MTN-025 (HOPE) DECLINER Population Screening and Enrollment Informed Consent Comprehension Assessment (ZULU)

Instructions: The assessment should be administered by the study staff member to the potential participant <u>after the informed consent</u> <u>discussion is completed</u> but before <u>the participant is asked to sign or mark the informed consent form</u>. 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
Ngicela ungitshele ukuqonda kwakho ngemiphumela	The dapivirine vaginal ring prevented about one-third of HIV infections overall.		·	
yocwaningo lwaAspire.	The dapivirine vaginal ring was safe, meaning it did not cause health problems.			
Yini inhloso yocwaningo lukaHOPE-lokuyeka?	To better understand ASPIRE participants' reasons for delay or refusal to take part in HOPE.			
Kuzoba kude kangakanani ukubamba iqhaza kwakho ocwaningweni?	It is expected that all procedures will be completed in one visit however multiple visits may be needed.			
Yini ocelwa ukuba uyenze kulolucwaningo?	Answer questions about your age, education, relationship stat health, sexual behaviors, and why you are declining HOPE participation.	us,		
	Possibly complete an in-depth interview to answer interview questions that will be written in notes and audio-recorded.	du		
Uma ukhethiwe, ngabe ukubuzwa	Give permission for HOPE researchers to access ASPIRE sturecords. A mutually agreeable place, e.g. participant home, study clinic	,		
okujulile kuzokwenzelwa kuphi?	neutral location.	, OI		
Ibuphi ubungozi obungenzeka ekubambeni iqhaza ocwaningweni?	Questions may cause embarrassment. Others may find out about your participation or treat you badly being in the study (social harms).	for		
Kuzokwenzekani uma unquma ukungalujoyini ucwaningo?	Free to make own decision about joining the study and can withdraw from the study at any time.			
Kuzokwenzekani uma ushintsha umqondo wakho bese unquma ukuthi ungathanda ukubamba iqhaza kucwaningo lweMTN-025?	You may enroll in MTN-025, provided the study is ongoing and are eligible.	d you		
Izovikeleka kanjani imininingwane engawe?	Information about participants is confidential and locked away Only people working on the study have access to participant information.			
Iziphi izinzuzo ezingenzeka ekubambeni iqhaza	There are no direct benefits.			
ocwaningweni?	Information provided may help researchers improve design of future studies.			
Kumele wenzenjani uma unemibuzo noma ukukhathazeka mayelana ngezempilo yakho noma ngokwenzeka ocwaningweni?	Must state how to contact study staff (i.e. by phone, return to o	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):		a. An b. Co an: c. An an d. No	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)	