

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
Ndicela undixelele into oyiqondayo ngeziphumo zophando lwe-ASPIRE	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.		
Yintoni injongo yophando lwe-HOPE?	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		
Ndicela undixelele ngemveliso yophando kwi-HOPE	All vaginal rings contain the study medication (dapivirine).		
Yintoni ocelwe ukuba uyenze kolu phando?	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.		
Yeyiphi imingcipheko engakho yokuthatha inxaxheba kuphando?	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)		
Kuza kwenzeka ntoni ukuba uthatha isigqibo sokungalujoyini uphando?	Free to make own decision about joining the study and can withdraw from the study at any time		
Ziza kukhuselwa njani iinkcukacha ezingawe?	Information about participants is confidential and locked away		
	Only people working on the study have access to participant information		
Zeziphi inzuzo ezingakho ngokuthatha inxaxheba kuphando?	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)		
Yintoni omawuyenze ukuba unemibuzo okanye uneenkxalabo ngempilo yakho okanye ngokwenzekayo kuphando?	Must state how to contact study staff (i.e. by phone, return to clinic)		
Outcome: <input type="checkbox"/> Demonstrated comprehension of all required points, decided to enroll in study <input type="checkbox"/> Demonstrated comprehension of all required points, decided <u>NOT</u> to enroll in study <input type="checkbox"/> Demonstrated comprehension of all required points, deferred enrollment decision <input type="checkbox"/> Did not demonstrate comprehension of all required points, needs more time/discussion <input type="checkbox"/> Unable to demonstrate comprehension of all required points, consent process discontinued <input type="checkbox"/> Other specify): _____		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)	
Staff Signature: _____		Date: _____	