

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
Chonde ndiuzeni kumvetsetsa kwanu pa zotsatira za kafukufuku wa 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.		
Kodi cholinga cha kafukufuku wa HOPE ndi chiyani?	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		
Chonde ndiwuzeni zipangizo zomwe zigwiritsidwe ntchito mukafukufuku wa HOPE	All vaginal rings contain the study medication (dapivirine).		
Kodi mukupemphedwa kuti mupange chiyani mukafukufukuyu?	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.		
Kodi zovuta zoyembekezereka potenga nawo mbali mu kafukufuku ndi zotani?	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)		
Kodi chidzachitike ndi chiyani ngati mwasankha kuti musalowe nawo mukafukufuku?	Free to make own decision about joining the study and can withdraw from the study at any time		
Kodi uthenga okhudza inu udzatetezedwa bwanji?	Information about participants is confidential and locked away		
	Only people working on the study have access to participant information		
Kodi phindu loyembekezereka potenga nawo mbali mukafukufu ndilotani?	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)		
Kodi mupange chiyani ngati muli ndi mafunso kapena nkhwana yokhudza umoyo wanu kapena yokhudza zomwe zikuchitika mukafukufuku?	Must state how to contact study staff (i.e. by phone, return to clinic)		

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<p>Outcome:</p> <ul style="list-style-type: none"><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): _____ <p>Staff Signature: _____ Date: _____</p>	<p>Optional Comment Codes:</p> <ul style="list-style-type: none">a. Answered correctly on first tryb. Could not answer at first but answered correctly with probingc. Answered incorrectly at first but answered correctly after discussiond. Not able to answer correctly at this timee. Other (describe)
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