

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
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 okana HOPE (HOPE-Decliner Study) ndi chiyani?	To better understand ASPIRE participants' reasons for delay or refusal to take part in HOPE.		
Kodi mudzakhala mukafukufukuyu nthawi yayitali bwanji?	It is expected that all procedures will be completed in one visit, however multiple visits may be needed.		
Kodi mukupemphedwa kuti mupange chiyani mukafukufukuyu?	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.		
Ngati mutasankhidwa, kodi gawo lofunsidwa mafunso mozama (mwakathithi) lidzachitikira kuti?	A mutually agreeable place, e.g. participant home, study clinic, or neutral location.		
Kodi zovuta zoyembekezereka potenga nawo mbali mu kafukufuku ndi zotani?	Questions may cause embarrassment.		
	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 chidzachitike ndi chiyani ngati mutasintha maganizo ndipo mwaganiza kuti mukufuna kutenga nawo mbali mukafukufuku wa MTN 025?	You may enroll in MTN-025, provided the study is ongoing and you are eligible.		
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 mukafukufuku ndilotani?	There are no direct benefits.		
	Information provided may help researchers improve design of future studies.		
Kodi mupange chiyani ngati muli ndi mafunso kapena nkhawa yokhudza umoyo wanu kapena yokhudza zomwe zikuchitika mukafukufuku?	<i>Must state how to contact study staff (i.e. by phone, return to clinic)</i>		

**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.

<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)
--	---