MTN-025 (HOPE) Enrollment Informed Consent Comprehension Assessment

Instructions: The assessment should be administered by the study staff member to the potential participant after the informed consent discussion is completed but before the participant is asked to sign or mark the informed consent form. The staff member administering the assessment should read the questions/statements below and mark the required points of comprehension.

PTID or Name:		**Date:**	
Question/Statement	**Required Points of Comprehension**	✓	**Comments**
Please tell me your understanding of the ASPIRE study results	The dapivirine vaginal ring prevented about one-third of HIV infections overall.		
	The dapivirine vaginal ring was safe, meaning it did not cause health problems.		
What is the purpose of the HOPE study?	To offer eligible participants access to the dapivirine vaginal ring as an HIV prevention method.		
	To collect additional information about safety and adherence of the dapivirine vaginal ring		
Please tell me about the study product in HOPE	All vaginal rings contain the study medication (dapivirine).		
What are you being asked to do in this study?	Be offered a dapivirine vaginal ring to use monthly for about one year.		
	Study procedures will be similar whether or not you choose the ring as an HIV prevention method.		
	Come to monthly clinic visits for the first 3 months, and then visits every three months for the rest of the study.		
	Have examinations and blood and urine tests, including HIV and pregnancy tests.		
	Receive counseling and answer questions about the vaginal ring and your sexual behaviors.		
	Some participants may be asked to have in-depth interviews or group discussions which are recorded.		
What are the possible risks of study participation?	Vaginal irritation, discomfort, or discharge, discomfort from exams or blood draws, potential HIV drug resistance (must mention at least one)		
	Others may find out about your participation or treat you badly for being in the study (social harms)		
What will happen if you decide not to join the study?	Free to make own decision about joining the study and can withdraw from the study at any time		
How will information about you be protected?	Information about participants is confidential and locked away		
	Only people working on the study have access to participant information		
What are the possible benefits of study participation?	Access to the dapivirine vaginal ring as an HIV prevention option.		
	Counseling, condoms, medical exams and tests, and clinical care (must state at least one)		
What should you do if you have questions or concerns about your health or about what is happening in the study?	Must state how to contact study staff (i.e. by phone, return to clinic)		

Outcome:

- ☐ Demonstrated comprehension of all required points, decided to enroll in study
- ☐ Demonstrated comprehension of all required points, decided NOT to enroll in study
- ☐ Demonstrated comprehension of all required points, deferred enrollment decision
- ☐ Did not demonstrate comprehension of all required points, needs more time/discussion
- ☐ Unable to demonstrate comprehension of all required points, consent process discontinued
- ☐ Other specify):_____

Staff Signature:_____ **Date:**_____

Optional Comment Codes:

a. Answered correctly on first try
b. Could not answer at first but answered correctly with probing
c. Answered incorrectly at first but answered correctly after discussion
d. Not able to answer correctly at this time
e. Other (describe)