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| **PTID** |  |  | **Staff Initial & Date** |  |

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| **Open-Ended Question/Statement** | | **Required Points of Comprehension** | **Assessed (✓)** | **Comments**  **(Enter code or other notes)** |
| 1 | **Please tell me your understanding of the purpose of the study.** | Testing how a gel (containing PC-1005) enters and exits the body; and testing safety of gel when used rectally. |  |  |
| 2 | **What are participants being asked to do in this study?** | Receive three doses of the gel administered rectally in increasing amounts over the course of 3-5 months. |  |  |
| Have physical and genital exams, rectal tissue and rectal fluid/vaginal fluid (if applicable) collected, blood and urine tests |  |  |
| Agree to refrain from using certain non-study medications, products and sexually activities prior to specific study visits and procedures |  |  |
| 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 |  |  |
| 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* |  |  |

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| **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) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |