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| Question | Answers | |  | **Comments** |
| Please describe your understanding of the purpose of this study. | Assess if vaginal rings containing experimental study drugs are safe | |  |  |
| To understand how the drugs in the vaginal rings enter and exit the body | |  |
| Please tell me about the different groups of participants in the study. | Participants will be randomly assigned 2:1 to use one of two different vaginal rings, each ring contains a different dose strength of the study drug combination | |  |  |
| Participants will not know which vaginal ring they will receive | |  |
| What do you understand that you are being asked to do in this study? | Use a vaginal ring for approximately 28 days without removing it (unless instructed to by a study clinician) | |  |  |
| Have pelvic and physical examinations | |  |
| Provide samples of urine, blood and vaginal fluid/tissue samples (biopsies). Some visits will require multiple samples to be taken over a long period time | |  |
| Use an effective birth control method and agree not get pregnant while in the study | |  |
| Abstain from engaging in receptive sexual activity (including anal, oral, and vaginal) and using other vaginal products (including sex toys) for the 5 days prior to the Enrollment Visit and for the duration for study participation | |  |
| Come for frequent study visits | |  |  |
| What do you understand about possible risks that might happen as a result of being in the study? | Pain or discomfort in genital area or other side effects, discomfort from exams or blood draws (must mention at least one) | |  |  |
| Possibly of social harms i.e. others may treat participants unfairly for being in the study | |  |
| 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? | There may not be direct benefits for participating in this study, but will receive counseling, medical exams and tests, clinical care, helping to find way to prevent HIV (must state at least one) | |  |  |
| What should you do if you have any questions about what is happening in this 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) | | |

1. **If you wanted to tell a friend or family member about this study, how would you describe it to them?**

Study objectives/purpose (testing if the vaginal ring is safe or how the study drugs enter/exit the body)

Study population (born female, between ages 18-45, sexually abstinent, HIV uninfected)

Overall study design (use ring for 28 days, randomized to one of two vaginal rings, 13 study visits in total)

1. **How do you think it would affect your day-to-day life to be in this study?**

Study duration: approximately 5 weeks, daily and weekly study visits required, some of which will be long

Perceived risks of study participation (discomfort with exams or blood draws, loss of confidentiality, discomfort with the personal nature of questions asked, possible vaginal irritation, discharge, or discomfort when using vaginal ring)

1. **What do you think you will get out of being in this study?**

HIV/STI education, counseling, and testing

Physical and pelvic exams and medical tests

STI treatment

Personal satisfaction/no direct benefit

1. **Do you think being in this study could help you avoid becoming infected with HIV?**

HIV education, counseling, and testing provided

Condoms provided at the final visit

Researchers do not yet know if study drugs will prevent HIV nor is this study able to test this

1. **Are there things about being in this study that you would be worried about?**

Embarrassment/worry/anxiety when answering interview questions about sexual activities

Embarrassment/worry/anxiety when discussing HIV/AIDS and risk behaviors

Worry/anxiety while waiting for or after receiving test results

The side effects of using the vaginal ring

1. **What kind of clinical procedures will you undergo in this study?**

Blood and urine collection

Vaginal and/or cervical fluid or tissue collection

Physical examination

Pelvic examination

1. **What might the study staff do if you miss a study visit?**

Mail, phone, other contacts to re-schedule the visit

Use provided locator contacts to reach the participant

1. **What are some reasons why the study staff might end your participation in the study?**

The study is stopped or cancelled

The staff feel it would be harmful for the participant to stay in the study

If you become infected with HIV or become pregnant

The participant is unable to attend study visits or complete study procedures

1. **What will the study staff do to protect your privacy and confidentiality during the study?**

Keep information about study participation and all study records confidential

Maintain privacy and confidentiality when conducting locator activities

However some study monitors or sponsors may review records