

Subject Case Report Forms

MTN025\_version 14.1\_02OCT2017 - ALL

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

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1. - What was this prior participant's ASPIRE PTID? \_\_\_\_\_

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2. - Was the participant contacted to participate in HOPE? Yes

No

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3. - Why was the ASPIRE participant not contacted to participate in HOPE? participant deceased during ASPIRE

participant HIV seroconverted during ASPIRE

participant was permanently discontinued from study product during ASPIRE

participant did not provide permission to be contacted for future studies

unable to reach participant

other

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3a. - If other, specify: \_\_\_\_\_

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4. - Did the participant conduct a screening visit for HOPE? Yes

No

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5. - Did the participant conduct a screening visit as part of the ...? Decliner population

MTN-025 main study

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**MTN025\_version 14.1\_02OCT2017: ALL**

**Form: Participant Date of Visit**

**Generated On: 02 Oct 2017 21:39:22**

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Date of Visit

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**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Eligibility Criteria - Decliner Population**  
**Generated On: 02 Oct 2017 21:39:22**

1. - Does this participant meet all eligibility criteria as part of the decliner population? Yes   
No

2. - Was the participant enrolled into the MTN-025 Decliner Population? Yes   
No

3. - Why was the participant not enrolled? Eligible, but participant did not complete all screening procedures   
Eligible, but participant declined enrollment   
Not eligible

Eligible, but participant declined enrollment, specify reason: \_\_\_\_\_

Reasons for ineligibility:

Record all that apply:

4a. - Not previously enrolled in MTN-020 (ASPIRE)

4b. - Unable/unwilling to provide written informed consent

4c. - Unable/unwilling to perform the Decliner Population study procedures

4d. - Did not decline MTN-025 (main) study trial participation

4e. - Other, including IoR discretion

4f. - Other, including IoR discretion specify: \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**

**Form: Enrollment – Decliner Population**

**Generated On: 02 Oct 2017 21:39:22**

1. - Date the participant marked or signed the study screening and enrollment MTN-025 Decliner Population consent form: \_\_\_\_\_

2. - Enrollment Date: \_\_\_\_\_

3. - Were all Decliner Population procedures completed on the Enrollment Date?

Yes

No

3a. - Date all Decliner Population procedures completed (if date is different than enrollment date): \_\_\_\_\_

MTN025\_version 14.1\_02OCT2017: ALL

Form: Eligibility Criteria

Generated On: 02 Oct 2017 21:39:22

Does this participant meet all eligibility criteria? Yes

No

Was the participant enrolled into HOPE? Yes

No

Why was the participant not enrolled? Eligible, but participant did not complete all screening procedures

Eligible, but participant declined enrollment

Not eligible

Eligible, but participant declined enrollment, specify reason: \_\_\_\_\_

Reasons for ineligibility:

Record all that apply:

Not previously enrolled in MTN-020 (ASPIRE)

Unable/unwilling to provide written informed consent

Unable/unwilling to provide adequate locator information

HIV infected at Screening or Enrollment

Declines effective method of contraception at Enrollment and for duration of study participation

Does not agree to not participate in other research studies for duration of study participation

Study product use permanently discontinued in response to AE or safety related concern with taking part in MTN-020 (ASPIRE) trial

Plans for relocation/travel per participant report at Screening

Grade 3 or higher Hemoglobin at Screening

Grade 3 or higher Pap results at Screening

Currently taking PEP at Enrollment

Participated in other research study involving drugs, medical devices, vaginal products, or vaccines within 60 days of Enrollment with the exception of MTN-020 (ASPIRE)

Pregnant at Screening/Enrollment or plans to become pregnant during study participation period

Currently breastfeeding

Diagnosed with UTI, PID, STI, or RTI which has not resolved or undergone complete treatment

Grade 3 pelvic exam finding at Screening or has not improved to non-exclusionary grading or resolved within 56 days or Screening

Grade 3 or higher AST/ALT at Screening

Grade 3 or higher Creatinine at Screening

Grade 3 or higher Platelet Count at Screening

Other, including IoR discretion

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**Form: Eligibility Criteria**

**Generated On: 02 Oct 2017 21:39:22**

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Other, including IoR discretion, Specify

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MTN025\_version 14.1\_02OCT2017: ALL

Form: Demographics

Generated On: 02 Oct 2017 21:39:22

Is this participant enrolled in MTN-025 or part of the Decliner Population? MTN-025 main study

Decliner Population

Sex Male

Female

Date of birth \_\_\_\_\_

Date of Birth Unknown

Age (Entered by Site) \_\_\_\_\_

Age \_\_\_\_\_

Age (Decliner population) \_\_\_\_\_

Is the participant currently married? Yes

No

Highest level of education No Schooling

Primary School, not complete

Primary school, complete

Secondary school, not complete

Secondary school complete

Attended college or university

Ethnic group or tribe Chewa

Lomwe

Yao

Tumbuka

Other African tribe

White

Zulu

Xhosa

Indian

Colored

Black

Shona

Ndebele

Other

If other, specify: \_\_\_\_\_

Number of alcohol drinks per week \_\_\_\_\_

Number of cigarettes per day \_\_\_\_\_

How long did it take the participant to travel from home to the clinic today? Less than 30 minutes

30-60 minutes

1-2 hours

Greater than 2 hours

\_\_\_\_\_ N/A

Does the participant earn an income of her own? Yes

No

How does she earn her income? Formal employment

Self-employment

Other

How many times has the participant been pregnant? \_\_\_\_\_

How many live births have the participant had? \_\_\_\_\_

Did the participant become pregnant since the end of ASPIRE? Yes

No

If yes, at the time of the pregnancy, was the participant taking Yes

any measures to avoid falling pregnant? No

What is the participant's religion? Christian

Muslim

Other

None

If Other religion, please specify: \_\_\_\_\_

How many times a week does the participant attend religious More than once a week

services? Once a week

Less than Once a week

Never

In the past four weeks, how often was the participant worried that Never

she will not have enough food? Rarely (Once or Twice)

Sometimes (3-10 times)

Often (More than 10 times)

Does the participant's household have: ...?

Electricity or solar panels Yes

No

A radio Yes

No

A cassette player Yes

No

A television Yes

No

A mobile telephone Yes

No

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Demographics**  
**Generated On: 02 Oct 2017 21:39:22**

A non-mobile telephone	Yes <input type="radio"/>
	No <input type="radio"/>
A refrigerator	Yes <input type="radio"/>
	No <input type="radio"/>
A table	Yes <input type="radio"/>
	No <input type="radio"/>
A sofa	Yes <input type="radio"/>
	No <input type="radio"/>
A bed	Yes <input type="radio"/>
	No <input type="radio"/>
A CD or digital music player	Yes <input type="radio"/>
	No <input type="radio"/>
A VCR/DVD player	Yes <input type="radio"/>
	No <input type="radio"/>
A car	Yes <input type="radio"/>
	No <input type="radio"/>
A motorcycle	Yes <input type="radio"/>
	No <input type="radio"/>
A bicycle	Yes <input type="radio"/>
	No <input type="radio"/>

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Baseline Medical History Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

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Does the participant have any medical history to report?

Yes

If 'Yes', complete the Baseline Medical History log.

No

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MTN025\_version 14.1\_02OCT2017: ALL

Form: Baseline Medical History

Generated On: 02 Oct 2017 21:39:22

Date medical history collected \_\_\_\_\_

Description of medical history condition/event \_\_\_\_\_

Is condition/event gradable? Yes

No

Toxicity (Severity) Grade Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially  
life-threatening)

Date medical condition/event started \_\_\_\_\_

Is the condition ongoing? Yes

No

Date medical condition/event ended/resolved \_\_\_\_\_

MTN025\_version 14.1\_02OCT2017: ALL

Form: Enrollment

Generated On: 02 Oct 2017 21:39:22

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1. - Date the participant marked or signed the study screening consent form \_\_\_\_\_

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2. - Date the participant marked or signed the study enrollment consent form \_\_\_\_\_

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3. - Did the participant agree to biological specimen and health data storage? Yes   
No   
Pending

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4. - HIV Status Positive   
Negative

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5. - Enrollment date \_\_\_\_\_

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**MTN025\_version 14.1\_02OCT2017: ALL**

**Form: Date of Visit**

**Generated On: 02 Oct 2017 21:39:22**

Did the participant complete this visit?

Yes

No

Visit Date: \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Follow-up Visit Summary**  
**Generated On: 02 Oct 2017 21:39:22**

Location of study visit: Clinic   
Home   
Other

If other, specify: \_\_\_\_\_

Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV? Yes   
No

Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV? Yes   
No

Was oral or topical PrEP used? Oral   
Topical   
Both

Is this an interim visit? Yes   
No

Reason for interim visit: (Mark all that apply)

AE report or follow-up

Return of ring or need for a new ring

Other

Other, specify: \_\_\_\_\_

Is this visit a PUEV, scheduled Study Exit Visit, or an early termination? Yes   
No

Visit type: PUEV   
Scheduled Termination   
Early Termination

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Behavior Assessment Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

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Was a Behavior Assessment questionnaire completed?

Yes

No

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Form: Behavior Assessment

Generated On: 02 Oct 2017 21:39:22

1. - At any time during the past three months, have you had a primary sex partner? By primary sex partner we mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main sex partner. Yes.   
No.

If no, please go to item 10.

2. - In the past 3 months, have you had vaginal sex with your primary sex partner? Yes.   
No.

3. - Does your primary sex partner know that you are taking part in this study? Yes.   
No.   
Not Sure.

4. - Does he know that you have been offered to use a vaginal ring as part of this study? Yes.   
No.   
Not Sure.

5. - Is your primary sex partner circumcised? By circumcised, we mean when the foreskin of the penis is removed/cut off. See visual aid. Yes.   
No.   
Don't Know.

6. - What is the HIV status of your primary sex partner? HIV positive.   
HIV negative.   
participant does not know

7. - Some people infected with the HIV virus are prescribed medications called antiretrovirals or ARVs by a doctor or nurse to help them live longer. Is your primary sex partner taking ARVs? Yes.   
No.   
Don't Know.

8. - In the past month, has your primary sex partner come to the study clinic? Yes.   
No.

If no, please go to item 9.

8a. - Did he come with you to the study clinic? Yes.   
No.

8b. - Did he receive counseling or other services from the study clinic? Yes.   
No.

8c. - Did he come to the study clinic for any other reason? Yes.   
No.

8c1. - .Specify: \_\_\_\_\_

9. - Have you had the same primary sex partner for the last three months? Yes.   
No.

10. - How many sex partners other than a primary sex partner have you had in the past 3 months? Fixed Unit: sex partners \_\_\_\_\_

11. - The next questions are about your relationship with your primary sex partner or any other partners. In the past 3 months, has your primary sex partner or ANY other current or previous partner ever: \_\_\_\_\_

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Form: Behavior Assessment

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11a. - Slapped you, hit you with a fist or something else, or beaten you? Yes.   
No.

12. - Kicked, dragged, pushed, pulled your hair, choked or burnt you? Yes.   
No.

13. - In the past 3 months, has your primary sex partner or ANY other current or previous partner ever forced you to have sex by holding you down or hurting you? Yes.   
No.

13a. - In the past 3 months, has anyone (not including current or past sexual partners) ever forced you to have sex by holding you down or hurting you? Yes.   
No.

14. - The next questions are about your sexual behavior in the past 7 days, not including today. In the past 7 days, how many acts of vaginal sex did you have? Fixed Unit: # of acts

The next questions are about your sexual behavior in the past 7 days, not including today. In the past 7 days, how many acts of vaginal sex did you have? Units # of acts

15. - I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex. In the past 7 days, during how many acts of vaginal sex was a male or female condom used? Fixed Unit: # of acts with a condom

The next questions are about your sexual behavior in the past 7 days, not including today. In the past 7 days, how many acts of vaginal sex did you have? Units # of acts with a condom

16. - During the last act of vaginal sex that you had, was a male and/or female condom used? Yes- Male Condom   
Yes- Female Condom   
Both.   
None.

17. - During the last act of vaginal sex that you had, was the vaginal ring in place? Yes.   
No.   
Not applicable.

18. - Does it bother you to wear the ring every day? Yes.   
No.   
Not applicable (hasn't used ring).

19. - At any time during the past 3 months, have you experienced a positive change, event, or experience in your life related to your study participation? Yes.   
No.

20. - At any time during the past 3 months, have you experienced a negative change, event, or experience in your life related to your study participation? Yes.   
No.

Complete Items 21-26 at PUEV or Early Termination Visit Only.

21. - How worried are you about having a vaginal ring inside of you every day for a year? very worried   
somewhat worried



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Form: Vaginal Practices Y/N

Generated On: 02 Oct 2017 21:39:22

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Was a Vaginal Practices questionnaire completed?

Yes

No

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1. - In the last 3 months, what have you used to control or manage the menstrual blood or spotting? NA

If NA, please go to paragraph above item 2.

1a. - Tissue, toilet paper, cloth or cotton wool put inside the vagina Yes.   
No.

1b. - Tissue, toilet paper, cloth or cotton wool placed in underwear/clothing Yes.   
No.

1c. - Tampon Yes.   
No.

1d. - Sanitary pad Yes.   
No.

1e. - Water without soap, inside the vagina Yes.   
No.

1f. - Water with soap, inside the vagina Yes.   
No.

1g. - Anything else? Yes.   
No.

1g1. - .Specify: \_\_\_\_\_

Please tell me about things you have put in your vagina in the last 3 months. These are things other than normal washing of the external vagina and other than to control or manage menses. Even though we ask women not to put certain things in the vagina while they are in the study, we know that this is not always possible. For example, things may be inserted inside the vagina to prepare for sex, to clean inside the vagina before or after sex, or to treat or heal the vagina. Please feel free to answer openly. I'll read a list and ask you to tell me what you used

2. - In the past 3 months, have you put any of the following inside your vagina?

2a. - Fingers, to clean or insert something Yes.   
No.

2b. - Traditional medicines Yes.   
No.

2c. - Anything to make the vagina dry or tight Yes.   
No.

2d. - Anything else? Yes.   
No.

2d1. - .Specify: \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Social Influences Assessment Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

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Was a Social Influences Assessment questionnaire completed?

Yes

No

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Form: Social Influences Assessment

Generated On: 02 Oct 2017 21:39:22

I would like to ask you some questions about people beside clinic staff who you talked to about the HOPE study.

1. - How many people in your life did you talk to about the HOPE study besides clinic staff? \_\_\_\_\_

Ask ALL items (2-6) starting first with Person 1 and THEN each subsequent person. Only complete items 2-6 for the number of people specified in Item 1. For example, if the participant indicates that she has only three people to whom she talked about HOPE, do not complete entries for Person 4 and Person 5. If more than 5 people are indicated, ask the participant to think of the five most important people to her among those reported in Item 1 and complete the following items.

2. - Person 1

2a. - What is your relationship with this person ?

Husband or primary partner

Sex partner other than primary partner

Mother

Father

Other family member

Someone you met during the study

Neighbor

Friend

Co-worker

Other

Other or other family member, specify: \_\_\_\_\_

2b. - Is this person male or female?

Male.

Female.

2c. - Did this person participate in HOPE?

Yes.

No.

Unknown.

2d. - How important to you is this person's view about the ring?

not important

a little important

very important

2e. - Overall, was this person in favour or against you using the ring?

in favour

against

neither (neutral)

N/A.

3. - Person 2

3a. - What is your relationship with this person?

Husband or primary partner

Sex partner other than primary partner

Mother

Father

Other family member

---

Someone you met during the study   
Neighbor   
Friend   
Co-worker   
Other

---

Other or other family member, specify: \_\_\_\_\_

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3b. - Is this person male or female? Male.   
Female.

---

3c. - Did this person participate in HOPE? Yes.   
No.   
Unknown.

---

3d. - How important to you is this person's view about the ring? not important   
a little important   
very important

---

3e. - Overall, was this person in favour or against you using the ring? in favour   
against   
neither (neutral)   
N/A.

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4. - Person 3

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4a. - What is your relationship with this person? Husband or primary partner   
Sex partner other than primary partner   
Mother   
Father   
Other family member   
Someone you met during the study   
Neighbor   
Friend   
Co-worker   
Other

---

Other or other family member, specify: \_\_\_\_\_

---

4b. - Is this person male or female? Male.   
Female.

---

4c. - Did this person participate in HOPE? Yes.   
No.   
Unknown.

---

4d. - How important to you is this person's view about the ring? not important



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	Someone you met during the study	<input type="radio"/>
	Neighbor	<input type="radio"/>
	Friend	<input type="radio"/>
	Co-worker	<input type="radio"/>
	Other	<input type="radio"/>

---

Other or other family member, specify \_\_\_\_\_

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6b. - Is this person male or female?	Male.	<input type="radio"/>
	Female.	<input type="radio"/>

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6c. - Did this person participate in HOPE?	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
	Unknown.	<input type="radio"/>

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6d. - How important to you is this person's view about the ring?	not important	<input type="radio"/>
	a little important	<input type="radio"/>
	very important	<input type="radio"/>

---

6e. - Overall, was this person in favour or against you using the ring?	in favour	<input type="radio"/>
	against	<input type="radio"/>
	neither (neutral)	<input type="radio"/>
	N/A.	<input type="radio"/>

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**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Study Exit Assessment Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

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Was a Study Exit Assessment completed?

Yes

No

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1. - During your participation in HOPE, did you attend any study organized group discussions, activities, or events that were not part of your usual scheduled study visit? (Interviewer to provide site-specific examples). Never.   
Once   
2 or more times

1a. - Did your partner attend any of these events with you? Never.   
Once   
2 or more times

2. - How many participants do you personally know in the HOPE study? \_\_\_\_\_  
Of these women, how many are:  
2a. - Friends you know from ASPIRE, before joining the HOPE study? \_\_\_\_\_  
2b. - Family members? \_\_\_\_\_  
2c. - Women you met through the HOPE study? \_\_\_\_\_  
2d. - Neighbours? \_\_\_\_\_  
2e. - .Other? \_\_\_\_\_  
.Other, specify: \_\_\_\_\_

The next questions are about your sexual behavior in the past 7 days, not including today.

3. - In the past 7 days, how many acts of vaginal sex did you have? Fixed Unit: # of acts  
\_\_\_\_\_

4. - I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex. In the past 7 days, during how many acts of vaginal sex was a male or female condom used? Fixed Unit: # of acts  
\_\_\_\_\_

5. - During the last act of vaginal sex that you had, was a male and/or female condom used? Yes- Male Condom   
Yes- Female Condom   
Both.   
None.

6. - I am going to read aloud some reasons why you may have disliked parts of the study or found them to be unsatisfactory. Please tell me which reasons apply to you.

a. - Waiting time at the clinic during your visits Yes.   
No.

b. - Having to return frequently to the clinic (every month or every three months) Yes.   
No.

c. - Having to keep the ring inserted all the time Yes.   
No.   
Not applicable.

d. - Having to keep the ring in during menses Yes.   
No.   
Not applicable.

e. - Having to keep the ring in during sex Yes.

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No.

Not applicable.

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f. - Having to use a contraceptive method throughout the study

Yes.

No.

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g. - Having your blood drawn

Yes.

No.

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h. - Having an HIV test done at all scheduled visits

Yes.

No.

---

i. - Having pelvic exams

Yes.

No.

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j. - Having to answer questions about your sexual behavior during the study

Yes.

No.

---

k. - Having to talk to a staff member about ring use

Yes.

No.

---

l. - Other.

Yes.

No.

---

.Other,specify: \_\_\_\_\_

---

7. - Were any of the rings dispensed to you ever used by someone else?

Yes.

No.

Not applicable.

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8. - In the future, if a vaginal ring similar to the one used in this study becomes widely available for HIV prevention, would you be interested in using it for HIV prevention?

Yes.

No.

Maybe.

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Form: Ring Adherence Y/N

Generated On: 02 Oct 2017 21:39:22

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Since the participant's last study visit, has she ever used a vaginal ring?

Yes

No

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Form: Ring Adherence

Generated On: 02 Oct 2017 21:39:22

1. - Did the participant disclose her ring use to her primary partner? Yes   
No   
Not applicable

2. - Since her last study visit, how many times in total has the participant had a vaginal ring out, excluding expected instances when a ring was briefly removed and replaced with a new ring? Fixed Unit: times

3. - How many of these times since the participant's last study visit was a vaginal ring out for more than 12 hours continuously? Fixed Unit: times

4. - Since the participant's last study visit, what is the longest number of days in a row the vaginal ring was out? Fixed Unit: days

5. - What are the reason(s) why the vaginal ring(s) were out?

Reason 1 \_\_\_\_\_

Reason 2 \_\_\_\_\_

Reason 3 \_\_\_\_\_

Reason 4 \_\_\_\_\_

Reason 5 \_\_\_\_\_

Reason 6 \_\_\_\_\_

Reason 7 \_\_\_\_\_

Other reason ring removed by participant or clinician, specify: \_\_\_\_\_

Other reason ring came out on its own, specify: \_\_\_\_\_

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Form: ACASI Tracking Y/N

Generated On: 02 Oct 2017 21:39:22

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Was an ACASI questionnaire completed at this visit?

Yes

No

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If no, please explain:

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Form: ACASI Tracking

Generated On: 02 Oct 2017 21:39:22

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ACASI collection date

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Which questionnaire was completed?

Baseline

Month 3

PUEV/Discontinuers

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Reason PUEV/Discontinuers ACASI questionnaire was completed:

scheduled PUEV

early termination

permanent product

discontinuation prior to

PUEV/early termination

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Were there any problems or issues related to the administration or completion of the questionnaire?

Yes

No

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If yes, please describe:

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Form: HIV Test Results

Generated On: 02 Oct 2017 21:39:22

Rapid HIV test 1 (Alere HIV Combo or backup)

Rapid HIV test 1 (Alere HIV Combo or backup) not done/not collected

Rapid HIV test 1 (Alere HIV Combo or backup) Kit

AlereTM HIV Combo

Oraquick ADVANCE HIV-1/2

Uni-GoldTM Recombigen® HIV-1/2

Not applicable

If not applicable, specify: \_\_\_\_\_

Rapid HIV test 1 (Alere HIV Combo or backup) collection date \_\_\_\_\_

Rapid HIV test 1 (Alere HIV Combo or backup)

Antibody positive

Antigen positive

Antibody and antigen positive

Negative

Rapid HIV test 2

Rapid HIV test 2 not done/not collected

Rapid HIV test 2 Kit

AlereTM HIV Combo

Oraquick ADVANCE HIV-1/2

Uni-GoldTM Recombigen® HIV-1/2

Not applicable

If not applicable, specify: \_\_\_\_\_

Rapid HIV test 2 collection date \_\_\_\_\_

Rapid HIV test 2

Positive

Negative

Geenius HIV-1/2 confirmatory test

Geenius HIV-1/2 confirmatory test not done/not collected

Geenius HIV-1/2 confirmatory test collection date \_\_\_\_\_

Geenius HIV-1/2 confirmatory test

HIV negative

HIV-1 indeterminate

HIV-2 indeterminate

HIV-1 positive

HIV-2 positive

HIV-2 positive with HIV-1-cross-reactivity

HIV positive undifferentiated (untypeable)

Plasma

Was plasma stored for HIV confirmatory testing? Yes

No

Not required

Plasma for HIV confirmatory testing collection date \_\_\_\_\_

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Form: HIV Test Results

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HIV RNA PCR

HIV RNA PCR not done/not collected

HIV RNA PCR collection date \_\_\_\_\_

HIV RNA PCR Fixed Unit: viral copies/mL

OR

Target not detected

HIV RNA PCR kit lower limit of detection

HIV RNA PCR kit Abbott M2000

Roche TaqMan

Gene Xpert

HIV RNA PCR kit lower limit of detection 20

40

OR

HIV RNA PCR kit lower limit of detection Fixed Unit: viral copies/mL

Absolute CD4+

Absolute CD4+ not done/not collected

Absolute CD4 collection date \_\_\_\_\_

Absolute CD4+ Fixed Unit: cells/mm<sup>3</sup>

Or

Unable to analyze

CD4 %

CD4 % not available

Or

CD4 % Fixed Unit: %

Final HIV status

Final HIV status HIV-1 and HIV-2 uninfected

HIV-1 infected

HIV-2 infected

HIV-1 and HIV-2 infected

pending

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Seroconverter Laboratory Results Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

---

Is the participant enrolled in MTN-015?

Yes

No

---

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Seroconverter Laboratory Results**  
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---

T CELL SUBSETS

---

T CELL SUBSETS not done/not collected

---

T CELL SUBSETS collection date \_\_\_\_\_

---

Absolute CD4+

---

Absolute CD4+ unable to analyze

---

Absolute CD4+ Fixed Unit: cells/mm3

---

CD4 %

---

CD4 % not available

---

CD4 % Fixed Unit: %

---

HIV RNA

---

HIV RNA PCR not done/not collected

---

HIV RNA PCR collection date \_\_\_\_\_

---

HIV RNA PCR Fixed Unit: viral copies/mL

---

HIV RNA PCR target not detected

---

HIV RNA PCR Kit Abbott M2000

Roche TaqMan

Gene Xpert

---

HIV RNA PCR Kit 20

Lower limit of detection 40

---

OR

---

HIV RNA PCR Kit Fixed Unit: viral copies/mL

Lower limit of detection

---

Seroconverter Plasma Storage

---

Seroconverter Plasma storage collection date \_\_\_\_\_

---

Seroconverter Plasma storage Stored

Not stored

---

Seroconverter Plasma storage reason not stored \_\_\_\_\_

---

MTN025\_version 14.1\_02OCT2017: ALL

Form: Pregnancy Test Result

Generated On: 02 Oct 2017 21:39:22

---

hCG for pregnancy

---

1. - hCG for pregnancy not done/not collected

---

1a. - Specimen collection date \_\_\_\_\_

---

1b. - hCG for pregnancy Positive   
Negative

---

First day of last menstrual period

---

2. - First day of last menstrual period \_\_\_\_\_

---

Or

---

2a. - amenorrheic for past 6 months   
no menses since participant's   
last visit

---

Last day of last menstrual period

---

3. - Last day of last menstrual period \_\_\_\_\_

---

Or

---

3a. - Ongoing

---

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Pregnancy Report and History**  
**Generated On: 02 Oct 2017 21:39:22**

1a. - First day of last menstrual period: \_\_\_\_\_

Or

1b. - Amenorrheic for past 6 months: \_\_\_\_\_

2. - Estimated date of delivery: \_\_\_\_\_

3. - What information was used to estimate the date of delivery?

3a. - Last menstrual period: \_\_\_\_\_ Yes

No

3b. - Initial ultrasound less than 20 weeks: \_\_\_\_\_ Yes

No

3c. - Initial ultrasound is greater than or equal to 20 weeks: \_\_\_\_\_ Yes

No

3d. - Physical Examination: \_\_\_\_\_ Yes

No

3e. - Conception date by assisted reproduction: \_\_\_\_\_ Yes

No

3f. - Other: \_\_\_\_\_ Yes

No

3f1. - Other, specify: \_\_\_\_\_

**Pregnancy History**

4. - Has the participant ever been pregnant before? \_\_\_\_\_ Yes

No

If No, end of form.

4a. - Is this the participant's first pregnancy since enrollment in this study? \_\_\_\_\_ Yes

No

If No, go to item 5.

4b. - Number of full term live births(  $\geq 37$  weeks): \_\_\_\_\_

4c. - Number of premature live births (less than 37 weeks): \_\_\_\_\_

4d. - Number of spontaneous fetal deaths and/or still births ( $\geq 20$  weeks): \_\_\_\_\_

4e. - Number of spontaneous abortions (less than 20 weeks): \_\_\_\_\_

4f. - Number of therapeutic/elective abortions: \_\_\_\_\_

4g. - Number of ectopic pregnancies: \_\_\_\_\_

5. - Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? \_\_\_\_\_ Yes

No

5a. - If yes, specify: \_\_\_\_\_

MTN025\_version 14.1\_02OCT2017: ALL

Form: Pregnancy Outcome Y/N

Generated On: 02 Oct 2017 21:39:22

---

Did this pregnancy have an obtainable outcome?

Yes

No

---

Outcome Number: \_\_\_\_\_

1. - How many pregnancy outcomes resulted from this reported pregnancy? \_\_\_\_\_

2. - Outcome Date: \_\_\_\_\_

3. - Place of delivery/outcome: Home   
Hospital   
Clinic   
Unknown   
Other

3a. - Other, specify: \_\_\_\_\_

4. - Specify outcome: Full term live birth ( $\geq$  37 weeks)   
Premature term live birth (<37 weeks)   
Stillbirth/intrauterine fetal demise ( $\geq$  20 weeks)   
Spontaneous abortion (< 20 weeks)   
Ectopic pregnancy   
Therapeutic/elective abortion   
Other

Other, specify: \_\_\_\_\_

4a1. - Method C-section   
Standard vaginal   
Operative Vaginal

5. - Provide a brief narrative of the circumstances: \_\_\_\_\_

6. - Were there any complications related to the pregnancy outcome? Yes   
No

6a. - Delivery-related complications  
Mark "none" or all that apply.

6a1. - None   
6a2. - Intrapartum hemorrhage   
6a3. - Postpartum hemorrhage   
6a4. - Non-reassuring fetal status   
6a5. - Chorioamnionitis   
6a6. - Other

Other, specify: \_\_\_\_\_

6b. - Non-delivery related complications  
Mark "none" or all that apply.

6b1. - None   
6b2. - Hypertensive disorders of pregnancy   
6b3. - Gestational diabetes

6b4. - Other

Other, specify: \_\_\_\_\_

7. - Were any fetal/infant congenital anomalies identified? Yes   
No   
Unknown

7a. - Congenital anomalies identified.  
Mark all that apply. Complete AE Log and EAE Reporting form.

7a1. - Central nervous system, cranio-facial

7a2. - Central nervous system, spinal

7a3. - Cardiovascular

7a4. - Renal

7a5. - Gastrointestinal

7a6. - Pulmonary

7a7. - Musculoskeletal/extremities

7a8. - Physical defect

7a9. - Skin

7a10. - Genitourinary

7a11. - Chromosomal

7a12. - Cranio-facial (structural)

7a13. - Hematologic

7a14. - Infectious

7a15. - Endocrine/metabolic

7a16. - Other

7b. - Specify congenital anomaly/defect AE \_\_\_\_\_

7c. - Describe the congenital anomaly/defect \_\_\_\_\_

Complete items 8-13 for live births only. Otherwise, end of form.

8. - Infant gender Male   
Female

9. - Infant birth weight Fixed Unit: kg

OR

Unavailable

10. - Infant birth length Fixed Unit: cm

OR

Unavailable

MTN025\_version 14.1\_02OCT2017: ALL

Form: Pregnancy Outcome

Generated On: 02 Oct 2017 21:39:22

11. - Infant birth head circumference Fixed Unit: cm

OR

Unavailable

12. - Infant birth abdominal circumference Fixed Unit: cm

OR

Unavailable

13. - Infant gestational age by examination in weeks Fixed Unit: Weeks

Infant gestational age by examination in days Fixed Unit: Days

OR

Unavailable

13a. - Method used to determine gestational age Ballard

Dubowitz

Other

13a1. - Other, specify:

MTN025\_version 14.1\_02OCT2017: ALL

Form: Specimen Storage

Generated On: 02 Oct 2017 21:39:22

Specimen type Hair

1a. - Hair for PK collection date \_\_\_\_\_

1b. - Hair for PK Stored   
Not stored

Reason hair collection/storage was not done

1c. - Reason hair collection was not done - Not required

1d. - Reason hair collection was not done - Unable to obtain hair sample

1d1 - Unable to obtain hair sample; specify reason: \_\_\_\_\_

1e. - Reason hair collection was not done - insufficient quantity of hair

1f. - Reason hair collection was not done - participant declined hair collection after counseling

1f1. - Participant declined hair collection after counseling; specify reason: \_\_\_\_\_

1g. - Reason hair collection was not done - other

1g1. - Other, specify reason: \_\_\_\_\_

Specimen type Vaginal Fluid Swab

2. - Self-Collected Vaginal Fluid Swab collection date: \_\_\_\_\_

2a. - Self-Collected Vaginal Fluid Swab Not Required   
Stored   
Not stored

2a1. - Self-Collected Vaginal Fluid Swab reason not stored: \_\_\_\_\_

2b. - Was blood visible on the swab? Yes   
No

2c. - Was a used ring in place at the time of swab collection? Yes   
No - ring removed prior to swab collection   
No - ring not in place at the start of visit   
No - new ring inserted prior to swab collection

Specimen type: Plasma

3. - Plasma Storage collection date: \_\_\_\_\_

3a. - Plasma Storage Not Required   
Stored   
Not stored

3a1. - Reason plasma not stored: \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**

**Form: Concomitant Medications Y/N**

**Generated On: 02 Oct 2017 21:39:22**

---

Is the participant taking any new concomitant medications that have not been previously reported or are there any updates to existing concomitant medications?

Yes

No

If 'Yes', please review or update the Concomitant Medications log.

---

MTN025\_version 14.1\_02OCT2017: ALL  
Form: Concomitant Medications  
Generated On: 02 Oct 2017 21:39:22

Medication Name \_\_\_\_\_  
Indication \_\_\_\_\_  
Date started \_\_\_\_\_  
Date stopped \_\_\_\_\_  
Continuing at end of study

Frequency PRN   
QD   
TID   
QID   
QHS   
ONCE   
BID   
Other

If other frequency, please specify: \_\_\_\_\_

Dose \_\_\_\_\_

Dose Units Grams   
Micrograms   
Milligrams   
Milliliters   
Capsules   
Drops   
Puffs   
Sachets   
Suppository   
Tablets   
Units   
Unknown   
Other

Other, specify: \_\_\_\_\_

Route PO   
IM   
IV   
TOP   
IHL   
VAG   
REC   
SC   
Other

If other route, please specify: \_\_\_\_\_

MTN025\_version 14.1\_02OCT2017: ALL

Form: Concomitant Medications

Generated On: 02 Oct 2017 21:39:22

If contraceptive, was it dispensed at research center? Yes

No

Taken for a reported AE? Yes

No

Applicable Adverse Event #1 \_\_\_\_\_

Applicable Adverse Event #2 \_\_\_\_\_

Applicable Adverse Event #3 \_\_\_\_\_

Applicable Adverse Event #4 \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**

**Form: Adverse Experience Y/N**

**Generated On: 02 Oct 2017 21:39:22**

---

Has the participant experienced any new adverse events or are there any updates to previously reported AEs?

Yes

No

If 'Yes', complete or update the Adverse Experience log.

---

MTN025\_version 14.1\_02OCT2017: ALL

Form: Adverse Experience

Generated On: 02 Oct 2017 21:39:22

Date reported to site \_\_\_\_\_

1. - Adverse Experience \_\_\_\_\_

2. - Onset Date \_\_\_\_\_

3. - Severity Grade

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Grade 5 (Death)

4. - Relationship to study product

Related

Not Related

5. - Study Product Administration

No change

Held

Permanently discontinued

N/A

6. - Status/Outcome

Continuing

Resolved

Death

Severity/frequency increased

Continuing at end of study participation

6a. - Status/Outcome Date \_\_\_\_\_

7. - Treatment

Mark "none" or all that apply.

7a. None

7b. - Medication(s)

7c. - New/prolonged hospitalization

Comment: \_\_\_\_\_

7d. - Procedure/Surgery

Comment: \_\_\_\_\_

7e. - Other

7e1. - Other, specify: \_\_\_\_\_

8. - Is this an SAE according to ICH guidelines? Yes

No

9. - Has/will this AE be reported as an EAE? Yes

No

10. - EAE Number \_\_\_\_\_

11. - Was this AE a worsening of a baseline medical condition? Yes

No

**MTN025\_version 14.1\_02OCT2017: ALL**

**Form: Adverse Experience**

**Generated On: 02 Oct 2017 21:39:22**

---

Comments:

---

---

MTN025\_version 14.1\_02OCT2017: ALL

Form: Laboratory Results

Generated On: 02 Oct 2017 21:39:22

Lab Name:

HEMOGRAM

Hemogram not done/not collected

Hemogram collection date

Hemoglobin

Not reported

Hemoglobin

Severity grade

- Grade 1 - Mild
- Grade 2 - Moderate
- Grade 3 - Severe
- Grade 4 - Potentially life-threatening
- Not gradable

Hemoglobin Adverse event

Hematocrit

Not reported

Hematocrit

MCV

Not reported

MCV

Platelets

Not reported

Platelets

Severity grade

- Grade 1 - Mild
- Grade 2 - Moderate
- Grade 3 - Severe
- Grade 4 - Potentially life-threatening
- Not gradable

Platelets Adverse event

WBC

Not reported

WBC

Severity grade

- Grade 1 - Mild
- Grade 2 - Moderate
- Grade 3 - Severe
- Grade 4 - Potentially life-threatening
- Not gradable

WBC Adverse event

DIFFERENTIAL

Lab Name: \_\_\_\_\_

Differential not done/not collected

Neutrophils

Not reported

Neutrophils

Severity grade

Grade 1 - Mild

Grade 2 - Moderate

Grade 3 - Severe

Grade 4 - Potentially  
life-threatening

Not gradable

Neutrophils Adverse event

Lymphocytes

Not reported

Lymphocytes

Severity grade

Grade 1 - Mild

Grade 2 - Moderate

Grade 3 - Severe

Grade 4 - Potentially  
life-threatening

Not gradable

Lymphocytes Adverse event

Monocytes

Not reported

Monocytes

Eosinophils

Not reported

Eosinophils

Basophils

Not reported

Basophils

SERUM CHEMISTRIES

Serum Chemistries not done/not collected

Serum Chemistries collection date

AST (SGOT)

Not reported

AST(SGOT)

Severity grade

Grade 1 - Mild

Grade 2 - Moderate

Grade 3 - Severe

Lab Name: \_\_\_\_\_

Grade 4 – Potentially life-threatening   
Not gradable

AST Adverse event \_\_\_\_\_

ALT (SGPT) \_\_\_\_\_

Not reported

ALT(SGPT) \_\_\_\_\_

Severity grade \_\_\_\_\_

Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

ALT Adverse event \_\_\_\_\_

Creatinine \_\_\_\_\_

Not reported

Creatinine \_\_\_\_\_

Severity grade \_\_\_\_\_

Grade 1 – Mild   
Grade 2 – Moderate   
Grade 3 – Severe   
Grade 4 – Potentially life-threatening   
Not gradable

Creatinine Adverse event \_\_\_\_\_

MTN025\_version 14.1\_02OCT2017: ALL

Form: STI Test Results

Generated On: 02 Oct 2017 21:39:22

---

Syphilis Serology

---

Syphilis Serology not done/not collected

---

Syphilis Serology collection date \_\_\_\_\_

---

Syphilis screening test Non-reactive   
reactive

---

Syphilis titer \_\_\_\_\_

---

Syphilis confirmatory test Negative   
Positive   
Indeterminate

---

Trichomonas Rapid Test

---

Trichomonas Rapid Test Not done/not collected

---

Trichomonas Rapid Test Collection date \_\_\_\_\_

---

Trichomonas Rapid Test Positive   
Negative

---

N. gonorrhoeae

---

N. gonorrhoeae not done/not collected

---

N. gonorrhoeae collection date \_\_\_\_\_

---

N. gonorrhoeae Positive   
Negative

---

C. trachomatis

---

C. trachomatis not done/not collected

---

C. trachomatis collection date \_\_\_\_\_

---

C. trachomatis Positive   
Negative

---

Exam Date \_\_\_\_\_

For items 1-11:

For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in the text field provided. If not evaluated, select "Not done".

1. - General appearance Not Done   
Normal   
Abnormal

If abnormal, specify: \_\_\_\_\_

2. - Abdomen/ Gastrointestinal Not Done   
Normal   
Abnormal

If abnormal, specify: \_\_\_\_\_

3. - Neck Not Done   
Normal   
Abnormal

If abnormal, specify: \_\_\_\_\_

4. - Lymph Nodes Not Done   
Normal   
Abnormal

If abnormal, specify: \_\_\_\_\_

5. - Heart/Cardiovascular Not Done   
Normal   
Abnormal

If abnormal, specify: \_\_\_\_\_

6. - Lungs/Respiratory Not Done   
Normal   
Abnormal

If abnormal, specify: \_\_\_\_\_

7. - Extremities Not Done   
Normal   
Abnormal

If abnormal, specify: \_\_\_\_\_

8. - Neurological Not Done   
Normal   
Abnormal

If abnormal, specify: \_\_\_\_\_

9. - Skin Not Done   
Normal   
Abnormal

---

If abnormal, specify: \_\_\_\_\_

10. - Eyes Not Done   
Normal   
Abnormal

---

If abnormal, specify: \_\_\_\_\_

11. - Ears, Nose, Throat Not Done   
Normal   
Abnormal

---

If abnormal, specify: \_\_\_\_\_

12. - Other Not Done   
Normal   
Abnormal

---

If other is abnormal, please specify the finding: \_\_\_\_\_

---

MTN025\_version 14.1\_02OCT2017: ALL

Form: Vital Signs

Generated On: 02 Oct 2017 21:39:22

---

Exam date	
1. - Weight	Fixed Unit: kg
2. - Body Temperature	Fixed Unit: C
3. - Systolic BP	Fixed Unit: mmHg
4. - Diastolic BP	Fixed Unit: mmHg
5. - Pulse	Fixed Unit: beats per minute
6. - Respirations	Fixed Unit: breaths per minute
7. - Height	Fixed Unit: cm

---

MTN025\_version 14.1\_02OCT2017: ALL

Form: Pelvic Exam

Generated On: 02 Oct 2017 21:39:22

---

Exam date \_\_\_\_\_

---

Pelvic exam assessment \_\_\_\_\_

Not Done

Abnormal findings

No abnormal findings

---

Abnormal findings. Mark all that apply.

VULVAR

---

vulvar edema

---

vulvar erythema

---

vulvar rash

---

vulvar tenderness

---

Bartholin's or Skene's gland abnormality

---

Vulvar lesions

---

ulcer

---

blister

---

pustule

---

peeling

---

ecchymosis

---

VAGINAL

---

vaginal edema

---

vaginal erythema

---

vaginal masses (polyps, myomas, possible malignancy)

---

vaginal abrasions or lacerations

---

vaginal tenderness

---

Abnormal vaginal discharge

---

slight

---

moderate

---

pooling

---

Vaginal lesions

---

ulcer

---

blister

---

pustule

---

peeling

---

ecchymosis

---

CERVICAL

---

cervical edema and/or friability

---

MTN025\_version 14.1\_02OCT2017: ALL

Form: Pelvic Exam

Generated On: 02 Oct 2017 21:39:22

cervical erythema	<input type="checkbox"/>
cervical masses (polyps, myomas, possible malignancy)	<input type="checkbox"/>
cervical motion tenderness	<input type="checkbox"/>
cervical discharge	<input type="checkbox"/>
Cervical lesions	
ulcer	<input type="checkbox"/>
blister	<input type="checkbox"/>
pustule	<input type="checkbox"/>
peeling	<input type="checkbox"/>
ecchymosis	<input type="checkbox"/>
GENERAL/OTHER	
odor (vaginal)	<input type="checkbox"/>
condyloma	<input type="checkbox"/>
condyloma, specify location: _____	
adnexal masses (based on bimanual exam; not pregnancy or infection-related)	<input type="checkbox"/>
uterine masses (based on bimanual exam)	<input type="checkbox"/>
uterine tenderness	<input type="checkbox"/>
adnexal tenderness	<input type="checkbox"/>
abnormal blood or bleeding	<input type="checkbox"/>
abnormal blood or bleeding; describe: _____	
Other abnormal findings	<input type="checkbox"/>
Other abnormal findings, specify (include anatomical location): _____	
Were any new pelvic finding AEs reported at this visit?	Yes <input type="radio"/>
	No <input type="radio"/>
Adverse event	_____
Adverse event	_____
Adverse event	_____
Cervical ectopy:	0% <input type="radio"/>
	1-25% <input type="radio"/>
	26-50% <input type="radio"/>
	51-75% <input type="radio"/>
	76-100% <input type="radio"/>

Date of completion: \_\_\_\_\_

What method(s) of contraception/family planning is the participant currently using?

Family Planning/Contraception Method:

- Spermicide
- Sponge
- Oral contraceptive birth control pills
- (Ortho Evra) – The Patch
- Implants
- Female Condoms
- Male Condoms
- Sterilization (tubal ligation/hysterectomy/laparoscopy/ other surgical procedure that causes sterilization)
- Diaphragm
- Intrauterine Device (IUD)
- Injectable contraceptive – Depo
- Injectable contraceptive – NET-EN
- Injectable contraceptive – Cyclofem
- Injectable contraceptive – Other
- Natural methods such as the withdrawal or rhythm method
- Sex with partner who had vasectomy
- Emergency contraception
- Other, specify

Other, specify: \_\_\_\_\_

Date Regimen Started: \_\_\_\_\_

Ongoing:

Date Regimen Stopped: \_\_\_\_\_

Reason(s) for changing or stopping the family planning method

Interested in long-acting reversible contraception (LARC) \_\_\_\_\_

Bleeding concerns

Specify the type of vaginal bleeding (select all that apply):

Heavy bleeding

Prolonged bleeding

Intermittent bleeding (e.g., spotting)

Less bleeding/no bleeding (e.g., no menses)

Break from hormones

Difficulty with adherence

Weight gain

Interested in getting pregnant

Became pregnant

Contraceptive choice not available

Bothered by pain

Partner objection

Medical contraindication

Specify: \_\_\_\_\_

Other reason

Specify: \_\_\_\_\_

No reason provided

COMPLETE AT ENROLLMENT ONLY Yes

Is this the same family planning method that the participant used at her last visit in ASPIRE? No

If yes, was there a break in use of this method for more than 1 month? Yes

No

Reason(s) for changing or stopping the family planning method the participant used at her last ASPIRE visit: (mark all that apply)

Interested in long-acting reversible contraception (LARC)

Bleeding concerns

Specify the type of vaginal bleeding (select all that apply):

Heavy bleeding

Prolonged bleeding

Intermittent bleeding (e.g., spotting)

Less bleeding/no bleeding (e.g., no menses)

Break from hormones

Difficulty with adherence

Weight gain

Interested in getting pregnant

Became pregnant

Contraceptive choice not available

Bothered by pain

Partner objection

Medical contraindication

Specify: \_\_\_\_\_

Other reason

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Family Planning**  
**Generated On: 02 Oct 2017 21:39:22**

---

Specify: \_\_\_\_\_

---

No reason provided

---

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Baseline Behavior Assessment Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

---

Was a Baseline Behavior Assessment questionnaire completed?

Yes

No

---

MTN025\_version 14.1\_02OCT2017: ALL

Form: Baseline Behavior Assessment

Generated On: 02 Oct 2017 21:39:22

Is this participant enrolled in MTN-025 or taking part of the Decliner Population? MTN-025 main study   
Decliner Population

1. - At any time during the past three months, have you had a primary sex partner? By primary sex partner we mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main sex partner. Yes.   
No.

2. - Is your primary sex partner the same partner you had when you exited ASPIRE? Yes.   
No.

3. - How old is your primary sex partner? Fixed Unit: Years

OR

3a. - Don't know (primary sex partner's age)

4. - Are you currently living with your primary sex partner? Yes.   
No.

5. - Does your primary sex partner provide you with financial and/or material support? Yes.   
No.

6. - Does your primary sex partner know that you have been offered to take part in this study? Yes.   
No.   
Not Sure.

7. - Does he know that you have been offered to use a vaginal ring as part of this study? Yes.   
No.   
Not Sure.

8. - Is your primary sex partner circumcised? By circumcised, we mean when the foreskin of the penis is removed/cut off. See visual aid. Yes.   
No.   
Don't Know.

9. - What is the HIV status of your primary sex partner? HIV positive.   
HIV negative.   
participant does not know

10. - Some people infected with the HIV virus are prescribed medications called antiretrovirals or ARVs by a doctor or nurse to help them live longer. Is your primary sex partner taking ARVs? Yes.   
No.   
Don't Know.

11. - In the past month, has your primary sex partner come to the study clinic? Yes.   
No.

11a. - Did he come with you to the study clinic? Yes.   
No.

11b. - Did he receive counseling or other services from the study clinic? Yes.   
No.

MTN025\_version 14.1\_02OCT2017: ALL

Form: Baseline Behavior Assessment

Generated On: 02 Oct 2017 21:39:22

11c. - Did he come to the study clinic for any other reason? Yes.   
No.

11c1. - .Specify:

12. - Have you had the same primary sex partner for the last 3 months? Yes.   
No.

13. - How many sex partners other than a primary sex partner have you had in the past 3 months? Fixed Unit: sex partners

14. - The next questions are about your relationship with your primary sex partner or any other partners. In the past 12 months, has your primary sex partner or ANY other current or previous partner ever:

14a. - Slapped you, hit you with a fist or something else, or beaten you? Yes.   
No.

14b. - Kicked, dragged, pushed, pulled your hair, choked or burnt you? Yes.   
No.

15. - In the past 12 months, has your primary sex partner or ANY other current or previous partner ever forced you to have sex by holding you down or hurting you? Yes.   
No.

15a. - In the past 12 months, has anyone (not including current or past sexual partners) ever forced you to have sex by holding you down or hurting you? Yes.   
No.

Now I am going to ask you some questions about your sexual behavior.

16. - In the past 3 months, how many times in total have you had vaginal sex? Fixed Unit: # of times

17. - The next questions are about your sexual behavior in the past 7 days, not including today. In the past 7 days, how many acts of vaginal sex did you have? Fixed Unit: # of acts

18. - I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex. In the past 7 days, during how many acts of vaginal sex was a male or female condom used? Fixed Unit: # of acts with a condom

19. - During the last act of vaginal sex that you had, was a male and/or female condom used? Yes- Male Condom   
Yes- Female Condom   
Both.   
None.

20. - In the past three months, how many times have you had anal sex? By anal sex, I mean when a man puts his penis inside your anus. Fixed Unit: # of times

21. - During the last act of anal sex that you had, was a male condom used? Yes.   
No.

The next questions are about HIV.

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Form: Baseline Behavior Assessment

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22. - In the past 12 months, was getting HIV something you have...  
never thought about   
rarely thought about   
thought about often

23. - How worried are you that you might get HIV in the next 12 months?  
very worried   
somewhat worried   
not at all worried

24. - How likely is it that you will become infected with HIV in the next 12 months?  
very unlikely   
somewhat likely   
very likely

25. - How certain do you feel that you can protect yourself from getting infected with HIV?  
very uncertain   
somewhat certain   
very certain

Now I am going to ask you some questions about the vaginal ring.

26. - How worried are you about having a vaginal ring inside of you every day for a year?  
very worried   
somewhat worried   
not at all worried

27. - How much protection do you feel that the Dapivirine ring can provide against HIV?  
the ring can provide a little protection   
the ring can provide some protection   
the ring can provide a lot of protection

[HOPE DECLINER GROUP ONLY]

[IF PARTICIPANT IS ENROLLED IN HOPE, GO TO ITEM 30]

I am going to read aloud a list of reasons why women may choose not to participate in HOPE. Please tell me all of the reason(s) that apply to you

28a. - You are not at risk for HIV  
Yes.   
No.

28b. - It does not matter to you if you get HIV  
Yes.   
No.

28c. - You are worried that the ring will harm your health  
Yes.   
No.

28d. - The ring is not as good at preventing HIV as you thought  
Yes.   
No.

28e. - You are worried people will think you are HIV positive  
Yes.   
No.

28f. - You want to avoid side effects you experienced in ASPIRE  
Yes.   
No.

28g. - You want to avoid side effects that you heard about in ASPIRE  
Yes.

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	No.	<input type="radio"/>
28h. - Waiting time at the clinic	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28i. - Having to return to the clinic frequently	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28j. - Having to keep the ring inserted all the time	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28k. - Having to keep the ring in during menses	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28l. - Having to keep the ring in during sex	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28m. - You or your partner want to get pregnant	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28n. - Having blood draws or other clinical procedures	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28o. - Having to answer questions about your behavior during the study	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28p. - Partner not supportive of study participation	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28q. - Family not supportive of study participation	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28r. - Other.	Yes.	<input type="radio"/>
	No.	<input type="radio"/>
28r1. - Other, specify.		
29. - What is the main reason that you are not willing to participate in HOPE?	a. You are not at risk for HIV	<input type="radio"/>
	b. It does not matter to you if you get HIV	<input type="radio"/>
	c. You are worried that the ring will harm your health	<input type="radio"/>
	d. The ring is not as good at preventing HIV as you thought	<input type="radio"/>
	e. You are worried people will think you are HIV positive	<input type="radio"/>
	f. You want to avoid side effects you experienced in ASPIRE	<input type="radio"/>
	g. You want to avoid side effects that you heard about in ASPIRE	<input type="radio"/>
	h. Waiting time at the clinic	<input type="radio"/>
	i. Having to return to the clinic frequently	<input type="radio"/>
	j. Having to keep the ring inserted all the time	<input type="radio"/>

- k. Having to keep the ring in during menses
- l. Having to keep the ring in during sex
- m. You or your partner want to get pregnant
- n. Having blood draws or other clinical procedures
- o. Having to answer questions about your behavior during the study
- p. Partner not supportive of study participation
- q. Family not supportive of study participation
- r. Other

I am going to read aloud a list of reasons why women may choose to participate in HOPE. Please tell me all of the reason(s) that apply to you.

30a. - To get tested for HIV Yes.   
No.

30b. - To get counseling on reducing risk of HIV and STIs Yes.   
No.

30c. - To help the community/to help fight the HIV epidemic Yes.   
No.

30d. - Because the ring can protect you against HIV Yes.   
No.

30e. - To make it safer for you to have sex without condoms Yes.   
No.

30f. - Because this is the only or best way for you to get health care Yes.   
No.

30g. - . Because you have friends who will probably participate in HOPE Yes.   
No.

30h. - Because you feel taken care of by the study staff Yes.   
No.

30i. - Because being in the study allows you to join social events at the clinic Yes.   
No.

30j. - Because being in the study helps you feel better about yourself Yes.   
No.

30k. - Because your study visits give you someone to talk to Yes.   
No.

30l - Because the study visit reimbursement money is helpful Yes.

---

No.

30m. - Other. Yes.

No.

---

30m1. - Other, specify. \_\_\_\_\_

31. - What is the main reason that you are willing to participate in HOPE? a. To get tested for HIV

b. To get counseling on reducing risk of HIV and STIs

c. To help the community/to help fight the HIV epidemic

d. Because the ring can protect you against HIV

e. To make it safer for you to have sex without condoms

f. Because this is the only or best way for you to get health care

g. Because you have friends who will probably participate in HOPE

h. Because you feel taken care of by the study staff

i. Because being in the study allows you to join social events at the clinic

j. Because being in the study helps you feel better about yourself

k. Because your study visits give you someone to talk to

l. Because the study visit reimbursement money is helpful

m. Other

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Baseline Vaginal Practices Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

---

Was a Baseline Vaginal Practices questionnaire done?

Yes

No

---

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Form: Baseline Vaginal Practices

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1. - In the last 3 months, have you had any menstrual bleeding or spotting? Yes.   
No.

In the last 3 months, what have you used to control or manage the menstrual blood or spotting?

2a. - Tissue, toilet paper, cloth or cotton wool put inside the vagina Yes.   
No.

2b. - Tissue, toilet paper, cloth or cotton wool placed in underwear/clothing Yes.   
No.

2c. - Tampon Yes.   
No.

2d. - Sanitary pad Yes.   
No.

2e. - Water without soap, inside the vagina Yes.   
No.

2f. - Water with soap, inside the vagina Yes.   
No.

2g. - Anything else? Yes.   
No.

2g1. - Anything else? Specify: \_\_\_\_\_

Please tell me about things you have put in your vagina in the last 3 months. These are things other than normal washing of the external vagina and other than to control or manage menses. Even though we ask women not to put certain things in the vagina while they are in the study, we know that this is not always possible. For example, things may be inserted inside the vagina to prepare for sex, to clean inside the vagina before or after sex, or to treat or heal the vagina. Please feel free to answer openly. I'll read a list and ask you to tell me what you used.

3. - In the past 3 months, have you put any of the following inside your vagina?

3a. - Fingers, to clean or insert something Yes.   
No.

3b. - Traditional medicines Yes.   
No.

3c. - Anything to make the vagina dry or tight Yes.   
No.

3d. - Anything else? Yes.   
No.

Anything else? Specify: \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Ring Collection and Insertion**  
**Generated On: 02 Oct 2017 21:39:22**

RING COLLECTION

If this is the Enrollment Visit, skip to item 3.

1. - Did the participant have a ring in place at the start of the visit? Yes   
No

1a. - Ring code for ring in place at start of visit: \_\_\_\_\_

1b. - When was a ring last in place? \_\_\_\_\_

1b1. - N/A (ring was not in place since last visit)

2. - Was a used or unused ring(s) collected, or expected to be collected, at this visit? Yes   
No

RING CHOICE

3. - Did the participant choose to use a new ring at this visit? Yes   
No   
Not applicable

4. - Did the participant accept to receive the ring(s) on a quarterly schedule? Yes   
No

4a. - If no, specify reason: \_\_\_\_\_

5. - What are the reasons that the participant opted to not use the ring at this visit? Mark all that apply and then end of form.

5a. - Participant undecided/not ready

5b. - Participant not interested

5c. - Ring less effective than participant wants

5d. - Side effects

Specify: \_\_\_\_\_

5e. - Participant intends to fall pregnant

5f. - Partner unsupportive or dislikes ring

5g. - Family or relative unsupportive ring

5h. - Participant prefers alternative HIV prevention method

5i. - Other

Other, specify: \_\_\_\_\_

RING PROVISION

6. - Was a ring provided at this visit? Yes   
No

6a. - Reason ring not provided: Participant on clinical hold

Participant has been permanently discontinued from product

Participant declined study ring

Scheduled PUEV

---

Early Termination

Other

---

Other, specify: \_\_\_\_\_

---

7. - Was a new ring inserted at this visit? Yes

No

---

7a. - Ring code of ring inserted: \_\_\_\_\_

7b. - Who inserted the new ring? Participant

Study Staff

---

8. - Was a ring in place at the end of the visit? Yes

No

---

8a. - Reason ring not in place at end of visit: Participant declined to have ring inserted at clinic visit

Participant had to leave before ring could be inserted

Other

---

Other, specify: \_\_\_\_\_

---

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Pharmacy Ring Dispensation**  
**Generated On: 02 Oct 2017 21:39:22**

Date vaginal ring(s) dispensed: \_\_\_\_\_

How many vaginal rings were dispensed at this visit? 1   
2   
3

Complete the ring code and lot number for each ring dispensed.

Vaginal Ring #1

Ring code: \_\_\_\_\_

Lot number: \_\_\_\_\_

Vaginal Ring #2

Ring code: \_\_\_\_\_

Lot number: \_\_\_\_\_

Vaginal Ring #3

Ring code: \_\_\_\_\_

Lot number: \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Additional Study Procedures Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

ACASI Tracking	Yes <input type="radio"/>	No <input type="radio"/>
Pelvic Exam	Yes <input type="radio"/>	No <input type="radio"/>
Physical Exam	Yes <input type="radio"/>	No <input type="radio"/>
Vital Signs	Yes <input type="radio"/>	No <input type="radio"/>
STI Test Results	Yes <input type="radio"/>	No <input type="radio"/>
Seroconverter Laboratory Results	Yes <input type="radio"/>	No <input type="radio"/>
HIV Test Results	Yes <input type="radio"/>	No <input type="radio"/>
Specimen Storage	Yes <input type="radio"/>	No <input type="radio"/>
Pregnancy Report and History	Yes <input type="radio"/>	No <input type="radio"/>
Participant Receipt	Yes <input type="radio"/>	No <input type="radio"/>
Participant Transfer	Yes <input type="radio"/>	No <input type="radio"/>
Pregnancy Outcome	Yes <input type="radio"/>	No <input type="radio"/>
Laboratory Results	Yes <input type="radio"/>	No <input type="radio"/>
Behavior Assessment	Yes <input type="radio"/>	No <input type="radio"/>
Vaginal Practices	Yes <input type="radio"/>	No <input type="radio"/>
Social Influences Assessment	Yes <input type="radio"/>	No <input type="radio"/>
Study Exit Assessment	Yes <input type="radio"/>	No <input type="radio"/>
Social Influences Assessment Supplement	Yes <input type="radio"/>	No <input type="radio"/>



Name of transferring study site:

- Blantyre CRS
- Botha's Hill CRS
- Chatsworth CRS
- Emavundleni CRS
- eThekwini CRS
- Isipingo CRS
- Malawi CRS
- MU-JHU Research Collaboration (MUJHU CARE LTD) CRS
- Seke South CRS
- Spilhaus CRS
- Tongaat CRS
- Verulam CRS
- Wits Reproductive Health and HIV Institute CRS (WRHI CRS)
- Zengeza CRS

Name of receiving study site:

- Blantyre CRS
- Botha's Hill CRS
- Chatsworth CRS
- Emavundleni CRS
- eThekwini CRS
- Isipingo CRS
- Malawi CRS
- MU-JHU Research Collaboration (MUJHU CARE LTD) CRS
- Seke South CRS
- Spilhaus CRS
- Tongaat CRS
- Verulam CRS
- Wits Reproductive Health and HIV Institute CRS (WRHI CRS)
- Zengeza CRS

Date participant records were sent to receiving study site: \_\_\_\_\_

Name of receiving study site: \_\_\_\_\_

Blantyre CRS

Botha's Hill CRS

Chatsworth CRS

Emavundleni CRS

eThekwini CRS

Isipingo CRS

Malawi CRS

MU-JHU Research Collaboration  
(MUJHU CARE LTD) CRS

Seke South CRS

Spilhaus CRS

Tongaat CRS

Verulam CRS

Wits Reproductive Health and  
HIV Institute CRS (WRHI CRS)

Zengeza CRS

Name of transferring study site: \_\_\_\_\_

Blantyre CRS

Botha's Hill CRS

Chatsworth CRS

Emavundleni CRS

eThekwini CRS

Isipingo CRS

Malawi CRS

MU-JHU Research Collaboration  
(MUJHU CARE LTD) CRS

Seke South CRS

Spilhaus CRS

Tongaat CRS

Verulam CRS

Wits Reproductive Health and  
HIV Institute CRS (WRHI CRS)

Zengeza CRS

Date informed consent signed at receiving site: \_\_\_\_\_

Did the participant provided informed consent for specimen storage  
at receiving study site? Yes

No

Date informed consent for specimen storage was signed: \_\_\_\_\_

MTN025\_version 14.1\_02OCT2017: ALL

Form: Missed Visit

Generated On: 02 Oct 2017 21:39:22

Target visit date: \_\_\_\_\_

Reason visit was missed:

- unable to contact participant
- unable to schedule
- appointment(s) within allowable
- window
- participant refused visit
- participant incarcerated
- participant admitted to a health
- care facility
- participant withdrew from study
- participant deceased
- other

Reason visit was missed - Other, specify: \_\_\_\_\_

Steps taken to address the missed visit (corrective action plan): \_\_\_\_\_

MTN025\_version 14.1\_02OCT2017: ALL

Form: Termination

Generated On: 02 Oct 2017 21:39:22

Termination Date \_\_\_\_\_

Reason for termination

scheduled exit visit/end of study

death

participant refused further participation

participant relocated, no follow-up planned

investigator decision

unable to contact participant

inappropriate enrollment

invalid ID due to duplicate screening/enrollment

other

Early study closure

Date of death \_\_\_\_\_

Specify: \_\_\_\_\_

Was termination associated with an adverse experience?

Yes

No

Don't Know

Specify AE \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Clinical Product Hold/Discontinuation Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

---

Does the participant have any clinical product holds/discontinuations  
to be applied?

Yes

No

---

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Clinical Product Hold/Discontinuation Log**  
**Generated On: 02 Oct 2017 21:39:22**

Date when study product hold was initiated: \_\_\_\_\_

- Why is study product being held?
- Pregnancy
  - Reactive rapid HIV test result
  - Adverse Experience
  - Breastfeeding
  - Allergic reaction to the study product
  - Report of PEP use for HIV exposure
  - Participant unable/unwilling to comply with the required study procedures, or otherwise might be put at undue risk by continuing product use per judgment of IoR/designee
  - Other

Other, specify: \_\_\_\_\_

Adverse Experience: \_\_\_\_\_

Concomitant Medication \_\_\_\_\_

Date of last study product use: \_\_\_\_\_

Or \_\_\_\_\_

Participant never used ring

- Was the participant instructed to resume study product use?
- Yes
  - No – hold continuing for another reason
  - No – early termination
  - No – hold continuing at scheduled PUEV
  - No – permanently discontinued

Date \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Vaginal Ring Tracking Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

---

Did the participant have any vaginal ring(s) provided?

Yes

No

---

---

RING PROVIDED

Ring Code \_\_\_\_\_  
Date ring provided \_\_\_\_\_  
Visit ring provided \_\_\_\_\_

RING RETURNED

Date ring returned \_\_\_\_\_  
Ring not returned

Ring not returned, specify reason: \_\_\_\_\_  
Visit ring returned \_\_\_\_\_

Ring Storage Stored   
Not stored

If not stored, specify reason: \_\_\_\_\_  
Mark checkbox if ring code is unknown when ring returned.

If ring was stored, how did the participant rate her ability to keep  
the ring inserted as instructed, per participant report? Very poor   
Poor   
Fair   
Good   
Very good   
Excellent

If ring was stored, how many days was the vaginal ring out for any  
reason, in total per participant report? Fixed Unit: # days ring was out  
during use

**MTN025\_version 14.1\_02OCT2017: ALL**

**Form: Protocol Deviation Y/N**

**Generated On: 02 Oct 2017 21:39:22**

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Have any protocol deviations occurred?

Yes

No

---

Site awareness date: \_\_\_\_\_

Deviation date: \_\_\_\_\_

Has or will this deviation be reported to local IRB/EC? Yes   
No

Has or will this deviation be reported to DAIDS as a critical event? Yes   
No

Type of deviation:  Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.   
 Study product management deviation: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.   
 Study product dispensing error: The wrong study product was dispensed to a participant on product hold. Pharmacy staff must follow up with the MTN Pharmacist separately.   
 Study product sharing: Participant has shared study product with another person or study participant   
 Study product not returned: Study product was not returned by the participant per protocol requirements.   
 Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol, and was not covered under local standard of care practice   
 Improper AE/EAE follow-up: use when an AE or EAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol   
 Unreported AE: Site staffs become aware of an AE, but do not report it per protocol requirements.   
 Unreported EAE: Site staffs become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements.

- Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member put a participant's name on a case report form.
- Physical assessment deviation: Include missed or incomplete physical/pelvic exam assessments.
- Lab assessment deviation: Include missed, or incomplete lab specimen collection
- Mishandled lab specimen: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
- Staff performing duties that they are not qualified to perform: use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not adequately qualified AND delegated to perform the procedure
- Questionnaire administration deviation: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed
- Counseling deviation: Protocol-required counseling was not done and/or not documented correctly
- Use of non-IRB/EC-approved materials: Include use of ANY study-related material that requires IRB or EC approval for use per site requirements
- Use of excluded concomitant medications, devices, or non-study products
- Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process
- Visit completed outside of window: Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, if visit 3.0 procedures are done in the visit 4.0 window
- Other

---

Description of deviation:

---

**MTN025\_version 14.1\_02OCT2017: ALL**

**Form: Protocol Deviation**

**Generated On: 02 Oct 2017 21:39:22**

Plans and/or action taken to address the deviation: \_\_\_\_\_

Plans and/or action taken to prevent future occurrences of the deviation: \_\_\_\_\_

Deviation reported by: \_\_\_\_\_ Fixed Unit: Staff code

MTN025\_version 14.1\_02OCT2017: ALL

Form: Social Impact Y/N

Generated On: 02 Oct 2017 21:39:22

---

Did a social impact occur?

Yes

No

---

Concisely describe social impact: \_\_\_\_\_

Onset date: \_\_\_\_\_

Reported at visit: \_\_\_\_\_

- Social impact type
- Personal Relationships - Had negative experiences with family (excluding partner)
  - Personal Relationships - Had negative experiences with significant other, spouse, or sex partner
  - Personal Relationships - Other - Had negative experiences with friends, neighbors or other community members
  - Travel/Immigration - Had problems obtaining formal permission to travel or enter another country, such as being denied a visa, or had a problem with immigration/naturalization
  - Employment - Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work
  - Education - Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school
  - Medical/Dental - Been refused medical or dental treatment, or treated negatively by a health care provider
  - Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems to housing
  - Other - Had other problems not covered in the list above

Did this involve physical harm to the participant? Yes   
No

Did this involve physical or other harm to participant's child(ren)? Yes   
No

What impact did this situation have on the participant's quality of life? Minimal disturbance   
Moderate disturbance; no significant impact   
Major disturbance with significant impact

MTN025\_version 14.1\_02OCT2017: ALL

Form: Social Impact

Generated On: 02 Oct 2017 21:39:22

---

Describe what was done by staff and participant to address social impact

Participant: \_\_\_\_\_

Staff: \_\_\_\_\_

Record current status: Unresolved   
Unresolved at end of study   
Unable to resolve; no further   
action taken   
Resolved

---

If either "unable to resolve; no further action" or "resolved" is marked, enter closure date: \_\_\_\_\_

---

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Social Benefit Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

---

Did a social benefit occur?

Yes

No

---

Concisely describe social benefit:

Reported at visit:

The social benefit was related to:

- Pride about project participation:
- Feels pride about participation in HOPE
- Feeling better about oneself:
- Improved self-esteem or feeling of empowerment
- Education: The study educated the participant or inspired /enabled participant to restart school or improve school performance
- Housing: The participant obtained better or improved her housing situation
- Nutrition/food: The participant was able to improve nutrition or amount of food intake for self or family.
- Improved communication: Participant learned more effective ways of communicating with family, friends, employers or others
- Work: Obtained or improved employment situation (includes informal work)
- Income: Obtained or increased income (includes getting study reimbursement)
- HIV testing: The participant received regular HIV testing
- Treatment of STIs: The participant was able to treat STIs
- Treatment of other illnesses: The participant was able to treat/consult with a doctor about other illnesses (non-STIs)
- Family Planning/Contraception: The participant was able to access contraception and family planning services
- Preventative care services: The participant was able to receive preventative health care such as pap smears.
- Staying HIV free: HOPE provided more effective ways for the participant to avoid becoming infected with HIV
- Altruism: Participant helping community/others by participating in HOPE
- Activities: Participant became involved in community activities
- Peer Support: Participant felt supported by or was able to provide support to peers

New relationships: Participant   
created new relationships  
Other

Other, specify: \_\_\_\_\_

What impact did this situation have on the participant's quality of life? Minimal   
Moderate - no significant impact   
Major - significant impact

Did this involve social benefit to someone other than the participant? Yes   
No

Person 1 (If yes, enter type of relationship) Partner   
Adult family member   
Child   
Other HOPE participant   
Friend   
Acquaintance   
Employer   
Other

Other, specify: \_\_\_\_\_

Person 2 (If more than one type of relationship) Partner   
Adult family member   
Child   
Other HOPE participant   
Friend   
Acquaintance   
Employer   
Other

Other, specify: \_\_\_\_\_

Person 3 (If more than 2 types of relationship) Partner   
Adult family member   
Child   
Other HOPE participant   
Friend   
Acquaintance   
Employer   
Other

Other, specify: \_\_\_\_\_

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Interim Visit Procedures**  
**Generated On: 02 Oct 2017 21:39:22**

Interim Visit Number	
Follow-up Visit Summary	Yes <input type="radio"/> No <input type="radio"/>
ACASI Tracking	Yes <input type="radio"/> No <input type="radio"/>
Pelvic Exam	Yes <input type="radio"/> No <input type="radio"/>
Physical Exam	Yes <input type="radio"/> No <input type="radio"/>
Vital Signs	Yes <input type="radio"/> No <input type="radio"/>
STI Test Results	Yes <input type="radio"/> No <input type="radio"/>
Seroconverter Laboratory Results	Yes <input type="radio"/> No <input type="radio"/>
HIV Test Results	Yes <input type="radio"/> No <input type="radio"/>
Specimen Storage	Yes <input type="radio"/> No <input type="radio"/>
Ring Collection and Insertion	Yes <input type="radio"/> No <input type="radio"/>
Pregnancy Report and History	Yes <input type="radio"/> No <input type="radio"/>
Participant Receipt	Yes <input type="radio"/> No <input type="radio"/>
Participant Transfer	Yes <input type="radio"/> No <input type="radio"/>
Pharmacy Ring Dispensation	Yes <input type="radio"/> No <input type="radio"/>
Pregnancy Outcome	Yes <input type="radio"/> No <input type="radio"/>
Laboratory Results	Yes <input type="radio"/> No <input type="radio"/>
Pregnancy Test Result	Yes <input type="radio"/> No <input type="radio"/>

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Interim Visit Procedures**  
**Generated On: 02 Oct 2017 21:39:22**

---

Behavior Assessment	Yes <input type="radio"/>
	No <input type="radio"/>
<hr/>	
Vaginal Practices	Yes <input type="radio"/>
	No <input type="radio"/>
<hr/>	
Social Influences Assessment	Yes <input type="radio"/>
	No <input type="radio"/>
<hr/>	
Study Exit Assessment	Yes <input type="radio"/>
	No <input type="radio"/>
<hr/>	
Social Influences Assessment Supplement	Yes <input type="radio"/>
	No <input type="radio"/>

---

**MTN025\_version 14.1\_02OCT2017: ALL**  
**Form: Social Influences Supplement Y/N**  
**Generated On: 02 Oct 2017 21:39:22**

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How many people did the participant report talking to about the HOPE study, per item 1 on the Social Influences Assessment? \_\_\_\_\_

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A Social Influences Supplement should only be completed if the participant indicated that she talked to 1 or more person(s) about the HOPE study, per Item 1 on the Social Influences Assessment. If the participant reported 0, then enter 0 and this is the end of form.

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Instructions for the Interviewer: Prior to administering this form, review the responses for "What is your relationship with this person" item for each Person the participant referenced on the Social Influences Assessment CRF. During the interview, please do not translate [Person X], but rather reference the relationship with this person the participant reported. For example, if the participant referred to Person 1 as her "Mother" and Person 2 as her "Friend" per the item "What is your relationship with this person", then reference "Mother" as Person 1 when administering questions corresponding to Person 1. Person 2 should reference "Friend" for questions corresponding to Person 2, etc.

Person 1

How well do you know [Person 1]? Not at all.   
A little.   
Very well.

Person 2

How well do you know [Person 2]? Not at all.   
A little.   
Very well.

How well does [Person 1] know [Person 2]? Not at all.   
A little.   
Very well.

Person 3

How well do you know [Person 3]? Not at all.   
A little.   
Very well.

How well does [Person 1] know [Person 3]? Not at all.   
A little.   
Very well.

How well does [Person 2] know [Person 3]? Not at all.   
A little.   
Very well.

Person 4

How well do you know [Person 4]? Not at all.   
A little.   
Very well.

How well does [Person 1] know [Person 4]? Not at all.   
A little.   
Very well.

How well does [Person 2] know [Person 4]? Not at all.   
A little.   
Very well.

How well does [Person 3] know [Person 4]? Not at all.

A little.   
Very well .

Person 5

How well do you know [Person 5]?  
Not at all.   
A little.   
Very well .

How well does [Person 1] know [Person 5]?  
Not at all.   
A little.   
Very well .

How well does [Person 2] know [Person 5]?  
Not at all.   
A little.   
Very well .

How well does [Person 3] know [Person 5]?  
Not at all.   
A little.   
Very well .

How well does [Person 4] know [Person 5]?  
Not at all.   
A little.   
Very well .