SAMPLE: DO NOT FAX TO DATAFAX

MTN 012/IPM 010 (187) DEM-1 (001)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Demographics

Visit Date

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

dd *MMM* *yy*

1. What is your date of birth?..... [ ][ ] [ ][ ][ ] [ ][ ] → If unknown, record age: [ ][ ] *years*

dd *MMM* *yy*

male *female*

2. What is your gender? ..... [X] [ ]

NOT APPLICABLE FOR THIS PROTOCOL.

yes *no*

3. Do you consider yourself to be Latino 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 form is used to document participant demographic information.

General Information/Instructions: This form is completed only once for each study participant, at the Screening Visit.

- **Visit Code:** There is no visit code field on this form since this form is only completed once at the Screening Visit.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant's estimate of his age. Do not complete both answers.
- **Item 2:** This item does not require a response. This item (gender) has been hard-coded as "male" for all study participants.
- **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.

SAMPLE: DO NOT FAX TO DATAFAX

MTN 012/IPM 010 (187) ENR-1 (070)

Participant ID

___ - _____ - _

Site Number Participant Number Chk

Enrollment

1. Was the participant, based on all inclusion and exclusion criteria, eligible for the study? ..... *yes* ☐ *no* ☐ → ***If no, end of form.***

2. Date the informed consent form for enrollment was marked or signed: ..... __ ___ __ (*dd* *MMM* *yy*)

3. Was the participant able and willing to provide written informed consent for specimen storage and future research?..... *yes* ☐ *no* ☐ → ***If no, go to item 4.***

   3a. Date the informed consent form for specimen storage and future research was marked or signed: ..... __ ___ __ (*dd* *MMM* *yy*)

4. Randomization envelope number: ..... ___

   4a. Date assigned: ..... __ ___ __ (*dd* *MMM* *yy*)

   4b. Time assigned: ..... __ : __ *24-hour clock* (*hr* *min*)

   4c. Randomization code: ..... ___

5. Date product dispensed by pharmacy: ..... __ ___ __ (*dd* *MMM* *yy*)

6. Is this participant circumcised or uncircumcised? ..... *circumcised* ☐ *uncircumcised* ☐

Comments: _____

Enrollment (ENR-1)

Purpose: This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants determined to be eligible for the study.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant is enrolled (that is, he is assigned a randomization envelope), and only after completion of the Enrollment Visit.

- **Visit Code:** There is no visit code field on this form since this form is only completed once at the Enrollment Visit.

Item-specific Instructions:

- **Item 1:** If response to this item is "no" (the participant was not eligible for this study), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.
- **Item 2:** Record a complete date.
- **Item 3:** Mark "yes" only if the participant gave consent to have his lab specimens stored for future research testing.
- **Item 3a:** Record a complete date.
- **Item 4:** Record the 3-digit envelope number present on the randomization envelope assigned to this participant.
- **Item 4a:** Record the date the randomization envelope was assigned to the participant. This date should match the "date assigned" recorded for this envelope on the MTN-012/IPM 010 Randomization Envelope Tracking Record.
- **Item 4b:** Record the time the randomization envelope was assigned to the participant. Use a 24-hour clock to record time. For example, if the randomization envelope was opened at 2:24 p.m., record 14:24. This time should match the "time assigned" recorded for this envelope on the MTN-012/IPM 010 Randomization Envelope Tracking Record.
- **Item 4c:** Record the participant's randomization code present on the prescription.
- **Item 5:** Record the exact day, month, and year study product was dispensed to this participant.
- **Item 6:** This item is based on results from the Genital Exam. It is not based on participant self-report.

SAMPLE: DO NOT FAX TO DATAFAX

MTN 012/IPM 010 (187) ENR-2 (071)

Participant ID

___ - ___ - ___

Site Number Participant Number Chk

Enrollment

7. Did the participant complete the CASI Baseline Behavioral Questionnaire at this visit? ..... *yes* ☐ *no* ☐ → ***If no, specify in Comments, and go to item 8.***

7a. Date CASI Baseline Behavioral Questionnaire was completed: ..... ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

SPECIMEN STORAGE

Specimen Collection Date

dd *MMM* *yy*

☐☐ ☐☐☐ ☐☐

8. Plasma ..... *stored* ☐ *not stored* ☐ → *Reason:* _____

Comments: _____

_____

☐ ☐ ☐ ☒ 16-FEB-11

N:\hivnet\forms\MTN_012\forms\m012_ENR.fm

0 1 Language

_____ Staff Initials / Date

Enrollment (ENR-2)

Item-specific Instructions:

- **Item 7:** Completion of the CASI Baseline Behavioral Questionnaire is required for all participants at the Enrollment Visit. If the required questionnaire was not done, specify the reason on the Comments lines.
- **Item 8:** Record the date that the specimen was *collected* for this visit. A complete date is required.

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MTN 012/IPM 010 (187)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Enrollment Eligibility

Visit Date

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

dd *MMM* *yy*

		yes	*no*
1.	At Screening, is the participant at least 18 years of age?	☐	☐
2.	Is the participant able and willing to provide written informed consent to be screened for and take part in the study?	☐	☐
3.	At Screening, is the participant able and willing to provide adequate locator information, as defined in site SOP?	☐	☐
4.	Is the participant able and willing to communicate in written and spoken English?	☐	☐
5.	At Screening, is the participant HIV-uninfected per HIV Testing Algorithm in Appendix II?	☐	☐
6.	Is the participant in general good health, according to clinical judgment of the Investigator of Record or designee?	☐	☐

If any items 1–6 are marked "no," participant is ineligible.

Enrollment Eligibility (non-DataFax) Page 1 of 2

Purpose: This form is used to document the participant's administrative, clinical, and laboratory eligibility for the study at screening and enrollment. 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 Eligibility 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.

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

MTN 012/IPM 010 (187)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Enrollment Eligibility

7. Does the participant have any of the following laboratory abnormalities at Screening:

		yes	no
7a.	hemoglobin < 10.0 g/dL?	☐	☐
7b.	platelet count < 100,000/mm^3?	☐	☐
7c.	white blood cell count < 2,000 cells/mm^3?	☐	☐
7d.	alanine transaminase (ALT) and/or aspartate aminotransferase (AST) > 2.5x the site laboratory upper limit of normal (ULN)?	☐	☐
7e.	serum creatinine > 1.3 x the site laboratory ULN?	☐	☐
7f.	calculated creatinine clearance less than 80 mL/min by the Cockcroft-Gault formula for males?	☐	☐

Note: *Otherwise eligible participants with any of the above exclusionary laboratory results may be re-tested. If a participant is re-tested and a non-exclusionary result is documented within 30 days of providing informed consent for Screening, the participant may be enrolled.*

		yes	no
8.	At Screening or Enrollment, is the participant diagnosed with an STI or reproductive tract infection (RTI) requiring treatment, per current Centers for Disease Control and Prevention (CDC) guidelines?	☐	☐
9.	At Screening or Enrollment, does the participant have a clinically apparent Grade 1 or higher genital exam finding (observed by study staff)?	☐	☐
10.	At Screening or Enrollment, does the participant have any Grade 1 or higher genital or urinary symptoms?	☐	☐
11.	At Screening or Enrollment, is the participant diagnosed with phimosis or hypospadias?	☐	☐
12.	At Screening or Enrollment, are penile, scrotal piercing or penile tattoos observed during genital examination?	☐	☐
13.	Does the participant have any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?	☐	☐

If any items 7–13 are marked "yes," participant is ineligible.

Enrollment Eligibility (non-DataFax) Page 2 of 2

No additional instructions.

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

MTN 012/IPM 010 (187)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

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.	Are you willing to abstain from the following during study participation:		
1a.	vaginal intercourse, even with a condom?	☐	☐
1b.	oral intercourse, even with a condom?	☐	☐
1c.	anal intercourse (including receptive anal intercourse), even with a condom?	☐	☐
1d.	masturbation and other activities that may cause irritation or injury to the penis?	☐	☐
1e.	using genitally-applied preparations (except use of usual cleansing products for genital hygiene) other than the study product?	☐	☐
1f.	non-urgent surgical procedures of the penis/GU area?	☐	☐
2.	Do you agree not to participate in other research studies involving drugs, medical devices, or genital products for the duration of study participation (until all follow-up visits are complete)?	☐	☐

If any items 1–2 are marked "no," participant is ineligible.

Behavioral Eligibility (non-DataFax) Page 1 of 2

Purpose: This form is used to document the participant's behavioral eligibility for the study at screening and enrollment. 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 Behavioral Eligibility 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.

General Information/Instructions: If the participant provides a response indicating he is ineligible, continue to administer this form until all items are completed. Refrain from indicating to the participant the reason why he is ineligible.

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

MTN 012/IPM 010 (187)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number | Participant Number | Chk

Behavioral Eligibility

3. Do any of the following apply to you:

		yes	no	N/A
3a.	known adverse reaction to any of the study products or components of the study products (ever)?	☐	☐	
3b.	post-exposure prophylaxis (PEP) for HIV exposure within 6 months prior to Enrollment?	☐	☐	
3c.	penile procedures (e.g., biopsy, circumcision) within 42 days or less prior to Enrollment?	☐	☐	
3d.	participation in any other research studies involving drugs, medical devices, or genital products within 30 days prior to Enrollment?	☐	☐	
3e.	within 3 months prior to Enrollment, history of a non-gonococcal urethritis and/or sexually transmitted infection (STI), including outbreak of genital herpes or condylomata?	☐	☐	
3f.	for uncircumcised men, the treatment of candidal balanoposthitis/balanitis within 30 days prior to Enrollment?	☐	☐	☐
3g.	history of recurrent dermatosis (e.g., eczema)?	☐	☐	
3h.	non-therapeutic injection drug use within 12 months or less prior to Screening?	☐	☐	
3i.	currently using an immunosuppressant (with the exception of local non-genital use of low potency products e.g., inhaled corticosteroid for asthma)?	☐	☐	

If "yes," participant is ineligible.

Behavioral Eligibility (non-DataFax) Page 2 of 2

No additional instructions.