**MTN-033 Screening Behavioral Eligibility Worksheet**

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

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

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| --- | --- | --- | --- |
| 1 | If you were to join this research study, would you be willing and able to return to the study clinic for all study visits and comply with study participation requirements? | Yes 🞎 | No 🞎 |
| 2 | In the past calendar year, have you engaged in consensual receptive anal intercourse at least once?  | Yes 🞎 | No 🞎 |
| 3 | If you were to join this research study, are you willing to not take part in other research studies involving drugs, medical devices, genital or rectal products or vaccines during your participation in the study (including the time between screening and enrollment)? | Yes 🞎 | No 🞎 |
| 4 | If you were to join this research study, are you willing to abstain from receptive anal intercourse (RAI), receptive oral anogenital stimulation (i.e., rimming), rectal stimulation via fingers, as well as the insertion of any non-study products into the rectum for 72 hours before and after each study visit?  | Yes 🞎 | No 🞎 |
| 5 | Have you ever had a known adverse (bad) reaction to latex or polyurethane?  | Yes 🞎 | No 🞎 |
| 6 | If you were to join this research study, do you anticipate using or are you unwilling to abstain from using any of the following prohibited medications during your participation in the study? These medications include anticoagulant medications, aspirin (greater than 81mg/day), non-steroidal anti-inflammatory drugs (NSAIDs), or any other drugs that are associated with increased likelihood of bleeding, rectally administered medications or products containing N-9 or corticosteroids and CYP3A inducers or inhibitors and hormone-replacement therapy in tablet, injectable or gel form. *[Note to interviewer: ensure list of strong CYP3A inducers/inhibitors is reviewed with participant]* | Yes 🞎 | No 🞎 |
| 7 | Have you ever had a known adverse (bad) reaction to any of the components of the study product, applicator or coital simulation device?  | Yes 🞎 | No 🞎 |
| 8 | In the past month, have you used pre-exposure prophylaxis (PrEP) for HIV prevention or are you unwilling to abstain from using PrEP during your participation in the study (including the time between screening and enrollment)? | Yes 🞎 | No 🞎 |
| 9 | In the past 6 months, have you used post-exposure prophylaxis (PEP) for HIV exposure? | Yes 🞎 | No 🞎 |
| 10 | In the past 6 months, have you used systemic immunomodulatory medications or do you anticipate using these medications during your participation in the study? | Yes 🞎 | No 🞎 |
| 11 | In the past 6 months, have you engaged in unprotected receptive anal intercourse or penile-vaginal intercourse with a partner who you know is HIV positive?  | Yes 🞎 | No 🞎 |
| 12 | In the past 12 months, have you used a needle to inject drugs that were not prescribed to you by a medical professional? | Yes 🞎 | No 🞎 |
| 13 | In the past 30 days, have you participated in any other research study involving drugs, medical devices, genital or rectal products or vaccines? | Yes 🞎 | No 🞎 |
| 14 | In the past 3 months, have you been diagnosed and treated for an anogenital STI? | Yes 🞎 | No 🞎 |

**For the participant to be eligible, responses to items 1-4 above must be ‘YES’ and responses to items 5-14 above must be ‘NO’. If any response to items 8-14 are “YES”, assess likelihood of eligibility by enrollment visit and proceed accordingly.**

Staff Initials/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_