## Open-Ended Question/Statement

<table>
<thead>
<tr>
<th>Question</th>
<th>Required Points of Comprehension</th>
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</table>
| 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): ____________________________________________________________

### 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)