SAMPLE: DO NOT FAX TO DATAFAX

MTN-021 (110) DEM-1 (001)

Participant ID

Site Number – Participant Number – Chk

Demographics

Form Completion Date

dd MMM yy

I will start by asking you some general questions about yourself.

1. What is your date of birth?..... dd MMM yy → If unknown, record age: years

2. **NOT APPLICABLE FOR THIS PROTOCOL.** What is your gender? male ☐ female ☒

3. Do you consider yourself to be Latina or of Hispanic origin? ..... yes ☐ no ☐

4. What is your race? *Mark all that apply.*

- ☐ 4a. American Indian or Alaskan Native
- ☐ 4b. Asian
- ☐ 4c. Black or African American
- ☐ 4d. Native Hawaiian or other Pacific Islander
- ☐ 4e. White
- ☐ 4f. other, specify: _____

Demographics (DEM-1)

Purpose: This interviewer-administered form is used to collect participants' demographic information.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment Visit.

- **Visit Code:** There is no visit code field on this form since this form is only administered once at screening.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers.
- **Item 3:** This item is based on self-definition. Per NIH policy, Latina or Hispanic includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
- **Item 4:** Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background. Per NIH policy, Latina is considered an ethnic group and not a race and should not be entered in item 4f.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN-021 (110)

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number / Participant Number / Chk)

Screening Behavioral Eligibility

Visit Date ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

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.

		yes	no
1.	Have you ever had an adverse or bad reaction to either of the study products?	☐	☐
2.	Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)?	☐	☐
3.	Do you have a current male sex partner who has ever had an adverse or bad reaction to latex?	☐	☐
4.	Are you currently breastfeeding?	☐	☐
5.	In the next 6 months, do you plan to become pregnant?	☐	☐

If yes to any of the above, participant is ineligible.

		yes	no
6.	Have you ever had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.	☐	☐
7.	Starting now and continuing throughout the study, if you intend to engage in sexual activity, are you willing to use male latex condoms provided by the study?	☐	☐
8.	Starting now and continuing throughout the duration of your study participation, if you intend to engage in sexual activity, are you willing to use an effective method of contraception? Effective methods include hormonal contraceptives (except contraceptive ring) or an intrauterine device (IUD).	☐	☐
9.	Starting now and continuing throughout the duration of your study participation, do you agree to not participate in other research studies involving drugs, medical devices, or vaginal products? ..... *Note to interviewer: This is not exclusionary if approval is granted by the PSRT and Protocol Chair.*	☐	☐
10.	Are you able and willing to comply with all study procedural requirements?	☐	☐

If no to any of the above, participant is ineligible.

		yes	no
11.	Throughout the duration of your study participation, are you able and willing to abstain from the use of vaginally-administered non-study products (other than tampons) and/or practices, such as douching?	☐	☐

If no, reassess at Enrollment for eligibility per the eligibility criteria.

Screening Behavioral Eligibility (Page 1)

Purpose: This interviewer-administered form is used to document the participant's behavioral eligibility for the study at the Screening Visit. Read all introductory statements and items aloud as they appear on the form. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

General Information/Instructions: If the participant provides a response indicating that she is ineligible for the study, continue to administer this form so that all items are completed. Refrain from indicating to the participant the reason why she is not eligible. The interviewer should provide examples as needed in order for the participant to be able to provide an accurate response. Refer to the Study-specific Procedures Manual (SSP) for relevant examples.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN-021 (110)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Behavioral Eligibility

		yes	no
12.	In the past year (12 months) have you used a needle to inject drugs that were not prescribed to you by a medical professional?	☐	☐
13.	In the past 6 months, have you used post-exposure prophylaxis (PEP) for HIV exposure?	☐	☐
14.	In the past 30 days, have you had a gynecologic or genital procedure (e.g. tubal ligation, dilation, or curettage)? ..... *Note to interviewer: This does not include biopsy for the evaluation of an abnormal pap result or endometrial biopsy that occurred more than 7 days prior to Enrollment.*	☐	☐
15.	In the past 30 days, have you had an IUD replaced, or do you anticipate an IUD replacement within the next 6 months?	☐	☐
16.	In the past 3 months (90 days), have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated?	☐	☐
17.	Are you currently participating in any other research study involving drugs, medical devices, or vaginal products?	☐	☐

If yes to any of items 12–17, reassess at Enrollment for eligibility per the eligibility criteria.

Screening Behavioral Eligibility (Page 2)

General Information/Instructions: If the participant provides a response indicating that she is ineligible for the study, continue to administer this form so that all items are completed. Refrain from indicating to the participant the reason why she is not eligible. The interviewer should provide examples as needed in order for the participant to be able to provide an accurate response. Refer to the Study-specific Procedures Manual (SSP) for relevant examples.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN-021 (110)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Enrollment Behavioral Eligibility

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

To confirm your eligibility for the study, I need to ask you a few more questions.

		yes	no
1.	Have you ever had an adverse or bad reaction to either of the study products?	☐	☐
2.	Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)?	☐	☐
3.	Do you have a current male sex partner who has ever had an adverse or bad reaction to latex?	☐	☐
4.	In the past year (12 months) have you used a needle to inject drugs that were not prescribed to you by a medical professional?	☐	☐
5.	In the past 6 months, have you used post-exposure prophylaxis (PEP) for HIV exposure?	☐	☐
6.	In the past 30 days, have you had a gynecologic or genital procedure (e.g. tubal ligation, dilation or curettage)? *Note to interviewer: This does not include biopsy for the evaluation of an abnormal pap result or endometrial biopsy that occurred more than 7 days prior to Enrollment.*	☐	☐
7.	In the past 30 days, have you had an IUD inserted, or do you anticipate an IUD replacement within the next 6 months?	☐	☐
8.	In the past 30 days, have you participated in any other research study involving drugs, medical devices, or vaginal products? *Note to interviewer: This is not exclusionary if approval is granted by the PSRT and Protocol Chair.*	☐	☐
9.	In the past 3 months (90 days), have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated?	☐	☐
10.	Are you currently breastfeeding?	☐	☐
11.	In the next 6 months, do you plan to become pregnant?	☐	☐

If yes to any of the above, participant is ineligible.

		yes	no
12.	Throughout the duration of your study participation, if you engage in sexual activity during the study, are you willing to use male latex condoms provided by the study?	☐	☐
13.	Throughout the duration of your study participation, do you agree to not participate in other research studies involving drugs, medical devices, or vaginal products? *Note to interviewer: This is not exclusionary if approval is granted by the PSRT and Protocol Chair.*	☐	☐

If no to either of items 12–13, participant is ineligible.

Enrollment Behavioral Eligibility (Page 1)

Purpose: This interviewer-administered form is used to document/confirm the participant's behavioral eligibility for the study at the Enrollment Visit, prior to enrollment/randomization. Read all introductory statements and items aloud as they appear on the form. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

General Information/Instructions: If the participant provides a response indicating that she is ineligible for the study, continue to administer this form so that all items are completed. Refrain from indicating to the participant the reason why she is not eligible. The interviewer should provide examples as needed in order for the participant to be able to provide an accurate response. Refer to the Study Specific Procedures Manual (SSP) for relevant examples.

SAMPLE: DO NOT FAX TO DATAFAX **Not a DataFax form. Do not fax to DataFax.**

MTN-021 (110)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Enrollment Behavioral Eligibility

14. Throughout the duration of your study participation, are you able and willing to abstain from the use of vaginally-administered non-study products (other than tampons) and/or practices, such as douching? ..... *yes* ☐ *no* ☐

15. Throughout the duration of your study participation, if you engage in sexual activity, are you willing to continue to use one of the following types of birth control: hormonal contraceptives (except contraceptive vaginal rings) or an intrauterine device (IUD)? ..... *yes* ☐ *no* ☐
Note to interviewer: An IUD must be inserted at least 30 days prior to enrollment.

16. Are you willing and able to comply with all study procedure requirements? ..... *yes* ☐ *no* ☐

If no to any of items 14–16, participant is ineligible.

Enrollment Behavioral Eligibility (Page 2)

General Information/Instructions: If the participant provides a response indicating that she is ineligible for the study, continue to administer this form so that all items are completed. Refrain from indicating to the participant the reason why she is not eligible. The interviewer should provide examples as needed in order for the participant to be able to provide an accurate response. Refer to the Study Specific Procedures Manual (SSP) for relevant examples.