

MTN-003D

Visit Procedures

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Visit Checklist

MTN-003D PTID:	Visit Date:
Procedures	
Initials	Procedures
Preparation	
	Audio-recorder checked (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: <input type="checkbox"/> ELIGIBLE ⇒ CONTINUE. <input type="checkbox"/> NOT ELIGIBLE ⇒ STOP. Document in Participant Status Form (PSF) and participant file notes.
	Explain, conduct, and document informed consent process per site SOPs: <input type="checkbox"/> 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. <input type="checkbox"/> 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: <ul style="list-style-type: none"> •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.
Comments: <i>Initial and date all comments.</i>	

- Step-by-step guide to visit procedures
- Each line to be completed (or write “NA”)



Scheduling the Visit

- Initial scheduling and reminder calls will be done in tandem with VOICE recruitment staff



Scheduling the Visit

- *Who, when and how to schedule date and time to interview participants?*
- *Reminder systems?*
- *What if participant does not turn up?*



Preparation

- ✓ Time confirmed with participant
- ✓ Appropriate space for interview identified and reserved
- ✓ Current versions of ICF, IDI guide, other tools (e.g. body map templates, study timeline, show card) and checklists
- ✓ Audio-recorder charged, has batteries, and tested that day for functionality



Outline of Procedures

- Informed consent
- Demographic Information (DEM) form
- Conduct IDI
- Complete Participant Status Form (PSF)



IDI Procedures: the Beginning

1. Greet participant
2. Confirm identity
 - *How will this be done?*
3. Confirm eligibility criteria
 - *How will this be done?*
4. Explain, conduct and document written informed consent



Demographic Form (DEM)

- Interviewer-administered prior to IDI
- Available in English and local language
- 30 questions:
 - Some new information
 - Some verbatim to VOICE CRF data to record updates/ changes since VOICE data captured



DEM Form

- CRF:
 - Complete all header and footer items: PTID, date, initials and date
 - Follow GCP in completing each question and making corrections (initial and date)
 - Use blue or black ink
 - Question guide on the reverse side

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dd

MMM

yy

MTN-003D Demographic Information Form (DEM)

INTERVIEWER READS: The following are some basic questions regarding your background to help us know what type of people participated in the discussion for this study. All the information you provide will be kept confidential and will not be shared with anyone else besides the research study staff.

1.	What is your date of birth?	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> or dd MMM yy If unknown, record age: <input type="text"/> <input type="text"/>
2.	How many children have you had who were alive at birth?	<input type="text"/> <input type="text"/>
3.	How many total children are you currently taking care of (i.e. children, grandchildren, etc.)?	<input type="text"/> <input type="text"/>
4.	What is your ethnic group or tribe? (<i>mark ethnic group/tribe code</i>)	<input type="text"/> <input type="text"/> Ethnic Tribe Code <input type="text"/> ₉₉ Other, specify: _____
5.	What is the language most spoken at home? (<i>mark language code</i>)	<input type="text"/> <input type="text"/> Language Code <input type="text"/> ₉₉ Other, specify: _____
6.	Do you currently earn an income of your own?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No → If No, go to item 8
7.	How do you earn your current income? (<i>mark all that apply</i>)	<input type="checkbox"/> ₁ Formal employment <input type="checkbox"/> ₂ Self-employment <input type="checkbox"/> ₃ Other, specify: _____

8.	What is your highest level of education? (<i>mark one</i>)	<input type="checkbox"/> ₁ No schooling <input type="checkbox"/> ₂ Primary school, not complete <input type="checkbox"/> ₃ Primary school, complete <input type="checkbox"/> ₄ Secondary school, not complete <input type="checkbox"/> ₅ Secondary school, complete <input type="checkbox"/> ₆ Attended college or university
9.	What is your religion? (<i>mark one</i>)	<input type="checkbox"/> ₁ Christian <input type="checkbox"/> ₂ Muslim <input type="checkbox"/> ₃ Other specify: _____ <input type="checkbox"/> ₄ None → If None, go to item 11
10.	How many times a week do you attend religious services? (<i>mark one</i>)	<input type="checkbox"/> ₁ More than once a week <input type="checkbox"/> ₂ Once a week <input type="checkbox"/> ₃ Less than once a week <input type="checkbox"/> ₄ Never
11.	Name of area/location where you currently live:	_____
12.	For how long have you lived in this location/area? (<i>mark one</i>)	<input type="text"/> <input type="text"/> or <input type="text"/> <input type="text"/> months years
13.	Do you consider this your home?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No, <i>specify</i> _____
14.	Do you, or does someone in your family, own the household you are currently living in?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No

15.	How many rooms are in the household you are currently living in?	<input type="text"/> <input type="text"/>
16.	Does your household have:...? (<i>read options and mark all that apply</i>)	<input type="checkbox"/> ₁ Electricity <input type="checkbox"/> ₂ A radio <input type="checkbox"/> ₃ A television <input type="checkbox"/> ₄ A mobile telephone <input type="checkbox"/> ₅ A non-mobile telephone <input type="checkbox"/> ₆ A refrigerator
17.	What kind of toilet facility does your household have? (<i>mark toilet facility code</i>)	<input type="text"/> <input type="text"/> Toilet Facility Code <input type="checkbox"/> ₉₉ Other, specify: _____
18.	What is the main source of drinking water for members of your household? (<i>mark water source code</i>)	<input type="text"/> <input type="text"/> Water Source Code <input type="checkbox"/> ₉₉ Other, specify: _____
19.	Do you own a mobile phone?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
20.	Are you currently married?	<input type="checkbox"/> ₁ Yes → if Yes, go to item 22 <input type="checkbox"/> ₂ No
21.	Do you currently have a primary sex partner? By primary sex partner, I mean a person you have sex with on a regular basis or who you consider to be your main partner.	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No → if No, go to 29
22.	Is your [husband/primary sex partner] the same partner you had when you <u>exited</u> VOICE?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No

23.	For how long have you had this partner? (<i>mark one</i>)	<input type="text"/> <input type="text"/> or <input type="text"/> <input type="text"/> months years
24.	How old is your [husband/primary sex partner]?	<input type="text"/> <input type="text"/> <input type="checkbox"/> ₉₉ Don't Know
25.	Are you currently living with your [husband/primary sex partner]?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
26.	Does he provide you with financial and/or material support?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
27.	Does he have any sex partners other than you?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No <input type="checkbox"/> ₃ Don't Know
28.	In the past 3 months , have you had vaginal sex with your primary sex partner? By vaginal sex we mean when a man puts his penis inside of your vagina.	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
29.	In the past 3 months , with how many other male partners have you had vaginal sex? By other male partners, we mean any man who is not your primary sex partner.	<input type="text"/> <input type="text"/>
30.	In total, how many different people have you had vaginal sex with in your lifetime ?	<input type="text"/> <input type="text"/>

IDI Procedures: the Middle

- Interview will follow guide
 - Primary research questions numbered
 - Probes bulleted
 - Notes to be taken in right-hand column of guide and on separate sheets of paper
 - Separate sheets must be labeled with PTID, date and staff initials

IDI Procedures: the Middle

- The guide is a guide, not a script.
Interview should flow naturally and flexibly
 - Acceptable to jump around
 - Acceptable to probe on spontaneous, relevant issues
 - Acceptable to rephrase probes
- However...
 - Ensure primary research questions are addressed



Social Harms Form

- Social harms related or unrelated to VOICE and/or MTN-003D may be mentioned during interview
 - Kaila will cover how to handle this



IDI Procedures: the End

- Complete Participant Status Form (PSF)

MTN-003D Participant Status Form (PSF)

1.	Complete VOICE PTID <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>		
		Yes	No
2.	Participant gave permission to be contacted for participation in future research?	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
3.	Participant contacted for participation in MTN-003D	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
4.	Participant scheduled for enrollment visit	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
5.	Participant presented for enrollment in MTN-003D	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
6.	Confirmation all MTN-003D eligibility criteria met	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
7.	Participant provided written informed consent for participation in MTN-003D	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
		ASSIGN 003D PTID	
8.	Date of enrollment in MTN-003D	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	
9.	Date IDI conducted	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	
10.	Date of termination from MTN-003D	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	
11.	Reason for non-enrollment or termination from 003D (<i>mark one</i>):	<input type="checkbox"/> ₁ Participant completed study <input type="checkbox"/> ₂ Participant did not give permission to be contacted <input type="checkbox"/> ₃ Participant refused participation, specify: _____ <input type="checkbox"/> ₄ Participant scheduled three times, did not show <input type="checkbox"/> ₅ Eligibility criteria not met, specify: _____ <input type="checkbox"/> ₆ Inappropriate enrollment <input type="checkbox"/> ₇ Enrollment targets met <input type="checkbox"/> ₈ Other, specify: _____	

Comments:

MTN-003D PTID

2013

Visit Date

26 SEP 12
 dd MMM yy

MTN-003D Participant Status Form (PSF)			
1.	Complete VOICE PTID	123-45678-1	
		Yes	No
2.	Participant gave permission to be contacted for participation in future research?	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
3.	Participant contacted for participation in MTN-003D	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
4.	Participant scheduled for enrollment visit	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
5.	Participant presented for enrollment in MTN-003D	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
6.	Confirmation all MTN-003D eligibility criteria met	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
7.	Participant provided written informed consent for participation in MTN-003D	<input checked="" type="checkbox"/> ₁ ASSIGN 003D PTID	<input type="checkbox"/> ₂ GO TO 11

8.	Date of enrollment in MTN-003D	26 SEP 12 dd MMM yy
9.	Date IDI conducted	26 SEP 12 dd MMM yy
10.	Date of termination from MTN-003D	26 SEP 12 dd MMM yy
11.	Reason for non-enrollment or termination from 003D (<i>mark one</i>):	<input checked="" type="checkbox"/> ₁ Participant completed study <input type="checkbox"/> ₂ Participant did not give permission to be contacted <input type="checkbox"/> ₃ Participant refused participation, specify: _____ <input type="checkbox"/> ₄ Participant scheduled three times, did not show <input type="checkbox"/> ₅ Eligibility criteria not met, specify: _____ <input type="checkbox"/> ₆ Inappropriate enrollment <input type="checkbox"/> ₇ Enrollment targets met <input type="checkbox"/> ₈ Other, specify: _____

Comments:



PSFs for Those Not Enrolled

- A PSF should be completed for all those randomly preselected to be part of MTN-003D

Example 1: Did Not Give PTC

MTN-003D PTID

9 9 9 9

Visit Date

26 SEP 12
 dd MMM yy

MTN-003D Participant Status Form (PSF)			
1.	Complete VOICE PTID	1 2 3 - 4 5 6 7 8 - 9	
		Yes	No
2.	Participant gave permission to be contacted for participation in future research?	<input type="checkbox"/> ₁	<input checked="" type="checkbox"/> ₂ GO TO 11
3.	Participant contacted for participation in MTN-003D	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
4.	Participant scheduled for enrollment visit	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
5.	Participant presented for enrollment in MTN-003D	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
6.	Confirmation all MTN-003D eligibility criteria met	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
7.	Participant provided written informed consent for participation in MTN-003D	<input type="checkbox"/> ₁ ASSIGN 003D PTID	<input type="checkbox"/> ₂ GO TO 11

8.	Date of enrollment in MTN-003D	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy
9.	Date IDI conducted	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy
10.	Date of termination from MTN-003D	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy
11.	Reason for non-enrollment or termination from 003D (<i>mark one</i>):	<input type="checkbox"/> ₁ Participant completed study <input checked="" type="checkbox"/> ₂ Participant did not give permission to be contacted <input type="checkbox"/> ₃ Participant refused participation, specify: _____ <input type="checkbox"/> ₄ Participant scheduled three times, did not show <input type="checkbox"/> ₅ Eligibility criteria not met, specify: _____ <input type="checkbox"/> ₆ Inappropriate enrollment <input type="checkbox"/> ₇ Enrollment targets met <input type="checkbox"/> ₈ Other, specify: _____
Comments: _____ _____ _____ _____		

Example 2: “No Show”

MTN-003D PTID

~~3007~~

9999

stun
26/SEP/12

Visit Date

26

dd

SEP

MMM

12

yy

MTN-003D Participant Status Form (PSF)			
1.	Complete VOICE PTID	1 2 3 - 7 7 7 7 7 - 2	
		Yes	No
2.	Participant gave permission to be contacted for participation in future research?	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
3.	Participant contacted for participation in MTN-003D	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
4.	Participant scheduled for enrollment visit	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
5.	Participant presented for enrollment in MTN-003D	<input type="checkbox"/> ₁	<input checked="" type="checkbox"/> ₂ GO TO 11
6.	Confirmation all MTN-003D eligibility criteria met	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
7.	Participant provided written informed consent for participation in MTN-003D	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 11
		ASSIGN 003D PTID	

8.	Date of enrollment in MTN-003D	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy
9.	Date IDI conducted	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy
10.	Date of termination from MTN-003D	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy
11.	Reason for non-enrollment or termination from 003D (<i>mark one</i>):	<input type="checkbox"/> ₁ Participant completed study <input type="checkbox"/> ₂ Participant did not give permission to be contacted <input type="checkbox"/> ₃ Participant refused participation, specify: _____ <input checked="" type="checkbox"/> ₄ Participant scheduled three times, did not show <input type="checkbox"/> ₅ Eligibility criteria not met, specify: _____ <input type="checkbox"/> ₆ Inappropriate enrollment <input type="checkbox"/> ₇ Enrollment targets met <input type="checkbox"/> ₈ Other, specify: _____

Comments:

Participant scheduled on 05/SEP/12, did not come. Rescheduled for 15/SEP/12, and she did not come. Said she was still interested. Rescheduled for 22/SEP/12, and did not come. Did not answer cell phone.




Post-Interview Procedures

1. Interviewers and note-takers: expand notes
2. Review CRFs for completeness and clarity
3. Check recording and copy audio-file to hard-drive
4. Complete Debrief Report template, send to RTI




Debrief Report

- Purpose: To provide a summary of the participant's attitudes towards the key themes, participant mood, unique comments, and any other important information in REAL TIME
- Will be discussed on study team calls and shared across sites.



MTN-003D
IDI Debriefing Report



Basic IDI Information:

PTID:	Date:
CRS/CTU:	Interviewer #1:
Venue:	Interviewer #2:
Person Completing Form:	Note-taker:

Debriefing Summary:


1. How did the IDI go today? *(Describe in detail your subjective impressions of how the participant behaved, their emotional reactions [excited, sad, laughed, bored, confused, disappointed etc.], and any other important information about the context and experience)*

2. What were the most important themes or ideas discussed? *(Describe in detail the most important ideas discussed within each of the main topic areas [motivations to join the trial, adherence, and anal sex] and any important issues that were raised)*
 - a. Motivation to join trial *(include risk perception and life events):*

 - b. Adherence *(discussion around measures and adherence reporting):*

 - c. Anal sex *(include lubricant/gel use):*

 - d. Other important issues *(may include thoughts on DSMB):*



3. Were there any unexpected or unanticipated findings? (*Record anything unexpected, unanticipated, or new that was learned from this IDI*)



Required Documentation

- Documentation of eligibility
- Documentation of ICF
- Complete visit checklists
- Interview notes, guides, materials (e.g. body map)
- Expanded notes
- Debrief Report
- A record of all contacts, and attempted contacts, with the participant.