the IDI will take place once the appropriate study visit procedures have been completed.

To begin the IDI, delegated staff should greet the participant, introduce themselves and explain their role in the discussion (e.g., interviewer/facilitator) and help the participant(s) get settled and comfortable in the interview space. The interviewer will describe how the interview will work, including that it will be recorded. The interviewer may start the discussion with an ice-breaker to increase rapport.

Split Visits: If IDI participants are not able to complete the interview on the same day as other study procedures, they may be rescheduled to come back and complete the interview on another day, ideally within one week of the initial visit, though it may be up to 28 days later. Any split visits must be documented in participant file notes.

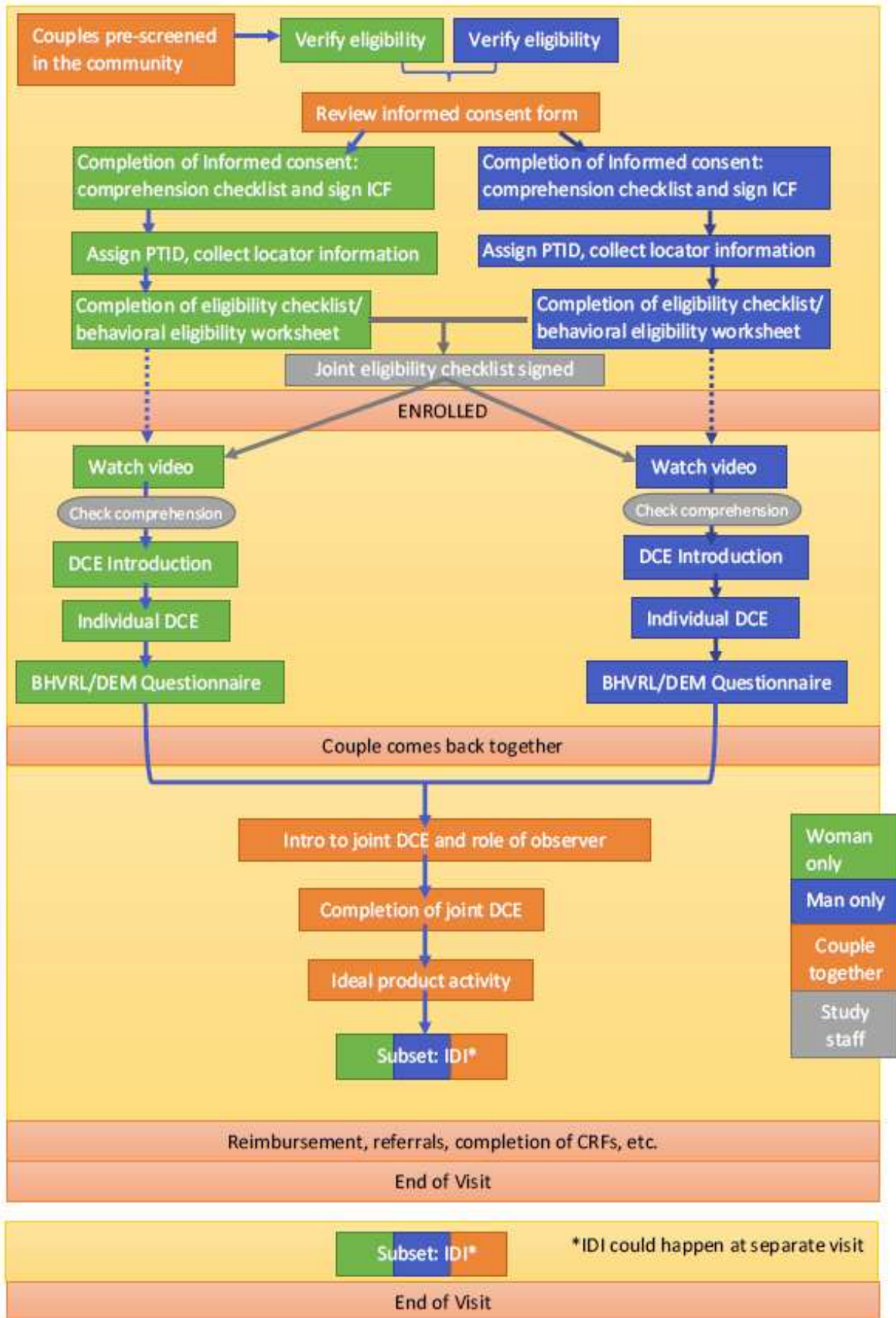
3.10.3 After the IDI is Completed

There are a number of steps to follow after the IDI is complete. They are as follows:

1. Immediately following the IDI, the participant(s) will be thanked and reimbursed according to site-specific IRB-approved informed consent forms.
2. The interviewer will complete their notes and complete the PSFs.
3. A debriefing report (DR) will be completed on the same day as the interview or within 24 hours if it is not possible to complete it on the same day. Once completed, the DR must undergo a QC process at the site prior to being circulated to the study team.

Further details on the management of the audio-files, transcription/ translation process, discussion notes, debriefing reports, CRFs, and transcripts is described in SSP Section 6 (Data Management).

Appendix 1: Study Visit Flow Diagram



Section 4: Informed Consent

4.	Introduction.....	4-1
4.1	Overview of Informed Consent Requirements and Procedures	4-1
4.2	Site-Specific Informed Consent Forms.....	4-2
4.3	SOP for Obtaining Informed Consent	4-2
4.4	Informed Consent for Screening and Enrollment.....	4-3
4.4.1	Informed Consent Procedures for Illiterate Participants	4-5
4.4.2	Couples Informed Consent Considerations.....	4-6
4.5	Comprehension Assessment	4-7
4.5.1	Comprehension Assessment Checklist.....	4-7
4.5.2	Documenting the Comprehension Assessment	4-7
4.6	Documenting the Informed Consent Process	4-8

4. Introduction

This section provides information on informed consent procedures for MTN-045. MTN-045 uses one consolidated Informed Consent Form (ICF) for Screening and Enrollment. For this study, consent for possible participation in in-depth interviews (IDI) is imbedded within the main consent form. No additional signatures are needed for this component of the study.

Depending on IRB/EC requirements, sites may choose to separate consent for any of these components. If this is done, each separate ICF must contain all required elements of informed consent.

This section contains general and specific information and instructions for administering ICFs. In addition, detailed guidance is provided on standardized approaches to the informed consent process that all sites must follow.

4.1 Overview of Informed Consent Requirements and Procedures

Informed consent is a process whereby an individual voluntarily expresses their willingness to participate in research, after having been informed of all aspects of the research that are relevant to their decision. Informed consent is rooted in the ethical principle of respect for persons. It is not merely a form or a signature, but a process, involving information exchange, comprehension, voluntariness, and documentation. Each of these aspects of the process is described in greater detail below. Please refer to the [ICH E6 Section 4.8](#) and the informed consent section of the DAIDS policy on [Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials](#) for further guidance on the informed consent process and documentation requirements.

US regulations (45 CFR 46.116) specify the elements of informed consent that must be conveyed to research participants through the informed consent process. It is the responsibility of the IoR, and all delegated study staff involved in the informed consent process, to provide all required information to potential study participants.

Based on the technical and regulatory reviews that are completed as part of the MTN protocol development and study activation processes, there is adequate assurance that once the MTN LOC (FHI 360) has activated a site for study implementation, site-specific ICFs specify all

information required by the regulations. However, responsibility for informed consent does not end with preparation of adequate ICFs.

It is the responsibility of the IoR or designated study staff to perform the following:

- Deliver all required information in a manner that is understandable to potential study participants
- Assure that informed consent is obtained in a setting free of coercion and undue influence
- Confirm that the participant comprehends the information
- Document each step of the process

4.2 Site-Specific Informed Consent Forms

A sample ICF is provided in protocol Appendix I. Sites are responsible for adapting the sample as needed for local use. Local adaptation may include reformatting the consent form in accordance with local IRB/EC requirements.

Sites are responsible for following procedures outlined in the [MTN MOP](#) and DAIDS [Protocol Registration Manual](#) when drafting and translating their site-specific ICFs. Unless waived by the local IRB/EC, site-specific ICFs must address the eight required elements of informed consent, as required by U.S. federal regulations at [45 CFR 46.116](#). All ICFs (English and translations and back-translations) must be reviewed and approved by MTN LOC (FHI 360) prior to IRB/EC submission. After ethics approval, ICFs must be submitted to and approved by the DAIDS PRO prior to their initial use.

Each site is responsible for preparing bulk supplies of its approved ICFs and for only using the currently-approved ICF version(s) during the study. It is recommended that sites consider the use of color-coding or other techniques to ensure that the various study ICFs be easily distinguishable and used appropriately. A system for tracking version control and approvals of ICFs is also recommended and should include, at a minimum, the version number and date of the ICF, as well as the implementation dates (start and end) indicating when a particular version was in use. If additional guidance on version control tracking is needed, sites are encouraged to ask the MTN LOC (FHI 360) for assistance.

Upon receiving final IRB/EC and any other applicable regulatory approval(s) for an amendment to the ICF(s), sites should implement the ICF(s) immediately and submit updated versions to DAIDS PRO per the timelines outlined in the Protocol Registration Manual.

4.3 SOP for Obtaining Informed Consent

As a condition for study activation, each site must establish an SOP describing the steps for conducting the IC process and obtaining informed consent from potential study participants. This SOP should contain, at minimum, the following:

- Information about applicable local laws, regulations and institutional policies pertaining to the IC process
- The minimum legal age to provide independent IC for research at the study site
- Procedures for determining participant identity and age
- Procedures for determining participant literacy
- Procedures for providing all information required for IC to the participant
- Procedures for determining participant comprehension of the required information
- Procedures to ensure that IC is obtained in a setting free of coercion and undue influence

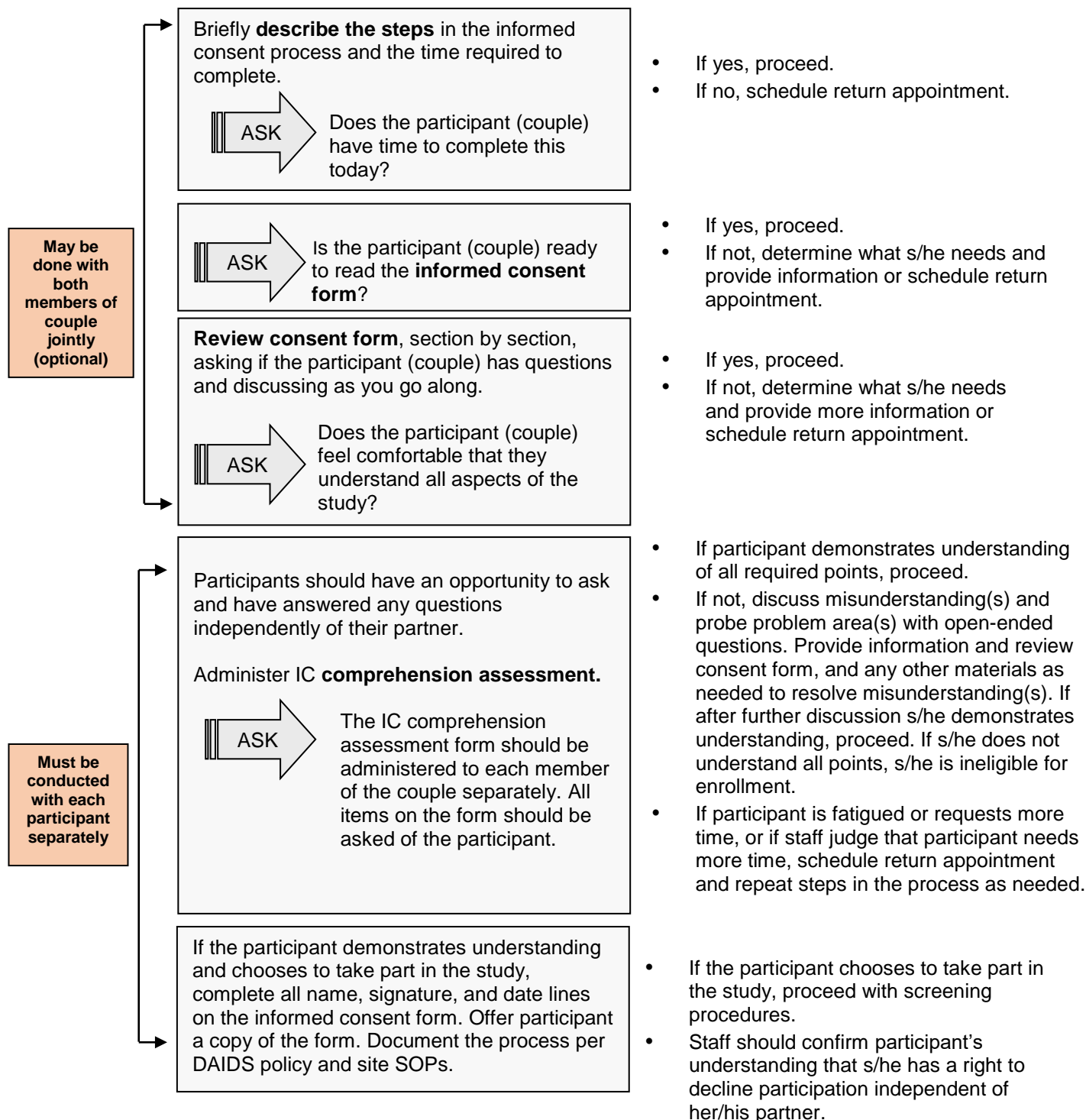
- Procedures for documenting the IC process
- Procedures for conducting part of the IC process with couples together, if applicable
- Storage locations for blank ICFs
- Storage locations for completed ICFs
- Procedures (e.g., color-coding) to ensure that different versions of the study ICF are easily distinguishable and used appropriately
- Procedures for implementing a change in version of the ICF used
- Staff training requirements
- Staff responsibilities for all the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

4.4 Informed Consent for Screening and Enrollment

Informed consent must be obtained before performing any “on-study” procedures at the Screening and Enrollment Visit. For participants who do not consent to study participation, no procedures should be performed and no data that can be linked to their name or other personal identifier(s) should be recorded.

An overview of the standardized approach to the informed consent process is provided in Figure 4-1 below. Additional details related to key steps in the process are provided in the remainder of this section.

**Figure 4-1
Overview of MTN-045 Informed Consent Process**



4.4.1 Informed Consent Procedures for Illiterate Participants




Illiterate participants may be consented and enrolled in MTN-045, providing they are otherwise willing and eligible and if independent consent is ensured. Site SOPs must outline the process for assessing participants for literacy and how independent consent is ensured for participants who are not literate. If the participant is illiterate (not able to read), an impartial literate witness who speaks the language of the participant must be present during the entire informed consent process/discussion with the participant. ICH GCP guidance identifies an "impartial" witness as a person who is independent of the study, who cannot be unfairly influenced by people involved with the study. The MTN CORE has received guidance from the US Food and Drug Administration's GCP office stating that the witness need not be "totally unaffiliated with the study." It may be possible, for example, to designate a "subject advocate." The site SOP for obtaining informed consent should define who may serve as the witness to the informed consent process. It should be noted, however, that a participant's partner may not serve as their impartial witness.

When a witness is present during the informed consent process, care should be taken to minimize the perception of coercion due to the presence of the witness. For example, the purpose of having the witness present should be clearly explained to the participant, with emphasis on the fact that the witness is there as a protection for the participant, not as an agent of the study per se.

This witness must sign and date the informed consent form to attest that the information therein and any other written information was accurately explained to, and apparently understood by, the participant, in the participant's language of fluency, and that informed consent was freely given by the participant. The participant's printed name, signature, and signature date lines on the informed consent form should be completed as described and illustrated in Figure 4-2 below. Following these procedures fulfills the protocol requirement for obtaining written informed consent from all study participants.

**Figure 4-2
Informed Consent Form Signature Lines for Illiterate Participants**

- Unless other conventions that have been endorsed by DAIDS are specified in site SOPs, the study staff member who completes the informed consent process/discussion with the participant should print the participant's name and date of informed consent below the "participant's printed name" and "date" line, respectively, together with a signed and dated note documenting the name of the person who made the entry and the date of the entry.
- The participant should add his or her fingerprint or make his or her mark above the "participant's signature" line.
- The witness will print, sign, and date in the section designated for "Witness"

SIGNATURES		
Participant Name	Participant Signature	Date
Mary Phiri		25 NOV 2009
<i>Participant name and date written by Martha Moore. MM 25 NOV 09</i>		
Martha Moore		25 NOV 2009
Name of Staff Person Conducting Consent Discussion	Study Staff Signature	Date
Debra Ross		25 NOV 2009
Witness Name	Witness Signature	Date

4.4.2 Couples Informed Consent Considerations

Study staff will explain the study to both members of the couple and determine their presumptive eligibility to participate in the study; both of these informed consent process components may be done with the potential participants either separately or together as a couple. However, to reduce the potential for coercion by one partner of the other, study staff will assess each participant's willingness to be in the study and confirm their eligibility separately from their partner (see SSP Manual Section 3 regarding eligibility assessment). This will be presented as a standard procedure so as not to raise concerns from either member of the couple. Participants will also sign individual consent forms, undergo comprehension assessment, and have an opportunity to ask questions about the study separately from their partner. As part of the individual consent process, study staff should confirm with the participant that their participation in the study is voluntary and their choice alone. Should the participant decline to partake for matters related to their relationship (such as coercion), staff should discuss this with the participant and come to an agreement with them about how study staff will communicate the couple's ineligibility to their partner.

4.5 Comprehension Assessment

The participant must not sign the ICF until s/he fully understands the information contained therein, including that pertaining to visit procedures. Site SOPs should explain the procedures that study staff are responsible for implementing to ensure that each participant understands the screening process and the study prior to signing the ICF and undertaking any study procedures, respectively.

A comprehension assessment should be conducted and documented prior to a participant signing the ICF. This assessment should occur with individual members of the couple after the participant has completed the informed consent discussion described above, but before s/he is asked to sign the ICF. It is expected that staff administering the informed consent and assessing comprehension be sufficiently knowledgeable about MTN-045 to make good judgments about the potential participant's understanding of the required information and their willingness to participate independent of their partner.

4.5.1 Comprehension Assessment Checklist

A sample open-ended enrollment informed consent comprehension assessment checklist is available on the [Study Implementation Materials](#) section of the MTN-045 webpage.

This tool is structured around open-ended questions that correspond with the required elements of informed consent for research. Each question should be read to potential participants, giving them time to respond to each one. Each question should be satisfactorily answered by the participant before moving to the next question. For each question, the assessment specifies points that must be included in the participant's response. These are identified on the tool as "Required Points of Comprehension."

Regardless of the method used to assess comprehension, if the assessment results indicate misunderstanding of any aspect of the study, staff should review those until the participant fully understands them.

If, after all possible efforts are exhausted, the participant is not able to demonstrate adequate understanding of the study, do not ask him/her to sign the ICF to screen/enroll in the study. Similarly, if the participant has concerns about possible adverse effects of participating in the study, including on his/her relationship, or indicates that s/he is being coerced to participate by his/her partner or may have difficulty adhering to the study requirements, do not ask him/her to sign the ICF.

4.5.2 Documenting the Comprehension Assessment

The comprehension assessment checklist tool is considered a study source document that should be completed, handled, and retained in the participant's study file like any other source document. After administering the assessment tool, staff should carefully review the form to verify that all required points have been satisfactorily addressed by the participant and that this is adequately documented. Consideration should be given to having two study staff members complete this verification because failure to document comprehension of all required points will be considered an informed consent process protocol deviation.

Comments may be recorded in a designated area on the form (and on the back of the form if additional space is needed) or on an Informed Consent Coversheet, a template of which is available on the MTN-045 webpage under Study Implementation Materials. All required points

must be satisfactorily addressed by the participant before proceeding to the final informed consent decision and signing of the ICF.

After the informed consent process is completed, the outcome of the process should be recorded directly on the comprehension assessment form (or in a chart note) and the staff member who completed the form should record his/her signature in the space provided. Detailed information on how comprehension will be assessed must be specified in the site Informed Consent SOP.

4.6 Documenting the Informed Consent Process

It is essential that all informed consent documentation (i.e. ICFs, IC coversheet, IC comprehension assessment tool) indicate that participant informed consent was obtained before any study procedures were conducted.

US FDA regulations and ICH E6 guidelines require that informed consent be documented by “the use of a written informed consent form approved by the IRB and signed and dated by the subject or the subject’s legally authorized representative at the time of consent.”

To fulfill this requirement, complete all signature and date lines on the ICF in dark ink. Legal names should be used. Fabricated/falsified names should not be used. Initials may not be used in place of a participant’s full surname, and it is strongly recommended that initials not be used in place of a participant’s full first name. However, if a participant commonly signs his/her name using an initial for first name, the initial may be used, provided this practice is acceptable per the policies of the study site institution(s).

The DAIDS policy on [Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials](#) lists detailed requirements and suggestions for documenting the informed consent process. All requirements listed in the DAIDS policy must be met. To meet the suggestions listed in the DAIDS policy, sites are strongly encouraged to use an Informed Consent Coversheet similar to the template provided on the MTN-045 webpage under Study Implementation Materials. Sites choosing to use a coversheet should list the coversheet as a source document in their Data Management SOP and should use the coversheet consistently to document all informed consent procedures undertaken with participants. The sample IC Coversheet indicates the items to be completed at the start of the informed consent session. The remainder should be completed at the end of the informed consent session.

If a site chooses not to utilize the IC Coversheet, all elements of the informed consent process must be adequately described in the site SOP for obtaining Informed Consent and documented in detail in a signed and dated chart note.

Regulations require that participants be given a signed copy of the ICF(s). If a participant opts not to receive a copy or if site IRB/EC policy mandates that a blank ICF be provided, document this on the IC coversheet or visit note and ensure that an alternative form of study contact information (e.g., a contact card or appointment card) is provided in lieu of the full signed/dated ICF.

Section 5: Safety and Counseling Considerations

5.	Introduction.....	5-1
5.1	Reporting of Social Harms and Unexpected Safety Events	5-1
5.1.1	Reports of Intimate Partner Violence (IPV).....	5-2
5.2	Counseling Considerations	5-3
5.3	Early Termination of Study Participation	5-4

5. Introduction

This section contains guidance on potential social harms and unexpected safety events, as well as counseling considerations for MTN-045.

5.1 Reporting of Social Harms and Unexpected Safety Events

MTN-045 is a socio-behavioral study which does not involve a study product nor clinical, laboratory or other procedures associated with significant risk to participants. Nonetheless, it is necessary to make provisions for the identification and proper reporting of unexpected safety events (UEs) and social harms (SHs) as reported by all MTN-045 participants. Anticipated risks to result from study participation are social harms and embarrassment when discussing sensitive issues. Additionally, because the study is being conducted with couples, there is also a risk that participation may disrupt the relationship, contribute to social harms or heighten conflict between members of the couple.

If any UEs are reported by participants during study participation, MTN-045 study staff, in consultation with the IoR/Study Coordinator, should assess the UE and determine clinical management per standard of care. IoRs should use their discretion in evaluating whether an event qualifies as “unexpected” but, generally, this is considered any event that is not outlined in the “*Risks and/or Discomforts*” section of the protocol sample informed consent form. If needed, participants should be referred to available local resources for care. No safety events will be captured in the study database, but all action taken to address the UE, as well as any referrals, must be documented in visit notes. The MTN-045 Management Team should be notified promptly of any UEs that occur, and sites should follow local IRB/EC requirements for reporting UEs, as needed. Finally, UEs may in some cases be considered DAIDS critical events. Sites should reference the current [DAIDS Critical Events Manual](#) on reporting critical events and consult their OCSO Program Officer as needed regarding critical event determination/reporting.

Social harms are defined as non-medical adverse consequences experienced by a study participant. For example, participants could be treated unfairly, experience negative repercussions in their professional or community leadership positions, or could have problems being accepted by their families, partners and/or communities. Any SH reported by participants during study participation should be fully documented in the participant file by MTN-045 staff. Sites should continue to document any social harms reported for a participant through 30 days after their participation in the study. This documentation will occur if the participant reports the social harm themselves, staff observes the social harm, or if clinic staff become aware of an event from a third party (e.g., family member, local authorities). All potential social harms should be documented on the Social Harms CRF. Events determined to be related to MTN-045 study participation should be indicated as such on the Social Harms CRF and reported to the DAIDS Medical Officer (MO) and MTN-045 Management Team.

Sites are responsible for reporting SHs to IRBs/ECs per local requirements and timelines. Study staff should use as much detail as possible to describe the event, including a full description of the event, severity of the event, action taken, approximate onset and resolution dates. Every effort will be made by study staff to provide appropriate care, counseling and referrals for the safety of the participant as needed.

Site-specific procedures for care, counseling, and referrals in the event of UEs and SHs should be outlined in site SOPs for Emergency Procedures, Social Harms and IPV Management. In addition to general management and care, sites should include in this SOP procedures for handling SHs or UEs in situations requiring immediate attention, including domestic violence and suicidal ideation or behavior.

The procedures will provide clear guidelines to site staff for referring participants in these situations to the relevant institution/body and providing feedback to the MTN-045 Protocol Team.

The Manual for Expedited Reporting of Adverse Events to DAIDS will not be used for this study, for the following reasons: 1) this study does not involve a study drug and is non-invasive; and, 2) adverse events are not primary or secondary objectives of the study. Untoward clinical or medical occurrences reported by study participants to have been experienced during study participation will be recorded in participant file notes.

5.1.1 Reports of Intimate Partner Violence (IPV)

According to the World Health Organization, **Intimate Partner Violence**, or IPV, refers to any behavior within an intimate relationship that causes physical, psychological or sexual harm to those in that relationship. It includes acts of physical aggression (slapping, hitting, kicking, or beating, for example), psychological abuse (intimidation, humiliation, and threats, for example), forced sexual intercourse or any other controlling behavior (including isolating a person from family or friends, monitoring their movements or restricting access to information or assistance, for example). Intimate partner violence also includes violence committed by former partners and individuals in dating relationships. Participants who disclose any form of violence by an intimate partner (or other family member) or sexual assault by any perpetrator should be offered immediate support, care, and referrals in accordance with all site- or study-specific SOPs. The World Health Organization (WHO) publication [Responding to intimate partner violence and sexual violence against women](#) is a useful resource that may help inform site-specific policies for responding to reports of sexual assault or other violence.

IPV may be reported directly to site staff through participants or other third-party sources or may be directly observed. If a participant mentions a social harm, study staff should actively listen to the participant's description of the problem and ask questions to obtain as much detail as possible about their perceptions of the severity of the harm, the cause of the harm, and the effects or consequences of the harm. This will include probing whether the social harm occurred as a result of study participation. If it is related to study participation, it will be reported in detail on the Social Harms CRF. IPV not related to study participation should be recorded in source documentation. Irrespective of whether IPV is related to study participation, participants should be provided the appropriate support, counseling, and referrals per site SOPs and social harm response plans to help manage any reported IPV, and steps should be taken as needed to improve participant safety.

Generally, responses to reports of IPV should include first line support – listening and offering comfort, help, and information/referrals to connect the participant to services and social support – as well as offering the participant an opportunity to provide a complete history of events, and receive relevant physical evaluations, and treatment and/or referral for any injuries. For further details on responding to IPV, sites should reference their IPV SOPs.

Given the nature of MTN-045 as a couple's study, there is a potential that social harms and/or IPV may occur during the study visit itself. Staff should use their discretion and potentially discontinue or pause study procedures if it is felt that continuing may escalate conflict and/or present risk of harm to either member of the couple. An example of how such a conversation could be framed is as follows: *"I want to pause what we are doing as I sense that something may be bothering you. We don't want the study procedures to create or increase any conflict in your relationship. Remember that your participation is voluntary, and you can choose to stop at any time. Let's take a short break and then we will check back in to see if you are both okay to continue?"*

There are no additional clinical management considerations for participants enrolled in this study. Participants who express concerns with social, psychological or clinical issues will be referred for appropriate care to services available at the CRS, or at nearby partnering facilities.

5.2 Counseling Considerations

Prior to study initiation, study staff teams at each site should discuss as a group, and with community representatives, what issues and problems are most likely to be encountered by participants at their site and should agree upon how these issues and problems should be handled if reported. Roles and responsibilities should be defined for all staff members, such that each staff member is aware of what actions s/he can appropriately take, and what actions should be referred to other members of the team. During study implementation, staff teams at each site should continue to discuss actual participant experiences, successful and unsuccessful response strategies, and other lessons learned among themselves and with community representatives. Based on these discussions and lessons learned, procedures for responding to issues and problems should be reassessed and updated as needed throughout the study.

The following are suggested strategies for responding to social harms that can be adapted and tailored to best meet participant needs at each site:

- When first responding to an issue or problem, discuss with the participant or couple referral to a site counselor. Depending on the specific issue, couple's or individual counseling may be offered. Ensure that other than information related to the social harm, no personal information will be shared with the counselor. If providing individual counseling, it should be emphasized that information discussed will not be shared with their partner. Counselors should follow procedures already established by the site when addressing and counseling for social harms. All counseling should be provided in a non-judgmental, client-centered manner that responds to current participant needs for information, education, support, motivation, skills-building, and/or referrals. The counselor should actively listen to the participant's description of the problem and ask questions to elicit as much detail as possible about the problem, including the participant's perception of the severity of the problem.
- Ask the participant for his or her thoughts on what can/should be done to address the problem, including what s/he would like study staff to do in response to the problem (if anything).
- Discuss with the participant any additional or alternative strategies that you might suggest to address the problem, and collaborate with him or her to develop a plan to try to address the problem.
- Take all possible action to try to address the problem, per the plan agreed upon with the participant.

- Provide referrals as needed/appropriate to other organizations, agencies, and service providers that may help address the problem.
- Document a summary of the reported event, action(s) taken, and outcomes thereof, and any referrals, in signed and dated visit notes. As needed, report on Social Harms CRF and notify relevant groups as outlined in Section 5.1 above.

5.3 Early Termination of Study Participation

Participants may voluntarily withdraw from the study for any reason at any time. The IoR may also withdraw participants from the study to protect their safety and/or if they are unwilling or unable to comply with required study procedures. Participants also may be withdrawn if the study sponsors, government or regulatory authorities, including the Office for Human Research Protections (OHRP) or site IRBs/ECs, terminate the study prior to its planned end date.

If participant withdrawal (voluntarily or otherwise) occurs, all study procedures should be discontinued immediately and the reason for withdrawal should be documented in the participant's record (e.g. visit notes). In addition, the MTN-045 Management Team should be informed. If the participant voluntarily withdraws consent during an individual-level study procedure (i.e., BDQ, DCE or individual IDI administration), staff should affirm the participant's right to withdraw and allow him or her to discontinue the procedure per his or her request. If, after their partner withdraws from the study, the other member of the couple is still willing to participate, staff may proceed with administering individual-level study procedures with him or her. Subsequent couple procedures should not be undertaken and both members of the couple should be withdrawn from the study. If voluntary withdrawal, by one or both members of a couple, occurs during the joint couple decision task or a couples IDI, procedures should be discontinued with both members of the couple and study withdrawal procedures undertaken. Staff should use discretion when managing involuntary withdrawals during an ongoing procedure and take the course of action that minimizes risk of social harms or other unanticipated safety events (to both the participant being withdrawn and their partner). Staff should confirm permission to maintain data already collected up until the point of participant withdrawal and document the outcome of these conversations and any other details relevant to the withdrawal in the participant's record (e.g. visit notes, debrief report). In addition, the MTN-045 Management Team should be notified.

Should participants who voluntarily withdraw from the study wish to re-join the study, they may do so if the accrual target has not yet been met, in consultation with the MTN-045 Management Team. Note that withdrawing consent and later re-joining the study requires signing a new informed consent form and is different from needing to stop and reschedule an interview based on unforeseen circumstances.

Section 6. Data Collection and Management

6.	Introduction	6-1
6.1	Case Report Forms (CRFs).....	6-2
6.1.1	Electronic Case Report Forms (eCRFs).....	6-2
6.1.2	Paper-based Case Report Forms	6-3
6.2	In-depth Interviews.....	6-4
6.3	Form and Guide Supply	6-4
6.4	Tablet Security and Storage	6-4
6.5	Form Security and Storage.....	6-4
6.6	How to Complete Interviewer-Administered Forms	6-5
6.7	Interrupted, Paused or Incomplete eCRFs	6-5
6.8	Data Management Flow.....	6-5
6.9	Site Transcript QC Process	6-8
6.10	RTI-Site CRF QC Process	6-9
6.11	RTI-Site Debrief Report QC Process.....	6-9
6.12	RTI-Site Transcript QC Process	6-10
6.13	Interview Modes and File Naming Conventions	6-10
6.14	Data Management SOP	6-11
6.15	Staff Training	6-12
6.16	Study Monitoring.....	6-12
	Appendix 6-1: Tablet Use and eCRF Completion.....	6-13
	Appendix 6-2: Secure File Transfer Protocol (SFTP).....	6-17
	Appendix 6-3: Transcript Formatting Expectations	6-22
	Appendix 6-4: Quality Control (QC) General Conventions for Transcripts and Debrief Reports	6-23
	Appendix 6-5: CRF Form Completion	6-27

6. Introduction

The purpose of this section is to provide site staff with information to complete and submit MTN-045 data.

The SDMC (Statistical and Data Management Center) for this study is RTI (Research Triangle Institute) International.

For questions about this section or about general data collection policies, procedures, or materials for MTN-045, please contact Ali Minnis (aminnis@rti.org) or Mary Kate Shapley-Quinn (mshapley@rti.org).

6.1 Case Report Forms (CRFs)

Table 6-01 lists the CRFs that are to be completed for MTN-045. Electronic CRFs (eCRFs) will be pre-loaded onto tablet computers and completed electronically, whereas paper-based CRFs will be filled out by hand.

Table 6-01: MTN-045 Case Report Form Completion Schedule

Form Acronym	Form Name	Completion Schedule	Population	Mode
DCE	Discrete Choice Experiment	During study visit	All enrolled	Electronic (tablet)
BDQ	Behavioral and Demographic Questionnaire	During study visit	All enrolled	Electronic (tablet)
PSF	Participant Status Form	During study visit	All enrolled	Paper
CO	MTN-045 Couples Observation Form	During study visit	All enrolled	Paper
IPA	Ideal Product Activity	During study visit	All enrolled	Paper
SH	Social Harms Report	If a social harm is reported	As needed	Paper
PD	Protocol Deviations Report	If a protocol deviation is identified	As needed	Paper

6.1.1 Electronic Case Report Forms (eCRFs)

Table 6-01 lists the eCRFs that are to be completed for MTN-045.

Detailed guidelines on eCRF completion are addressed in Appendix 6-1. There is a brief overview here.




1. Each site will have tablet computers that are pre-loaded with the data collection materials. The DCE and BDQ will be administered in private rooms where the participant and interviewer will not be interrupted or overheard.
2. Once the participant is situated in the room, staff should introduce themselves (if not done already), and complete the following:
 - a. Explain the upcoming procedures (watch the study video, complete the Individual DCE and BDQ, then rejoin their partner and complete the Couple's DCE)
 - b. Watch video, allow opportunity for questions or re-watch any portion of the video
 - c. Show placebo product forms
 - d. Open Qualtrics, select the "Individual" survey option, and enter information on the Home Screens
 - e. Lead participant through introductory information and questions before the DCE
 - f. Use practice questions throughout the introductory section to verify the participant's comfort and understanding of using touch screens as well as understanding of the product characteristics that will be used to compose the products participants will be asked to compare and choose between
 - g. Review any terms, definitions, or explanations that may be unknown or misunderstood by the participant
 - h. Go through the introduction to the DCE questions with the participant and ensure that they understand the upcoming activity

- i. Go through DCE choices with the participant, ensuring that the participant comprehends the choice sets, reviews all product characteristics, and how to indicate which they would prefer

The Individual DCE and BDQ will be continuous: once the interviewer launches the Individual DCE and it is completed, it will automatically launch the BDQ. Once the Individual DCE and BDQ have been completed and the End Survey screen thanking the participant has been reached, the data will be transmitted automatically to the Qualtrics server. At this point, the Individual DCE and BDQ data will not be accessible for editing at the site.

Once each member of the couple has completed their BDQ, the couple will come back together. The interviewer will relaunch the Qualtrics shortcut and select the “Couple” option to begin the Couple’s DCE. Again, once the Couple’s DCE is complete and the End Survey-Thank you screen has been reached, the data will be transmitted automatically to the Qualtrics server. At this point, the Couple’s DCE data will not be accessible for editing at the site.

Using the tablets:

1. **Orientation:** The entire DCE survey is designed to be administered with the tablet computer held in portrait mode (short edge on top/bottom, long edge on sides) to minimize the need to scroll-down. This is particularly critical in the choice set portion of the interview where the participant must be able to see all of the attributes to inform his or her preference for option A or B. Scrolling could bias the participant’s responses and impact data quality. Interviewers should ensure the tablet is positioned with this orientation throughout, even when using the tablet cases.
2. **Switching between interviewer and participant:** Red stop sign screens are placed at two points in the DCE to indicate that the tablet should be passed from the interviewer to the participant, or vice versa. If the participant is holding the tablet, the interviewer should be able to see the tablet screen so that they know when the screen is reached that indicates the tablet should be handed back to the interviewer
3. **Back buttons:** Only use the red forward and back buttons at the bottom of the screen  that are built into the Qualtrics survey. Do not use the back button on the browser , or the back button built into the tablet. 

Each site’s study coordinator or designee will log eCRFs (by PTID) that are completed on tablet computers each day. This will be logged in an Excel document (“Enrolled” tab of the Screening and Enrollment Tracker), saved with the current date in the filename each time it is updated, and sent weekly on a Friday (or other date as specified in the SOP) to the RTI data management team (MTN045datamgmt@mtnstopshiv.org). Study staff at each site will also have access to a Qualtrics dashboard that lists all eCRFs completed along with the associated PTID and completion date. This dashboard can be used to check that all eCRFs completed on tablets are logged as complete in Qualtrics, and to provide back-up documentation of dates of completion. The RTI Study Coordinator or Data Manager will review the log against the Qualtrics database on the day of receipt.

6.1.2 Paper-based Case Report Forms

Table 6-01 lists the paper-based case report forms that are to be completed for MTN-045. Please note that a Social Harms (SH) or protocol deviation (PD) form must be completed when an MTN-045 study-related SH or PD is identified.

Please refer to Appendix 6-5 for general guidelines on completing paper-based CRFs. Detailed form completion instructions are provided on the back of each form page. These instructions include the purpose of each form as well as how each form should be completed. Some items on forms are straightforward and do not require specific instructions. Therefore, instructions for all form items are not listed on the back of each form; rather, instructions are provided only for those items needing a detailed explanation.

Most forms include a line in the lower-right corner for a staff member's initials and the date on which the form was completed. When more than one staff member records data on a paper CRF, the site should designate the staff member who has primary responsibility for the form. This individual completes the staff initials/date field. The individual not identified in the staff initials/date field writes his/her initials and date next to each data element for which he/she is responsible. A similar process should be followed when a new data element is added to a CRF, whether by the original designated staff member or a new staff.

6.2 In-depth Interviews

Table 6-02 lists the interview guides that are to be used for MTN-045.

Table 6-02: MTN-045 Interview Guides

Guide Shorthand	Guide Name
Couples IDI Guide	MTN-045 Couples In-depth Interview Guide

The IDIs for this study will be conducted in a semi-structured format that follows a discussion guide, allowing for iteration, probing, and digression on relevant themes. IDIs will be audio-recorded, transcribed, and translated into English. Written notes will be taken during the interview. Notes may be recorded directly on the discussion guide, or on separate sheets of paper. Staff may record notes in other languages and extrapolate and translate responses immediately following the interview for later use in completing debrief reports (described in the Data Management SOP).

6.3 Form and Guide Supply

All master Case Report Forms and guides needed for MTN-045 will be supplied by RTI and should be printed locally. The current version of all forms (English and local language) will be posted on the MTN-045 website. The site is responsible for maintaining an adequate supply of the current version of blank CRFs and guides in all languages. One copy of previous versions of CRFs and guides should be maintained in an archive, and all other copies destroyed.

Should there be any updates to the eCRFs, a Data Communique will be sent out via email indicating the updates that were made and any needed action by site teams.

6.4 Tablet Security and Storage

All tablet computers should be stored in locked locations with limited access when not in use. All tablets will be password protected.

6.5 Form Security and Storage

Form storage will be detailed in the Data Management SOP for each site. It is recommended that study forms be stored in a flat file with either secure closures or a hard-cover binder for each participating couple/individual. To maximize confidentiality, all storage locations should be locked and have limited access.

- Hardcopies of all notes, guides, and checklists are stored in MTN-045 files.

- Paper CRFs are stored in MTN-045 couple data files.
- Participant consent forms are stored in a separate secure location.

6.6 How to Complete Interviewer-Administered Forms

The DCE and accompanying BDQ, as well as the IDI guide are interviewer-administered.

Note: Questions on the Couples Observation Form should not be read verbatim or asked directly of participants; rather, the form should be used by staff as a guide to document the necessary information from participant observations.

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is critical that interviewers take a non-biased, non-judgmental approach to participant interviews. Study staff should ensure participants feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.

6.7 Interrupted, Paused or Incomplete eCRFs

As each question of the eCRF is completed, responses are automatically saved; there is no “Save” button, as saving happens automatically once navigating to the next page. Responses are stored as ‘Responses in Progress’ until the End Survey-Thank you screen is reached whereby the responses move from ‘Responses in Progress’ to ‘Recorded Responses.’

If the eCRF is mistakenly closed, relaunch the eCRF and it will open to the last completed response. Closing the eCRF will pause the session, and the eCRF will continue to open to the last participant’s completed response for up to 7 days. If a participant decides he or she does not wish to continue the eCRF and stops before reaching the end of the survey, the interviewer must submit blank responses for the rest of the questions and advance to the End Survey-Thank you screen in order to record partial data as completed to the server. Note, the DCE questions cannot be skipped. If the participant decides not to continue before completing the DCE portion of the eCRFs, contact the study data management team (MTN045datamgmt@mtnstopshiv.org) to close out the survey.

If a participant decides to stop and continue the eCRF on another day, staff will need to contact the data management team to close the session and allow for the tablet to be used to start a new eCRF session. Until the session is closed by RTI, the tablet will not be able to be used for other participants. The RTI data management team can provide a hyperlink to return to the participant’s paused eCRF session at a later date.

6.8 Data Management Flow

MTN-045 data will be captured from electronic and paper-based CRFs and the IDIs administered at the site. All IDIs will be audio-recorded and note-taking is required during each session to supplement the audio recording.

As described in the site’s Data Management SOP, each site must perform two Quality Control (QC) review steps prior to data entry of paper-based CRFs and uploading IDI data to RTI. While paper-based CRFs, debrief reports, and transcripts are being reviewed, it is important that they be stored and tracked systematically.

- QC Review Step # 1 (same day as visit):
 - After the full IDI visit or IDI visit but before the participant has left the clinic, the interviewer should conduct an initial quality control (QC) check of the following:
 - Review visit checklists to ensure all required procedures were completed
 - Review paper-based CRFs to ensure completion

- CO
- IPA
- PSF
- SH (if needed)
- PD (if needed)
- Review all interview notes for clarity
- Same day as IDI, as soon as possible following the IDI:
 - The Interviewer (or note taker, if applicable) should verify that the audio recorder properly recorded the session. The audio file should be copied onto the password-protected hard drive of a computer at the site.
 - If the audio recording did not work, the interviewer will review the IDI 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 CRF for missing source documentation.
 - As detailed in the Visit Checklists (available on the MTN-045 website), notes from the interview should be entered electronically into the Debrief Report (DR) form (using the DR Template, available on the MTN website) on the same day as the IDI session and should undergo a site-level QC review.
 - The audio file should be saved onto a secure, limited-access server (as back-up) as source documentation of the interview. The file will be labeled with the ID number of the participant.

NOTE on Audio File Destruction: As mentioned in SSP Manual Section 2 (Documentation Requirements), audio files of IDIs are considered source documentation and will NOT be destroyed until directed by DAIDS following study completion. Audio files will be retained for at least three years following study completion, or an alternate timeframe as directed by site IRBs/ECs. The destruction process will be the responsibility of the site Investigator or his/her designee and should be specified in the site Data Management SOP. If required, sites may invite members of their community/CAB to observe the destruction. Once complete, destruction should be documented in the study files and confirmed via email with the data center (RTI).

- MTN-045 QC Review Step #2 (1 week – 1 month after visit)
 - Within one week of the visit: Before paper CRFs are entered into REDCap and before debrief reports are uploaded to the SFTP site, a second QC review should occur. The goal of this second QC review (as outlined in the site's Data Management SOP) is to correct data inconsistencies/errors and to ensure accuracy and completion, so that QC notes are prevented or minimized. This review should be done by someone other than the staff member who originally filled out the forms or wrote the report. Prior to entering CRFs into REDCap or uploading DRs to the SFTP:
 - All forms and reports:
 - Review visit checklists to ensure all required procedures were completed
 - Ensure no participant identifiers other than the PTID are present on the forms
 - Ensure the PTID is correct, and is the same on all forms/documents

- Ensure the Visit Date is correct, and is the same on all documents (unless in the case of split visit, in which case this should be marked in the comments on the visit checklist)
- Filename matches appropriate file naming convention (outlined in section 6.13)
- Paper CRFs:
 - Make sure a response has been recorded for each item, as required
Make sure skip patterns have been followed correctly
 - If a response box with “other”, “specify”, or “describe” line is selected, ensure text is present on this line
 - Make sure text responses are legible
- DRs:
 - All information in heading of DR is filled in and accurate
 - All sections of the DR template are filled in, listening to audio file sections as needed for accuracy and clarification
 - Double check PTID and visit date are accurate
 - After internal QC of the DR, sites should remove all comments and tracked changes so the document is clean when sending to RTI.
 - Sites will document which staff member reviewed each debrief report on the debrief report heading.
 - Once DR review is complete, sites should transmit the DR to RTI via SFTP (see process outlined in Appendix 6-2).
- Paper CRF Data Entry (1 week – 1 month after visit)
 - Each CRF will be entered into a REDCap database developed by RTI by two members of the site’s data team. A third member of the site’s data team will compare the two entered versions of each CRF.
 - Data entry practices:
 - Enter multiple response question data as completed on the paper CRF, even if a skip pattern was not followed correctly. If two responses were selected for a question requiring a single response, do not mark a response in the REDCap database.
 - All open-ended text response data (e.g. other specifies and comment fields) should be entered in all CAPS (uppercase). Do not correct spelling errors; enter text and all punctuation as it appears on the paper CRF.
 - Double data reconciliation
 - After all CRFs for a couple have been double entered, the “Data Comparison” tool in REDCap will be used to identify any discrepancies across the two entries.
 - All discrepancies are to be reconciled by reviewing the original paper CRF and selecting which of the two entries was correct, or by entering a new response that correctly reflects the response on the paper CRF.
 - A final, merged version of the two entries is created after the comparison is completed.
 - The site-specific procedures for data double-entry and reconciliation will be outlined in each site’s Data Management SOP.

NOTE: Additional details on data management will be outlined in each site's Data Management SOP. Data for quantitative analysis will be collected electronically in Qualtrics for the DCE and manually on paper CRFs at the site. Data should be checked for accuracy, clarity and completeness at the site.

- IDI (Within one month following interview): The audio file should be used to transcribe and translate the discussion per the process described in the Data Management SOP (using the Transcript Template, available on the MTN website). All transcripts will be simultaneously translated (when conducted in a local language) and transcribed in English unless there are unique local language sayings that should be preserved. These sayings can be kept in the local language with explanatory notes provided in parentheses to explain their meanings. All expanded notes will be written in English. Formatting guidelines are provided in Appendix 6-3. More details on guidelines for proper transcript punctuation, formatting and common QC issues can be found in Appendix 6-4. The completed transcript should undergo the internal QC process outlined in section 6.9 and uploaded to the SFTP within one month following the IDI.

6.9 Site Transcript QC Process

Quality checks of the transcription/translation should be performed at the site as described in the Data Management SOP and outlined below. This will include the following:

- A second staff member (i.e. one who did not translate the interview) who is fluent in the local language should listen to the entire audio file while reading the English transcript. The quality of **the first three transcripts per transcriber/translator** will be checked in this manner to determine that the quality of translation is sufficient. If the quality is insufficient, the IOR or designee can do more thorough checking of the subsequent three transcripts and provide feedback to the translator. These reviews will be continued in batches of three until the quality is acceptable for each transcriber.
- Following this determination, systematic quality checks will include listening to **at least three, 5-minute spots** per interview of the audio file as compared to the transcript for 10% of transcripts.
- Sites will **log the QC process** (including which transcripts were reviewed in its entirety and which were spot checked and by whom). Prior to start of the study, sites should send the template of what their QC log will look like to RTI. During the study, sites will send this QC log sheet to RTI **monthly**.
- If at any time the site coordinator decides that the direct transcription from audio to English transcript is not consistently of high quality, he/she will consult the MTN-045 Management 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.
- The text of each transcript should still be reviewed by a second staff member (who did not translate the interview) in its entirety even if the entire audio file is not reviewed for completion, content clarity and typos. **Sites will document which staff member reviewed each transcript on the transcript heading.**
- Once a transcript is deemed ready for RTI review, the transcriber should certify that the transcript is an authentic representation of the audio recording by adding his/her name and date to the top portion of the transcript.
- In addition to quality checks of the transcription, **a different staff member than the interviewer should also review the audio file of the first 2 IDIs for each interviewer** to provide feedback on moderating and interviewing techniques (e.g. adequacy of probing, appropriate linking of topics, fidelity to the guide, etc.) The feedback will serve to provide additional training to the interviewers and also to improve on the quality of the

data collected. Note-takers may serve this role for interviewers. If a different staff member performs this function, participants must be asked if they are comfortable having additional staff present during an interview. **All staff who sit in or participate in interviews should be documented in the debrief report and transcript headings.**

6.10 RTI-Site CRF QC Process

Once all CRFs for a couple have been double data entered, compared, reconciled, and merged into a third, final record in REDCap at the site:

- Final merged records will be reviewed and missing or potentially incorrect data will be collated into a Quality Control (QC) report.
- The QC report will be sent via e-mail to the study site weekly. Sites are asked to correct or clarify any problems identified on the QC reports and rectify the query only in the final, merged RedCap entry **within one week**.
- When RTI receives the communication that RedCap entries have been updated, RTI staff will review the corrected entries and determine whether the QC can be resolved. If the QC is resolved, no further action from the site is necessary. If the QC was not resolved adequately, RTI will write a more detailed query, which will be communicated to the site in the next QC Report. If the site determines a query cannot be resolved, RTI will make note and remove it from any future QC reports.

6.11 RTI-Site Debrief Report QC Process

Once a DR is received by RTI, RTI will then conduct a QC review of the Debrief Reports (DR), which will include the following process:

- DR will be read and reviewed by RTI data team members and queries will be made on the report using MS Word's review features. The following are examples of queries:
 - Typos that lead to ambiguous meaning: e.g. "sore the medication" vs. "store the medication" (track changes may be used for straightforward typo corrections)
 - Sentences that don't make sense
 - Clarification of local terms used
- RTI will upload the QCed DR on the SFTP site **within one week** of receipt of the DR.
- **Within one week** of receiving the DR from RTI, the site is asked to correct or clarify any problems identified in the report directly in the report text using track changes and confirm the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query. The corrected DR is then uploaded onto the SFTP site.
- When the revised information is received by RTI, the Qualitative Data Manager or a designated data team member reviews the corrected issues and either deems the issue resolved or requires further follow-up. If further clarification is necessary, RTI will upload the DR onto the SFTP site again and email the site. This process continues with the site until all necessary changes are made on the DR.
- Once all queries have been resolved, RTI will remove all comment bubbles and accept all tracked changes to create a final and "clean" copy of the DR in Word.
- A final PDF version of the DR will also be created. Both versions will be saved to an encrypted drive. The final PDF will be password protected and emailed to the site team and MTN045qualitative@mtnstopshiv.org simultaneously.

6.12 RTI-Site Transcript QC Process

After the site-level QC process described above is completed, the English language transcript will be uploaded to SFTP for RTI to review. RTI should receive an English language transcript within **one month** (30 days) of the interview or discussion date. Transcripts will then undergo a QC process similar to that of the debrief reports:

- Each transcript will be reviewed by a member of RTI's data team and queries will be made on the transcript using Microsoft Word's review feature (comment bubbles will primarily be used; track changes may be used for minor or straightforward typos). The QC includes the identification of the following:
 - Problems such as typos that lead to ambiguous meaning, confusing terms or missing/potentially incorrect data
 - 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.
- RTI-reviewed transcripts will be uploaded to the SFTP for the site **within approximately two weeks** of transcript receipt.
- The site must then respond to all comments **within two weeks** of receipt of the reviewed transcript. Responses will be made by making changes directly to the transcript using track changes and confirming the status (e.g. 'done', 'corrected', 'not needed', etc.) of each query within the comment bubble. When in-text changes are unable to be made, the site reviewer should respond using the comment box in the reviewing mode of MS Word. The corrected transcript is then uploaded onto the SFTP site.
- When the revised information is received by RTI, the Qualitative Data Manager or a designated data team member reviews the corrected issues and either deems the issue resolved or requires further follow-up. If further clarification is necessary, RTI will upload the transcript onto the FTP site again and email the site. This process continues with the site until all necessary changes are made on the DR.
- Once there are no additional issues, RTI will accept all changes, save a clean, final copy of the transcript on an encrypted drive, and will upload to the SFTP for the site's records.
- The participant's final English transcript, and the final local language transcript (if applicable) must all be stored in the participant's file, or per site Data Management SOP.

Refer to Appendix 6-4 for more details on quality control general conventions.

An MTN-045 Qualitative Data Tracking Log (or equivalent) will be completed by RTI to maintain record of each debrief report and interview that is received along with details regarding the date of receipt, query status, and finalization date.

6.13 Interview Modes and File Naming Conventions

Interview Mode is the term used to describe the kind of interview that is being conducted in MTN-045. The abbreviations and definitions are as follows:

- C-IDI: Couples In-depth Interviews (i.e. jointly administered)
- M-IDI: Male partner In-depth Interviews
- F-IDI: Female partner In-depth Interviews

All data files should be named according to a standard naming format. The name should include the Study Name (MTN-045), interview mode, followed by the couples' ID, data type abbreviation (debrief report (DR), transcript (TS)), and the date the interview was conducted, in *ddMMMyy* format. There should be an underscore with no spaces between each part of the name, for example **"MTN-045_C-IDI_11111_DR_15OCT19"**.

Each time a document is edited, the editor should add his or her initials to the file name without changing any other part of the file name. There is no need to include the editor's initials in the first iteration of the file that is sent to RTI for review. It is only upon subsequent review (during the QC process with RTI) that it becomes necessary to include the editor's initials.

For example, the file sent to RTI would be labeled, "**MTN-045_C-IDI_11111_DR_15OCT19**" and after initial review from RTI it would become "**MTN-045_C-IDI_11111_DR_15OCT19_JR**". After the site reviews it would become "**MTN-045_C-IDI_11111_DR_15OCT19_JR_NM**", etc. Once the document is finalized, RTI will remove all initials and replace with "v1.0" so it becomes, "**MTN-045_C-IDI_11111_DR_15OCT19_v1.0**".

The Debrief Report and Transcript Templates provided on the MTN website have a field in the header that is built to match the file name. After the file is renamed, staff will go to the header, right-click on the file name field, and select "update field" before saving.

Table 6-03: Example of File Naming Convention throughout the RTI-Site QC process:

Original File Name	File Name after First Review (By JR)	File Name after Second Review (by NM)	File Name once Finalized
MTN-045_C-IDI_11111_DR_15OCT19	MTN-045_C-IDI_11111_DR_15OCT19_JR	MTN-045_C-IDI_11111_DR_15OCT19_JR_NM	MTN-045_C-IDI_11111_DR_15OCT19_v1.0

6.14 Data Management SOP

As a condition for study activation, each study site must have an SOP for Data Management. This SOP should be reviewed and followed in combination with the information contained in the study protocol and this SSP Manual.

The Data Management SOP contains information on and outlines site staff responsibilities for several data topics, including but not limited to:

- Staff responsibilities
- Couples' ID and Participant ID (PTID) assignment (see SSP Manual Section 3)
- Couples' study file organization
- Source Data and Source Documentation
- Data storage
- Record retention
- Data collection procedures (DCE, CRF and IDI)
- Participant confidentiality
- Site data quality control (QC) processes
- Timing of form data transmission to SFTP
- RTI data QC processes
- Timing of qualitative data transmission

6.15 Staff Training

Site staff who collect data, enter data on debrief reports, or who manage and transfer participant data will receive protocol and SSP Manual training. The site IoR or designee is also responsible for notifying RTI and FHI 360 of any new staff and of the site's plans for training any new staff on study procedures. When new staff members join a site team, or when existing staff members assume new study responsibilities, this must be documented on the site delegation of duties (DoD) Log and the updated log must be sent to FHI 360. Additional training will be made available as needed by RTI staff to train and monitor quality of site data management or to provide training on new study procedures.

6.16 Study Monitoring

In addition to data quality monitoring and checks described above, FHI 360 and/or RTI may review study records during the course of the study through onsite or remote review of select couples' files. Sites will be asked to provide copies of couples' files for review. FHI 360 and/or RTI will review these documents and provide feedback to sites either by e-mail or conference call.

Appendix 6-1: Tablet Use and eCRF Completion

The DCE questionnaire will be completed using an electronic instrument administered on an Android operating system, loaded onto a Lenovo Tab 4, 10.1” tablet computer. RTI will provide 05 of these tablet computers to each site. The tablets should be stored in a secure, locked location, plugged in when not in use, and the batteries should be fully charged at the start of every workday. The complete user manual can be found here: [Lenovo TAB4 User Manual](#).

a. Turning on, unlocking, and locking the tablet computer

1. If turning on from sleep mode, press the Power button, smaller button on the top corner of the tablet.
2. If turning on from fully powered-off mode, press and hold the Power button.
3. Next, to unlock the tablet, swipe up from the bottom of the tablet screen, and enter the password when prompted by pressing the password line. Type the password and select the “Enter” or check mark on the right side of the keyboard.
4. The tablet can be locked by pressing the Power button on the top of the tablet. The tablet will automatically lock after 2 minutes of inactivity.


b. Navigating the tablet screens

1. To return to the home screen, press the white outlined “O” button at the bottom of the screen.
2. To display and manage all open apps and pages, press the “□” button at the bottom of the screen.
3. To close an application, press the “□” button at the bottom of the screen and swipe the app window right or left.
4. To launch the eCRF survey through Qualtrics, select the Qualtrics bookmark saved to the Home screen of the tablet.
5. Links to start the video are saved to the Home screen of the tablet. There are two icons saved on the home screen, one for the English version of the survey and one for the Shona/Luganda version. The icon is a white square with a red film reel labeled “CUPID Video”.
6. The tablet can be used in portrait or landscape mode, and the screen will automatically adjust depending on how the tablet is physically oriented. Note that the interview is designed to be administered with the tablet in portrait mode, with the edge buttons (power and volume) oriented on top.

c. Connecting to the wireless network

It is necessary to connect the tablet to WiFi internet in order to administer the eCRFs (DCE and BDQ).

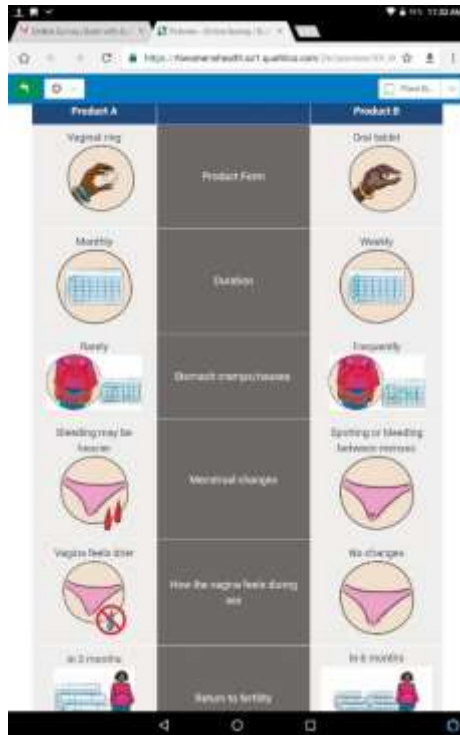
To connect the tablet computer to a wireless internet connection, complete the following steps:

1. Tap the  icon at the bottom of the screen
2. Select the “Settings” icon and then under “Wireless & networks” press “WLAN”
3. Make sure the WLAN switch is in the On position, and tap the WLAN Wifi network to connect to the internet.

Steps for administering the Individual DCE portion of the visit

1. At the start of the visit:
 - a. Ensure the battery is fully charged and the tablet computer is available for the visit.
 - b. Ensure the tablet has a functioning internet connection.
 - c. Begin the visit procedures, starting with the CUPID video.
2. Showing the video

- a. To show the CUPID video, select the language version required from the Home screen.
 - b. The volume on the tablet may be adjusted by pressing the Volume buttons on the top of the tablet.
 - c. Note that an internet connection is not required in order to show the video.
3. Administering the survey with the participant: Select the Qualtrics icon on Homescreen
 The survey consists of three sections that are each administered in slightly a different way: an introductory section, the choice sets, and a set of follow-up questions that cover topics including preferences, demographics, and sexual behavior.
- The purpose of the first section is to introduce the attributes of the hypothetical products in the DCE. The structure consists of text that is read aloud by the interviewer accompanied by images that the interviewer shows to the participant.
 - The second section consists of the choice sets. During this section, the participant is handed the tablet so that they can select answers themselves and will make choices between **9** pairs of hypothetical products. The interviewer should guide the participant through at least the first two choice sets, plus additional sets if needed for comprehension, by describing the choice activity, introducing the concept of two hypothetical products depicted as columns of attributes, or characteristics, and reading the attributes aloud. The attributes corresponding to each hypothetical product are displayed vertically in a column labeled as “Product A” or “Product B.” Once the participant has demonstrated understanding and ability to make choices on their own, the interviewer can hand the tablet to the participant for them to continue making choices on their own, while the interviewer observes and assists as needed.
 - In situations where this is not possible, be sure the participant has the tablet placed in front of them (in portrait mode) for easy viewing and decision-making in selecting their preferred products.
 - The tablet screen should always resemble the following during the choice sets:



NOTE: the blue bar across the top of the choice set only appears in the training version and will not appear during the survey.

- The third section consists of follow-up questions regarding product preferences. This section includes photos that the interviewer will show to the participant
- The last portion is a demographic questionnaire (BDQ) administered by the interviewer. After the participant has completed the choice set activity, the interviewer should pick up and hold the tablet, and administer the questions in a similar way to administering questions on a paper-based questionnaire.

Step-by-step instructions on how to administer the survey are as follows:

- a. Select the survey for the individual
- b. Complete the first screens, which are electronic cover sheets that are not read aloud to participants, by entering the Site ID, Couple ID, the Couple ID again, Sex ID, indicating the date of the interview, entering the interviewer initials, and interview location.
- c. To move to the next screen, tap the red forward arrow button at the bottom right of the screen.
- d. The first portion of the survey is interviewer-administered with visual aids. The interviewer should sit next to the participant, hold the tablet between herself and the participant, and read the questions aloud to him/her. The interviewer or participant can go back to a previous screen by tapping the red back arrow button at the bottom left, if necessary.
- e. The default language is English. The language of the form may be changed at any point during the interview. To change the questionnaire to another language version, tap the box indicating the interview language at the top of the screen. Note that the intro screens that are not read aloud to the participant will remain in English.
- f. The choice set portion of the survey is participant-administered in portrait mode with the interviewer assisting, after reading through the first two choices aloud to the participant. When the survey prompts the participant to select their preferred product, the interviewer should allow them to tap the response corresponding to their selection. Note that participants are not able to skip out of these choice-set questions, so if a participant refuses to answer a question in this section, they will not be able to proceed through the remaining questions.
 - a. For the first two choice sets, the interviewer should read the introductory statement aloud, and describe each product by going down the column and reading each attribute and level, starting with product A and then moving on to product B.
 - b. Next, allow the participant to choose their preferred product by tapping the appropriate area of the screen.
 - c. After the first two choice sets, the participants may proceed through and make choices by themselves, if they seem comfortable. The interviewer should stand by to observe and answer any questions or explain anything that is unclear. If needed, the interviewer can read any question or portion of text aloud during this section, but the participant should have the tablet visible in front of them (in portrait mode) and should tap their preferred product to select it.
 - d. Note that responses to these questions are required, and the program will not allow the participant to advance to the next screen until a preferred product has been selected.
- g. After all 9 choice sets have been completed, a final set of questions will appear. This section is interviewer-administered.
 - a. Note that participants may refuse to answer questions in this section. To indicate a participant has refused to answer, leave the question blank and continue to the next screen. The interviewer will be prompted to either go back and answer the question or confirm that the participant refused to answer. The appearance of this prompt is an indication that a question on the screen has been left blank.

- h. At the end of the questionnaire, when the interview is complete, an exit screen thanking the participant will appear. Enter any comments or notes about the interview and select the languages used for the survey. You must then hit the red forward arrow to transmit the final completed survey to the Qualtrics server. When you see the screen that says “We thank you for your time spent taking this survey. Your response has been recorded” the survey is complete, and the data has been transmitted to the Qualtrics server.
 - a. The comments field should be used to document any problems, abnormalities or insights at the end of the interview.
 - i. Examples of issues that should be documented in this comments field by the interviewer include: the participant had a two-year old child with her, so she was tired and distracted; the WiFi got disconnected after Question 7; the tablet had a problem resetting during the consent process; etc.

Steps for administering the Couple DCE portion of the visit

1. Select the Qualtrics icon on the Home screen.
2. Select that the survey is for the Couple.
3. Complete the first screens, which are electronic cover sheets that are not read aloud to participants, by entering the Site ID, Couple ID, the Couple ID again, the PTIDs for each member, date of the interview, interviewer initials, and interview location.
4. The couple will complete 9 choice set questions (just like in the Individual portion) but there is no introduction section and there are no follow-up questions.
5. At the end of the 9 choice sets, an exit screen thanking the participant will appear. Enter any comments or notes and select the languages used for the DCE choice sets. You must then hit the red forward arrow to transmit the final completed survey to the Qualtrics server. When you see the screen that says “We thank you for your time spent taking this survey. Your response has been recorded” the survey is complete, and the data has been transmitted to the Qualtrics server.

Interview Completion and Participant Reimbursement

Once responses are complete, the interviewer should ensure the questionnaire is saved by advancing all the way to the “thank you” screen and close out of the program. Note that if a participant decides he or she does not wish to complete the interview, and stops halfway through, the interviewer must submit blank responses for the rest of the questions and advance to the end of the survey in order to record and send the partial data to the server.

Appendix 6-2: Secure File Transfer Protocol (SFTP)

Overview

Secure File Transfer Protocol (SFTP) is a highly secure file directory used to transfer manually files from one computer to another computer. MTN-045 will use SFTP to transfer **large files** (unable to attach to an email) and/or **files with personally identifiable information**. Files with personally identified information **MUST** always be transferred in a secured way and should never be sent via email. Data needs may change throughout the study timeline and, as such, use-cases for SFTP and this SOP will evolve over time. Current (as of 31OCT2019) use-cases for SFTP include:

1. CRFs (CO, SH, PD) – *only if requested*
2. Debrief Reports
3. Transcripts

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.

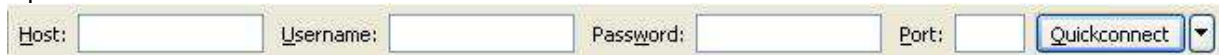
Connect to SFTP with FileZilla

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**



The image shows a screenshot of the FileZilla Quickconnect bar. It contains four input fields: 'Host:', 'Username:', 'Password:', and 'Port:'. To the right of these fields is a 'Quickconnect' button with a dropdown arrow on its right side.

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:

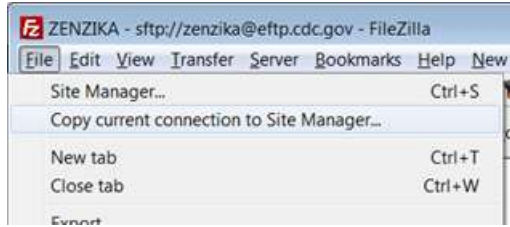
MTN-045 SSP Manual, Section 6, Version 1.0, 12NOV2019
Protocol Version 1.0 (25FEB2019)

- **Uganda:** MTN045-MU-JHU
- **Zimbabwe:** MTN045-UZCHS-CTRC

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!

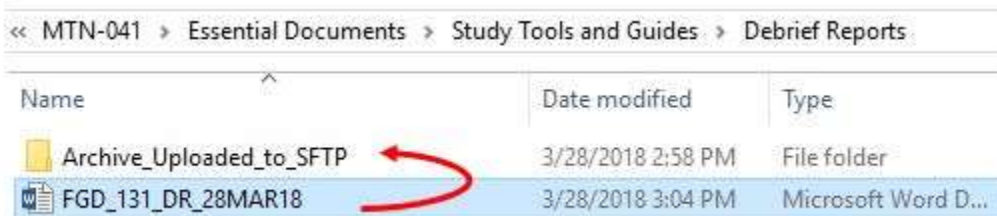
Transfer Files

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 of 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.



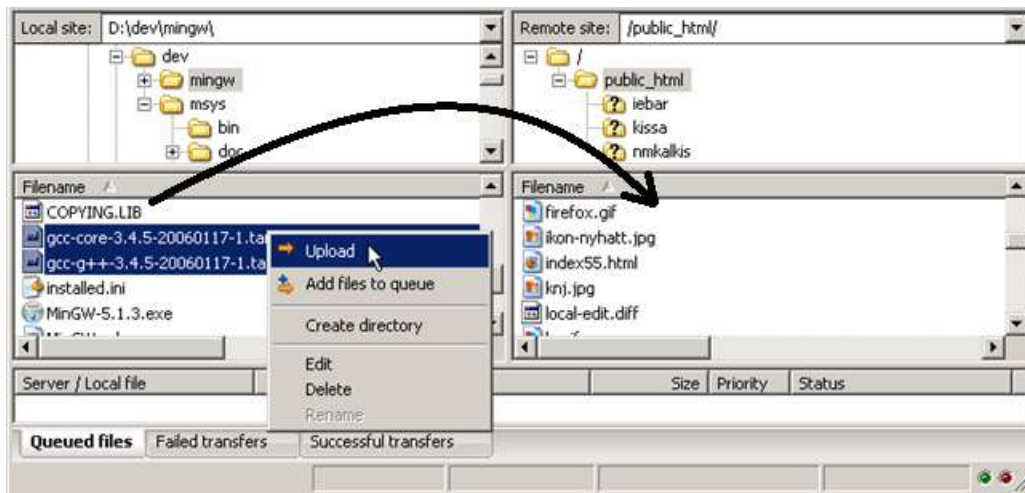
In the above photo, you can see that the upload is called FGD_131_DR_28MAR18.docx, which adopts the standard naming scheme for MTN-045. The name of the file tells us the file contains a *debrief report* from FGD number 131 conducted on March 28, 2018. Please adopt the naming scheme for files uploaded to SFTP:

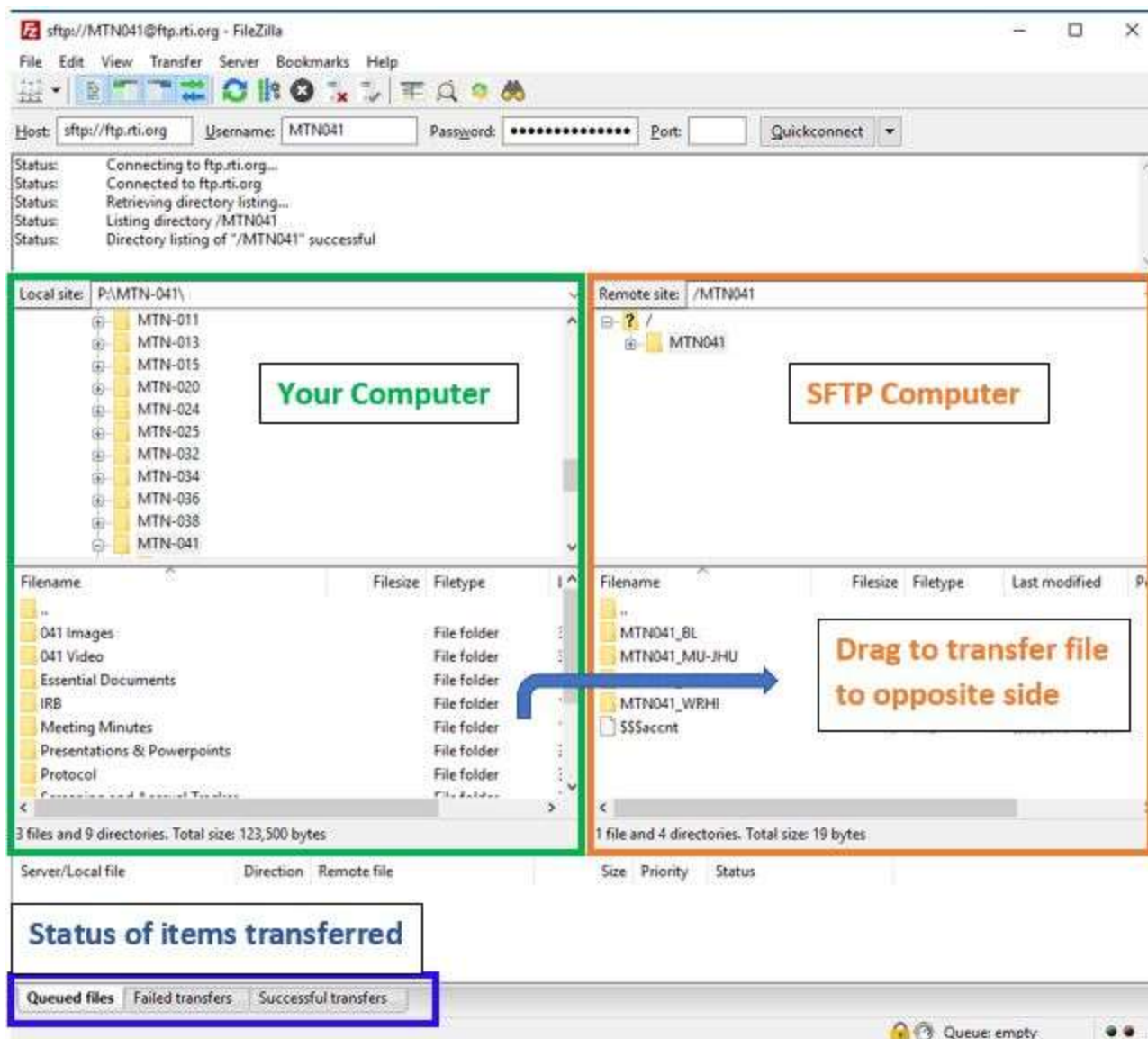
File	File Type	Name
------	-----------	------

CRF, Debrief Report, or Transcript	MS Word Doc	IDI_2001_DR_28MAR18.docx IDI_2001_TR_28MAR18.docx
------------------------------------	-------------	--

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 dropping 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 SFTP 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 be 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 that the people who most need the file have received and downloaded the file before they delete it.

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 (mshapley@rti.org) with any questions about this process.

Appendix 6-3: Transcript Formatting Expectations

Formatting Expectations:

- Heading should include filename of transcript.
- Use consistent Times New Roman or similar, 11 or 12-point font and 1.15 spacing.
- Header within document includes: Interview Type, Participant(s) ID, Interview Date, Audio Recording Length, Transcriber Name, Translator Name
- Certification of transcript
- After header, label next section “**Interview Text**,” insert a hard return and begin transcribing the content of the audio file verbatim.
- Use “I:” before Interviewer remarks and “R:” before respondent remarks.
- Auto-number the transcript by paragraph so that each time the Interviewer or Respondent begins a new response, this should be indicated by a new number
- Replace all references to individual names or other identifying data with pseudonyms noted by [brackets]
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets]
- Explanation of unclear meanings, cultural terms, etc. can be noted by [brackets]
- Long pauses can be represented by use of an ellipsis “...”
- Spell check the transcript for any spelling and grammar errors
- Filename should follow instructions described above in section 6.13

Appendix 6-4: Quality Control (QC) General Conventions for Transcripts and Debrief Reports

This general convention guidance is designed to help ensure qualitative data documents are clean, accurate and easily understandable. The goal is to create a transcript or debrief report that is clear enough so someone who is not familiar with the study could step in, pick up the document, and understand what is happening with minimal need for interpretation.

In order to make sure that across sites and studies there are consistent standards for how documents are created, the following guidelines have been created. The QC guidelines should help the QC process be smooth and efficient and eliminate confusion as much as possible.

The following are the three most common query types identified by the RTI data center in the QC process:

- A. **Punctuation:** correct punctuation is critical for making sure that the reader can read the document easily and understand the flow of the conversation (in the case of transcripts). Additionally, some punctuation can actually change the meaning of a sentence.
 - i. There are some punctuation issues that differ slightly between American and British English, *please inform RTI reviewers if there is something that comes up in the QC process that is just due to differences in grammar systems.*
 - ii. This document offers some general points on punctuation. However, it does not contain comprehensive information on the use of commas, periods, ellipses, colons, semicolons, quotation marks, etc. If there is doubt about general punctuation “rules,” please consult one of the many online guides to [punctuation](#). The review process is not aiming for *perfect* punctuation, just consistent punctuation that will allow the reader to easily understand the document they are reading.
- B. **Formatting:** Following the formatting guidelines for transcripts, summary reports, and debriefing reports, as outlined below, is important for making sure that they can be read and organized efficiently. It also allows analysts to easily understand the narrative and other pertinent information about what occurred during the interview or focus group.
- C. **Content:** Due to the nature of our research, there are often times when the content of documents is hard to understand – this can be due to language differences, cultural context, local jargon, or non-verbal cues. The reviewer will try to identify places where the meaning of something may be unclear, with the hope that the reviewers at a study site can provide clarifying information if possible.

Common issues in debriefing reports, and transcripts

- A. **Punctuation**
 - i. **Long responses:** Although some respondents – for many different reasons – give very short and cursory responses during interviews, oftentimes the best information comes out when respondents open up. This results in longer and more complicated responses. In order for them to be read and understood correctly, appropriate punctuation must be used. This includes periods at the end of each sentence, commas where natural breaks between phrases occur, quotation marks when the participant is quoting someone’s thoughts or words, ellipses when there is a long pause between thoughts, etc.
 - ii. **Punctuating the ends of lines:** There must be *some* kind of punctuation at the end of every line in a transcript (period, dash, question mark, exclamation point, ellipsis). Quotation marks, parentheses, commas, and brackets do not, in and of themselves, show the end of a line.

- a) **Speaker trails off:** If a speaker trails off while talking during an interview, use ellipses to show that pause.
 - b) **Speaker changes tracks (mid-sentence or mid-word):** When a speaker is in the middle of saying something, then stops, punctuation is used to show the reader that there was an abrupt change. This is indicated with a dash.
 - c) **Speaker is interrupted:** Sometimes the interviewer cuts off the respondent or vice versa. In that case, there should be a dash at the end of the line to show that the speaker didn't finish what they were saying because someone else cut them off. If this is not apparent in the transcript, adding an explanation that the speaker was interrupted can be done in brackets.
 - d) **Quotes, brackets and parentheses:** these types of punctuation marks separate out a section of text, but need a period, dash, question mark, exclamation point or ellipsis in addition to the quotation mark, bracket, or parentheses to show the end of a sentence.
- iii. **Audible noises:** Audible noises such as coughs, doors opening, cars honking, phones ringing or vibrating, and papers shuffling should be indicated by describing the sound inside of brackets.
 - iv. **Information added to transcript:** It is common that the reader needs more information to understand what the interviewer and/or participant is talking about. In those cases, if the interviewer or someone else at the site can provide information to help the reader understand, information should be added in brackets, within the same sentence that it is clarifying. Below in section C is more information about unclear responses.
 - v. **Punctuation quick reference:**

Name of punctuation	Symbol	When to use
Period	.	At the end of a sentence that is not an exclamation or question
Comma	,	To show pauses and natural breaks within sentences
Quotation marks	“ ”	To show where the speaker is repeating someone's words or thoughts
Dash	-	To show where someone abruptly changes tracks in a sentence or when someone is interrupted.
Question mark	?	At the end of each sentence that is a question
Exclamation point	!	At the end of each sentence that is an exclamation
Ellipsis	...	To show a pause where someone trails off
Brackets	[]	To show additional information added to the transcript to help understand it better, and to denote sounds that occurred during the interview, including where audio was paused and restarted
Parentheses	()	Recommend not to use

B. Formatting

- i. **Line numbers:** Use the line numbering function in Word to auto-number each line of text.
- ii. **Capitalization**

a) **Lines:** The beginning of each new line must be capitalized, as it is considered a new sentence.

b) Sentences: The beginning of each new sentence must be capitalized. That means that after each period, question mark, exclamation point, and ellipses or dash if they marked the end of a sentence, the next letter (after the appropriate space) must be capitalized.

c) Quotes, brackets, and parentheses: These can often be part of another sentence or standing alone. If they are at the beginning of a sentence or standing alone, the first letter must be capitalized. If they are within another sentence but not at the beginning, they do not need the first letter to be capitalized.

d) Proper nouns: All proper nouns (people, official names of places, official/brand names of things) should be capitalized. In these kinds of documents, most often the proper nouns used are people's names, the names of cities or towns, names of hospitals or organizations, and brand names of pharmaceutical products.

iii. **Speaker indication:** Each time the speaker changes, there should be an indication of the speaker

Example for speaker indication to show: ("I:" for the interviewer, "R:" for the respondent, or "Pseudonym:" in the case of focus group discussions) then a space, then the transcribed text of what that person said, starting with a capital letter. The quotation marks used in this parenthesis are ONLY to show that it is something that would be written like that in a transcript – in an actual transcript, quotation marks would not be used around the indication of who the speaker is.

iv. **Spacing:** In general, there should be only *one* space in between every word, and one space after punctuation before the next word.

v. **Text size, margins, font and line spacing:** These should be kept consistent across all transcripts and may be specified in your site SOP. Either 11 or 12-point font, standard margins, Calibri or Times New Roman and 1.15 spacing are recommended.

vi. **Footers:** Insert a footer with Page X of X on the right-hand side so the length of the transcript can be easily tracked.

vii. **Spellcheck:** Spellcheck should be used to check for any errors of spelling or grammar.

C. Content

i. **Unclear response:** RTI reviewers will query documents for sections that are unclear and where they would like the interviewer to fill in if there is any missing information due to language differences, local jargon, or cultural context that the reviewers may not have information about. These clarifications should be added into the text of the transcript, in brackets.

a) If the lack of clarity is due to transcription errors, typos, or missing punctuation, the correction should be made to the existing text of the transcript, not added in brackets.

b) The use of "may" and "can" can be confusing. I.e., "I may use the ring in the future" could mean that the respondent would be permitted to use the ring, that she would possibly use the ring, or that she would use the ring. "I cannot tell my partner about the ring" could mean that the respondent is incapable of telling her partner, or that she does not want to tell her partner. Please clarify, if possible, in

the transcript when text like this is ambiguous, and RTI reviewers will also query if it seems unclear.

c) If interviewer is not able to clarify where queried, it is completely acceptable to reply to the comment that, “there is no further information available.”

ii. **Use of local language:** In the information at the beginning of each report that includes the place of the interview, date, name of interviewer and note-taker, etc., there should also be a place to indicate the language(s) in which the interview was conducted. Depending on how the local language is used, the convention will be slightly different. There will also be some variation depending on the SOP. In the absence of specific guidance from the SSP, these are the default guidelines:

a) If the entire interview is in a local language, the transcriber will listen to the audio, and do a direct “one-step” translation to English so the original transcript will thus be in English.

1. If the participant uses a phrase or term in the local language that does not translate into English, that term should be left in the local language, in italics, and an explanation given in brackets.

b) Important phrases or idioms spoken in the local language should be retained in *italics*, and a direct translation will be placed in brackets – like a text clarification – along with any needed description of what the phrase means.

c) If a portion of the interview transitions into local language from English, the transcriber should place an explanation of that transition in brackets where the transcript changes to a language other than English, then do a direct translation for the portion conducted in a local language, and then indicate in brackets where the interview transitions back into English.

iii. **Pseudonyms:** Replace all references to individual names or other identifying data with pseudonyms. If the name of a location such as a town or city is mentioned it is fine to keep that name as-is, as long as it is not so specific it would easily identify the participant.

Appendix 6-5: CRF Form Completion

1. General Guidelines

Based on Good Clinical Practices (GCPs), the following guidelines should be used for completing CRFs:

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.
- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible while staying within the boundaries of the boxes.
- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction “Mark all that apply.”
- A response is required for every item unless instructed otherwise by a skip pattern.
- **Never** use correction fluid (“white-out”) or correction tape on CRFs.
- Remove any paper clips, staples, or other attachments before uploading CRFs.
- The site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.

2. How to Mark Response Boxes

Many items on CRFs have a box or series of boxes for recording a response. Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a slash or other character.



Mark only one response box for each item unless the “Mark all that apply” instruction is present.

3. How to Record Numbers

Some questions on CRFs include boxes for recording a numeric response. The numbers in these boxes need to be recorded clearly. The following instructions should be followed when recording numeric responses:

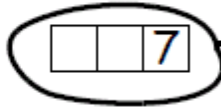
- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

The following example shows how a value of 7 is recorded when three response boxes are provided:

Correct:

0 0 7

Incorrect:



→ This example would result in a QC note.

- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

In the following example, the 4 could be misinterpreted as a 7 or a 1:

Correct:

4

Incorrect:



- Write the number(s) simply, with few loops.

The following example shows the format in which numbers will be most easily read. Also included are some commonly used formats that may be difficult to identify.

Easily Identified:

0 1 2 3 4 5 6 7 8 9

Difficult to Identify:



4. How to Record Dates

Dates are recorded using the “dd MMM yy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yy” represents the last two digits of the year.

The month field must be filled in with the three-letter abbreviation *in English*. Abbreviations are shown in the table below.

Month	Abbreviation	Month	Abbreviation
January	JAN	July	JUL
February	FEB	August	AUG
March	MAR	September	SEP
April	APR	October	OCT
May	MAY	November	NOV
June	JUN	December	DEC

For example, June 6, 2015 is recorded as:

0	6	J	U	N	1	5
<i>dd</i>		<i>MMM</i>			<i>yy</i>	

Sometimes, only a month and a year are required (e.g., diagnosis date for a pre-existing condition), in which case the response boxes will look like this:

<i>MMM</i>			<i>yy</i>

A diagnosis date of October 2015 would be recorded as follows:

<i>MMM</i>			<i>yy</i>		
O	C	T	1	5	

5. Data Corrections and Additions

Sometimes, data on a CRF may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a QC report or as a result of site review of the CRF before uploading.

It is important to make these changes to the original CRF—**never** copy data onto a new form. After making the change, the CRF *must* be re-sent to RTI.

Note: If a correction or addition is made to one page of a multiple-page CRF, only re-upload the page that was changed. Initial and date all changes or additions.

Note: Never write over an entry once it is recorded. Use the standards outlined in the following paragraphs when changing, clarifying, or amending data.

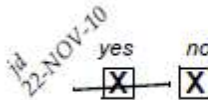
Whenever an entry on a CRF is changed, do the following:

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),
- place the correct or clarified answer near the box, and
- initial and date the correction as shown below:



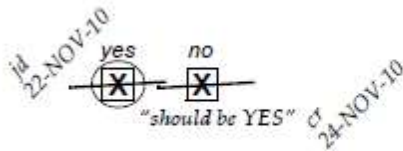
If an **X** is marked in the wrong response box, correct it by doing the following:

- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and
- initial and date the correction as shown below:



If the correct answer has previously been crossed out, do the following:

- circle the correct item,
- write an explanation in the white space near the item, and
- initial and date all corrections as shown below:

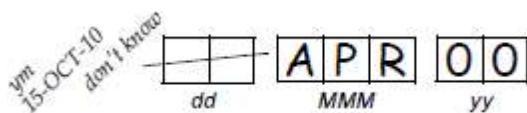


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is uploaded for the first time.

6. How to Handle Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer, draw a single horizontal line through the blank boxes and initial and date the item. It is helpful to write “don’t know,” “refuses to answer,” “UNK” (unknown), “N/A” (not applicable), or “REF” (refused) near the blank boxes.

For example, when recording a date, if the exact day is not known, draw a single horizontal line through the “dd” boxes and write “don’t know” next to the response boxes, as shown below:



A skip pattern is the **only** valid reason to leave a response blank. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial form completion, or as an update to the form.

Section 7. Data Communiqués

7. Introduction7-1

7. Introduction

For MTN-045, RTI will use “Data Communiqués” to document and communicate data decisions and procedures that are made or revised during the study. By using Data Communiqués, RTI avoids having to re-distribute a revised version of the Data Collection and Management section of this SSP Manual every time a form completion clarification or revision is made.

Data Communiqués are considered official study documentation. As such, each time a Data Communiqué is sent (via email), please circulate it among relevant staff for their review, document training in site essential files, print the Data Communiqué, and place it in this section of each MTN-045 SSP Manual binder in your possession. Consider each Data Communiqué an official part of the SSP Manual.

Each Data Communiqué sent will consist of three sections: 1) a Reminders section, used to remind sites of specific data collection or forms completion procedures; 2) a Clarification section, used to clarify data collection or form completion procedures; and 3) an Updates section, used to communicate when an updated version of a form is being issued or to notify the sites that an updated version of the forms instructions is about to be distributed (for example).

Note that a “Data Communiqué” does not request specific actions or corrections to a particular participant’s data - it is just a listing of general items to keep in mind when performing data collection for the study.