

MTN-025 Screening Behavioral Eligibility Worksheet

PTID: _____

VISIT CODE: 1. 0

VISIT DATE: _____

I am now going to ask you some questions about yourself. Some of these questions are personal and sensitive, but remember that we do not have your name on these papers. All of your answers will be kept confidential.

1	If you were to join this research study, would you be willing to use an effective method of contraception for the duration of the study, which is expected to be about one year? Effective methods include hormonal methods other than the contraceptive ring, such as oral contraceptive pills, contraceptive injections or implants, the intrauterine contraceptive device, or sterilization.	Yes <input type="checkbox"/>	No <input type="checkbox"/> *
2	If you were to join this research study, would you agree not to take part in any other research studies involving drugs, medical devices, vaginal products, or vaccines?	Yes <input type="checkbox"/> ^	No <input type="checkbox"/>

***If the response to item 1 is "NO", assess likelihood of eligibility by enrollment visit and proceed accordingly.**

^In order for the participant to be eligible, the response to item 2 above must be 'YES' at Screening.

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

3	During your study participation, which is expected to be for about one year, do you plan to move away from the study clinic area?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	During your study participation, which is expected to be for about one year, do you plan to travel away from the study clinic area for more than 12 consecutive weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	Are you currently taking Post-exposure prophylaxis (PEP) for HIV exposure?	Yes <input type="checkbox"/> ψ	No <input type="checkbox"/>
6	Do you intend to have a child while you are in the study, which is expected to be for about one year?	Yes <input type="checkbox"/> *	No <input type="checkbox"/>
7	Are you breastfeeding now?	Yes <input type="checkbox"/> *	No <input type="checkbox"/>
8	In the past two months, have you taken part in any other research study of medicines, medical devices, vaginal products, or vaccines?	Yes <input type="checkbox"/> *ϣ	No <input type="checkbox"/>

In order for the participant to be eligible, the responses to items 3-4, above must be 'NO'.

ψ PEP use at Screening is not exclusionary. Participants may be enrolled after the PEP regimen is complete and a negative HIV test is documented with 56 days of providing informed consent for Screening. If the response to Item 5 is "YES", assess expected completion date of PEP treatment regimen and schedule the participant's enrollment visit accordingly.

***If the responses to any of items 6-8 are "YES", assess likelihood of eligibility by enrollment visit and proceed accordingly.**

ϣ Participation in MTN-020 or the MTN-025 'Decliner Population' does not preclude MTN-025 full study participation in the future.

(Staff Initials/Date)

Version 1.0 dated 13 April 2016