Section 20. An Exploratory Study of Potential Sources of Efficacy Dilution in the VOICE Trial

This section describes study-specific procedures for MTN-003D, *An Exploratory Study of Potential Sources of Efficacy Dilution in the VOICE Trial*, a sub-study of the VOICE study. MTN-003D will be conducted at the MRC, UZ-UCSF, and MU-JHU study sites in Durban, Harare, and Kampala, respectively. Therefore, the MRC, UZ-UCSF, and MU-JHU sites must maintain this section of the Study-Specific Procedures (SSP) Manual in its entirety. All other VOICE sites not participating in MTN-003D are not required to maintain this SSP section. For clarity of documentation, however, all VOICE sites should maintain a reference copy of Version 1.0 of this page (20-1), dated 12 October 2012, in their respective VOICE SSP manuals.

20.1 Introduction

This Study Specific Procedures (SSP) manual section specifies the sources of procedural information available to MTN-003D sub-study staff, the responsibilities of MTN-003D Investigators of Record (IoRs), and the process by which each study site is approved to begin implementation of MTN-003D. The updated v2.0 MTN-003D SSP manual describes the procedures per Version 2.0 of the protocol.

20.1.1 Sources of Procedural Information

All study procedures must be conducted in accordance with the MTN-003D protocol. The purpose of this manual is to supplement the protocol, not to replace or substitute it. In the event that this manual is inconsistent with the protocol, the specifications of the protocol take precedence. Please alert the MTN-003D Study Operations Team (described below) of any such inconsistencies. Study implementation questions that are not answered by the protocol or this manual should be directed to the MTN-003D Study Operations Team. This group consists of representatives of the MTN Coordinating and Operations Center (CORE-FHI 360), RTI International, and the Protocol Chairs. This group can be reached using the following email address:

mtn003d-ops@mtnstopshiv.org

20.1.2 Investigator Responsibilities

MTN-003D must be conducted in accordance with the United States Code of Federal Regulations and the International Conference on Harmonization Consolidated Guidance for Good Clinical Practice. Copies of these regulations and guidelines are referenced in the MTN Manual of Operations (MOP) which can be accessed at:

http://www.mtnstopshiv.org/node/187

The DAIDS policies on *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 regulations and guidelines in accordance with DAIDS expectations. These policies can be accessed at:

http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch

MTN-003D also must be conducted 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. Sites may use their own filing structure for essential documents or may refer to Section 3.1 of the VOICE SSP manual for a suitable model.

The IoR at each site must sign both an Investigator Signature From and a DAIDS Investigator of Record Form to formally indicate his/her agreement to conduct MTN-003D in accordance with the study protocol and all applicable regulations, policies, and guidelines. The protocol signature page can be found on page xiv of the protocol. The DAIDS Investigator of Record Form can be located on the DAIDS Regulatory Support Center webpage: http://rsc.tech-res.com/protocolregistration/. The obligations and responsibilities assumed by the IoR when signing the Investigator Agreement are listed on the form. IoRs may delegate their obligations and responsibilities for conducting MTN-003D to other study staff members; however, 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.

Consistent with the regulations, guidelines, and policies cited above, the IoR at each site must obtain and maintain Institutional Review Board and/or Ethics Committee (IRB/EC) approval of MTN-003D throughout the period of study implementation. See Section 9.4 of the MTN Manual of Operations (MOP) for detailed information on IRB/EC submission, review, approval, and documentation requirements. All sites are encouraged to request an 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.

20.1.3 Study Activation Process

Prior to undertaking any study procedures outlined in version 1.0 or any subsequent versions of the protocol, each site must obtain final approval to conduct MTN-003D from all responsible regulatory authorities and IRBs/ECs. Prior to initiating version 1.0, each site also must complete protocol registration procedures with the DAIDS Regulatory Support Center Protocol Registration Office and study activation procedures with DAIDS and the MTN CORE (FHI 360). Detailed information on the requirements of these pre-implementation steps can be found in Section 11.3 of the MTN MOP. On a site-by-site basis, the MTN CORE (FHI 360) will issue a Site-Specific Study Activation Notice when all study activation requirements have been met. At each site, no protocol-specified study procedures may be undertaken prior to issuance of the Site-Specific Study Activation Notice.

20.2 Protocol

A complete reference copy of the MTN-003D protocol is available on the MTN website: http://www.mtnstopshiv.org/node/4494

Any study protocol clarification memos, letters of amendment, or full protocol amendments, will similarly be posted on the MTN website and must be filed with essential documentation.

Further information on the content and required handling of protocol clarification memos, letters of amendment, and full amendments is available in Section 10.2 of the MTN MOP.

20.3 Documentation Requirements

Study staff are responsible for proper collection, management, storage, quality control, and quality assurance of all study-related documentation, related to the MTN-003D study. A unique set of essential documents as they pertain to the MTN-003D study should be maintained separately from the parent study. This section contains information on the essential documents that each study site must maintain throughout the study. It also contains information related to establishing adequate and accurate participant research records — commonly referred to as the "participant file" — for MTN-003D.

20.3.1 Essential Documents

The DAIDS policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* specifies the essential documents that study sites must maintain for DAIDS-sponsored studies, including MTN-003D. When required documents are modified or updated, the original and all updated versions must be maintained. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location. In its policy on *Requirements for Manual of Operational Procedures*, DAIDS requires study sites to establish a standard operating procedure (SOP) for maintaining essential documents. The SOP developed for VOICE should be followed for MTN-003D.

When developing an essential documents filing structure for MTN-003D, study sites are encouraged to consider their experiences implementing previous MTN protocols. While taking into account these experiences, the structure should be tailored to meet the specific needs of MTN-003D and ensure that all required documents are properly filed. Three tips for the suggested filing structure are provided below:

- Essential documents may be stored in files and/or in binders. The files/binders may be further subdivided, consolidated, and/or re-organized if desired.

- Insert a contents sheet as the first page(s) of each file/binder. File documents for each binder in ascending date order (most recent documents in front).

- It is assumed that MTN-003D participant files will be stored separately from the other essential documents. Section 20.3.2 below provides information on the required contents of these files. Screening and Enrollment Logs (which are described in Section 20.4.6 of this manual) should be stored in the study clinic or data management area, and not necessarily with the other essential documents.

20.3.2 Participant File Documentation

Study sites must maintain adequate and accurate participant file records containing all information pertinent to MTN-003D for each study participant. If a participant was enrolled in Stage 1, her Stage 2 study documentation should be stored with her Stage 1 study documentation. Sites may find it useful to create a method to demarcate the Stage(s) that each participant is in.

20.3.2.1 Participant File Contents

Participant files should contain all of the following elements:

- Basic participant identifiers.
- Documentation that the participant provided written permission to be contacted by VOICE staff for future research studies.
- Documentation that the participant met the study's selection (eligibility) criteria.
- Documentation that the participant provided written consent to participate in the study prior to the conduct of any study procedures.
    - Note: Any questions the participant asks during the written IC process (and responses to these questions) should be documented in file notes or on the informed consent cover sheet.
- A record of all contacts, and attempted contacts, with the participant documented per Good Clinical Practices (GCP) and DAIDS source documentation guidelines.
- A record of all study activities that took place and interview data captured during the conduct of the study.
    - All notes recorded by study staff on interview guides and/ or separate sheets of paper and/ or tools (e.g. body mapping template, study timeline) for the in-depth interviews (IDI) are to be filed in the participant file; separate files can be created to store all FGD group information such as checklists, notes, and participant lists.
- Referrals made (including for social harms or unexpected safety events reported).
- Reason for any deviation required from procedures outlined in the protocol, site SOPs or this SSP manual.

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with reasons for the deviations, efforts made to correct the deviations, and efforts made to prevent similar deviations in the future (see the MTN website at http://www.mtnstopshiv.org/ for the protocol deviation template used for all MTN studies). It is also recommended that a copy of all protocol deviations recorded at the site be maintained in one central file with the Essential Documents. Additional details regarding protocol deviation reporting requirements are found in Section 20.3.4.

20.3.2.2 Concept of Source Data and Source Documentation

The International Conference on Harmonization Consolidated Guidance for Good Clinical Practice (ICH-E6) defines the terms source data and source documentation. Please refer to section 3.2.2 of the VOICE SSP manual and to the VOICE Source Documentation SOP for more detail.

For MTN-003D, participant files contain several source documents:

- **Narrative participant file notes**: File notes should be used to document visit procedures (including verification of permission to contact and the IC process if not documented elsewhere), communicate any deviations from SOPs, any protocol deviations that are not recorded on other source documents, any referrals made that were not documented elsewhere, or contacts with all participants if the Participant Contact Log is not used for this purpose.

- **Case Report Forms (CRFs) and non-CRF forms:** The case report forms for this study are designed for use with the RTI data management system described in Section 20.11 of this manual. RTI will provide the master versions of these forms to the site, and printing will be coordinated locally. RTI will also provide several additional study-specific forms (non-CRFs) to the site. See Table 20-1 for a listing of all forms for this study. All CRFs and other forms used in this study can be found on the MTN-003D website.
- **Qualitative Guides for IDIs & FGDs:** Notes taken on IDI discussion guides, tools (i.e. body mapping template and timeline tool) or separate pieces of paper during qualitative data collection are source documents and must be kept in the participant file. Separate files can be created to store all FGD group information such as checklists, notes, participant lists and annotated FGD discussion guides and tools.

    - Transcriptions and translations of audio files are also considered to be source documentation for these interviews (final local language and the final translated version) and must be kept in the participant file. As such, once QC'd and considered "final" by the site, each page of local language transcripts must be certified. This means that each page of the printed transcript should be initialed/dated by the person doing the transcription, indicating that it is an exact copy of the audio recording. Audio files will be destroyed once they have been transcribed, QC'd, certified, and considered "final" by the data center (RTI), as described in section 20.11.9 of this manual.

- Other source documents (e.g., site-specific checklists, worksheets) as identified in the site Source Documentation SOP.

20.3.2.3 Document Organization

Study staff must make every effort to store all study records securely and confidentially. Participant files 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 (flat files) or thin folders. All screening documentation — for potential participants who eventually enroll in the study as well as for those who do not enroll — must be maintained and available for monitoring throughout the study. Flat files may be maintained for participants who enroll, if the files have some kind of secure mechanism (i.e. rings, clasps) to hold papers. Otherwise, documentation should be transferred to files that have secure mechanisms for holding papers. Pocket files are not adequate as loose papers may still fall out.

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. To maximize participant confidentiality, the PTID should be used whenever possible, and records that bear names or other personal identifiers, such as locator forms and informed consent forms, must be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location — including RTI or a local data management center— must be identified by PTID only. Table 20-1 gives a list of documents used for MTN-003D and whether name, PTID, or both are used.

Table 20-1: Listing of MTN-003D Study Documents

Document Name	Name/ Initials only	PTID only	Name/Initials and/or PTID
Locator Form*	X		
Permission to Contact Form*			**X**
Recruitment Lists		X†	
Recruitment Checklist/Scripts		X‡	
Screening and Enrollment Logs			**X**
Consent Forms	X		**X**
IC Comprehension Checklists	X		
Participant Contact Logs		X	
Case Report Forms (DEM & PSF)		X	
Visit Checklists		X	
Discussion Guides, Notes and Tools		X	
IDI and FGD Debriefing Reports		**X**	

Visit Checklists: The sample checklists in Section Appendix 20-1 of this manual provide an example of convenient tools to fulfill the requirement of documenting all study activities that take place at each IDI and FGD visit with study participants. Checklists used for IDIs and FGDs should be filed with the participant files. Every item in the left column of the checklist should be ticked or marked 'NA'. If visit procedures deviate from what is outlined in the checklist, documentation of this should be in the comments section or at the bottom of the checklist.

All on-site databases must be secured with password-protected access systems. 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.

As a condition for study activation, each study site must establish an SOP for Data Management. This SOP minimally should contain the following elements:

- Procedures for assigning PTIDs, and linking PTIDs to participant names
- Procedures for establishing participant files
- During-visit participant file and CRF review procedures
- Post-visit participant file and CRF review procedures and timeframes
- CRF data transfer procedures, including timeframes, CRF storage locations before and after data transfer, and mechanisms for identifying when forms have been transferred
- Data collection using the discussion guides
- Storage locations for blank CRFs and guides
- Storage locations for documents identified by participant names or other personal identifiers
- Storage locations for documents identified by PTID
- Handling of participant study files for off-site contacts and visits
- Confidentiality protections, including the process for the destruction of audio files
- Other ethical and human subjects considerations

* The Locator Form and Permission to Contact Form are VOICE forms that will be used for verifying eligibility and recruiting participants for MTN-003D. If possible, a certified copy of these forms will be made for MTN-003D study files. Otherwise, a chart note will document this information in the MTN-003D file.

† This will be the VOICE PTID, rather than the MTN-003D PTID since it will be used prior to enrollment.

- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

20.3.3 Record Retention Requirements

Please refer to Section 3.4 of the VOICE SSP manual. The documents for MTN-003D must be maintained (at least) for the same timeframe as those for the VOICE study. No documents may be destroyed without written permission from DAIDS.

20.3.4 Protocol Deviation Reporting and Oversight

A comprehensive Network Protocol Deviation (PD) policy, which is in compliance with U.S. federal regulations, is a key component of ensuring participant safety, preserving the scientific integrity of research studies and fulfilling sponsor reporting obligations. The MTN has adopted a revised Protocol Deviation Policy effective for all studies in which accrual is initiated on or after June 1, 2012.

Reporting

Centralized reporting and tracking of PDs is imperative to both ensuring the safety of our study participants and to preserving the scientific integrity of research studies, while allowing the Network to meet its obligations to study sponsors. All deviations from the protocol will be reported centrally as soon as possible, but not later than 3 working days once the site staff is aware of the deviation.

The procedure for reporting a PD is as follows:

- A deviation is identified at the site
- Fill out a PD Form for the deviation, scan it and email the document to mtnregulatory@mtnstopshiv.org within 3 working days of identifying the PD. Please include the protocol ID #, your site's DAIDS ID # and the words Protocol Deviation in the subject line of the email (ex. MTN-003D, Site 12345, Protocol Deviation)
    - If a PD involves multiple PTIDs a separate PD form should be filled out for each PTID involved
    - If there is a question about if something is a PD or not please contact mtnregulatory@mtnstopshiv.org for support. The 3 day window for reporting a PD will not start until a PD is confirmed by MTN Regulatory.

Some, but not all protocol deviations, may be considered Critical Events which are reportable directly to the DAIDS, per the DAIDS policy Identification and Classification of Critical Events. Sites are also to follow local requirements regarding reporting protocol deviations to local regulatory bodies.

Oversight

A central file of deviations will be maintained and will be available as requested by Network Leadership, DAIDS, OCSO, Protocol Teams, the Network Evaluation Committee, and other Network groups as needed.

The MTN Regulatory Department will review, track and maintain PDs, regardless of cause. The MTN Regulatory Department will, on a regular basis, distribute PD information to the Protocol Team and if further information is required, contact the site.

20.4 Participant Accrual

This section provides information on requirements and procedures for recruiting, screening, and enrolling participants in MTN-003D. Informed consent considerations are provided in Section 20.5.

20.4.1 Study Accrual Plan and Site-Specific Accrual Targets

Study Participant Accrual Plan

Each site is responsible for developing its own accrual plan for both Stage 1 and Stage 2 that can be described in the site Accrual SOP. However, as accrual is dependent on participation in the VOICE study, it is recommended that the section of the accrual plan addressing MTN-003D is developed in cooperation with the VOICE clinical staff, if still available for consultation. Working in collaboration with the VOICE clinical staff, the Community Working Group (CWG), and local Community Advisory Board (CAB) is encouraged. Please contact FHI 360 to help facilitate any of this process as needed.

The accrual plan should minimally contain the following elements:

- Site-specific accrual targets
- Methods for tracking actual accrual versus accrual targets
- 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 accrual plan if needed to meet site-specific accrual goals.

Site-Specific Accrual Targets

Stage 1

Approximately 20 former VOICE participants per site (MU-JHU, UZ-UCSF, MRC Isipingo, and MRC Overport) are targeted to be enrolled in MTN-003D Stage 1. The total accrual time anticipated for this study is 28 weeks, however given the small enrollment targets per site, it is anticipated that the site specific accrual period will take place over a period of approximately two to four weeks. The three participant subgroups and approximate enrollment targets are shown in Table 20-2. As seen in this table, approximately half of participants from each group will be enrolled from the VOICE gel arms (active and placebo) and half from the VOICE tablet arms (Truvada, tenofovir or placebo).

Table 20-2: Stage 1 Approximate Enrollment Targets per Site

Participant Group	~No. of Gel Participants/Site	~No. of Tablet Participants/Site	~Total No. of Participants/Site
Participants reporting anal sex	1	1	**2**
Participants who acquired HIV during VOICE	1	1	**2**
All other women	8	8	**16**

All potentially eligible participants will be randomly pre-selected by SCHARP, based on several criteria: 1) all participants pre-selected will have been on product for a minimum of three months, 2) the anal sex sub-sample will be selected based on reporting of anal sex during VOICE ("anal sex status"), and 3) the HIV positive sub-sample will be selected based on confirmed incident HIV infection per laboratory results and in accordance with the VOICE study algorithm ("seroconversion/ HIV status").

Note: Following the first set of interviews, it was found that additional probing needed to be considered during IDI administration. Consequently operational guidance was distributed to provide direction on the additional probing areas of interest [See section 20.6 Visit Procedures for more information about integrating additional probing into IDI administration]. To ensure an adequate number of participants were asked the additional probes, target enrollment was increased by 10%. These additional eight participants are to be distributed among the sites based on the number of interviews conducted at the site prior to the probe additions. Six additional participants are to be conducted at the UZ-UCSF site increasing their total enrollment target to 26 and two participants at the MU-JHU site, increasing their total enrollment target to 22. The target sample size was not increased for MRC since they had not yet begun participant interviews.

To ensure participant confidentiality, all site staff, including the study interviewers, will be blinded to anal sex reporting status. It is assumed that for other reasons, the VOICE site staff may already be aware of HIV seroconversion status; however, the study interviewers should be blinded to participant HIV status. Maintaining confidentiality of a participant's anal sex and HIV status during VOICE will be instrumental to ensuring the integrity of the study, and procedures to maintain this confidentiality should be outlined in the site accrual SOP. It is understood that irrespective of anal sex or HIV status reported/identified during VOICE, a participant may disclose anal sex practices or her HIV status during the interview, and this information will be evident to those at the interview, as well as staff involved with reviewing, transcribing/translating and analyzing those data. Table 20-3 outlines blinding status for each group of study staff.

Table 20-3: Stage 1 Blinding Status by Staff Group

MTN-003D Staff Group:	Blinded to:	Point of Unblinding:
RTI	Seroconversion status Anal sex status	Post data analysis
Pop Council	Seroconversion status Anal sex status	Post data analysis
FHI 360	N/A	N/A
Site Staff	Anal sex status	Post data analysis
Study Interviewers (including all DTHF staff)	Seroconversion status Anal sex status	Post data analysis

Prior to the start of the study four MTN-003D Recruitment Lists (RL) will be generated by SCHARP and distributed to the sites by FHI 360. The four lists will be broken down by participant characteristics as follows: 1) gel HIV-negative women (including those reporting anal sex), 2) tablet HIV-negative women (including those reporting anal sex), 3) gel HIV positive women, 4) tablet HIV positive women (See Table 20-4). Recruitment of participants into the study from each of the four lists should occur **in sequential order**; however, sites may recruit from multiple lists simultaneously. Enrollment status will be recorded on the RLs, and the outcome of each VOICE PTID considered for potential enrollment should be recorded on the Participant Status Form (PSF). A sample template of this list is pasted below in Table 20-5.

Note: A revised version of the participant recruitment list was distributed to sites on January 9, 2013 along with instructions on how to proceed with contacting and enrolling participants. The previous versions of the Participant Recruitment lists should be kept in the essential files as source documentation.

Table 20-4: Stage 1 Participant Type by Recruitment List

List 1G:	List 1T:	List 2G:	List 2T:
• Gel participants • Anal sex sub-sample (min of 3) • All other women (min of 20)	• Tablet participants • Anal sex sub-sample (min of 3) • All other women (min of 20)	• Gel participants • HIV-positive sub-sample	• Tablet participants • HIV-positive sub-sample

The MTN-003D Study Coordinator at each site is responsible for updating the recruitment status on these lists regularly and communicating progress with FHI 360 at a minimum of once per week by e-mailing a copy of the Recruitment List. As show in Table 20-3 above, FHI 360 will not be blinded to anal sex or HIV status and will therefore be responsible for ensuring that adequate sub-sample targets are met.

Table 20-5: Stage 1 Sample Template of Recruitment List

VOICE PTID	Study Arm (Gel/ Tablet)	VOICE SEV Date (if complete)	Did participant give PTC? (If no, do not contact)	Participant enrolled in MTN-003D (Y/N)	Staff Initials

Stage 2

Approximately 36-48 former VOICE participants per CTU (MU-JHU, UZ-UCSF, and MRC[§]) for a total of 108-144 participants are targeted to be enrolled in MTN-003D. The total accrual time anticipated for this study is 7 months, however given the small enrollment targets per site, it is anticipated that the site specific accrual period will take place over a period of 6-8 weeks. Approximate enrollment targets by drug detection level, study group, and HIV status are shown in Table 20-6.

[§] Note: for Stage 2 part of the protocol, the Durban, South Africa sites (Isipingo and Overport) are combined into one site.

Table 20-6: Stage 2 Approximate Enrollment Targets per Site

Drug Detection Level**	Study Group	~ No. of IDIs/FGDs * HIV(+)	HIV(-)	~Total No. of Participants
Low drug detection per PK results	**Gel**	**2 IDI**	**4 IDI 2 FGD⌂**	**18**
	Tablet	**2 IDI**	**4 IDI 2 FGD⌂**	**18**
High drug detection per PK results	**Gel**	**2 IDI**	**4 IDI**	**6**
	Tablet	**2 IDI**	**4 IDI**	**6**

⌂ Approximately 6 participants will take part in each FGD. No fewer than 4 participants should be in a FGD. If a large number of participants shows up for an FGD (e.g. 12 or more) and site staff prefer to conduct 2 simultaneous or consecutive groups with those women, that is acceptable.
*At the discretion of MTN-003D leadership, and in consultation with DAIDS and NIMH, these projections may be modified
** In order to fill each group's quota and meet recruitment targets, participants with "low" or "low/inconsistent" adherence levels will be recruited for "low drug detection groups." Likewise, participants with "high" or "high/inconsistent" adherence levels will be recruited for "high drug detection groups"

All potentially eligible participants will be randomly pre-selected by SCHARP, based on the following criteria: 1) all participants pre-selected will have been on product for a minimum of three months, and 2) have pharmacokinetic (PK) data available. Women will be recruited from Stage 1 and 003D naïve participants.

Prior to the start of the study eight MTN-003D Stage 2 Recruitment Lists (RL) will be generated by SCHARP and distributed to the sites by FHI 360. The eight lists will be broken down by participant characteristics as indicated in Table 20-7. Recruitment of participants into the study from each of the eight lists should occur **in sequential order** (i.e. starting with the first person on the list and subsequently moving down the list); however, sites may recruit from multiple lists simultaneously. **Note** that several IDIs (at least 2-3) with HIV negative participants identified as having low drug levels per PK results should be conducted prior to the FGDs with this sub-sample so that those participants who are open about their non-adherence during the Stage 2 IDI may be identified and asked to participate in a subsequent FGD as they are being scheduled. A participant may voluntarily disclose that she acquired HIV after she exited VOICE. If that is the case, she may still continue with the IDI and/or FGD as per assignment; however she should be counseled to consider her comfort level when participating in an "HIV-negative" focus group. Ultimately, the participant should decide on whether to enroll in the study, and complete the interview and/or focus group.

Enrollment status will be recorded on the RLs, and the outcome of each VOICE PTID considered for potential enrollment should be recorded on the Stage 2 Participant Status Form (PSF). A sample template of this list is pasted below in Table 20-8.

Table 20-7: Stage 2 Participant Type by Recruitment List

1G:	1T:	2G:	2T:
• Gel participants • HIV-negative • Low drug detection	• Tablet participants • HIV-negative • Low drug detection	• Gel participants • HIV-negative • High drug detection	• Tablet participants • HIV-negative • High drug detection
3G:	**3T:**	**4G:**	**4T:**
• Gel participants • HIV-positive • Low drug detection	• Tablet participants • HIV-positive • Low drug detection	• Gel participants • HIV-positive • High drug detection	• Tablet participants • HIV-positive • High drug detection

Once screening and enrollment begins, the MTN-003D Study Coordinator at each site is responsible for updating the recruitment status on these lists regularly and communicating progress with FHI 360 at a minimum of once per week by e-mailing a copy of the Recruitment List. FHI 360 will be responsible for ensuring that adequate sub-sample targets are met.

Table 20-8: Stage 2 Sample Template of Recruitment List

VOICE PTID	VOICE SEV Date (if complete)	Did participant give PTC? (If no, do not contact)	Participant enrolled in MTN-003D (Y/N)	Staff Initials

20.4.2 Assignment of Participant ID and FGD Numbers

For all MTN-003D participants, RTI will assign a range of MTN-003D participant ID numbers (PTIDs). The site should assign one PTID to each participant after informed consent for the study has been obtained. PTIDs are assigned in sequential order within the range as participants are enrolled in the study. Staff should ensure that each PTID is assigned only once and may track this by using a Screening and Enrollment Log. Once a participant has received a PTID, she will maintain that same PTID throughout the entire study.

The Stage 1 and Stage 2 Participant Status Forms (PSF) will capture both the VOICE PTID and the MTN-003D PTID (if enrolled) of the participant. The MTN-003D PTID should be used for all subsequent MTN-003D documentation. Staff should enter a "placeholder" PTID of "9999" on the PSF for all individuals who are identified for recruitment or screened, but not enrolled.

MTN-003D PTID boxes are located near the upper left corner of each CRF page. The PTIDs used for this study are four digits long and are formatted as "XXXX".

Table 20-9: Range of PTIDs and FGD Numbers by Site

Site	PTID Range	FGD # Range
MRC Isipingo	1001-1099	101-199[**]
MRC Overport	2001-2099[††]	
UZ-UCSF	3001-3099	301-399
MUJHU	4001-4099	401-499

Participants enrolled in Stage 2, who previously participated in Stage 1, will maintain the same MTN-003D PTID as assigned during Stage 1. Stage 2 participants not previously enrolled in Stage 1 will receive a new PTID. New PTIDs will be assigned beginning with those numbers not previously assigned in Stage 1.

[**] Because the two MRC sites (Isipingo and Overport) are combined into one site for Stage 2 data collection, only one range of numbers will be used to number the FGDs.

[††] Although the two MRC sites are combined into one site for Stage 2 data collection, individual PTIDs will still reflect the two sites (Isipingo or Overport) where the individuals participated in VOICE. This allow will those individuals who participate in Stage 1 and 2 to maintain their existing PTIDs.

All FGDs conducted during Stage 2 should be numbered in sequential order using the range of numbers assigned in Table 20-9. To distinguish the FGD numbers from the PTIDs, FGD numbers are three digits long and are formatted as "XXX". Note that each participant included within an FGD will still receive a unique PTID per the specified PTID ranges.

20.4.3 Screening Definition and Eligibility Criteria

Screening for this study primarily refers to recruitment procedures undertaken by site staff to contact and obtain a verbal expression of willingness to join/enroll in the study, and to schedule the participant for her MTN-003D visit. Screening for MTN-003D participation will begin after the participant's VOICE termination visit. The first step of screening involves verification of a former VOICE participant's permission to be contacted (PTC). Only pre-selected participants who have given PTC will be contacted. After checking PTC status, a former VOICE staff member will contact the potential participant using locator information provided during VOICE. The staff member will follow the recruitment checklist/script, found on the MTN website, to describe the MTN-003D study. Potentially interested participants will then be scheduled for an enrollment visit. All contacts and contact attempts should be documented in Participant Contact Logs or File Notes. A copy of the Recruitment Checklist should be maintained in Participant Files for all participants who are successfully contacted.

20.4.4 Definition of Enrollment Procedures

MTN-003D staff will meet potential participants at the designated time and venue agreed by the participant during screening contact. The first step of the visit will be to undergo the informed consent process. After the administration of the informed consent and all participants questions have been addressed; but before signing the informed consent, site staff should administer the informed consent comprehension checklist. Participants will be considered enrolled in MTN-003D after they have provided written informed consent. At this point, they should be assigned a MTN-003D PTID (see section 20.4.2 above).

In-Depth Interviews (IDIs) should ideally be conducted the same day written informed consent is obtained. If it is not possible to conduct the IDI until a later date than IC administration, the IC should be reviewed again immediately prior to the IDI, and this should be documented in the participant file. Further information on the informed consent process is provided in Section 20.5.

For Focus Group participants who did not participate in a Stage 2 IDI, informed consent should be conducted on the same days as the Group Discussion. For scheduling or logistics reasons this may not always be possible, in which case IC may be administered prior to the FGD, however this is not encouraged, as it may lead to defaulting. If the IC administration occurs on a different day than the day when the FGD is conducted, the IC should be reviewed again immediately prior to the FGD and this should be documented in the participant file.

Each participant will be assessed for eligibility before/during the informed consent process at which point study staff can verify inclusion criteria 1 and 2 and exclusion criteria 1 are met. The study eligibility criteria is listed in MTN-003D Protocol Section 5 and further discussed in this section below.

***NOTE**: For MTN-003D, SCHARP will only select participants who meet the product use criteria established below, as well as the PK criteria for Stage 2, so as to obviate the need for MTN-003D staff to verify inclusion criteria 3 or 4 in VOICE files.*

Inclusion and exclusion criteria are as follows:

Inclusion Criteria:
1) Able and willing to perform the study procedures
2) Able and willing to provide informed consent in one of the MTN-003D study languages
3) Participated in VOICE and received at least three consecutive months of study product at any time during VOICE trial participation
4) Stage 2 participants must have PK data available *[**NOTE:** Women from Stage 1 who have PK data available will be considered eligible for Stage 2.]*

Exclusion Criteria:
1) Has any condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.

***NOTE**: This exclusion criterion is standard across all MTN protocols and may be used to justify a range of reasons for participant exclusion from MTN-003D. For example, if a participant is enrolled in another HIV prevention study (e.g. ASPIRE) by the time she is approached for MTN-003D participation, the IoR may decide to exclude her if s/he feels it might complicate interpretation of MTN-003D data.*

20.4.5 Screening and Enrollment Timeframe

Recruitment/screening, accrual, and enrollment procedures for Stage 1 MTN-003D will begin upon study activation and continue for approximately two to four weeks at each site or until the estimated 20 participants per site are enrolled. Stage 2 recruitment/screening, accrual, and enrollment procedures will continue for approximately six to eight weeks at each site or until the estimated 48 participants per site are enrolled.

20.4.6 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 study sites to document screening and enrollment activity on Screening and Enrollment Logs. Screening and Enrollment Logs will provide a comprehensive picture of all participants screened and enrolled in the study. Each participant that is screened for MTN-003D should be logged, and should also have a completed Stage 1 or 2 Participant Status Form, which will indicate enrollment into MTN-003D or reasons for ineligibility (including not providing PTC). Each person who provides informed consent is provided with the next chronological PTID; those who do not provide consent do not receive a MTN-003D PTID from the range of valid PTIDs, rather “9999” will be entered in the MTN-003D PTID location. Examples of a Screening and Enrollment Log can be found in Section Appendix 20-3. The site is encouraged to modify this as needed.

This log will include VOICE PTID, MTN-003D PTID if enrolled, participant name if enrolled, screening date, and enrollment date or reason for non-enrollment (if applicable).

20.4.7 Weekly MTN-003D Progress Reports

Once MTN-003D accrual is initiated, study staff will report the total number of participants screened and enrolled to FHI 360 on a weekly basis, along with other key progress indicators, as necessary. FHI 360 will send a Screening and Enrollment report to the MTN-003D protocol team on a weekly basis containing the information provided by the sites.

20.5 Informed Consent

Please refer to Section 5 of the VOICE SSP manual. The general principles, policies, instructions, and guidelines contained in that section also apply to MTN-003D.

Written informed consent for all participants must be obtained before performing any MTN-003D data collection activities. *Note that participants who provided written informed consent for Stage 1 must still provide written informed consent for Stage 2.*

Language of informed consent: All consent procedures should be conducted in the primary language of the participant. If the written informed consent form is requested in a language that is *different* from the language the procedure was conducted in, this discrepancy should be documented on the informed consent cover sheet or in the participant file notes.

Documentation of informed consent: An informed consent cover sheet can be used with each informed consent form as a way to document informed consent procedures. Per DAIDS policy, each step must be documented, either using this cover sheet or an alternate method as described in the site Informed Consent SOP.

Comprehension of informed consent: Comprehension of the informed consent process must also be documented per the site Informed Consent SOP. Study staff are responsible for determining whether potential participants comprehend all information required to make an informed decision about study participation before proceeding to make a final enrollment decision. The MTN-003D Informed Consent Comprehension Checklist (see the MTN website) will assist staff in assessing participant comprehension to ensure that participants understand all information required to make an informed decision.

The checklist will be administered to each potential participant after she has completed the informed consent discussion and before she is asked to sign or mark the informed consent form. The checklist should not be presented to participants as a "test," but rather as a way of double-checking that study staff have fulfilled their responsibility to provide all information needed for the participant to make an informed decision about enrolling in the study.

The checklist is structured around eight open-ended questions that correspond with the required elements of informed consent for research. Each question should be read to the potential participant, giving her time to respond to each one. Please note that all required points must be satisfactorily addressed by the participant, and checked off, before proceeding to the final informed consent decision and signing or marking of the informed consent form.

When responding to the various questions, potential participants may report back more information than is included on the checklist. This is acceptable, as long as the required information is reported back. However, if any misinformation is reported back, study staff should explain the correct information before proceeding to another question.

Once administration of the comprehension checklist discussion begins, it is possible that the participant may spontaneously mention many of the required points, without each separate question being asked. In these cases, study staff should check off the relevant points on the checklist and then ask the remaining questions, or probe about the remaining points. It doesn't hurt to ask a question that a participant may have already answered in her response to a previous question. However, if staff are confident that a previous response was adequate, the specific question and/or point does not need to be repeated.

The comprehension checklist is considered a study source document that should be completed, handled, and retained along with the participant's IC form. After administering the checklist, study staff should carefully review the checklist to verify that all required points have been satisfactorily addressed by the participant and that this is adequately documented on the checklist (i.e., with a check mark beside each point).

20.5.1 Informed Consent Procedures for Illiterate Participants

If a participant is not literate in any of the study languages, an impartial literate witness must be present during the entire informed consent process/discussion with the participant. The impartial witness will be asked to sign and date the informed consent form to attest that the information in the informed consent form was accurately explained to and apparently understood by the participant. 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. Refer to Section Appendix 5-1 of the VOICE SSP manual for a summary of considerations for obtaining informed consent from illiterate participants.

At each site, the informed consent process for MTN-003D will be conducted according to the site Informed Consent SOP.

20.6 Visit Procedures

This section provides information on requirements and procedures for conducting data collection in MTN-003D.

20.6.1 Visit Scheduling

Ideally participants enrolled into Stage 1 or 2 of MTN-003D will have their IDI/FGD conducted on the same day as enrollment. However, there may be some individuals who participate in an IDI as well as an FGD. For these cases, the date of enrollment will be the date the IDI is conducted since the IDI will always occur prior to participation in an FGD. In other select cases, the IDI/FGD may be scheduled for a more convenient time, if necessary, and this should be documented in the comments section of the PSF form. Additionally, Staff may need to be flexible in scheduling IDIs/FGDs by allowing for after-hours and weekend meeting times, and/or alternate venues to make the meetings convenient for the participants provided the venue is conducive for the IDI/FGD. Staff will also need to consider the availability of all necessary interview staff when scheduling participants for their IDI/FGD.

20.6.2 Preparing for the IDI/FGD

Before each data collection visit, the following should occur:

- Ensure the correct versions (English and local language) of the discussion guide, tools, CRFs and informed consent are printed and ready for use.
- For Stage 1: Review data collection tools and operational guidance on areas for additional probing, distributed on January 7, 2013.

- For Stage 2: Review data collection tools and ensure staff is aware of which category of participant they will be interviewing (i.e. overall PK classification and corresponding PK discussion tool, study product assignment, and HIV status). The tea pot PK discussion tool has 5 distinct categories (A-E) representing different levels of adherence. Category A refers to a participant who was 100% adherent, category E refers to a participant who was 0% adherent. Categories B, C, and D refer to those who were inconsistent adherers. Each potential participant is identified with a specific category, represented on sites' recruitment lists. Site staff will review the participant's designated category on the recruitment list in order to utilize the correct row/category on the PK discussion tool for each interview.
- Ensure the applicable staff member has reminded participant of her visit per site SOP.
- Confirm the availability of the interview venue.
- Confirm that the audio-recorder is charged and/or has batteries and is functioning correctly.

20.6.3 Data Collection Procedures

All interviewer-administered CRFs and guides should be administered in the primary language of the participant (as indicated on the ICF). Any deviation from this should be documented in the participant file notes. A visit checklist should guide the order of procedures for each IDI/FGD. See Section 20.7 for more information.

20.6.4 In-Depth Interview/Focus Group Discussion Procedures

The IDIs/FGDs will be conducted in a private location to maintain the confidentiality and safety of the participants. This may be a community hall, the participant's home (for IDIs), or another venue preferred by the participant that is quiet enough for audio-recording. If requested by the participant, it may also be conducted at the VOICE clinic. For those individuals who participated in a Stage 1 IDI and are subsequently participating in a Stage 2 IDI, sites should make their best effort to use the same interviewer for both data collection events.

Upon arrival for the IDI/FGD visit, the participant will be greeted and offered refreshments (if feasible). The MTN-003D staff will introduce themselves and explain their background, roles during the discussion (e.g. interviewer/facilitator, observer, note-taker) as well as describe the relationship between the local and the external behavioral interviewer from DTHF (if applicable). The MTN-003D staff will then confirm eligibility and conduct the written informed consent procedures. Following the informed consent process and prior to the interview, a staff member will assign a PTID. The PSF form should be initiated prior to the discussion and completed after the discussion is finished. The demographic form (DEM) and presentation of PK results (Stage 2 only) must be administered to participants individually. The DEM may be administered either before or after the IDI/FGD. However the presentation of the PK results must be administered before the FGD (so that it can be done with each participant individually) or during the IDI. Staff members should know in advance the PK results of the particular participant they plan to talk to such that they are able to pre-identify which line of the illustrative PK results visual (i.e. the teapot tool) best matches the participant's individual level results. Interviewers should record which line of the illustration was used to present PK results (i.e. A-E) to a given participant on the debriefing report. Independently of the participant's PK results, staff should stay neutral during the presentation of the results. The representative meaning of the teapot (overall drug level detected for all visits where tested) and the tea cups (sample display of multiple visits with drug detectable/ not detectable) should be explained to the participant. During the presentation of PK results, staff members should ensure participant's understanding of the illustration as well as of her PK results; furthermore staff members should be cognizant of the participant's reaction upon

hearing the results and should record this immediately either directly on the PSF or on separate notes that can later be transcribed on the PSF keeping in mind the categorical responses. Note that for Stage 2 FGD participants, written informed consent may have already occurred prior to the date of the scheduled FGD. In this case, staff should ensure that all required documentation is in place for all participants prior to the start of the FGD. The IDI/FGD will follow a discussion guide utilizing available tools when appropriate (described in Table 20-10), but will allow for iteration, probing and digression on relevant themes. IDIs/FGDs will be audio-recorded and later transcribed and translated by agreed upon study staff. Following the IDI/FGD, the participant(s) will be thanked for their time and reimbursed for travel and time.

Table 20-10: Stage 2 Discussion Tools

Discussion Guide Section	Tool	Intention, Use and Requirements
A	MTN Educational Factsheet	• Provide interviewer with background information on VOICE results • Not to be used directly with participants
A	MTN Press Release – VOICE Results	• Provide interviewer with background information on VOICE results • Not to be used directly with participants
A	VOICE News Articles	• To remind participants of the VOICE results • For optional use with participants when discussing VOICE results (explanation of English headlines should be provided if needed)
B	Teapot Tool*	• Should be consistently used as the primary tool for discussing participant PK results with each participant. • Interviewers should identify in advance which line of the tool corresponds to the participant's overall PK level
B	Timeline Tool	• For optional use with those participants with inconsistent drug detected to help think about life events happening during times of non-use • Should only be used as a secondary tool to the teapot tool so as to avoid getting into specific details of periods of use vs. non-use with participants
C	Pictures of HIV Prevention Products	• Reference guide, similar to timeline tool, that interviewer can optionally use to help probe on preferred product formulations for future HIV prevention products. • Intention is to provide a sense of alternative formulations (i.e. ring, injection, implant, barrier method, etc.) or administration patterns/timing compared to the products used in VOICE (i.e. daily, coitally, monthly, etc.)
C	Theme Identification Exercise*	• Should be used with each IDI participant to help probe about other factors that may have influenced adherence. Cards may also be used optionally in FGD.

*If these tools are not used in their designated interview modality, please chart note an explanation.

Immediately following each IDI/FGD, the facilitator should complete their notes, ensure that any markings made on relevant tools (i.e. body mapping and timeline tools) are fully explained through comments on the tools, and update and/or complete the PSF. A debriefing

report should be completed on the same day as the discussion and will undergo a QC process prior to being circulated to the study team.

Further description of the management of the audio-files, discussion notes, debriefing reports, CRFs, visit checklists and transcripts is described in Section 20.11.9.

20.7 Visit Checklists

Section Appendix 20-1 contains examples of checklists detailing the protocol-specified procedures that must be completed at the MTN-003D study visit. These checklists should be modified as needed to ensure they fit with systems at the site, then reviewed by the MTN CORE (FHI 360) for approval prior to implementation. The checklist also specifies the data collection forms that must be completed at the visit. See Section 20.3.2.3 for more information on visit checklists.

20.8 Participant Retention

The majority of data collection activities for MTN-003D are one-time only events, thus participant retention is not applicable.

20.9 Reporting of Social Harms and Unexpected Safety Events

MTN-003D is a qualitative study with no clinical procedures and no investigational products. Nonetheless, because MTN-003D is a sub-study to an FDA-regulated trial, it is necessary to make provisions for the identification and proper reporting of unexpected safety events/concerns (UE) and social harms (SH) as reported by all MTN-003D participants.

If any UEs are reported by participants during study participation, the MTN-003D study staff, in consultation with the study coordinator/IoR, should contact clinical staff within the site to assess the UE and determine clinical management per standard of care. If needed, participants should be referred to available resources within the area for care. All procedures to address the UE, as well as any referrals, must be documented in participants' study files.

Any social harm reported by participants during study participation or up to 30 days afterwards, should be fully documented in the participant file by the MTN-003D staff and social harms related specifically to the MTN-003D study documented on the Social Harms CRF. 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 referrals as needed. While only those social harms reported up to 30 days after study participation will be recorded and reported, every effort will still be made to provide appropriate care, counseling, and referrals to those presenting after this period.

Each site will provide listings of social harms related to MTN-003D participation that are reported by study participants to the MTN-003D Protocol Team at a minimum of every month per any applicable DAIDS requirements. Any social harm related to MTN-003D that results in an adverse event, should be reported within three days of site awareness. Additionally, sites will develop a Participant Safety Monitoring SOP for emergency procedures to be used in situations of social harm and when situations that require immediate attention are identified, including domestic violence, suicidal ideation or behavior. The procedures will provide clear guidelines for MTN-003D researchers to refer participants in these situations to the relevant institution/body.

20.10 Counseling Considerations

As specified in Section 8 of the MTN-003D protocol, participants may experience social harms as a result of participation in MTN-003D. If a social harm is reported by a participant every effort will be made by MTN-003D study staff to provide referrals to appropriate resources to ensure the safety of the participant.

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 he/she 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 referral to a site counselor. Ensure that other than information related to the social harm, no personal information will be shared with the counselor. Counselors should follow procedures previously established for VOICE when addressing and counseling for social harms. 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. Record all pertinent details in signed and dated chart notes.
- Ask the participant for her thoughts on what can/should be done to address the problem, including what she 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 her to develop a plan to try to address the problem. Document the plan in signed and dated chart notes.
- Take all possible action to try to address the problem, per the plan agreed upon with the participant. Document all action taken, and outcomes thereof, in signed and dated chart notes.
- Follow all problems to resolution or stabilization.
- Provide referrals as needed/appropriate to other organizations, agencies, and service providers that may be able to help address the problem.
- If the reported social harm is associated with an AE document the AE on the study file and report to the MTN-003D operations team. Also report the issue or problem to all IRBs/ECs responsible for oversight of MTN-003D, if required per IRB/EC guidelines.

20.11 Data Collection

Only data collection issues unique to MTN-003D are covered in this section.

For questions about this section or about general data collection policies, procedures, or materials for MTN-003D, please contact Liz Montgomery (emontgomery@rti.org) or Miriam Hartmann (mhartmann@rti.org).

20.11.1 PTIDs

For all participants, there will be a MTN-003D PTID distinct from the VOICE PTID of the participant. There will be a link to the VOICE participant's VOICE PTID on the Stage 1 and 2 Screening and Enrollment Logs, and PSFs.

For more information on assigning PTIDs for MTN-003D, please refer to Section 20.4.2 of this manual.

20.11.2 Study Visit Timing

MTN-003D participants may complete up to three visits where they participate in a Stage 1 single IDI and/or Stage 2 single IDI, and/or Stage 2 FGD.

Target Days and Visit Windows: There are no specific target dates or visit windows for MTN-003D. Rather, there are guidelines for when qualitative data should be collected, as described in the data collection timeline (Section 20.6.1).

Split Visits: If an IDI participant is not able to complete the interview in one day, she may be rescheduled to come back and complete the rest of the interview on another day, ideally within one week of the initial visit. Any split visits must be documented in participant file notes. If an individual is unable to complete participation in an FGD (i.e. she leaves the FGD before it is complete), this should be documented in the debriefing notes for the FGD as well as in the participant file notes. She will not rejoin another FGD unless determined necessary by the management team. Any split visits must be documented in participant file notes.

Missed Visits: If an enrolled IDI participant does not present for a scheduled IDI, study staff should document this in the participant file notes and reschedule this visit as soon as possible. Every effort should be made to reschedule the IDI for a convenient time for the participant. If a participant is re-scheduled on three separate occasions and continues to miss their visit, study staff should consult the MTN-003D Operations Team to determine if the participant should continue to be considered for recruitment/enrollment. If an FGD participant does not present for a scheduled FGD, they may be rescheduled to participate in a remaining FGD if another one is planned that is applicable to their study group (i.e. tablet or gel).

Interim Visits: It is not expected that any interim visits will occur for MTN-003D. However, participants may come into the clinic for more information or questions related to MTN-003D. In such circumstances, this should be documented in participant file notes, including reason for the visit and summary of any discussion.

20.11.3 Visit Codes

In MTN-003D, there will not be visit codes. Rather, the visit date and PTID will be recorded on all documentation.

20.11.4 Case Report Form Completion Schedule

Table 20-11 lists the case report forms that are required to be completed at MTN-003D visits. Additionally, a Social Harms (SH) form is required to be completed when an SH related to MTN-003D study participation is reported.

Table 20-11: MTN-003D Case Report Form Completion Schedule

Form Acronym	Form Name	Completion Schedule
PSF	MTN-003D Participant Status Form	Upon determination of ineligibility or study completion
DEM	MTN-003D Demographic Form	On date of qualitative discussion

20.11.5 Form Supply

All master case report forms and guides needed for MTN-003D will be supplied by RTI and should be printed locally. The current version of all forms (English and local language) will be kept on the MTN-003D website. The site is responsible for maintaining an adequate supply of the current version of CRFs (blank) 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.

20.11.6 Form Storage

Form storage will be detailed in each site's Data Management SOP. It is recommended that for each participant study forms be stored in a flat file with either secure closures or a hard-cover binder (see also Section 20.3.2.3). Hardcopies of all notes, guides, and checklists are stored in MTN-003D files. CRFs are stored in MTN-003D participant data files. Participant consent forms are stored in a separate secure location. To maximize confidentiality, all storage places are locked and have limited access.

20.11.7 How to Complete Interviewer-Administered Forms

For MTN-003D, the Demographic Form, Stage 1 In-depth Interview Guide, and Stage 2 Discussion Guide are interviewer-administered.

Case Report Forms

Please refer to Section 14.5 of the VOICE SSP manual for general guidelines on completing case report forms. 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.

In-depth Interviews/Focus Group Discussions

The IDIs/FGDs for this study will be conducted in a semi-structured format, audio-recorded, and written notes taken during the interview. Notes may be recorded directly on the discussion guide, on separate sheets of paper, and on tools used during the IDI/FGD, such as the body mapping template and timeline tool (i.e. to explain any markings made). Staff may record notes in other languages and extrapolate and translate responses immediately following the interview for later use in completing debriefing reports (described in Section 20.11.9 and the Data Management SOP). For the MTN-003D discussion guides the following information is provided as general information about the collection of data.

20.11.8 Qualitative Interview Techniques[⌗⌗]

- **Maintain Confidentiality.** Respect confidentiality at all times. Be careful not to comment to other family members or neighbors about anything that you learned during the interview. This is especially important when interviewing participants about their sexual behaviors. Ask FGD participants to be respectful of confidentiality, and not to share personal information from fellow FGD participants.

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

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

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

- **Do Not Respond to Questions.** If the participants ask you questions that are the focus of the interview, do not answer them. Your answers might influence how the participant will answer the rest of the questions. Instead, turn the question around and ask them what they think. You may also offer to answer questions after the discussion is complete and/or refer them to someone else who can answer their question.
    - *Example: Well, I was hoping you could help me understand what people in this community say about how you catch the HIV virus.*

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

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

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

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

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

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

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

20.11.9 Data Flow: Quantitative Data Management

Data for quantitative analysis will be collected manually on CRFs at the site. Data should be checked for accuracy, clarity and completeness at the site. Completed CRFs for all screened and enrolled participants should be e-faxed to RTI, MTN003D@rti.org, for data entry on a regular basis. At the beginning of the study, completed CRFs should be transmitted to RTI within two working days of completion. Once a high standard of data quality has been confirmed, CRFs may be batched and e-faxed one time per week.

Staff training: Site staff who collect data or who manage participant data will receive training at the study initiation training. Additional training will be available as needed at site visits made by RTI or FHI 360 staff to train and monitor quality of site data management, or to provide training on new study procedures (e.g. Stage 2 activities).

Report Generation and Communication: Reports will be generated at RTI as necessary. Frequent email communication between RTI and site staff will occur to continuously address questions that emerge and ensure that RTI and the sites are in sync throughout the quantitative data management process.

See Section Appendix 20-2 for flow chart of the MTN-003D quantitative data flow.

20.11.10 Data Flow: Qualitative Data Management

MTN-003D qualitative data will be captured from the IDI/FGD given at the site. All IDIs/FGDs will be audio-recorded and notes are taken during each session whenever possible to supplement the audio recording. Immediately following the IDI/FGD, the Interviewer (or Note-Taker, if involved) will verify that the audio recorder properly recorded the session. If the recording did not work, the interviewer will review the guide and expand the notes they have taken during the discussion to serve as an alternate transcript. The audio file is copied onto the password protected hard drive of the Interviewer and onto the hard drive of a

computer at the site, and the file is uploaded to a secure (encrypted) FTP[§§] server for RTI and/or DTHF (if not present at the IDI/FGD).

As detailed in the Visit Checklists (Section Appendix 20-1), the Interviewer's (or Note-taker if present) notes should be entered electronically into the Debriefing Report form (created in Microsoft Word) on the same day as the IDI/FGD session and should undergo a site-level QC review. This report is emailed to RTI within one week of the interview in Word format, along with scanned copies of any IDI tools that contain notes or comments. RTI will then conduct a QC review of the Debriefing Reports, which will include the following process:

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

RTI should receive an English language transcript within **one month** of the discussion date. Following the IDI/FGD session, the audio-file should be used to transcribe and translate the discussion by the designated behavioral consultant team, DTHF, per their respective SOPs. An example of a formatted transcript is available in Appendix 20-5. Quality checks of the local language transcript and English translation should be performed at the site. After this site level QC process, the English language transcript will be emailed to RTI for review where it will undergo a similar QC process to that of the debriefing reports:

- Each transcript is reviewed by a member of RTI's data team and queries will be made on the transcript using comment bubbles. The QC may include the identification of the following:
  - Problems such as typos that lead to ambiguous meaning, confusing terms or missing /potentially incorrect data
  - 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/FGDs.
- RTI-reviewed transcripts will be emailed to the site within approximately **two weeks** of transcript receipt.
- The site then responds to all comments within **two weeks** of receipt of the reviewed transcript. Responses will be made either through changes directly in the transcript using track changes or through using the comment box in the reviewing mode of MS Word,

[§§] *Encrypted FTP is set by RTI's IT department with encryption security settings dictated by MTN-003D compliance regulations. FTP use is account, username, and password protected with only designated team members from RTI and the site given access. The encrypted FTP site tracks user activity and file uploads making it easy to manage precisely by whom and when new files are updated, what changes are made, and what versions are most current. See Appendix 20-4 for FTP instructions.*

when in-text changes are unable to be made. When changes in the text reflect content that was not spoken verbatim by the participant or interviewer, they will be inserted in [brackets].

- After the revised transcript is received by RTI, a designated staff member reviews the corrected areas and deems the issue resolved or further follows up with the site until all necessary changes are made.
- Once RTI finds no additional issues, RTI will accept all changes, remove all comment bubbles, and finalize the transcript. Sites will be notified of this finalization status via email when a final version of the transcript is emailed to the site for their files.

As mentioned in Section 20.3.2.2, audio files of IDIs/FGDs will be destroyed following finalization of transcripts. 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).

A MTN-003D Qualitative Data Tracking Log (or equivalent) will be completed by RTI to maintain record of each debriefing report and interview that is submitted along with details regarding the submission date, query status, and finalization date.

The final guide with completed columns, the final local language transcript (with each page certified as an exact copy of the audio file, initialed and dated) and the final English transcript must all be stored in the IDI/FGD data file, or per site Data Management SOP.

File Naming Conventions: All data files should be named according to a standard naming format. The name should include the PTID, followed by the data collection group (FGD/IDI), data type (audio file, PSF, DEM, debrief report, transcript), and the date the discussion was conducted. Each time a document is edited, the editor should add their initials to the filename without changing any other part of the filename. For the first iteration of the file that is sent to RTI for review, there is no need to include the editor's initials. It is only upon subsequent review (QCing) that this occurs. For example, when reviewed for the first time, *"**1001_FGD_ Transcript_18NOV12"*** would become *"**1001_FGD_ Transcript_18NOV12_CM"*** and *"**1001_FGD_ Transcript_18NOV12_CM_NM"*** for the second revision. Once the document is finalized, all initials will be removed from the name and replaced with the word "FINAL."

Staff Training: Site staff who collect data on the guides, enter data onto the debriefing reports, and transfer data to RTI will be instructed and in communication with RTI as described above in the staff training section. Internal debriefings with the Site Investigator will be held weekly to discuss debriefing reports and transcripts, and to address team questions or training needs.

See Section Appendix 20-2 for flow chart of the MTN-003D qualitative data flow.

20.11.11 Study Monitoring

In addition to data quality monitoring and checks described above, FHI 360 will conduct monitoring of this study through remote review of select participant and/or FGD files. Sites will be asked to provide copies of participant files for review. FHI 360 will review these documents and provide feedback to sites either by e-mail or conference call.

Interim Reviews: During Stage 2, the study team will suspend data collection after ~12 IDIs and ~3 FGDs with participants identified as having low drug detection levels, provided that at least two countries have contributed data, to determine whether to: a) proceed with full data collection per protocol; b) limit data collection activities; or c) terminate data collection

activities. This decision will be made amongst the Protocol Chairs and key members of the protocol team, based on an evaluation as to whether the interviews are successful in yielding new data and insight into VOICE non-adherence.

Appendix 20-1: Sample Visit Checklists

Stage 1 IDI Visit Checklist

MTN-003D PTID:	Visit Date:
Initials	**Procedures**
	Preparation
	Audio-recorder checked to ensure functionality (power supply, extra batteries, etc.)
	Venue confirmed and participant reminded of visit date/time/location.
	Supplies gathered: pen and stationery for note-taking, consent form, IDI guide, refreshments (if applicable), reimbursement
	Participant Arrival, IC & Data Collection
	Greet participant and offer refreshments
	Confirm participant identity
	Confirm eligibility criteria: ❒ ELIGIBLE ⇒ CONTINUE. ❒ NOT ELIGIBLE ⇒ STOP. Document in Participant Status Form (PSF) and participant file notes.
	Explain, conduct, and document informed consent process per site SOPs: ❒ Willing and able to provide written informed consent ⇒ CONTINUE, have participant sign ICF, collect signed form, and offer a copy for participant to take home. ❒ NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes.
	Administer Demographic Information Form (DEM)
	Review IDI ground rules: • No right or wrong answers • Use pseudonyms when providing responses • Information shared remains confidential • Cell phone off
	Administer the IDI guide
	Complete PSF
	Thank and reimburse the participant
	Post IDI (Immediately following IDI)
	Check audio recording to verify that the session was properly recorded.

MTN-003D PTID:	Visit Date:
Initials	**Procedures**
	Preparation
Comments: *Initial and date all comments.* _____ _____ _____ _____ _____ _____	

Stage 2 IDI Visit Checklist

MTN-003D PTID:	Visit Date:
Initials	**Procedures**
	Preparation
	Audio-recorder checked (power supply, extra batteries, etc.)
	Supplies gathered: pen and stationery for note-taking, consent form, discussion guide, refreshments (if applicable), reimbursement
	Verification of participant status (PK results, HIV status, and study product group)
	Participant Arrival, IC & Data Collection
	Greet participant and offer refreshments
	Confirm participant identity
	Explain, conduct, and document informed consent process per site SOPs: ❒ Willing and able to provide written informed consent ⇒ CONTINUE, have participant sign ICF, collect signed form, and offer a copy for participant to take home. ❒ NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes.
	Confirm eligibility criteria: ❒ ELIGIBLE ⇒ CONTINUE. ❒ NOT ELIGIBLE ⇒ STOP. Document in Participant Status Form (PSF) and participant file notes.
	Administer Demographic Information Form (DEM)
	Review IDI ground rules: • No right or wrong answers • Use pseudonyms when providing responses • Information shared remains confidential • Cell phone off
	Conduct sections A-B of the Stage 2 Discussion Guide
	Complete PK Response section of PSF or note response to PK discussion in interview notes and record on PSF immediately following IDI.
	Conduct section C of the Stage 2 Discussion Guide, including completion of the theme card exercise.
	[*For HIV positive participants*] Conduct section D of the Stage 2 Discussion Guide.
	FGD Determination Is participant HIV negative, with "low drug detection" levels, and was open about non-adherence during this IDI? ❒ Yes ❒ No Is participant willing to join an FGD with her peers? ❒ Yes ❒ No ❒ N/A [participant did not meet above criteria]

MTN-003D PTID:	Visit Date:
Initials	**Procedures**
	Preparation
	Thank and reimburse the participant
	Post IDI (Immediately following IDI)
	Complete PSF
	Check audio recording to verify that the session was properly recorded.
	Expand notes and complete debriefing report

Comments: *Initial and date all comments.*

_____

_____

_____

_____

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_____

Stage 2 FGD Group Visit Checklist

FGD No.:	Visit Date:
Initials	**Procedures**
	Preparation
	Audio-recorder checked (power supply, extra batteries, etc.)
	Supplies gathered: pen and stationery for note-taking, consent forms, PSFs, discussion guide, refreshments (if applicable), reimbursements
	Verification of participant status (PK results and study product group)
	Participant Arrival, IC & Data Collection
	Greet participants and offer refreshments
	Complete procedures with all individual FGD participants as outlined on the FGD Individual Participant Visit Checklist.
	Review FGD ground rules: • No right or wrong answers • Use pseudonyms when providing responses • Information shared remains confidential • Cell phone off
	Conduct sections A & C of Stage 2 Discussion Guide
	Thank and reimburse the participants
	Post FGD (Immediately following FGD)
	Check audio recording to verify that the session was properly recorded.
	Expand notes and complete debriefing report
Comments: *Initial and date all comments.* _____ _____ _____ _____ _____ _____	

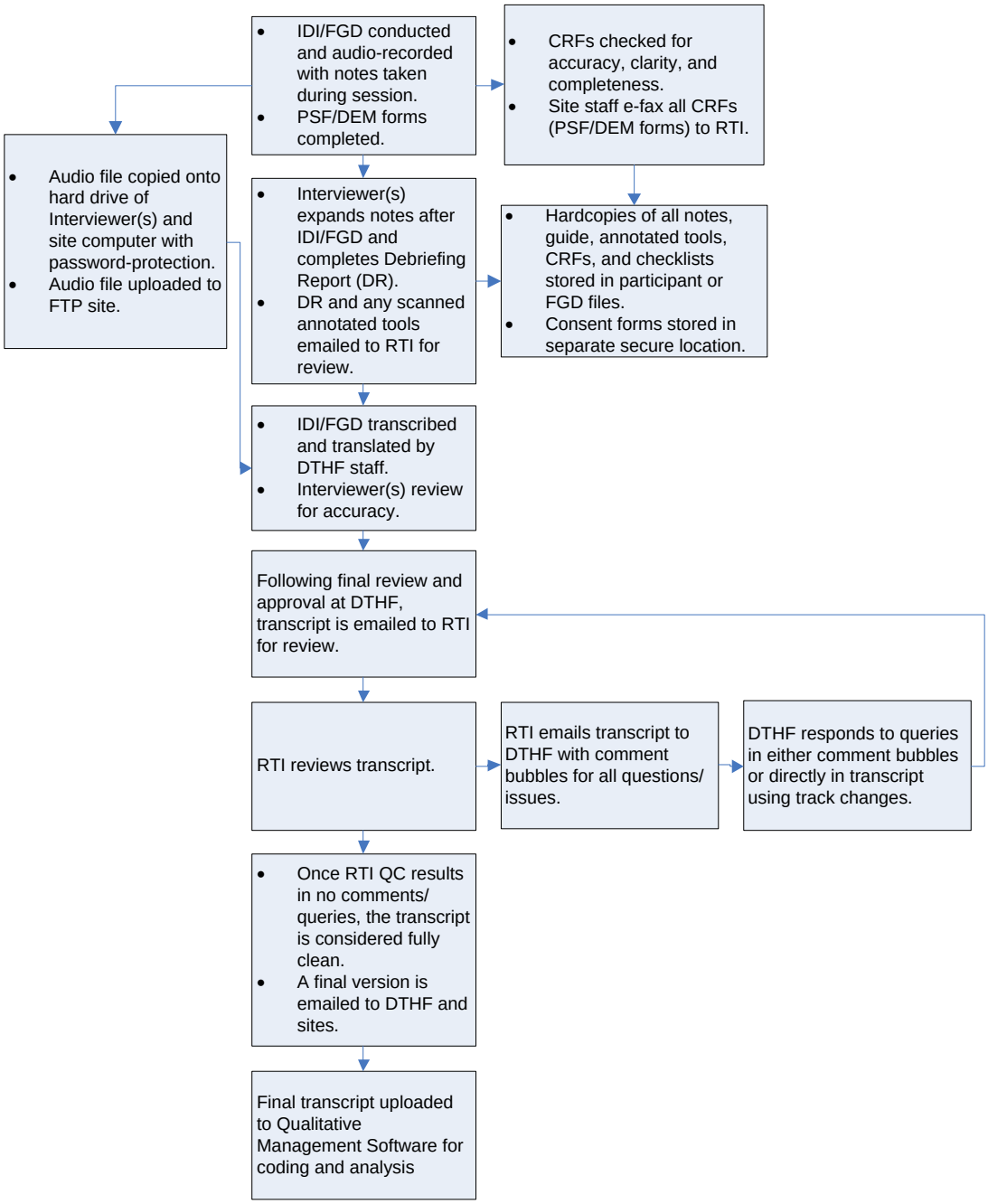
Stage 2 FGD Individual Participant Visit Checklist

MTN-003D PTID:	FGD No.:	Visit Date:

Initials	Procedures
	Participant Arrival, IC & Data Collection
	Confirm participant identity
	[*If participant has **not** already participated in a Stage 2 IDI*:] Explain, conduct, and document informed consent process per site SOPs: ❒ Willing and able to provide written informed consent ⇒ CONTINUE, have participant sign ICF, collect signed form, and offer a copy for participant to take home. ❒ NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes.
	Confirm eligibility criteria: ❒ ELIGIBLE ⇒ CONTINUE. ❒ NOT ELIGIBLE ⇒ STOP. Document in Participant Status Form (PSF) and participant file notes.
	[*If participant has **not** already participated in a Stage 2 IDI*:] • Administer Demographic Information Form (DEM) • Conduct sections A-B of the discussion guide • Complete PK Discussion Response on the PSF (Q 8)
	Post FGD (Immediately following FGD)
	Complete PSF

Comments: *Initial and date all comments.*

Appendix 20-2: Quantitative and Qualitative Data Flow



Appendix 20-3: Example Screening and Enrollment Log

VOICE PTID	PTC Given	Screening Date***	Scheduled Enrollment Visit Date	Staff Conducting Screening	Enrollment Date†††	MTN-003D PTID	Participant Name (if enrolled)	If not enrolled, reason for non-enrollment	Staff Conducting Enrollment
	[Y/N]	[dd/MMM/yy]	[dd/MMM/yy]	[Initials]	[dd/MMM/yy]				[Initials]

*** The screening date is the date the recruitment script is administered.
††† The Enrollment date is the date the IC is administered.

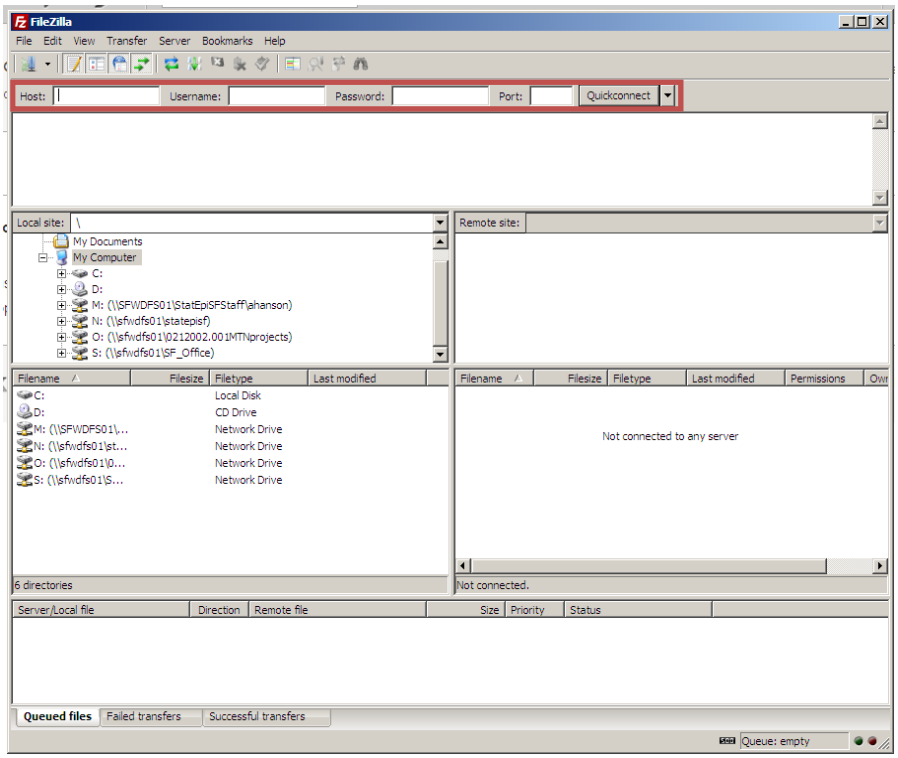
Appendix 20-4: File Transfer Protocol Instructions

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

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

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

- Click on the QuickConnect button.



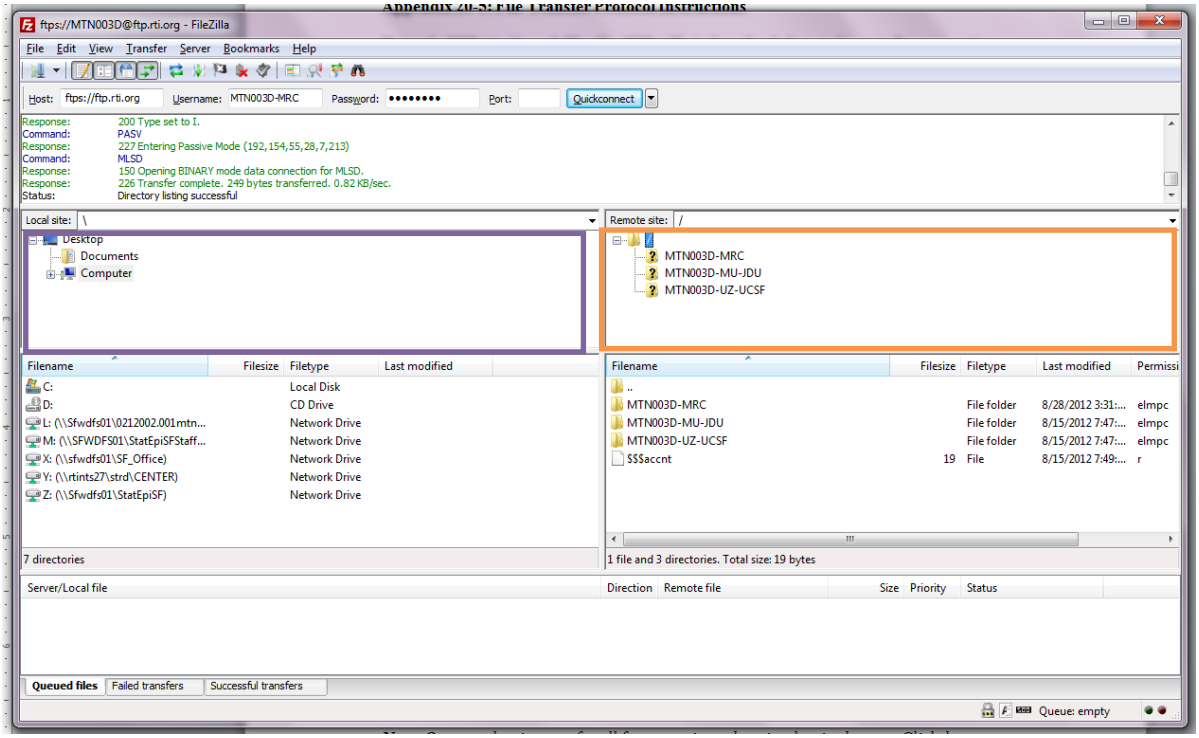
***Note**: Once you log-in once, for all future sessions, there is a log-in shortcut. Click the gray arrow to the right of the QuickConnect button and select the address listed. This will automatically connect you to the FTP site without having to enter all of the log-in information.*

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

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

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

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



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

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

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

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

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

Appendix 20-5: Example Formatted IDI Transcript

Participant ID: 1001/ **Study Group:** Gel / **HIV Status:** HIV positive / **Drug Detection:** High / **Interview Date**: 28 November 2012/ **Clinical Site**: MRC/ **Audio File Name**: 1001_Audio File_28NOV12.WMA/ **Audio Recording Length**: 45m:11s/ **Interviewer Name(s)**: Funeka Mthembu / **Transcriber**: Hlamalani Rikhotso / **Translator**: Khosi Mbuli/ **Interview Language**: IsiZulu & English

Interview Text:

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

Formatting Tips:

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

Example Formatted FGD Transcript

FGD No.: 101/ **Participant IDs:** 1001, 1024, 1028, 1029, 1031 / **Study Group:** Gel / **FGD Date**: 28 November 2012/ **Clinical Site**: MRC/ **Audio File Name**: 1001_Audio File_28NOV12.WMA/ **Audio Recording Length**: 45m:11s/ **Interviewer Name(s)**: Funeka Mthembu / **Transcriber**: Hlamalani Rikhotso / **Translator**: Khosi Mbuli/ **Interview Language**: IsiZulu & English

Interview Text:

1. I: (Laughs).Thanks for coming, we really appreciate this and we hope that we are going to use this hour fruitfully and to learn from you as we said before. All right, what can you tell us about the tablets? Anywhere you can start…

2. *Candy: Okay my name is Candy. I have been taking tablets but I had complications in the beginning. I used to feel dizzy, vomit, maybe my body was not used to them, but I came to the clinic and they told me that is the process I have to go through and it will eventually stop. I think I am now used to taking the tablets. I just want to ask that I am taking the tablets is there something happening in my bodies?*

3. I: Okay. Since you know; I'm not sure if some of you have similar concerns; as to what will happen to your bodies since you are no longer taking the tablet? But those are the questions that can be answered by the nurses and doctors because we [are] not nurses, so we don't want to give misinformation; information that is not appropriate. So we will jot [write] that down and later on, we will call a nurse to explain. Okay

4. *Pinky: I want to know that if the programme stops, I mean the VOICE, the MTN programmes, is there another programme or will it continue to maybe next year?*

5. I: If the MTN study stops?

6. *Pinky: Yes… because they say my last day is the 28th.*

Formatting Tips:

- Header Includes: FGD No., Participant IDs, Study Group, FGD Date, Clinical Site, Audio File Name, Audio Recording Length, Interviewer Name, Transcriber Name, Translator Name, Interview Language
- After header, label next section "**Interview Text**," insert a hard return and begin transcribing the content of the audio file verbatim.
- Use "I:" before Interviewer remarks and insert the participant's pseudonym before respondent remarks. Italicize all respondent remarks.
- Auto-number the transcript by paragraph so that each time the Interviewer or Respondent begins a new response, this should be indicated by a new number
- Replace all references to individual names or other identifying data with pseudonyms
- Any mumbling, laughing or silences recorded in transcript can be noted by [brackets]
- Long pauses can be represented by use of an ellipsis "…"
- Insert a footer with page X of X on right-hand side
- Spell check the transcript for any spelling and grammar errors