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| **PTID** |  | **DATE** |  |  | **Staff Signature** |  | **Staff Date** |  |

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| **Open-Ended Question/Statement** | | **Required Points of Comprehension** | **Assessed (✓)** | **Comments**  **(Enter code or notes)** |
| **1** | **Please tell me your understanding of the purpose of the study.** | Testing how study drug (Tenofovir) enters and exits the body. |  |  |
| Testing safety of the TFV ring as compared to a placebo. |
| **2** | **Tell me what you understand about the two different groups in the study.** | Women will be randomly assigned to their group and cannot choose which one they are in. |  |  |
| One group will receive a VR with the study drug and the other group will receive a VR with no study drug (placebo); both to wear continuously for about 91 days/13 weeks. |
| **3** | **What are participants being asked to do in this study?** | Wear one of two rings for a total of about 91 days/13 weeks. |  |  |
| Have physical and pelvic exams and cervical biopsies. Provide blood, vaginal fluid, rectal fluid, and urine for testing. |  |  |
| Agree not to put anything in the vagina for the duration of the study. Agree to abstain from receptive vaginal sexual practices and tampon use for certain times periods prior to study visits. |  |  |
| Use an effective contraceptive method for the duration of the study. |
| **4** | **What are the possible risks for participants in the study?** | Side effects from the study drug, risks of vaginal ring use, discomfort from exams or blood draws, embarrassment about discussion topics, anxiety about test results, possible social harms *(must mention at least two).* |  |  |
|  |  |
| **5** | **What will happen if you 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 participant information |  |  |
| **7** | **What are the possible benefits for participants in the study?** | Counseling, medical exams, tests, clinical care *(must mention at least one)* |  |  |
| **8** | **What should you do if you have questions about your health or the study?** | *Must state how to contact study staff* |  |  |

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| **Outcome** |  | **Optional Comment Code** | |
| * Demonstrated comprehension of all required points, decided to enroll. * Demonstrated comprehension of all required points, decided NOT to enroll. * Demonstrated comprehension of all required points, deferred enrollment decision. * Did not demonstrate comprehension of all required points (yet), needs more time/discussion. * Unable to demonstrate comprehension of all required points, consent process discontinued. * Other (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  | **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) |