

## MTN-005 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 a non-medicated vaginal ring		
	Testing if ring is safe to use (does not cause bad effects)		
	Testing if women are willing and able to use the ring as directed (adherence)		
	There is no drug in the ring		
2 Please tell me about the different groups of women in the study.	There are 2 groups in the study		
	Some women will use a vaginal ring		
	Some women will not use the vaginal ring but still have the same study visits		
3 What are participants being asked to do in this study?	Come for monthly clinic visits for 4 months		
	Depending on group -- keep the ring inserted in the vagina for 3 months		
	Have examinations and blood and urine tests, including HIV and pregnancy tests		
	Use reliable family planning and not get pregnant while in the study		
	Not to use any vaginal products except for tampons during menses and study approved condoms		
	Not take part in other studies involving drugs, medical devices, or vaginal products		
4 What are the possible risks for participants in the study?	Ring may cause bad effects ( <i>must mention at least one - e.g. irritation, increased discharge, discomfort during intercourse</i> )		
	Others may treat participants 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, 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>		
<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 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): _____		<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> _____			