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| **Name** |  | **Date** |  |  | **Staff Signature** |  | **Staff Date** |  |

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| **Open-Ended Question/Statement** | **Required Points of Comprehension** | **Assessed (✓)** | **Comments** **(Enter code or notes)** |
| **1** | **What do you understand to be the purpose of the study?** | To find out if men who have sex with men and transgender women and men find acceptable and can tolerate three different ways to potentially deliver anti-HIV/antiretroviral drugs into the rectum.  |  |  |
| To understand whether men who have sex with men and transgender men and women are willing to use these three rectal products as part of their usual practices around receptive anal sex.  |
| To evaluate if each study product is safe when applied rectally and used before receptive anal sex.  |
| **2** | **Tell me what you understand about what happens in the study.** | Participants will use three rectally-administered placebo products (i.e. product with no active medicine/drug) – a douche, insert and suppository – for one month (4 weeks) each, in random order.  |  |  |
| **3** | **What are participants being asked to do in this study?** | Adhere to study requirements (e.g. attend all study visits, respond to SMS/IM queries, refrain from use of non-study rectally-applied products) |  |  |
| Have physical, rectal or genital exams and pelvic exams, if applicable. Provide blood, rectal fluid, urine, throat cultures and, if applicable, vaginal fluid, for testing.  |  |  |
| Answer questions about use of the study products. |  |  |
| Use an effective contraceptive method (individuals who can get pregnant only). |
| Participants will be asked to use the assigned product prior to receptive anal sex. Participants who do not have receptive anal sex in a week will be asked to use the product in its absence. |  |  |
| **4** | **How much time will participants be expected to spend in the study?** | Participants will be asked to attend 8 total clinic visits, once every four and five weeks. Total length of participation will be approximately 3 ½ months. |  |  |
| **5** | **What are the possible risks of participating in the study?**  | Pain or discomfort in rectal and genital area or other side effects, discomfort from exams or blood draws *(must mention at least one).* |  |  |
| Embarrassment and anxiety about discussions and tests results. |  |  |
| Loss of privacy/confidentiality. |
| **6** | **What will happen if you decide not to join the study?**  | Free to make one’s own decision about joining  |  |  |
| No change in access to health care whether or not one joins the study. |  |  |
| **7** | **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. |  |  |
| **8** | **What are the possible benefits of participating in the study?**  | Counseling, medical exams/tests, clinical care, contribution to HIV research, free male condoms and lubricant *(must mention at least one)* |  |  |
| **9** | **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) |