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

MTN007 (172)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Enrollment Visit Eligibility

Form Completion Date

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

dd *MMM* *yy*

I now need to ask you one more question regarding your study participation. There is no right or wrong answer, so please be as honest and as accurate as you can.

1. Do you agree to not participate in any other trials involving drugs, medical devices, or genital products while you are on this study? .....

yes	*no*
☐	☐

If no, participant is ineligible.

End of interview.

2. *Within the past 12 months, did the participant report a history of excessive daily alcohol use (as defined by the CDC as heavy drinking consisting of an average consumption of more than 2 drinks per day for men, and more than 1 drink per day for women), frequent binge drinking, or illicit drug use that includes any injection drugs, methamphetamines (crystal meth), heroin, or cocaine, including crack cocaine? .....*

yes	*no*
☐	☐

If yes, participant is ineligible.

Screening Consent (SC-1)

Purpose: This form is used to document that a participant provided written informed consent for screening for this study. This form must be completed for each participant who is assigned an MTN 007 Participant ID.

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

- **Visit Code:** There is no visit code field on this form because this form is only completed once at screening.
- ***Note****: If a participant is being re-screened, a new Screening Consent form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening, form completion and transmission procedures.*

Item-specific Instructions:

- **Item 1:** According to the protocol, a participant must be "≥ age of 18 at screening, verified per site SOP." Participants who are under 18 years should not be screened for the study.
- **Comments:** Record any necessary or additional information on the lines provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN007 (172) 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?..... [ ][ ] [ ][ ][ ] [ ][ ] → If unknown, record age: [ ][ ] *years*

dd *MMM* *yy*

male *female*

2. What is your gender?..... ☐ ☐

yes *no*

3. Do you consider yourself to be Latino/a or of Hispanic origin? ..... ☐ ☐

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 his/her Enrollment Visit.

- **Visit Code:** There is no visit code field on this form since this form is only administered once at screening.
- ***Note:*** *If a participant is being re-screened, a new Demographics form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening, form completion, and transmission procedures.*

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 his/her age. Do not complete both answers.
- **Item 2:** This item must be self-identified by the participant.
- **Item 3:** This item is based on self-definition. Per NIH policy, Latino/a 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, Latino/a is considered an ethnic group and not a race and should not be entered in item 4f.

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MTN007 (172)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Visit Eligibility

Form Completion Date

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

dd *MMM* *yy*

I am now going to ask some questions about you, your sexual behaviors, and your health. There are no right or wrong answers, so please be as honest and as accurate as you can. Some of the questions may seem personal, but please remember that all of your answers will be kept confidential.

		yes	no
1.	For this study, are you wiling and able to communicate in English?	☐	☐
2.	Are you available to return for all study visits, barring any unforeseen circumstances?	☐	☐
3.	Have you had consensual receptive anal intercourse at least once in the last year?	☐	☐
4.	Are you willing to abstain from receptive anal intercourse for the duration of study participation (approximately 4–8 weeks)?	☐	☐
5.	Are you willing to abstain from insertion of anything rectally, including sex toys, other than study gel, for the duration of study participation (approximately 4–8 weeks)?	☐	☐
6.	Do you agree to use study-provided condoms for the duration of the study for vaginal and insertive anal intercourse?	☐	☐
7.	Do you agree not to participate in any other trials involving drugs, medical devices, or genital products while you are in this study?	☐	☐

If no to any, participant is ineligible.

		yes	no
8.	Do you have any known HIV-infected partners?	☐	☐

If yes, participant is ineligible.

		yes	no
9.	Do you anticipate that you will use any of the following medications during the period of study participation:		
9a.	Heparin, including Lovenox?	☐	☐
9b.	Warfarin?	☐	☐
9c.	Plavix (clopidogrel bisulfate)?	☐	☐
9d.	Rectally administered medications (including over-the-counter products)?	☐	☐
9e.	Aspirin?	☐	☐
9f.	Non-steroidal anti-inflammatory drugs (NSAIDS)?	☐	☐
9g.	Any other drugs that are associated with increased likelihood of bleeding following mucosal biopsy?	☐	☐

Interviewer: *Provide examples of medicines, if needed.*

If yes to any, participant must be willing to abstain from use during study participation.

[ ][ ][X][ ] 08-SEP-10

/networks/hivnet/forms/MTN_007/forms/m007_nonDF_screen_elig.fm

[0][1] Language

Staff Initials / Date

Screening Visit Eligibility (non-DataFax) - Page 1

Purpose: This form is used to document the participant's eligibility at the Screening Visit.

General Information/Instructions: This is a mixed form—some of the items (items 1–16) are interviewer administered while some of the items (items 17–18) are not. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

- ***Note:*** *If a participant is being re-screened, a new Screening Visit Eligibility form must be completed as part of the subsequent screening attempt. See the Data Collection Section of the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion procedures.*

Item-specific Instructions:

- **Items 1–16:** If the participant provides a response indicating that he/she is ineligible for the study, continue to administer this form through item 16. Do not inform him/her that he/she is ineligible for the study until the form has been completely administered. Also, refrain from indicating to the participant the reason why he/she is ineligible, to prevent socially desirable reporting.
- **Items 9a–9f:** If the participant is unfamiliar with any medications listed, provide specific examples. For example, if a participant does not know what a non-steroidal anti-inflammatory drug (NSAID) is the interviewer could say, "for example, ibuprofen (such as Advil or Motrin) or naproxen (such as Aleve)." Any example of a NSAID is fine to mention.
- **Item 9g:** Please provide examples of medicines for this item.

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MTN007 (172)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Screening Visit Eligibility

10. Would you be willing to abstain from the following medications during the period of study participation:

	yes	no
10a. Heparin, including Lovenox?	☐	☐
10b. Warfarin?	☐	☐
10c. Plavix (clopidogrel bisulfate)?	☐	☐
10d. Rectally administered medications (including over-the-counter products)?	☐	☐
10e. Aspirin?	☐	☐
10f. Non-steroidal anti-inflammatory drugs (NSAIDS)?	☐	☐
10g. Any other drugs that are associated with increased likelihood of bleeding following mucosal biopsy?	☐	☐

Interviewer: *Provide examples of medicines, if needed.*

If no to any, participant is ineligible.

11. In the last 4 weeks, have you used any of the following:

	yes	no
11a. systemic immunomodulatory medications?	☐	☐
11b. rectally administered medications?	☐	☐
11c. rectally administered products (including condoms) that contain N-9?	☐	☐
11d. any investigational products?	☐	☐
11e. post-exposure prophylaxis for HIV exposure?	☐	☐

Interviewer: *Provide examples of medicines and/or products, if needed.*

If yes to any, schedule the Enrollment Visit at least 4 weeks after last use.

12. Would you be willing to abstain from use of the following during the period of study participation:

	yes	no
12a. systemic immunomodulatory medications?	☐	☐
12b. rectally administered medications?	☐	☐
12c. rectally administered products (including condoms) that contain N-9?	☐	☐
12d. Any investigational products?	☐	☐

Interviewer: *Provide examples of medicines and/or products, if needed.*

If no to any, participant is ineligible.

Screening Visit Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Items 10a–10f:** If the participant is unfamiliar with any medications listed, provide specific examples. For example, if a participant does not know what a non-steroidal anti-inflammatory drug (NSAID) is the interviewer could say, “for example, ibuprofen (such as Advil or Motrin) or naproxen (such as Aleve).” Any example of a NSAID is fine to mention.
- **Item 10g:** Please provide examples of medicines for this item.
- **Items 11a–11e:** Please provide examples of medicines for these items.
- **Items 12a–12d:** Please provide examples of medicines for these items.

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

MTN007 (172)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Screening Visit Eligibility

For female participants only.

13. Are you postmenopausal, meaning have you gone through menopause? ..... *yes* ☐ *no* ☐ → ***If yes, go to item 15.***

14. Are you using, or willing to use, an acceptable form of contraception for the duration of the study (acceptable forms of contraception include: barrier methods, IUD, hormonal contraception, surgical sterilization, or vasectomization of male partner)? ***Note: if the female participant has female partners only, this is an acceptable form of contraception (i.e., a barrier method).*** ..... *yes* ☐ *no* ☐ → ***If no, participant is ineligible.***

15. Are you currently breastfeeding? ..... ☐ ☐

16. Do you intend to breastfeed during study participation? ..... ☐ ☐ → ***If yes to either, participant is ineligible.***

Complete items 17 and 18 after the interview.

17. Was the subject willing and able to provide adequate locator information, as defined in the site SOP? ..... *yes* ☐ *no* ☐ → ***If no, participant is ineligible.***

For female participants of childbearing potential only.

18. Screening hCG pregnancy test result: ..... *negative* ☐ *positive* ☐ → ***If positive, participant is ineligible.***

Screening Visit Eligibility (non-DataFax) - Page 3

Item-specific Instructions:

- **Items 13–16:** These items are for female participants only. For male participants, leave these items blank.

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

MTN007 (172)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Enrollment Visit Eligibility

Form Completion Date

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

dd *MMM* *yy*

I now need to ask you one more question regarding your study participation. There is no right or wrong answer, so please be as honest and as accurate as you can.

1. Do you agree to not participant in any other trials involving drugs, medical devices, or genital products while you are on this study? .....

yes	*no*
☐	☐

If no, participant is ineligible.

End of interview.

2. *Within the past 12 months, did the participant report a history of excessive daily alcohol use (as defined by the CDC as heavy drinking consisting of an average consumption of more than 2 drinks per day for men, and more than 1 drink per day for women), frequent binge drinking, or illicit drug use that includes any injection drugs, methamphetamines (crystal meth), heroin, or cocaine, including crack cocaine? .....*

yes	*no*
☐	☐

If yes, participant is ineligible.

Enrollment Visit Eligibility (non-DataFax) - Page 1

Purpose: This form is used at the Enrollment Visit to document the participant's eligibility with regard to two eligibility criteria. This form is completed once, at the participant's Enrollment Visit.

General Information/Instructions: This is a mixed form—one item (item 1) is interviewer administered while item 2 is not. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

- ***Note:*** *If a participant is being re-screened, a new Enrollment Visit Eligibility form must be completed as part of the subsequent screening attempt. See the Data Collection Section of the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion procedures.*