

MTN-020 Enrollment Informed Consent Comprehension Checklist

Name or PTID:

Date:

Open-Ended Question/Statement	Required Points of Comprehension	✓	Comments
1 Please tell me your understanding of the purpose of the study.	Testing if vaginal ring is safe to use		
	Testing if vaginal ring may prevent getting HIV		
2 Please tell me about the different groups of women in the study.	Women will receive one of two different vaginal rings -- some have study medication and some do not		
	Women can not choose their group		
	No one knows who receives which vaginal ring		
3 What are participants being asked to do in this study?	Wear a vaginal ring for about 1-2 years		
	Come for monthly clinic visits for about 1-2 years		
	Have examinations and blood and urine tests, including monthly HIV and pregnancy tests		
4 What are the possible risks for participants in the study?	Pain or discomfort in genital area or other side effects, discomfort from exams or blood draws, potential HIV drug resistance (<i>must mention at least one</i>)		
	Others may treat you badly for being in the study (social harms)		
5 What will happen if women decide not to join the study?	Free to make her own decision about joining the study		
	No change to her access to health care whether she joins the study or not		
6 How will information about participants in the study be protected?	Information about participants is confidential, private, and locked away		
	Only people working on the study have access to her information		
7 What are the possible benefits for participants in the study?	Counseling, condoms, contraception, medical exams, tests, clinical care, helping to find ways to prevent getting HIV (<i>must mention at least one</i>)		
8 What should participants do if they have questions or concerns about their health or about what is happening in the study?	<i>Must state how to contact study staff</i>		
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 NOT 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 (yet), 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:			