MTN-025 (HOPE) DECLINER Population Screening and 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-decliner study?	To better understand ASPIRE participants' reasons for delay or refusal to take part in HOPE.		
How long will your study participation last?	It is expected that all procedures will be completed in one visit, however multiple visits may be needed.		
What are you being asked to do in this study?	Answer questions about your age, education, relationship status, health, sexual behaviors, and why you are declining HOPE participation.		
	Possibly complete an in-depth interview to answer interview questions that will be written in notes and audio-recorded.		
	Give permission for HOPE researchers to access ASPIRE study records.		
'If selected, where will the in-depth interviews take place?	A mutually agreeable place, e.g. participant home, study clinic, or neutral location.		
What are the possible risks of study participation?	Questions may cause embarrassment.		
	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.		
What will happen if you change your mind and decide you would like to take part in the MTN-025 trial?	You may enroll in MTN-025, provided the study is ongoing and you are eligible.		
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?	There are no direct benefits.		
	Information provided may help researchers improve design of future studies.		
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)