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| --- | --- | --- | --- | --- |
| Name or PTID: Date: | | | | |
| Question | Answers | |  | **Comments** |
| Please describe your understanding of the purpose of this study. | Assess if a gel containing an experimental drug is safe when used rectally | |  |  |
| To understand how the drug in the gel enters and exits the body | |  |
| Please tell me about the different sequences in the study. | Participants will be randomly assigned to use the gel: at one time using an applicator and at a separate time using a dildo. | |  |  |
| What are you being asked to do in this study? | After today’s visit, come for 5-6 follow-up visits | |  |  |
| Insert a gel in the rectum 2 times in the clinic over the course of the study | |  |
| Have genital and physical examinations | |  |
| Provide samples of urine, blood and rectal fluid and tissue (biopsies) | |  |
| Abstain from engaging in receptive anal sex, rimming, rectal stimulation and using other non-study products in the rectum 72 hours before and after each visit | |  |
| What are some possible risks of participating in the study? | Pain or discomfort in genital area or other side effects; discomfort from exams or blood draws; pain/bleeding during/after biopsies (must mention at least one) | |  |  |
| Gel may cause side effects (must mention at least one: irritation and discomfort, diarrhea, gas, bloating, abdominal pressure) | |  |
| Possibility of social harms, e.g. others may treat participants unfairly for being in the study | |  |
| How much time will you be expected to spend at the clinic for this study? | Participants may spend at least 4-5 hours in the clinic on each dosing day and up to a couple of hours for each of the other visits | |  |  |
| What will happen to you if you decide not to join the study? | Free to make own decision about joining the study and can withdraw from the study at any time | |  |  |
| No change to regular medical care/benefits whether you join the study or not | |  |
| How will the information about you be protected? | Information about participants is confidential and locked away | |  |  |
| Only people working on the study have access to participant information | |  |
| What are the benefits to you of participating in this study? | Counseling, condoms, medical exams and tests, clinical care, helping to find ways to prevent HIV (must state at least one) | |  |  |
| What should you do if you have any questions related to the study? | Must state how to contact study staff (i.e., by phone, return to clinic) | |  |  |
| Outcome:Demonstrated comprehension of all required points, decided to enroll in studyDemonstrated comprehension of all required points, decided NOT to enroll in studyDemonstrated comprehension of all required points, deferred enrollment decisionDid not demonstrate comprehension of all required points, needs more time/discussionUnable to demonstrate comprehension of all required points, consent process discontinuedOther specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Staff Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | Optional Comment Codes:a. Answered correctly on first tryb. Could not answer at first but answered correctly with probingc. Answered incorrectly at first but answered correctly after discussiond. Not able to answer correctly at this timee. Other (describe) | | |