|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name:** |  | **Staff Signature:** |  | **Date: (DD/MM/YY)** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Open-Ended Question/Statement** | **Required Points of Comprehension** | **Assessed (✓)** | **Comments** **(Enter code or other notes)** |
| 1 | **What do you understand to be the purpose of this study?** | To test if an insert (containing Tenofovir Alafenamide [TAF]/Elvitegravir [EVG]) is safe when used rectally and to understand how the product enters/exits the body and whether it is acceptable to users |  |  |
| 2 | **What are participants being asked to do in this study?** | Receive two doses of the insert rectally over the course of 6-13 weeks |  |  |
| Have physical and rectal exams, rectal tissue and rectal fluid/vaginal fluid (if applicable) collected, throat swabs, blood and urine tests, take part in interviews |  |  |
| Refrain from using certain non-study medications and products, and refrain from certain sexual activities prior to specific study visits and procedures |  |  |
| Use an effective contraceptive method for the duration of the study (if applicable) |  |  |
| 3 | **What are the possible risks for participants in the study?**  | Discomfort in abdomen, genital discharge or other side effects, discomfort from exams, biopsies, and blood draws *(must mention at least one)* |  |  |
| Embarrassment and anxiety about discussions and test results, possible social harms  |  |  |
| 4 | **What will happen if you decide not to join the study?**  | Free to make his/her own decision about joining the study |  |  |
| No change to his/her access to health care whether he/she joins the study or not |  |  |
| 5 | **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 his/her information |  |  |
| 6 | **What are the possible benefits for participants in the study?**  | Counseling, medical exams, tests, clinical care *(must mention at least one)* |  |  |
| 7 | **What should participants do if they have questions or concerns about their health or about what is happening in the study?** | *Must state how to contact study staff* |  |  |
| **Outcome** | **Optional Comment Code** |
| * 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.
* 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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |