**Screening Behavioral Eligibility Worksheet (Page 1 of 2)**

PTID: \_\_\_ \_\_\_ \_\_\_- \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_\_- \_\_\_ VISIT CODE: 1. 0

VISIT DATE: \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

**To confirm eligibility for the study, ask the participant the following questions and mark her responses accordingly.**

|  |  |  |  |
| --- | --- | --- | --- |
| 1 | Are you willing to comply with all study procedure requirements, including, clinical and laboratory assessments, vaginal and rectal examinations, urine and blood testing, as well as attendance at all scheduled study visits? | Yes 🞎 | No 🞎 |
| 2 | If you were to join this research study, would you be willing to use male condoms provided by study staff each time you have vaginal or anal sex while you are in the study? | Yes 🞎 | No 🞎 |
| 3 | If you were to join this research study, would you be willing to use an effective method of contraception for the next 3 months? Includes: hormonal methods other than vaginal rings, IUD inserted at least 42 days (6 weeks) before Enrollment, sterilization of you or partner at least 42 days (6 weeks) before Enrollment, you self-identify as a woman who has sex with women exclusively, you have been sexually abstinent (no sex) for at least 3 months before enrollment and have the intention to remain sexually abstinent for the duration of study  | Yes 🞎 | No 🞎\* |
| 4 | Are you willing to not insert any non-study vaginal or rectal products or objects into the vagina or butt for the duration of the study product use periods and for 24 hours before period initiation and period end visits? Including, but not limited to, spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), vaginal/rectal douches, enemas, mom-study approved lubricants, sex toys (vibrators, dildos, etc.) | Yes 🞎 | No 🞎 |
| 5 | Do you agree that you will not take part in other research studies involving drugs, medical devices, or vaginal/rectal products for the duration of study participation? | Yes 🞎 | No 🞎\* |
| 6 | Are you willing to not insert any non-study products into the vagina or butt for 3 days before and after the collection of tissue samples? | Yes 🞎 | No 🞎 |
| 7 | Are you willing to not have vaginal or anal sex, for 3 days before and after the collection of tissue samples? | Yes 🞎 | No 🞎 |
| 8 | Are you willing to abstain from the use of non-steroidal anti-inflammatory drugs (NSAIDs), aspirin and/or other drugs that are associated with the increased likelihood of bleeding for 3 days before and after the collection of tissue samples? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, the responses to items 1, 2, and 4 above must be ‘YES’.**

**\*If the responses to items 3 or 5 are “NO”, assess likelihood of eligibility by enrollment visit and proceed accordingly.**

**Rectal and Vaginal Tissue Subset only- In order for the participant to be eligible, the responses to items 6-8 above also must be ‘YES’.**

\_\_\_\_\_\_\_\_\_\_\_ (Staff Initials/Date) Version 2.1 dated 3 September 2013

**Screening Behavioral Eligibility Worksheet (Page 2 of 2)**

PTID: \_\_\_ \_\_\_ \_\_\_- \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_\_- \_\_\_ VISIT CODE: 1. 0

VISIT DATE: \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ \_\_

**To confirm eligibility for the study, ask the participant the following questions and mark her responses accordingly.**

|  |  |  |  |
| --- | --- | --- | --- |
| 9 | Have you ever had a known adverse or bad reaction to tenofovir gel?  | Yes 🞎 | No 🞎 |
| 10 | Have you ever had a known adverse or bad reaction to latex, such as latex condoms or latex gloves? | Yes 🞎 | No 🞎 |
| 11 | Has your current male sex partner ever had an adverse or bad reaction to latex, such as latex condoms or latex gloves? | Yes 🞎 | No 🞎 |
| 12 | Have you ever been tested for and been told you had Hepatitis B? | Yes 🞎 | No 🞎 |
| 13 | In the past year, have you used a needle to inject drugs that were not prescribed to you by a medical professional? | Yes 🞎\* | No 🞎 |
| 14 | In the past 6 months, were you prescribed medicine for any STIs? | Yes 🞎\* | No 🞎 |
| 15 | In the past 2 months, were you prescribed medicine for any reproductive tract infections (RTIs) such as a yeast infection or bacterial vaginosis [BV])? | Yes 🞎\* | No 🞎 |
| 16 | In the past 6 months, have you used Post-exposure prophylaxis (PEP) or Pre-exposure prophylaxis (PrEP)? | Yes 🞎\* | No 🞎 |
| 17 | In the past 3 months, have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated? | Yes 🞎\* | No 🞎 |
| 18 | Do you intend to have a child in the next 3 months? | Yes 🞎 | No 🞎 |
| 19 | Are you breastfeeding now? | Yes 🞎 | No 🞎 |
| 20 | In the past 42 days (6 weeks) have you had a gynecologic or genital procedure—such as tubal ligation, dilation, or curettage (D & C)? | Yes 🞎\* | No 🞎 |
| 21 | In the past 42 days (6 weeks) have you participated in any other research study involving drugs, medical devices, or vaginal/rectal products? | Yes 🞎\* | No 🞎 |
| 22 | Do you anticipate having an IUD replaced within the next 3 months or have you had an IUD inserted in the past42 days (6 weeks)? | Yes 🞎\* | No 🞎 |
| 23 | Have you ever had any problems with bleeding? | Yes 🞎 | No 🞎 |

**In order for the participant to be eligible, the responses to items 9-12, 18, and 19 above must be ‘NO’.**

**\*If the responses to any of items 13-17, 20-22 are “YES”, assess likelihood of eligibility by enrollment visit and proceed accordingly.**

**Rectal and Vaginal Tissue Subset only- In order for the participant to be eligible, the response to item 23 must also be ‘NO’.**

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