

## 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
<b>Ndicela undixelele into oyiqondayo ngeziphumo zophando lwe-ASPIRE</b>	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.		
<b>Yintoni injongo yophando lomlanduli lwe-HOPE?</b>	To better understand ASPIRE participants' reasons for delay or refusal to take part in HOPE.		
<b>Uthatho-nxaxheba kuphando luza kuqhuba ixesha elingakanani?</b>	It is expected that all procedures will be completed in one visit, however multiple visits may be needed.		
<b>Yintoni ocelwe ukuba uyenze kolu phando?</b>	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.		
<b>Ukuba ukhethiwe, luza kubanjelwa phi udliwano-ndlebe olunzulu?</b>	A mutually agreeable place, e.g. participant home, study clinic, or neutral location.		
<b>Yeyiphi imingcipheko engakho yokuthatha inxaxheba kuphando?</b>	Questions may cause embarrassment.		
	Others may find out about your participation or treat you badly for being in the study (social harms).		
<b>Kuza kwenzeka ntoni ukuba uthatha isigqibo sokungalujoyini uphando?</b>	Free to make own decision about joining the study and can withdraw from the study at any time.		
<b>Kuza kwenzeka ntoni ukuba utshintsha ingqondo yakho uze ugqibe ukuba ungathanda ukuthatha inxaxheba kuvavanyo lwe-MTN-025?</b>	You may enroll in MTN-025, provided the study is ongoing and you are eligible.		
<b>Ziza kukhuselwa njani iinkcukacha ezingawe?</b>	Information about participants is confidential and locked away.		
	Only people working on the study have access to participant information.		
<b>Zeziphi inzuzo ezingakho ngokuthatha inxaxheba kuphando?</b>	There are no direct benefits.		
	Information provided may help researchers improve design of future studies.		
<b>Yintoni omawuyenze ukuba unemibuzo okanye iinkxalabo ngempilo yakho okanye ngokwenzekayo kuphando?</b>	<i>Must state how to contact study staff (i.e. by phone, return to clinic)</i>		
<b>Outcome:</b> <input type="checkbox"/> Demonstrated comprehension of all required points, decided to enroll in study <input type="checkbox"/> Demonstrated comprehension of all required points, decided <b>NOT</b> 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): _____		<b>Optional Comment Codes:</b> 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)	
<b>Staff Signature:</b> _____		<b>Date:</b> _____	