MTN-003D Informed Consent Process

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The “Informed Consent Process”

- Informed consent is a process by which an individual voluntarily expresses her willingness to participate in research, after having been informed of all aspects of the research that are relevant to her decision.
- It is not merely a form or a signature, but involves information exchange, comprehension, voluntariness, and documentation.

Reminders (1)

- Written informed consent for all participants must be obtained before performing any MTN-003D data collection activities.
- All consent procedures should be conducted in the primary language of the participant.

Reminders (2)

- 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.

Reminders (3)

- Per DAIDS policy, each step of the informed consent process must be documented, either using a cover sheet or an alternate method as described in the site Informed Consent SOP.

Comprehension Assessment

- 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 will be used as a tool to assist staff in assessing participant comprehension to ensure that participants understand all information required to make an informed decision.

IC Comprehension Checklist

Name:			Date:	
Open-Ended Question/Statement		Required Points of Comprehension	✓	Comments
1	Please tell me your understanding of the purpose of the study.	To better understand VOICE participant's use of study product		
		To better understand VOICE participant's sexual behavior		
2	How long will the study last?	There will be only one interview and it will take about 3 hours		
3	What are participants being asked to do in this study?	Answer interview questions that will be written on a form		
		Answer interview questions that will be audio-recorded		
		Questions will include information about different ways women used study product during VOICE and sexual behaviors, including anal sex		
4	What are the possible risks for participants in the study?	Questions may cause embarrassment		
		Others may find out about participation in the study		
		Loss of confidentiality		
5	What will happen if women decide not to join the study?	Free to make her own decision about joining the study		
		No change to her access to health care whether she joins the study or not		
6	How will information about participants in the study be protected?	Information about participants is confidential, private, and locked away		
		Only people working on the study have access to the information		
7	What are the possible benefits for participants in the study?	There are no direct benefits		
		Information provided may help researchers improve counseing materials		
8	What should participants do if they have questions or concerns about their health or about what is happening in the study?	*Must state how to contact study staff*		

Outcome	Optional Comment Codes
☐ Demonstrated comprehension of all required points, decided to enroll in study.	a. Answered correctly on first try
☐ Demonstrated comprehension of all required points, decided NOT to enroll in study.	b. Could not answer at first but answered correctly with probing
☐ Demonstrated comprehension of all required points, deferred enrollment decision.	c. Answered incorrectly at first but answered correctly after discussion
☐ Did not demonstrate comprehension of all required points (yet), needs more time/discussion.	d. Not able to answer correctly at this time
☐ Unable to demonstrate comprehension of all required points, consent process discontinued.	e. Other (describe)
☐ Other (specify):_____	

Site Discussion

- Please describe the informed consent process at your site
  - Where will the process will take place?
    - How will you ensure confidentiality?
  - Who at your site is responsible for obtaining IC?
  - How will the process be documented?

What are your questions about the informed consent process?