

HPTN 035 Enrollment Informed Consent Comprehension Checklist, Version 1.1 (12 April 2006)

PTID:

Date:

Open-Ended Question/Statement	Required Points of Comprehension	✓	Comments
1 Please describe your understanding of the purpose of the study.	study is testing two experimental gels		
	testing to learn if gels are safe		
	testing to learn if gels may prevent HIV		
	study may not prove gels work		
2 What do you understand that you are being asked to do in this study?	asked to use condoms and perhaps gel with each act of vaginal sex		
	have pelvic exams and HIV tests		
	come for monthly visits for up to 30 months		
	not get pregnant in next 30 months		
3 What do you understand about possible risks that might happen as a result of being in the study?	gel may irritate skin inside or outside vagina		
	gel may have other side effects		
	possibility of social harms		
4 What will happen if you do not join the study?	free to make her own decision about joining		
	no effect on access to care when decide to join or not		
5 Please tell me about the different groups of women in the study.	there are different gels		
	not everyone receives a gel		
	no one knows who receives which gel		
6 How will the information about you be protected?	participant information is kept under lock and key		
	only people working on the study have access		
7 What are the benefits to you of participating in this study?	counseling, condoms, tests, clinical care, benefit to science or community (should mention at least one from ICF)		
8 What should you do if you have any questions about what is happening in the study?	must articulate how to contact study staff		

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 to another visit.
- Did not demonstrate comprehension of all required points (yet), needs more time/discussion, rescheduled for another visit.
- Unable to demonstrate comprehension of all required points, consent process discontinued.
- Other (specify): _____

Staff Signature:

Optional Comment Categories:

- a. Answered correctly on first try
- b. Could not answer at first, but answered correctly after some probing/discussion
- c. Answered incorrectly at first, but answered correctly after discussion
- d. Not able to answer correctly at this time
- e. Other (describe)