MTN-025 (HOPE) Case Report Forms

VERSION 1.0, 21-JUN-2016

Administrative Forms

Pre-Screening Outcome

Pre-Screening Participant ID: _____

1	What was this prior participant's ASPIRE PTID?	☐☐☐ - ☐☐☐☐☐☐ - ☐
2	Was the participant contacted to participate in HOPE?	☐ Yes → *If yes, go to item 4.* ☐ No
3	Why was the ASPIRE participant not contacted to participate in HOPE?	☐ unable to reach participant ☐ participant was permanently discontinued from study product during ASPIRE ☐ participant HIV seroconverted during ASPIRE ☐ participant deceased during ASPIRE ☐ participant did not provide permission to be contacted for future studies ☐ other, specify: _____ *End of Form.*
4	Did the participant conduct a screening visit for HOPE?	☐ Yes ☐ No
Comments:		

Form Instructions – Pre-Screening Outcome

Purpose:
This form is used to document pre-screening process information for each ASPIRE participant, including information on whether the ASPIRE participant was contacted and screened for HOPE.

General Instructions:
Complete this form for every MTN-020/ASPIRE participant at your site.

Item-specific Instructions:

Item 2:	Mark "participant was permanently discontinued from study product during ASPIRE" if the participant was permanently discontinued from study product due for any clinical reason other than HIV seroconversion. Mark "participant did not provide permission to be contacted for future studies" if the participant indicated that she did not wish to be contacted for future studies while participating in MTN-020.
Item 4:	Mark "yes" if the ASPIRE participant attended a Screening Visit as part of MTN-025 or as part of the Decliner Population. Mark "no" If the participant did not sign a screening informed consent form for MTN-025 or for the Decliner Population.

Eligibility Criteria

Participant ID: _____

1	Does this participant meet all eligibility criteria?	☐ Yes ☐ No → *If no, go to item 2.*
1a	Obtain signature	_____ *Signature of Investigator of Record (or designee)* *Date*
1b	Obtain signature	_____ *Signature of second staff member verifying eligibility* *Date*
2	Was the participant enrolled into HOPE?	☐ Yes → *If yes, end of form*. ☐ No
3	Why was the participant not enrolled?	☐ eligible, but participant did not complete all screening procedures → *End of Form.* ☐ eligible, but participant declined enrollment, specify reason: _____ → *End of Form.* ☐ not eligible
4	Reasons for ineligibility. *Record all applicable codes (see back of form).*	☐ ☐☐ ☐ ☐☐ ☐ ☐☐ ☐ ☐☐ ☐ ☐☐
Comments:		

Form Instructions – Eligibility Criteria

Purpose:
This form is used to document participant eligibility for enrollment in to MTN-025/HOPE study or reasons for study ineligibility.

General Instructions:
Complete this form for each participant screened for this study. Complete this form once it is confirmed whether the participant will enroll in the study. If the participant is not enrolled, this is the only form that is completed for the participant.

If the participant has more than one screening attempt, update this form with data from the most recent screening attempt. Do not complete a new form for each screening attempt.

Item-specific Instructions:

Item 3:	Mark 'participant did not complete all screening procedures' when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 56-day window.
Item 4:	Select the codes below and record a reason code for each reason why the participant was deemed ineligible for study participation. Refer to the Eligibility Checklist for the Screening and Enrollment Visit. If the reason for ineligibility is not listed, record the code "99" (other) and briefly describe the reason in the Comments section.

Reasons for HOPE ineligibility Codes:

01	Not previously enrolled in MTN-020 (ASPIRE)	**11**	Currently taking PEP at Enrollment
02	Unable/unwilling to provide written informed consent	**12**	Participated in other research study involving drugs, medical devices, vaginal products, or vaccines within 60 days of Enrolment with the exception of MTN-020 (ASPIRE)
03	Unable/unwilling to provide adequate locator information	**13**	Pregnant at Screening/Enrollment or plans to become pregnant during study participation period
04	HIV infected at Screening or Enrollment	**14**	Currently breastfeeding
05	Declines effective method of contraception at Enrollment and for duration of study participation	**15**	Diagnosed with UTI, PID, STI, or RTI which has not resolved or undergone complete treatment
06	Does not agree to not participate in other research studies for duration of study participation	**16**	Grade 3 pelvic exam finding at Screening or has not improved to non-exclusionary grading or resolved within 56 days or Screening
07	Study product use permanently discontinued in response to AE or safety related concern with taking part in MTN-020 (ASPIRE) trial	**17**	Grade 3 or higher AST/ALT at Screening
08	Plans for relocation/travel per participant report at Screening	**18**	Grade 3 or high Creatinine at Screening
09	Grade 3 or higher Hemoglobin at Screening	**19**	Grade 3 or higher Platelet Count at Screening
10	Grade 3 or high Pap results at Screening	**99**	Other, including IoR discretion

Enrollment

Participant ID: _____

1	Date the participant marked or signed the study screening consent form	dd MMM yy ☐☐ ☐☐☐ ☐☐
2	Date the participant marked or signed the study enrollment consent form	dd MMM yy ☐☐ ☐☐☐ ☐☐
3	Did the participant agree to biological specimen and health data storage?	☐ Yes ☐ No ☐ Pending
4	HIV status	☐ Negative ☐ Positive
5	Enrollment Date	dd MMM yy ☐☐ ☐☐☐ ☐☐

Form Instructions - Enrollment

Purpose:
This form is used to document a participant's study enrollment. This form is completed at Enrollment for participants who have provided informed consent and who are eligible to participate in the study.

General Instructions:
Complete this form for each participant who is enrolled into HOPE.

Item-specific Instructions:

Item 3:	The consent for left-over specimen and health data storage item can be updated if the participant changes her consent decision after enrollment. Update this item as needed if the participant changes her consent during the study.
Item 4:	Record the participant's HIV status as determined by testing performed on the day of enrollment. If 'positive', do not enroll the participant.

Eligibility Criteria - Decliner Population

Participant ID: _____

1	Does this participant meet all eligibility criteria as part of the decliner population?	☐ Yes ☐ No → *If no, go to item 2.*
1a	Obtain signature	_____ *Signature of Investigator of Record (or designee)* *Date*
1b	Obtain signature	_____ *Signature of second staff member verifying eligibility* *Date*
2	Was the participant enrolled into the MTN-025 Decliner Population?	☐ Yes → *If yes, end of form.* ☐ No
3	Why was the participant not enrolled?	☐ eligible, but participant did not complete all screening procedures → *End of Form.* ☐ eligible, but participant declined enrollment → *End of Form.* ☐ not eligible
4	Reasons for ineligibility: *Record all applicable codes (see back of form).*	☐ ☐☐ ☐ ☐☐
Comments:		

Form Instructions – Eligibility Criteria - Decliner Population

Purpose:
This form is used to document participant eligibility for enrollment into the Decliner Population, or reasons for study ineligibility.

General Instructions:
Complete this form for each participant screened to be part of the Decliner Population. Complete this form once it is confirmed whether the participant will enroll as part of the Decliner Population. If the participant is not enrolled as part of the Decliner Population, this is the only form that is completed for the participant.

If the participant completes another screening attempt, update this form with data from the most recent screening attempt. Do not complete a new form for the additional screening attempts.

Item-specific Instructions:

Item 3:	Mark 'participant did not complete all screening procedures' when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 56-day window.
Item 4:	Select the codes below and record a reason code for each reason why the participant was deemed ineligible for study participation. Refer to the Eligibility Checklist for the Screening and Enrollment Visit. If the reason for ineligibility is not listed, record the code "99" (other) and briefly describe the reason in the Comments section.

Reasons for ineligibility Codes:	
01	Not previously enrolled in MTN-020 (ASPIRE)
02	Unable/unwilling to provide written informed consent
20	Unable/unwilling to perform the Decliner Population study procedures
21	Did not decline MTN-025 (main) study trial participation
99	Other, including IoR discretion

Enrollment – Decliner Population

Participant ID: _____

1	Date the participant marked or signed the study screening and enrollment MTN-025 Decliner Population consent form:	dd MMM yy ☐☐ ☐☐☐ ☐☐
2	Enrollment Date:	dd MMM yy ☐☐ ☐☐☐ ☐☐
3	Were all Decliner Population procedures completed on the Enrollment Date?	☐ Yes → *If yes, end of form.* ☐ No
3a	Date all Decliner Population procedures completed:	dd MMM yy ☐☐ ☐☐☐ ☐☐
Comments		

Form Instructions – Enrollment – Decliner Population

Purpose:
This form is used to document a participant's study enrollment as part of the Decliner Population.

General Instructions:
Complete this form only if the participant enrolls in the study as part of the Decliner Population.

Item-specific Instructions:

Item 2:	Record the date that the participant enrolled as part of the Decliner Population. A participant is considered enrolled in the study once a participant has provided written informed consent and it has been determined she is eligible for the study.
Item 3a:	Record the date all of the decliner population procedures were completed only if this date is different than the Enrollment date. A complete date is required.

Follow-up Visit Summary

Participant ID: _____
Visit Date: _____

Administered at each scheduled visit and interim visits, as needed.		
1	Location of study visit	☐ Clinic ☐ Home ☐ Other, specify: _____
2	Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV?	☐ Yes → *If yes and currently using PEP, complete Product Hold/Discontinuation Log. Record on Concomitant Medication Log.* ☐ No
3	Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV?	☐ Yes ☐ No → *If no, go to item 4.*
3a	Was oral or topical PrEP used?	☐ Oral ☐ Topical ☐ Both *Record on Concomitant Medications Log.*
4	Is this an interim visit?	☐ Yes ☐ No → *If no, end of form.*
4a	Reason for interim visit (*Mark all that apply)*:	☐ AE report or follow-up ☐ Return of ring or need for a new ring ☐ Other, specify: _____
4b	Which forms, besides this form, were newly completed for this interim visit? *Mark 'none' or all that apply.*	☐ None → *End of form.* ☐ Ring Collection/Insertion ☐ Vaginal Ring Tracking Log ☐ Specimen Storage ☐ Laboratory Results ☐ HIV Test Results ☐ Pelvic Exam ☐ Pregnancy Test Result ☐ Other, specify: _____ ☐ Other, specify: _____

Form Instructions – Follow-up Visit Summary

Purpose:
This form is used to summarize information from each follow-up visit performed for a participant.

General Instructions:
This form is completed for each scheduled visit. This form is also completed for interim visits/contacts where a new form (other than the Follow-up Visit Summary) is completed.

Item-specific Instructions:

Item 1:	If this contact with a participant is over the phone and results in new forms that need to be completed, mark the "other, specify" box and record "phone contact" on the line provided.
Item 2:	If the participant has taken post-exposure prophylaxis (PEP) since her last visit, mark the "yes" box. If the participant is currently using PEP, a Clinical Product Hold/Discontinuation (PH) log page must be completed.
Item 3:	Record if the participant has used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV and indicate whether oral or topical PrEP was used. If either or both were used, update the Concomitant Medications (CM) Log.
Item 4b:	Mark the newly-completed forms (in addition to this form) that are being submitted for the interim visit/contact. If "other, specify" is marked, record the form names in the space provided.

ACASI Tracking

Participant ID: _____

Visit Date: _____

1	Was an ACASI questionnaire completed at this visit?	☐ Yes ☐ No *If no, record reasons in Comments. End of form.*
1a	Which questionnaire was completed?	☐ Baseline ☐ Month 3 ☐ PUEV/Discontinuers → *If baseline or Month 3 is marked, go to item 2.*
1b	Reason PUEV/Discontinuers ACASI questionnaire was completed:	☐ scheduled PUEV ☐ early termination ☐ permanent product discontinuation prior to PUEV/early termination
2	Were there any problems or issues related to the administration or completion of the questionnaire?	☐ Yes ☐ No → *If no, end of form.*
2a	Describe:	
Comments		

Form Instructions - ACASI Tracking

Purpose:
This form is used to document participant completion of the Audio Computer-assisted Self Interview (ACASI) questionnaires at Enrollment and during follow-up.

General Instructions:
Complete this form at Enrollment, Month 3, and at the participant's Product Use End Visit (PUEV) or early termination visit.

Additionally, complete this form (and the PUEV/Discontinuers ACASI questionnaire) if the participant is permanently discontinued from study product (as documented by a Clinical Product Hold/Discontinuation Log).

Item-specific Instructions:

Item 2a:	Use this space to describe when and why multiple ACASI questionnaires are completed for a participant at a visit or if the incorrect ACASI questionnaire is completed at a visit. If there are any unusual details related to the ACASI questionnaire administration or completion, describe them here.

Protocol Deviation Log

Participant ID: _____

Have any protocol deviations occurred? ☐ Yes ☐ No		
1	Site awareness date	dd MMM yy ☐☐ ☐☐ ☐☐
2	Deviation date	dd MMM yy ☐☐ ☐☐ ☐☐
3	Has or will this deviation be reported to local IRB/EC?	☐ Yes ☐ No
4	Has or will this deviation be reported to DAIDS as a critical event?	☐ Yes ☐ No
5	Type of deviation	☐☐ *deviation code (See back of form for code listing)*
6	Description of deviation:	
7	Plans and/or action taken to address the deviation:	
8	Plans and/or action taken to prevent future occurrences of the deviation:	
9	Deviation reported by: ☐☐☐☐ *staff code*	

Form Instructions – Protocol Deviation Log

Purpose:
These form documents and reports protocol deviations identified for each study participant.

Generation Information/Instructions:
Complete this form each time a protocol deviation is identified. Consult the MTN Regulatory Team (mtnregulatory@mtnstopshiv.org) and the Study Management Team if you are unsure if an event required reporting as a deviation.

Item-specific Instructions:

Item 2:	Record the date the event occurred (start date).
Item 5:	Record the two-digit category code that best described the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.
Item 6:	Briefly describe the specific details of the deviation.
Item 9:	Record staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.

Code	Description	Code	Description
01	**Inappropriate enrollment:** The participant enrolled and not all eligibility requirements were met.	**12**	**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.
02	**Failure to follow trial randomization or blinding procedures**: Include instances where randomization procedures were not followed by site staff or product blinding procedures were not followed by pharmacy staff.	**13**	**Physical assessment deviation**: Include missed or incomplete physical/pelvic exam assessments.
03	**Study product management deviation**: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.	**14**	**Lab assessment deviation**: Include missed, or incomplete lab specimen collection.
04	**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.	**15**	**Mishandled lab specimen**: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
05	**Study product use/non-use deviation**: Participant did not use the study product (including refusals) or used it incorrectly (i.e., not in accordance with protocol requirements).	**16**	**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.
06	**Study product sharing**: Participant has shared study product with another person or study participant	**17**	**Questionnaire administration deviation**: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
07	**Study product not returned**: Study product was not returned by the participant per protocol requirements.	**18**	**Counseling deviation**: Protocol-required counseling was not done and/or not documented correctly
08	**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	**19**	**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.
09	**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	**20**	**Use of excluded concomitant medications, devices, or non-study products**
10	**Unreported AE**: Site staffs become aware of an AE, but do not report it per protocol requirements.	**21**	**Informed consent process deviation**: Examples include failure to accurately execute and/or document any part of the informed consent process.
11	**Unreported EAE**: Site staffs become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements.	**22**	**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.
99	**Other**		

Social Impact Log

Participant ID: _____

Did a social impact occur? ☐ Yes ☐ No		
1	Concisely describe social impact:	
2	Onset date:	dd MMM yy ☐☐ ☐☐☐ ☐☐
3	Reported at visit:	_____
4	Social impact code	☐☐ *See back for codes and definitions.*
4a	Did this involve physical harm to the participant?	☐ Yes ☐ No
4b	Did this involve physical or other harm to participant's child(ren)?	☐ Yes ☐ No
5	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
6	Describe what was done by staff and participant to address social impact:	
6a	Participant:	
6b	Staff:	
7	Record current status:	☐ Unresolved ☐ Unresolved at end of study ☐ Unable to resolve; no further action taken ☐ Resolved ***If either is marked, enter closure date:*** dd MMM yy ☐☐ ☐☐☐ ☐☐

Form Instructions – Social Impact Log

Purpose:
Complete this form when recording the occurrence, update, and resolution of adverse social impacts reported by participants at any time during the study.

General Instructions:
This form should be completed only when a participant has a negative experience associated with study participation.

Item-specific Instructions:

Item 2:	Record the date the negative experience first started. At minimum, a month and year are required.
Item 4:	Use the Code List below to code the social impact. Use leading zeros when needed.
Item 5:	Assess the impact of the social harm on the participant's quality of life based on participant self-report.
Item 7:	This item may be updated at subsequent visits.

Code	Definition
01 Personal Relationships	Had negative experiences with family (excluding partner)
02 Partner Relationships	Had negative experiences with significant other, spouse, or sex partner
03 Personal Relationships – Other	Had negative experiences with friends, neighbors or other community members
04 Travel/Immigration	Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization
05 Employment	Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work
06 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
07 Medical/Dental	Been refused medical or dental treatment, or treated negatively by a health care provider
08 Housing	Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing
09 Other	Had other problems not covered in the codes above

Social Benefit Log

Participant ID: _____

Did a social benefit occur? ☐ Yes ☐ No						
1	Concisely describe social benefit:					
2	Reported at visit:			_____		
3	The social benefit was related to: *Mark all that apply.*	Did this involve social benefit to someone other than the participant?	Person 1 (*If yes, enter relationship code*)	Person 2 *(If more than one type of relationship)*	Person 3 *(if more than 2 types of relationship)*	What impact did this situation have on the participant's quality of life?
a. ☐☐		☐ Yes ☐ No	☐☐ Other, specify:____	☐☐ Other, specify:____	☐☐ Other, specify:____	☐ Minimal ☐ Moderate - no significant impact ☐ Major - significant impact
b. ☐☐		☐ Yes ☐ No	☐☐ Other, specify:____	☐☐ Other, specify:____	☐☐ Other, specify:____	☐ Minimal ☐ Moderate - no significant impact ☐ Major - significant impact
c. ☐☐		☐ Yes ☐ No	☐☐ Other, specify:____	☐☐ Other, specify:____	☐☐ Other, specify:____	☐ Minimal ☐ Moderate - no significant impact ☐ Major - significant impact
d. ☐☐		☐ Yes ☐ No	☐☐ Other, specify:____	☐☐ Other, specify:____	☐☐ Other, specify:____	☐ Minimal ☐ Moderate - no significant impact ☐ Major - significant impact
e. Other, specify:____ _____		☐ Yes ☐ No	☐☐ Other, specify:____	☐☐ Other, specify:____	☐☐ Other, specify:____	☐ Minimal ☐ Moderate - no significant impact ☐ Major - significant impact
Comments						

Form Instructions – Social Benefit Log

Purpose:
Complete this form when recording the occurrence, update, and resolution of social benefits reported by participants at any time during the study.

General Instructions:
This form should be completed only when a participant has a positive experience associated with study participation.

Item-specific Instructions:

Item 3:	Refer to the list of Social Benefit Codes below.

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

Relationships	
Code	**Description**
01	**Partner**
02	**Adult family member**
03	**Child**
04	**Other HOPE participant**
05	**Friend**
06	**Acquaintance**
07	**Employer**
08	**Other, specify**_____

Termination

Participant ID: _____

1	Termination Date	dd MMM yy ☐☐ ☐☐☐ ☐☐ *Date the site determined that the participant was no longer in the study.*
2	Reason for termination *Mark only one.*	☐ 2a. scheduled exit visit/end of study → *End of form.*
		☐ 2b. death, *indicate date and cause if known*
		2b1. date of death: dd MMM yy ☐☐ ☐☐☐ ☐☐ OR ☐ *date unknown*
		2b2. cause of death: _____ _____ OR ☐ *cause unknown* ↓ *Complete or update Adverse Experience Log*
		☐ 2c. participant refused further participation, specify: _____
		2d. NOT APPLICABLE FOR THIS PROTOCOL (participant unable to adhere to visit schedule)
		☐ 2e. participant relocated, no follow-up planned
		☐ 2f. investigator decision, specify: _____
		☐ 2g. unable to contact participant
		2h. NOT APPLICABLE FOR THIS PROTOCOL (HIV Infection)
		☐ 2i. inappropriate enrollment → *End of form.*
		☐ 2j. invalid ID due to duplicate screening/enrollment → *End of form.*
		☐ 2k. other, specify: _____
		☐ 2l. Early study closure → *End of form.*
3	Was termination associated with an adverse experience?	Yes ☐ No ☐ don't know ☐ → *If no or don't know, end of form.* If yes, specify AE CRF Number: ____ (*drop-down menu)*

Form Instructions - Termination

Purpose:
This form is completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Item-specific Instructions:

Item 1:	A complete date is required.
Item 2:	Mark only the primary reason for termination.
Item 2a:	Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit
Item 2b1:	At a minimum, the month and year are required.
Item 2l:	Early study closure: Only mark 2l when instructed by SCHARP
Item 3:	If the participant's study termination was associated with an AE, mark "yes" and specify the AE CRF number. In Medidata Rave, choose the AE from the drop-down list.

Missed Visit

Participant ID: _____

1	Target Visit Date	dd MMM yy ☐☐ ☐☐☐ ☐☐
2	Reason visit was missed *Mark only one.*	☐ 2a unable to contact participant
		☐ 2b unable to schedule appointment(s) within allowable window
		☐ 2c participant refused visit
		☐ 2d participant incarcerated
		☐ 2e participant admitted to a health care facility → *Complete Adverse Experience Log, as applicable.*
		☐ 2f participant withdrew from study → *Complete a Termination form.*
		☐ 2g participant deceased → *Complete a Termination form. Complete an Adverse Experience Log.*
		☐ 2h other, specify: _____
3	Steps taken to address the missed visit (corrective action plan):	
Comments:		

Form Instructions – Missed Visit

Purpose:
Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the Study-specific Procedures (SSP) manual.

General Instructions:
Confirm that the visit was missed before completing a Missed Visit form. Complete this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the visit code of the visit that was missed. Record the date the form was completed. This will not necessary be the target date of the missed visit. A complete date is required.

Item-specific Instructions:

Item 1	Record the target date of the visit. A complete date is required.
Item 2	Record the reason the participant missed the visit.

Participant Receipt

Participant ID: _____

Form Completion Date: _____

Note: <u>Do not</u> assign a new Participant ID. Record the Participant ID assigned by the original study site.		
1	Name of receiving study site	_____
2	Name of transferring study site	_____
3	Date informed consent signed at receiving site	dd MMM yy ☐☐ ☐☐☐ ☐☐
4	Did the participant provided informed consent for specimen storage at receiving study site?	☐ Yes ☐ No → *If no, end of form.*
4a	Date informed consent for specimen storage was signed	dd MMM yy ☐☐ ☐☐☐ ☐☐
Comments:		

Purpose:
Complete this form when a transferred participant has been provided informed consent at the receiving study clinic/site.

General Instructions:
The Participant Receipt form is completed by the receiving site (the site at which the participant will be continuing his or her study visits).

For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP) manual, and/or Manual of Operations (MOP).

Item-specific Instructions:

Participant ID	Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.
Item 3:	A complete date is required.
Item 4a:	A complete date is required.

Participant Transfer

Participant ID: _____

Form Completion Date: _____

Note: Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.		
1	Name of transferring study site	_____
2	Name of receiving study site	_____
3	Last completed visit with participant	_____
4	Date participant records were sent to receiving study site	dd MMM yy ☐☐ ☐☐☐ ☐☐
Comments:		

Form Instructions – Participant Transfer

Purpose:
Complete this form when a participant is transferring to another study clinic/site.

General Information/Instructions:
The Participant Transfer form is completed by the transferring site (the site that the participant is leaving).

For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP) manual, and/or Manual of Operations (MOP).

Item-specific Instructions:

Item 4:	A complete date is required.

Ring Dispensation/Collection Forms

Pharmacy Ring Dispensation

Participant ID: _____

Visit Date: _____

1	Date Vaginal Ring(s) dispensed:	dd MMM yy ☐☐ ☐☐☐ ☐☐
2	Time Vaginal Ring(s) dispensed:	☐☐:☐☐ *24-hour clock*
3	How many vaginal rings were dispensed at this visit?	☐
Complete the ring code and lot number for each ring dispensed.		
Vaginal Ring #1		
4	Ring code	☐☐.☐
4a	Lot number	☐☐☐☐☐☐
Vaginal Ring #2		
5	Ring code	☐☐.☐
5a	Lot number	☐☐☐☐☐☐
Vaginal Ring #3		
6	Ring code	☐☐.☐
6a	Lot number	☐☐☐☐☐☐
Vaginal Ring #4		
7	Ring code	☐☐.☐
7a	Lot number	☐☐☐☐☐☐
Comments:		

Form Instructions – Pharmacy Ring Dispensation

Purpose:
This form is used to collect vaginal ring dispensation information, including the lot number associated with each vaginal ring. This form is completed by pharmacy staff only.

General Instructions:
Complete this form at all study visits at which study product is dispensed to a participant.

Item-specific Instructions:

Item 1	Record the exact day, month, and year study product was dispensed to the participant.
Item 4-7a:	Record the ring code and lot number of each vaginal ring dispensed at this visit. A ring code and lot number can be provided for up to four dispensed rings. For example, if three vaginal rings are dispensed at a study visit, complete items 4-6a to indicate the ring code and lot numbers for each of the three rings and leave items 7 and 7a blank.

Vaginal Ring Tracking Log

Participant ID: ____________________

RING PROVIDED			RING RETURNED					
Ring Code	**Date Ring Provided** (dd-MMM-yy)	**Visit**	**Date Ring Returned** (dd-MMM-yy)	**Visit**	**Ring Storage**	**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?**	**If ring was stored, how many days was the vaginal ring out for any reason, in total per participant report?**
☐☐.☐	_ _/_ _ _/_ _		_ _/_ _ _/_ _ ☐ Ring not returned, specify reason:________		☐ Stored ☐Not stored → *If not stored, specify reason:______*	☐ → End of form	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent	☐☐ # days ring was out during use
☐☐.☐	_ _/_ _ _/_ _		_ _/_ _ _/_ _ ☐ Ring not returned, specify reason:________		☐ Stored ☐Not stored → *If not stored, specify reason:______*	☐ → End of form	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent	☐☐ # days ring was out during use
☐☐.☐	_ _/_ _ _/_ _		_ _/_ _ _/_ _ ☐ Ring not returned, specify reason:________		☐ Stored ☐Not stored → *If not stored, specify reason:______*	☐ → End of form	☐ Very poor ☐ Poor ☐ Fair ☐ Good ☐ Very good ☐ Excellent	☐☐ # days ring was out during use

Form Instructions (Vaginal Ring Tracking Log)

Purpose:
This form is used to collect information on each study vaginal ring that is provided to the participant and returned to the clinic. This form also documents whether each ring was stored, and ring use per participant report.

General Instructions:
Complete a separate entry for each vaginal ring that is provided to a participant.

At Ring Dispensation:
- Complete the "Ring Provided" section of the vaginal ring tracking log each time a study vaginal ring is provided to a participant. Specify the Ring Code, visit, and the date that the ring was provided.
- Leave remaining items for the log entry blank

At Ring Return:
- Complete the "Ring Returned" portion of the Vaginal Ring Tracking Log when each provided study vaginal ring is expected to be returned to the clinic.

Item-specific Instructions:

Date Ring Returned	If a ring is marked as 'not returned', specify the reason that the ring was not returned. Update this item if the ring is returned at a later date.
Ring Storage	Document if the ring was stored. Mark 'not stored' if the ring was set for destruction, returned to the pharmacy (unused), or not stored for any other reason. Specify the reason why ring was not returned.
Mark checkbox if ring code is unknown when ring returned	If the ring code of a ring is unknown at the time of return, mark the checkbox. No additional items for this ring should be completed.
Days Vaginal Ring was Out	If the participant does not remember the exact number of days the ring was out, a best estimate should be provided by the participant.

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Ring Collection and Insertion

Participant ID: _____ Visit Date: _____

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 → *If no, go to 1b.*
1a	Ring code for ring in place at start of visit:	☐☐.☐ *Skip to item 2.*
1b	When was a ring last in place?	dd MMM yy ☐☐ ☐☐☐ ☐☐ OR ☐ 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 → *Update the Vaginal Ring Tracking Log.* ☐ No
RING CHOICE		
3	Did the participant choose to use a new ring at this visit?	☐ Yes ☐ No → *If no, go to item 5.* ☐ NA
4	*[COMPLETE AT MONTHS 3-9 ONLY]* Did the participant choose to receive the ring(s) on a monthly or quarterly schedule?	☐ Monthly ☐ Quarterly
5	What are the reasons that the participant opted to **not** use the ring at this visit? *Mark all that apply.*	☐ Participant undecided/not ready ☐ Participant not interested ☐ Ring less effective than participant wants ☐ Side effects, specify:_____ ☐ Participant intends to fall pregnant ☐ Partner unsupportive or dislikes ring ☐ Family or relative unsupportive ring ☐ Participant prefers alternative HIV prevention method ☐ Other, specify:_____ END OF FORM.
RING PROVISION		
6	Was a ring provided at this visit?	☐ Yes → *If yes, complete Vaginal Ring Tracking Log and go to item 7.* ☐ 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, Specify: _____ → *End of form.*
7	Was a new ring inserted at this visit?	☐ Yes ☐ No → *If no, go to item 8.*
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 → *If yes, end of form.* ☐ 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, specify: _____

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Form Instructions (RCI)

Purpose:
This form is used to document the rings that are inserted and collected for each participant for the duration of the study. The form also captures the participant decision to use the ring and whether she chooses to accept the ring on a monthly or quarterly schedule.

General Instructions:
Complete this form at Enrollment and at each scheduled follow-up visit including the Product Use End Visit (PUEV). Complete at interim visits as needed and at early termination visits, as applicable. If the participant has been permanently discontinued from study product, this form is not required to be completed at visits following the permanent discontinuation.

Item-specific Instructions:

Item 1b:	If the vaginal ring was not in place at the start of the visit, record the date the vaginal ring was last in place since the participant's last visit. If the participant is unable to recall the exact date, obtain the participant's best estimate. At a minimum, the month and year are required. If the ring was not in place at any time since this form was last completed, mark the 'not applicable' box.
Item 3:	Mark the "NA" box if this question is not applicable to the participant at this visit. For example, if the participant is on clinical product hold, has been permanently discontinued from study product, or if this visit after her expected study product use period (e.g., her PUEV or early termination visit, if applicable).
Item 2 and Item 6:	If one or more vaginal rings were dispensed or collected at this visit, update the applicable ring entry on the Vaginal Ring Tracking Log.
Item 6a:	If the reason that a ring is not dispensed is due to or associated with an adverse event, document the adverse event on the Adverse Experience (AE) Log.

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Ring Adherence

Participant ID: _____
Visit Date: _____

1	Since the participant's last study visit, has she ever used a vaginal ring?	☐ Yes ☐ No → *If no, end of form*
2	Did the participant disclose her ring use to her primary partner?	☐ yes ☐ no ☐ NA
3	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?	____ times *If 00, end of form.*
4	How many of these times since the participant's last study visit was a vaginal ring out for more than 12 hours continuously?	____ times *If 00, go to item 6.*
5	Since the participant's last study visit, what is the longest number of days in a row the vaginal ring was out?	____ days
6	What are the reason(s) why the vaginal ring(s) were out? *Record all codes that apply. See back of form for code listing.*	Reason code 6a. _____ 6b. _____ 6c. _____ 6d. _____ 6e. _____ 6f. _____ 6g. _____
If there is a reason that is not represented in the Reason Code list, mark item 6h or 6i, as applicable, and record the reason on the adjacent specify lines. Otherwise, leave items 6h and 6i blank.		
6h	Other reason ring removed by participant or clinician, specify: _____	
6i	Other reason ring came out on its own, specify: _____	
Comments:		

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Form Instructions – RA

Purpose:
This form is used to document the participant's self-reported study ring use during follow-up.

General Instructions:
Complete this form at the each scheduled monthly and quarterly study visit, and the Product Use End Visit (PUEV), and at an early termination visit, as applicable.
Item-specific Instructions:

Item 2:	Enter 'NA' if the participant does not have a primary partner.
Item 3:	The purpose of this question is to capture all instances since her last study visit when the ring was expelled or was removed, excluding when a participant is expected to replace a new ring on a monthly basis (at a scheduled visit or at home during the quarterly follow-up phase). Do not count instances when the ring was removed and momentarily out to be replaced for a new ring.
Item 6:	Refer to the list of Reason Codes below. Record the two-digit code that corresponds to each reason the vaginal ring was out during since the participant's last study visit. Up to seven Reason Codes may be recorded (items 6a-6g). At least one reason code in item 6 if the ring was out since the last visit.

REASONS RING REMOVED BY PARTICIPANT OR CLINICIAN	
Hygienic or Physical Reasons	
Code	**Description**
10	**Discomfort/symptoms:** Ring caused discomfort/participant experienced genital or other symptoms
11	**Ring falling out:** Ring was partially falling out
12	**Ring placement:** Didn't feel the ring was correctly placed
13	**Ring presence:** Wanted to look at the ring or see if the ring was still in place
14	**Menses/Bleeding:** Had or was expecting menses/any type of genital bleeding or spotting
15	**Cleaned ring:** Removed ring to clean it
16	**Cleaned vagina:** Removed ring to clean vagina
17	**Felt sick:** Felt sick/had non-genital side effects from the ring
Psychosocial or Sexual Reasons	
18	**Emotional worries:** Had emotional worries about the ring
20	**Partner ring knowledge:** Did not want husband or primary sex partner to know about ring
21	**Partner concerns/objections:** Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring
22	**Family concerns/objections:** Family member (other than husband/primary sex partner) did not like the ring and/or wanted her to remove/stop using the ring
23	**Friend or peer concerns/objections:** Friend or peer did not like the ring and/or wanted her to remove/stop using the ring
24	**Removal for sex:** Participant or partner did not want to have vaginal sex with the ring in place
25	**Discomfort during sex:** The ring feeling uncomfortable or painful during vaginal sex
26	**Partner felt ring during sex:** The sex partner feeling the ring during sex
27	**Showed ring:** Removed ring to show it to someone
28	**Not having sex:** Participant was not having sex so she decided to remove/stop using the ring
50	**Interfered with sexual pleasure:** The ring interfered with her sexual pleasure
51	**Interfered with partner's sexual pleasure:** the ring interfered with her partner's sexual pleasure
52	**Disliked ring:** Removed ring because did not like the ring
53	**Partner disliked ring:** Removed ring because partner did not like the ring
54	**Participant wanted to get pregnant**
55	**Partner wanted her to get pregnant**
Study-related or Procedural Reasons	
30	**Product hold:** Participant placed on product hold
31	**Product permanently discontinued:** Participant permanently discontinued from product
32	**Procedure:** Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam) that was *not* conducted at a regularly scheduled study visit
35	**Delay in insertion of new ring:** Ring removed between study visits and there was a delay in new ring insertion
34	**Missed visit:** Participant removed ring due to missed scheduled visit
REASONS RING CAME OUT ON ITS OWN	
40	**Urination**
41	**Bowel movement:** Having a bowel movement

42	**Sex:** Having sex or just finished sex
43	**Physical activity:** Physical activity (other than sex),including lifting heavy objects
44	**Body position:** Was squatting or sitting or changing body position (i.e., move from lying down to standing up)
45	**Menses:** Had her menses

Clinical Forms

Vital Signs

Participant ID: _____

Visit Date: _____

VITAL SIGNS					
1	Weight	☐☐☐ *kg*	4	Pulse	☐☐☐ *beats per minute*
2	Body Temp	☐☐.☐ ◦*C*	5	Respirations	☐☐ *beats per minute*
3	BP	☐☐☐/☐☐☐ *mmHg*	6	Height	☐☐☐ cm OR ☐ *not required*

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Form Instructions – Vital Signs

Purpose:
This form is used to document the participant's vital signs.

General Instructions:
Complete this form at Screening, Product Use End Visit (PUEV), and as indicated at all other study visits.

Item-specific Instructions:

Item 6:	This item is required at Screening only.

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Physical Exam

Participant ID: _____
Visit Date: _____

FINDINGS *Items 9-18 may be omitted from assessment after the Screening Visit.*						
		Not done		**Normal**	**Abnormal**	**Notes**
1	General appearance	☐		☐	☐	
2	Abdomen/ Gastrointestinal	☐		☐	☐	
3	Neck	☐		☐	☐	
4	Lymph Nodes	☐		☐	☐	
5	Heart/Cardiovascular	☐		☐	☐	
6	Lungs/Respiratory	☐		☐	☐	
7	Extremities	☐		☐	☐	
8	Neurological	☐		☐	☐	
9	Skin	☐		☐	☐	
10	Eyes	☐		☐	☐	
11	Ears, Nose, Throat	☐		☐	☐	
12	Other	☐		☐	☐	
Record abnormal findings on Baseline Medical History Log or Adverse Experience Log as applicable.						
Comments:						

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Form Instructions – Physical Exam

Purpose:
This form is used to document the participant's physical exam findings.

General Instructions:
Complete this form at Screening, Product Use End Visit (PUEV), and as indicated at all other study visits. If abnormal findings are found, for items 1-12, transcribe the information on the **Baseline Medical History Log** or **Adverse Experience Log form(s)**.

Item-specific Instructions:

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 Notes field provided. If not evaluated, mark "not done" and record the reason in Notes. Normal findings may also be described in Notes, but is not required.
Item 12:	If abnormal, specify the body system being referenced and describe the findings in the Notes. If no other abnormal findings are identified, mark "not done".

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Adverse Experience log

Participant ID: _____ Date Reported to Site: _____

Has the participant experience any Adverse Events during the study? ☐ Yes ☐ No		
1	Adverse Experience (AE) _____ *Record diagnosis, if available. Include anatomical location, if applicable.*	
2	Onset Date	☐☐ ☐☐ ☐☐☐☐ *dd MMM yy*
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 *Record rationale or alternative etiology in Comments.*
5	Study Product Administration	☐ No change ☐ Held ☐ Permanently discontinued ☐ N/A
6	Status/Outcome	☐ Continuing ☐ Resolved ☐ Death ☐ Severity/frequency increased *(Report as a new AE)* ☐ Continuing at end of study participation
7	Status/Outcome Date *Leave blank if item 6 is "continuing" or "continuing at end of study participation"*	☐☐ ☐☐ ☐☐☐☐ *dd MMM yy*
8	Treatment *Mark "none" or all that apply.*	☐ None ☐ Medication(s) *Report on Concomitant Medications Log.* ☐ New/prolonged hospitalization *Comment:*_____ ☐ Procedure/Surgery *Comment:* _____ ☐ Other, specify:_____
9	Is this an SAE according to ICH guidelines?	☐ Yes ☐ No
10	Has/will this AE be reported as an EAE?	☐ Yes → If yes, specify EAE Number: _____ ☐ No
11	Was this AE a worsening of a baseline medical condition?	☐ Yes ☐ No
Comments:		

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Form Instructions

Purpose:
To document all MTN-025 Adverse Experiences (AEs) required to be reported per protocol. This includes all genital, genitourinary, reproductive system, and laboratory AEs as well as all other Grade 2 or higher AEs, all SAEs, and all AEs that result in permanent product discontinuation.

General Instructions:
Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate AE on separate AE Log pages as applicable. If a cluster of symptoms reported on separate AE Log page is later attributed to a single diagnosis, change the earliest reported symptom page to the diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE Log pages (insert page #s).

Item-specific Instructions:

Date Reported to Site	Record the date the site became aware of the AE. For lab AEs, record the date the lab result was received.
Item 1	Use medical terminology to describe the AE. Do not include text on the relationship to study product or timing of AE onset with regard to product use. For lab abnormalities, record the lab name with the direction (i.e., increased or decreased). For example, "increased ALT".
Item 2	At a minimum a month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE (onset of first symptom if diagnosis has multiple associated symptoms); date of the study visit/study exam (for physical or pelvic exam findings); specimen collection date (for lab abnormality AEs).
Item 3	Record the severity grade using the current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums).
Item 4	Mark 'related' if there is a reasonable possibility that the AE may be related to the study agent. Mark 'not related' if there is not a reasonable possibility that the AE is related to the study agent. Provide the clinical rationale (the reason) the AE is judged to be 'related' or 'not related' in the Comments section for each reported AE.
Item 5	- ***No change***: Mark if there is no change to the participant's planned use of study product as a result of the AE. This option should be marked if the participant is still in the product use period and the AE does not result in a clinician initiated product hold or permanent discontinuation of study product. - ***Held***: Mark if the AE results in a clinician initiated product hold. If multiple AEs are reported at the same visit, mark 'held' for each AE contributing to the hold. A Clinical Product Hold/Discontinuation Log entry should be completed for each AE with 'held' marked. In an AE results in a hold, then a permanent discontinuation, update this item to 'permanent discontinuation' at the time that the participant is permanently discontinued, - ***Permanently discontinued*:** Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark "permanently discontinued" for each AE contributing to the permanent discontinuation. For each AE completed with this box marked, there should be a PH log entry with item 4 marked, "no – permanently discontinued". - ***N/A (not applicable*:** Mark if the AE's onset date (item 2) is on or after the participant's PUEV or early termination visit date. Also mark this box if the AE's onset date is on or after the date of permanent discontinuation.
Item 6	***Continuing***: AE is continuing at the time it is first reported *Resolved:* AE is no longer present or has returned to baseline severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated. ***Death***: Mark only if the severity grade of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to 'continuing at the end of study participation" ***Severity/frequency increased***: If an AE increases in severity/frequency after it has been first reported on this form, line through the 'continuing' box and mark 'severity/frequency increased'. Record the date of increase as the 'Status/Outcome Date." Report the increase in severity/frequency as a new AE. For this new AE, the 'onset date' (item 2) will be the same as the "Status/Outcome Date" (item 6a) of the first reported AE/ Note that decreases in severity (AE improvements) are not recorded as ne AEs. ***Continuing at end of study participation***: Mark this box whenever an AE is continuing at the time of participant termination from the study.
Item 7	A month and year are required at a minimum. Record one of the following, as appropriate: the date on which the participant reports no longer experience the AE or associated symptoms, or the date of the study visit or specimen collection at which it is first noted the AE has resolved or returned to baseline status.
Item 8	Mark 'medication(s)' only if the participant reports taking the medication, If medication is indicated, but not yet used, mark 'other' and describe the medication indicated; mark 'medication(s)' once the medication has been used.
Items 9 and 10	For questions about ICH guidelines and EAE reporting, refer to the current *Manual for Expedited Reporting of Adverse Events to DAIDS.* If item 9 is 'yes', provide the EAE number and complete any subsequent updates to this form on the applicable EAE form.

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Grade 1 Adverse Experience log

DO NOT DATA ENTER THIS FORM INTO MEDIDATA RAVE UNLESS INSTRUCTED BY SCHARP.

Participant ID: _____ Date Reported to Site: _____

1	Adverse Experience (AE) _____ *Record diagnosis, if available. Include anatomical location, if applicable.*	
2	Onset Date	☐☐ ☐☐ ☐☐ *dd MMM yy*
3	Severity Grade	☒ Grade 1 (Mild)
4	Relationship to Study Product	☐ Related ☐ Not related *Record rationale or alternative etiology in Comments.*
5	Study Product Administration	☐ No change ☐ Held ☐ Permanently discontinued ☐ N/A ***If held or permanently discontinued, stop – record on Adverse Experience Log.***
6	Status/Outcome	☐ Continuing ☐ Resolved Death ☐ Severity/frequency increased *(Report as a new AE)* ☐ Continuing at end of study participation
7	Status/Outcome Date *Leave blank if item 6 is "continuing" or "continuing at end of study participation"*	☐☐ ☐☐ ☐☐ *dd MMM yy*
8	Treatment *Mark "none" or all that apply.*	☐ None ☐ Medication(s) *Report on Concomitant Medications Log.* ☐ New/prolonged hospitalization ***If new/prolonged hospitalization, stop – record on Adverse Experience Log.*** ☐ Procedure/Surgery *Comment: -* _____ ☐ Other, specify: _____
9	Is this an SAE according to ICH guidelines?	☐ Yes ☒ No
10	Has/will this AE be reported as an EAE?	☐ Yes ☒ No
11	Was this AE a worsening of a baseline medical condition?	☐ Yes ☐ No
Comments:		

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Form Instructions

Purpose:
To document MTN-025 Grade 1 non-genital, non-laboratory Adverse Experiences (AEs). All genital, genitourinary, reproductive system, and laboratory value AEs, all other AEs grade 2 and higher, all SAEs, and any AE resulting in a clinical product hold or permanent product discontinuation are reported using the Adverse Experience (AE) Log.

General Instructions: **THIS FORM IS NOT DATA ENTERED INTO MEDIDATA RAVE**
If the AEs documented on Grade 1 Adverse Experience (GAE) Log pages are needed in the study database, SCHARP will provide specific instructions at that time.

Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate AE on separate GAE/AE Log pages as applicable.

Item-specific Instructions:

Item 1	Use medical terminology to describe the AE. Do not include text on the relationship to study product or timing of AE onset with regard to product use.
Item 2	At a minimum a month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE (onset of first symptom if diagnosis has multiple associated symptoms); date of the study visit/study exam (for physical or pelvic exam findings).
Item 3	The severity grade item has been hard-coded as Grade 1. No action required for this item. If the AE is Grade 2 or higher, mark this form for delete and report using an AE Log page
Item 4	Mark 'related' if there is a reasonable possibility that the AE may be related to the study agent. Mark 'not related' if there is not a reasonable possibility that the AE is related to the study agent. Provide the clinical rationale (the reason) the AE is judged to be 'related' or 'not related' in the Comments section for each reported AE.
Item 5	- ***No change****:* Mark if there is no change to the participant's planned use of study product as a result of the AE. This option should be marked if the participant is still in the product use period and the AE does not result in a clinician initiated product hold or permanent discontinuation of study product. - ***Held****:* If the AE results in a clinical product hold, stop completion of this form and record the AE on an AE Log page. Mark this form for delete. - ***Permanently discontinued*****:** If the AE results in permanent discontinuation of study product, stop completion of this form and record the AE on an AE Log page. Mark this form for delete. - ***N/A (not applicable*****:** Mark if the AE's onset date (item 2) is on or after the participant's PUEV or early termination visit date. Also mark this box if the AE's onset date is on or after the date of permanent discontinuation.
Item 6	***Continuing****:* AE is continuing at the time it is first reported *Resolved:* AE is no longer present or has returned to baseline severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated. ***Severity/frequency increased****:* If an AE increases in severity/frequency after it has been first reported on this form, line through the 'continuing' box and mark 'severity/frequency increased'. Record the date of increase as the 'Status/Outcome Date." Report the increase in severity/frequency as a new AE. For this new AE, the 'onset date' (item 2) will be the same as the "Status/Outcome Date" (item 6a) of the first reported GAE. Note that decreases in severity (AE improvements) are not recorded as ne AEs. ***Continuing at end of study participation****:* Mark this box whenever an AE is continuing at the time of participant termination from the study.
Item 7	A month and year are required at a minimum. Record one of the following, as appropriate: the date on which the participant reports no longer experience the AE or associated symptoms, or the date of the study visit or specimen collection at which it is first noted the AE has resolved or returned to baseline status.
Item 8	Mark 'medication(s)' only if the participant reports taking the medication, If medication is indicated, but not yet used, mark 'other' and describe the medication indicated; mark 'medication(s)' once the medication has been used.
Items 9 and 10	For questions about ICH guidelines and EAE reporting, refer to the current *Manual for Expedited Reporting of Adverse Events to DAIDS.* If item 9 is 'yes', complete any subsequent updates to this form on the applicable EAE form.

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Concomitant Medications Log

Participant ID: _____

Has the participant taken any concomitant medications? ☐ Yes ☐ No

Medication Name _____

Indication _____

Date Started
☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Date Stopped
☐☐ ☐☐☐ ☐☐ OR ☐-Continuing
dd *MMM* *yy* at end of study

Taken for a reported AE?
☐ Yes → If yes, specify AE CRF Number: ____ (*drop-down menu)*
☐ No

****Frequency: Mark only one.**
□ PRN
□ QD
□ TID
□ QHS
□ ONCE
□ BID
□ QID
□ Other, Specify: _____

Dose/Units

****Route** *Mark only one.*
□ PO
□ IM
□ IV
□ TOP
□ IHL
□ VAG
□ REC
□ SC
□ Other, specify: _____

If contraceptive, was it dispensed at research center?
☐ Yes
☐ No

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Form Instructions – Concomitant Medications

Purpose:
This form is used to document all medications taken by the participant starting at the Screening Visit. This includes, but is not limited to: prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive hormonal medications, preventive medications and treatments (e.g., allergy shorts, flu shots, and other vaccinations), herbal preparations, vitamin supplements, and naturopathic preparations.

General Instructions:
Complete this form once a participant has enrolled in the study. Complete an entry for each medication taken by the participant during study participation.

Item-specific Instructions:

Concomitant Medications Yes/No	If 'yes' is selected in Medidata Rave, the Concomitant Medications Log form appears dynamically.
Medication Name	Record the trade name of the medication (not the generic name) whenever possible. If a trade name is not available or not reportable per national guidelines, record the generic name of the medication. A combination medication can be recorded as one entry using the generic name. If a combination medication does not have a generic name, or the generic name is unknown, each active ingredient must be reported as a separate entry.
Indication	For health supplements, such as multivitamins, record 'general health'. For preventive medications, record 'prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza").
Start Date	If the participant is unable to recall the exact date of medication initiation, obtain participant's best estimate. At a minimum, the year is required. For injections, record each injection as a separate entry, with the same date used for start and stop date. For oral contraceptives, record the start date (and stop date) for each pill pack.
Stop Date	At the participant's Termination/Study Exit Visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked. At a minimum, the month and year are required.
Frequency	Below is a list of common frequency abbreviations: **Prn**: as needed **qd:** every day **tid:** three times daily **qhs:** at bedtime **Once:** one time **bid:** twice daily **qid:** four times daily **other, specify:** alternative dosing schedule
Dose/Units	If the participant does not know the exact dose or unites (e.g., "250 mg"), record an estimate (e.g., "1 tablet"). If no information on dose or units is known, draw a single line through the blank response box and initial and date. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., "one pill" or "one tablespoon").
Route	Below is a list of common route abbreviations: **PO**: oral **IV:** intravenous **IHL:** inhaled **REC:** rectal **I** **M:** intramuscular **TOP:** topical **VAG:** vaginal **SC:** subcutaneous **other, specify:** alternative routes
If contraceptive, was it dispensed at research center?	Mark the 'yes' box if the medication is a contraceptive, regardless of indication, and it was dispensed by the study site pharmacy. This item should be completed if a contraceptive is dispensed to a participant for reasons other than family planning (e.g., to treat an AE). If the participant is taking contraceptive pills dispensed by a local health clinic at Screening, then starts receiving oral contraceptives dispensed by the site pharmacy at Month1, record a new entry for the OCPs at Month 1 with this item marked 'yes'. Keep the original "no' response for the OCP entry made at the Screening Visit, and add a stop date to this entry as needed.

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Family Planning Log

Participant ID: _____ Staff Initials/Date: ____

1	What method(s) of contraception/family planning is the participant currently using?				
	Family Planning/Contraception Method	**Date Regimen Started**	**Date Regimen Stopped**	**COMPLETE AT ENROLLMENT ONLY**	
				Is this the same family planning method that the participant used at her last visit in ASPIRE?	**Reason for changing or stopping the family planning method the participant used at last ASPIRE visit (mark all that apply)?**
				☐ Yes → *End of form.* ☐ No	☐ Bothered by bleeding side effects ☐ bothered by pain ☐ bothered by other side effects ☐ wanted to get pregnant ☐ wanted a break from the method ☐ partner objection ☐ family planning method not available ☐ friend or family member suggested a change ☐ difficulty using the method ☐ other, specify: _____
				☐ Yes → *End of form.* ☐ No	☐ Bothered by bleeding side effects ☐ bothered by pain ☐ bothered by other side effects ☐ wanted to get pregnant ☐ wanted a break from the method ☐ partner objection ☐ family planning method not available ☐ friend or family member suggested a change ☐ difficulty using the method ☐ other, specify: _____

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Form Instructions – Family Planning Log

Purpose:
This form is used to document the methods of contraception/family planning used by the participant at during study follow-up per participant self-report.

General Instructions:
Complete this form at the Enrollment Visit and each time a participant starts or stops using a contraceptive or Family Planning method during the study.

Item-specific Instructions:

Item 1:

Complete a row for each method of contraception/family planning the participant reports using during study participation. If a participant has stopped a contraception method since her last visit, provide the stop date. If a participant is currently using a contraception method, leave the Date Regimen Stopped field blank.

If the day portion of the date cannot be obtained, write "UNK" in the white space. At a minimum, a month and year are required.

If marked, record the date the participant started using the current contraceptive regimen under "Date Regimen Started".

If a participant is on oral contraceptives and started on 11-Mar-16, record this as the date the regimen started (even if she has missed pills or an occasional pill pack during that time). Do not record the start date of her most recent/current pill pack.

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

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Pelvic Exam

Participant ID: _____

Visit Date: _____

1	Pelvic exam assessment	☐ Not done → *If not done, end of form.* ☐ Abnormal findings ☐ No abnormal findings → *If no abnormal findings, go to item 2.*

1a Abnormal findings. *Mark all that apply.*

VULVAR	VAGINAL	CERVICAL	GENERAL/OTHER
☐ vulvar edema ☐ vulvar erythema ☐ vulvar rash ☐ vulvar tenderness ☐ Bartholin's or Skene's gland abnormality <u>Vulvar lesions</u> ☐ ulcer ☐ blister ☐ pustule ☐ peeling ☐ ecchymosis	☐ vaginal edema ☐ vaginal erythema ☐ vaginal masses (polyps, myomas, possible malignancy) ☐ vaginal abrasions or lacerations ☐ vaginal tenderness <u>Abnormal vaginal discharge</u> ☐ slight ☐ moderate ☐ pooling <u>Vaginal lesions</u> ☐ ulcer ☐ blister ☐ pustule ☐ peeling ☐ ecchymosis	☐ cervical edema and/or friability ☐ cervical erythema ☐ cervical masses (polyps, myomas, possible malignancy) ☐ cervical motion tenderness ☐ cervical discharge <u>Cervical lesions</u> ☐ ulcer ☐ blister ☐ pustule ☐ peeling ☐ ecchymosis	☐ odor (vaginal) ☐ condyloma, specify location: _____ ☐ adnexal masses (based on bimanual exam; not pregnancy or infection-related) ☐ uterine masses (based on bimanual exam) ☐ uterine tenderness ☐ abnexal tenderness ☐ abnormal blood or bleeding; describe: _____ _____

1b	☐ Other abnormal findings, specify (include anatomical location): *Complete or update Baseline Medical Conditions Log or Adverse Experience Log, as applicable.*	
2	Were any new pelvic finding AEs reported at this visit?	☐ Yes → *If yes, specify AE CRF Number: ____ (drop-down menu)* ☐ No
3	Cervical ectopy:	☐ 0% ☐ 1-25% ☐ 26-50% ☐ 51-75% ☐ 76-100%

Form Instructions – Pelvic Exam

Purpose:
This form is used to document the participant's pelvic exam assessment.

General Instructions:
Complete this form at Screening, Product Use End Visit (PUEV), and when as clinically indicated at all other study visits. Transcribe information from the Pelvic Exam Diagrams form onto this form.

Item-specific Instructions:

Item 1a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark "other abnormal findings, specify" and describe the abnormal finding on the line provided, including anatomical location. In general, for abnormal findings reported as adverse events on an AE log, use text from item 1a as the AE descriptive text. Note that any genital bleeding related to changes in contraceptive method is not considered an abnormal finding and is not an AE.

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Pelvic Exam Diagrams (non-CRF)

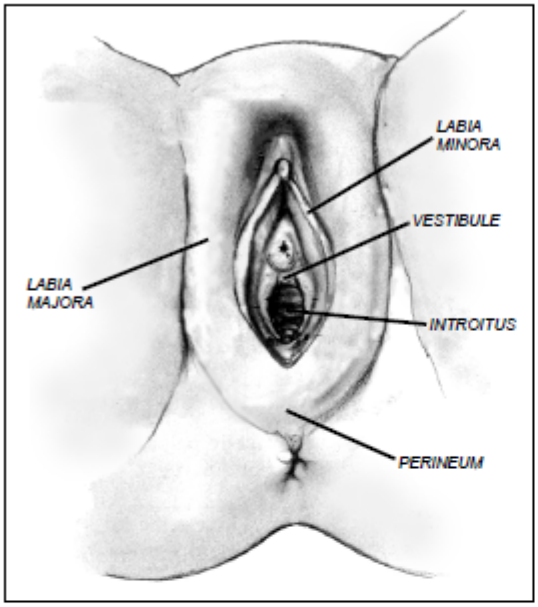
Participant ID: _____ Exam Date: ____/_____/_____

☐ no abnormal findings observed

Speculum Type — *Pederson* ☐ *Graves* ☐ *Cusco* ☐

Speculum Size — *small* ☐ *medium* ☐ *large* ☐

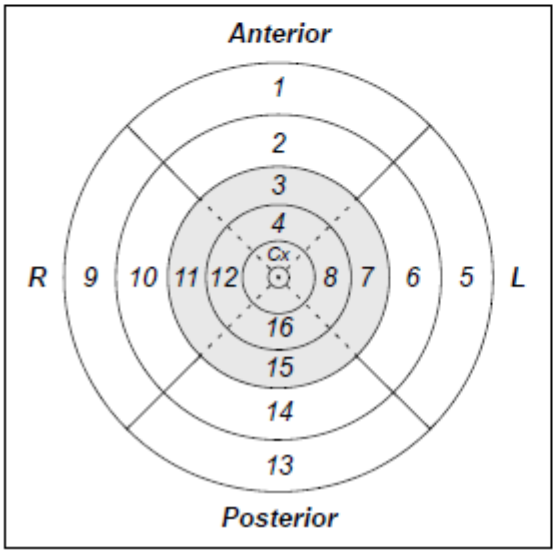
External Genitalia



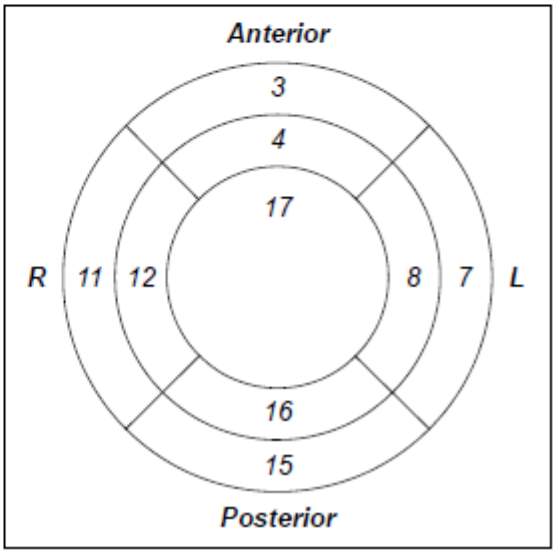
Legend for Vagina/Cervix

1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

Vagina



Cervix



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Form Instructions - Pelvic Exam Diagrams (non-CRF)

Purpose:
This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).

General Information/Instructions:
This form is completed at the Screening Visit and at the Product Use End Visit (PUEV), and whenever a pelvic exam is clinically indicated during the study. Transcribe information onto the appropriate Pelvic Exam CRF and store this form in the participant's chart notes.

Item-specific Instructions:

Findings:	All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal should only be recorded on this form and not on any Pelvic Exam CRF. The following findings are considered normal variants: • Anatomic variants • Gland openings • Nabothian cysts • Mucus retention cysts • Gartner's duct cysts • Blood vessel changes other than disruption • Skin tags • Scars • Cervical ectopy If there are no abnormal findings observed, mark the 'no abnormal findings observed" box.
Documenting findings on the cervix:	If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).

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Baseline Medical History Log

Participant ID: _____

1	Does the participant have any medical history to report?	*yes* ☐ *no* ☐
2	Date medical history collected:	_____ dd MMM yyyy
3	Description of medical history condition/event:	_____
4	Is condition/event gradable?	*yes* ☐ *no* ☐
5	Toxicity (Severity) Grade	_____
6	Date medical history condition/event started:	__ __ __ __ __ __ __ __ MMM yyyy
7	Is the condition ongoing?	*yes* ☐ *no* ☐
8	Date medical history condition/event ended/resolved:	__ __ __ __ __ __ __ __ MMM yyyy
Comments:		

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Form Instructions – Baseline Medical History Log

Purpose:
This form is used to document information on the participant's baseline medical history, including but not limited to: history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions ongoing at screening and/or that occur between screening and enrollment.

General Information/Instructions:

- At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing.
- At the Enrollment Visit, review and update as needed. Those conditions that are ongoing at the time of enrollment (including ongoing chronic conditions) are considered the participant's pre-existing conditions.
- During follow-up, review and update the "Is the Condition Ongoing?" and "Date medical history condition/event ended/resolved" fields as needed.
- Do record baseline medical conditions identified during follow-up. Write a chart note to explain why the entry was added after the Enrollment Visit.

Item-specific Instructions:

Description of medical history condition/event:	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate condition. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT".
Date Medical History Condition/Event Started	If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required.
Is Condition/event gradable?	If a condition is not gradable, mark the 'no' box. Review and update as needed for conditions that are ongoing during the study.
Toxicity (Severity) Grade:	For each condition, grade the severity using the current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums).
Is the condition ongoing?	Mark "yes" for chronic conditions, as well as any other conditions that are currently ongoing. During each follow-up visit, routinely follow up on any and all ongoing conditions. If a condition resolves during follow-up, change the response to "no", and enter the date the condition/event ended or resolved.
Date Medical History Condition/Event Ended/Resolved	If a condition resolves or increases in severity or frequency during participant follow-up, update this item with the date of resolution.
Comments	This field is optiona. Use it to record any additionally relevant information about the condition, including any associated symtoms/signs.

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Pregnancy Outcome

Participant ID: _____

☐ Outcome unobtainable → *End of form.*

Outcome Number:		_____ *If Outcome Number recorded is 2 or greater, go to item 2.*
1	How many pregnancy outcomes resulted from this reported pregnancy?	☐
2	Outcome Date	☐☐ ☐☐☐ ☐☐ *dd MMM yy*
3	Place of delivery/outcome	☐ Home ☐ Hospital ☐ Clinic ☐ Unknown ☐ Other, specify: _____
4	Specify outcome. *Mark only one.*	☐ 4a. Full term live birth (≥ 37 weeks) ***If marked, go to item 4a1.*** ☐ 4b. Premature term live birth (<37 weeks) ***If marked, go to item 4a1.*** ☐ 4c. Stillbirth/intrauterine fetal demise (≥ 20 weeks) ☐ 4d. Spontaneous abortion (< 20 weeks) ☐ 4e. Ectopic pregnancy ☐ 4f. Therapeutic/elective abortion ☐ 4g. Other, specify: _____ ***Items 4a-4f: If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on an AE Log. Complete an EAE Reporting form, if applicable.***
4a1	Method	☐ C-section ☐ Standard vaginal ☐ Operative Vaginal ***If full term live birth, go to item 6.***
5	Provide a brief narrative of the circumstances:	
6	Were there any complications related to the pregnancy outcome?	☐ Yes ☐ No →*If no, go to item 7.*
6a	Delivery-related complications *Mark "none" or all that apply.*	☐ None ☐ Intrapartum hemorrhage ☐ Postpartum hemorrhage ☐ Non-reassuring fetal status ☐ Chorioamnionitis ☐ Other, specify: _____
6b	Non-delivery related complications *Mark "none" or all that apply.*	☐ None ☐ Hypertensive disorders of pregnancy ☐ Gestational diabetes ☐ Other, specify: _____

7	Were any fetal/infant congenital anomalies identified?	☐ Yes ☐ No ☐ Unknown ***If no or unknown, go to the statement above item 8.***
7a	Congenital anomalies identified. *Mark all that apply.* ***Complete AE Log and EAE Reporting form.***	☐ Central nervous system, cranio-facial ☐ Central nervous system, spinal ☐ Cardiovascular ☐ Renal ☐ Gastrointestinal ☐ Pulmonary ☐ Muscoloskeletal/extremities ☐ Physical defect ☐ Skin ☐ Genitourinary ☐ Chromosomal ☐ Cranio-facial (structural) ☐ Hematologic ☐ Infectious ☐ Endocrine/metabolic ☐ Other
7b	Specify congenital anomaly/defect AE CRF Number: ____ (*drop-down menu)*	
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	_____ kg ***OR*** ☐ Unavailable
10	Infant birth length	_____ cm ***OR*** ☐ Unavailable
11	Infant birth head circumference	_____ cm ***OR*** ☐ Unavailable
12	Infant birth abdominal circumference	_____ cm ***OR*** ☐ Unavailable
13	Infant gestational age by examination	_____ weeks _____ days ***OR*** ☐ Unavailable ***If unavailable, end of form.***
13a	Method used to determine gestational age	☐ Ballard ☐ Dubowitz ☐ Other, specify: _____

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Form Instructions - Pregnancy Outcome

Purpose:
This form is used to report pregnancy outcome information for a pregnancy reported post-enrollment. Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that pregnancy outcome is unobtainable.

General Information/Instructions:
A pregnancy outcome is required for each pregnancy report that is completed for a participant.

Item-specific Instructions:

Outcome Number	A pregnancy outcome can be an infant or fetus. The conception of twins, for example, will result in reporting of two outcomes. For a pregnancy resulting in one outcome, record "1" here. For a pregnancy with multiple outcomes, record the outcome number corresponding to the outcome data recorded on the form.
Outcome unobtainable	If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the form.
Item 1:	If the pregnancy results in two or more outcomes, complete a pregnancy outcome form for each outcome. Each Pregnancy Outcome form will have the same visit date, but different outcome number. For example, one Pregnancy Outcome form will have an outcome number =1 and the second form will have an outcome number =2, and so on.
Item 2:	A complete date is required.
Item 3:	Enter the place of delivery/outcome. If 'other' is selected, specify in the corresponding text field.
Item 4:	If the outcome is spontaneous fetal death, still birth, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an adverse event (AE). If a therapeutic/election abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under item 8, "Treatment." If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-specific Procedures (SSP) manual, and *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2* for guidance on AE and expedited AE reporting requirements. If 'other' is selected, specify in the corresponding text field.
Item 4a1:	"Operative vaginal" delivery includes delivery with forceps and/or vacuum. The "Method" is only required if the outcome was a 'full term live birth' or 'premature term live birth'.
Item 5:	Included information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.
Item 7a:	If a woman on study has a baby with congenital anomaly, report the event on a Adverse Experience (AE) Log, if prior to termination. On the AE log, record "Congenital Anomaly in Offspring" in Item 1, record the Outcome Date as the Onset Date, and record the specific anomaly on the Comments line. Also submit an Expedited Adverse Event (EAE) Reporting form.
Items 9-12:	Record the information as documented in medical reports. If no medical record documentation of the information is available, complete this item based on participant report. Mark the "unavailable" box if no medical record documentation is available and the participant does not know the information.
Item 13:	Record the infant's gestational age at birth. If the infant's gestational age is determined using the Ballard method, please record "0" in the "days" box. Mark the 'unavailable' box if no medical record documentation of the infant's gestational age is available.

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Pregnancy Report and History

Participant ID: _____

Pregnancy Report		
1	First day of last menstrual period	☐☐ ☐☐☐ ☐☐ *dd* *MMM* *yy* *OR* ☐ Amenorrheic for past 6 months
2	Estimated date of delivery	☐☐ ☐☐☐ ☐☐ *dd* *MMM* *yy*
3	What information was used to estimate the date of delivery?	
	3a. Last menstrual period 3b. Initial ultrasound <20 weeks 3c. Initial ultrasound ≥ 20 weeks 3d. Physical Examination 3e. Conception date by assisted reproduction 3f. Other, specify: _____	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No
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(≥37 weeks)	☐☐
	4c. Number of premature live births (<37 weeks)	☐☐
	4d. Number of spontaneous fetal deaths and/or still births (≥20 weeks)	☐☐
	4e. Number of spontaneous abortions (<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 *If no, end of form.*
5a	If yes, specify:	

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Form Instructions – Pregnancy Report and History

Purpose:
Complete this form when reporting a pregnancy of a study participant post enrollment through termination.

General Information/Instructions:
A Pregnancy Report and History form is required for each new pregnancy that the participant experiences during the study.

Item-specific Instructions:

Item 1:	A complete date is required. Record best estimate if date not known.
Item 2:	A complete date is required.
Item 3d:	Physical examination includes fundal height, uterine size by pelvic exam, and/or fetal heart rate.
Item 5:	Include information on pregnancy complications and fetal/infant congenital anomalies experienced prior to enrolling in the study as well as any conditions experienced/reported during the study.

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Clinical Product Hold/Discontinuation Log

Participant ID: _____

Have any clinical product holds/discontinuations been applied? ☐ Yes ☐ No		
1	Date when study product hold was initiated:	☐☐☐☐☐☐☐☐ *dd MMM yy*
2	Why is study product being held? *Mark only one per page.*	☐ Pregnancy
		☐ Reactive rapid HIV test result
		☐ Adverse Experience → Specify AE CRF Number: ____ (*drop-down menu)*
		☐ Breastfeeding
		☐ Allergic reaction to the study product → Specify AE CRF Number: ____ (*drop-down menu)*
		☐ Report of PEP use for HIV exposure → Specify Con med CRF Number: ____ (*drop-down menu)*
		☐ 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, specify: _____
3	Date of last study product use	☐☐☐☐☐☐☐☐ *dd MMM yy* OR ☐ *participant never used ring*
4	Was the participant instructed to resume study product use?	☐ Yes → **Date ring inserted:** *dd MMM yy* ☐☐☐☐☐☐☐☐
		☐ No – hold continuing for another reason → **Date:** ☐☐☐☐☐☐☐☐
		☐ No – early termination → **Date:** ☐☐☐☐☐☐☐☐
		☐ No – hold continuing at scheduled PUEV → **Date:** ☐☐☐☐☐☐☐☐
		☐ No – permanently discontinued → **Date:** ☐☐☐☐☐☐☐☐ ↓ ***Complete ACASI Tracking form***
Comments:		

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Form Instructions – Clinical Product Hold/Discontinuation Log

Purpose:
This form is used to document temporary clinical holds and clinical permanent discontinuations of study product use as instructed by study site staff. This form is completed each time a participant is instructed by study staff to temporarily stop (hold) or permanently discontinue study product use. If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete one Clinical Product Hold/Discontinuation Log page for each reason.

This form should be completed for participants who choose and choose **not** to use the study ring during HOPE.

Item-specific Instructions:

Item 2:	Note that participant decline or refusal of study product is not documented as a product hold. Do not record this as a reason in "other, specify."
Item 3:	Record the last date the study product was present in the vagina. Use a best estimate if the actual date cannot be determined. ***Note:*** Do not wait for information about product resumption or permanent discontinuation to complete the form – complete this form as soon as items 1 through 3 have been completed. Update each log entry once item 4 is known. Mark 'participant never used ring' in the event that a participant has never used the ring (i.e. participant chose not to use ring) during HOPE prior to a product hold.
Item 4:	If "no – hold for another reason" is marked, record the date that the participant would have been instructed to resume study product use based on resolution of the reason indicated in item 2. If "no – permanently discontinued" is marked, record the date the permanent discontinuation was initiated.

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Laboratory Forms

STI Test Results

Participant ID: _____

1	**Syphilis Serology**	☐ Not done/not collected → *Go to item 2.*	***Specimen collection date*** *dd MMM yy* ☐☐ ☐☐☐ ☐☐
1a	Syphilis screening test		*Non-reactive* ☐ *reactive* ☐ *If non-reactive, go to item 2.*
1a1	Syphilis titer		1: ☐☐☐☐
1b	Syphilis confirmatory test		☐ Negative ☐ Positive ☐ Indeterminate
2	**Trichomonas Rapid Test**	☐ Not done/not collected	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Negative ☐ Positive
3	***N. gonorrhoeae***	☐ Not done/not collected	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Negative ☐ Positive
4	***C. trachomatis***	☐ Not done/not collected	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Negative ☐ Positive
At Screening, record STI diagnoses in Baseline Medical Conditions Log form when applicable. *Complete or update Adverse Experience Log during follow-up, if applicable.*			
Comments:			

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Form Instructions- STI Test Results

Purpose:
This form is used to document STI test results performed by the local site laboratory.

General Instructions:
Complete this form at the Screening Visit, the participant's Product Use End Visit (PUEV), at early termination (as applicable) and as indicated during the study.

- **Specimen Collection Date**: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
- **Not done/Not collected:** Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments line.

Item-specific Instructions:

Items 1-4:	During follow-up, if a test result(s) recorded on this form indicates that the participant has a new (or increased severity) laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on an Adverse Experience (AE) Log.

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Laboratory Results

Participant ID: _____

1		**Hemogram**	☐ Not done/not collected → *Go to item 2.*	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐
1a	☐ Not Reported	Hemoglobin		☐☐.☐ *g/dL* Severity grade (*if applicable)* ☐ Complete AE Log as *applicable.*
1b	☐ Not Reported	Hematocrit		☐☐.☐ *%*
1c	☐ Not Reported	MCV		☐☐.☐ *fL*
1d	☐ Not Reported	Platelets		☐☐☐☐.☐ *x $10^3/mm^3$* Severity grade (*if applicable)* ☐ Complete AE Log as *applicable.*
1e	☐ Not Reported	WBC		☐☐☐☐.☐ *x $10^3/mm^3$* Severity grade (*if applicable)* ☐ Complete AE Log as *applicable.*
Differential			☐ Not done → *Go to item 2.*	
1f	☐ Not Reported	Neutrophils		**Absolute Count** ☐☐☐☐☐ *cells/mm^3* Severity grade (*if applicable)* ☐ Complete AE Log as *applicable.*
1g	☐ Not Reported	Lymphocytes		**Absolute Count** ☐☐☐☐ *cells/mm^3* Severity grade (*if applicable)* ☐ Complete AE Log as *applicable.*

1h	☐ Not Reported	Monocytes		**Absolute Count** ☐☐☐☐ *cells/mm^3*
1i	☐ Not Reported	Eosinophils		**Absolute Count** ☐☐☐☐ *cells/mm^3*
1j	☐ Not Reported	Basophils		**Absolute Count** ☐☐☐☐ *cells/mm^3*
2		**Serum Chemistries**	☐ Not done/not collected → *End of form.*	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐
2a	☐ Not Reported	AST (SGOT)		☐☐☐☐ *U/L* Severity grade (*if applicable)* ☐ Complete AE Log as *applicable.*
2b	☐ Not Reported	ALT (SGPT)		☐☐☐☐ *U/L* Severity grade (*if applicable)* ☐ Complete AE Log as *applicable.*
2c	☐ Not Reported	Creatinine		☐☐.☐ *mg/dL* **OR** ☐☐☐.☐ *µmol/L* Severity grade (*if applicable)* ☐ Complete AE Log as *applicable.*

Form Instructions – Laboratory Results

Purpose:
This form is used to provide data on the participant's laboratory test results.

General Information/Instructions:

Use this form to report the hematology, differential, and liver and rental function test results obtained from specimens collated at Screening, the Product Use End Visit (PUEV), and as indicated during the study as they become available.

- **Specimen Collection Date**: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
- **Not done/Not collected:** Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage.

Results Reporting:	• Results should be documented on the form usingthe units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-020 Management Team. Note that the following units are equivalent: IU/L = U/L l/l x 100 = % 10^9/L = 10^3/mm^3 = 10^3/µL For creatinine, only record the result in the units listed on the source document. • If the site lab does not report results to the same level of precision allowed on the form, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. - If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.
Severity Grade:	• If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results. If a value is below severity grade 1, leave the "Severity Grade," "AE Log page #," and "not reportable as an AE" boxes blank. • Always compare the severity grade range to the value that was recorded on the form (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade. • Record any Grade 1 or higher lab values on the Pre-Existing Conditions form or
Adverse Experience (AE) Log, as applicable.	

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Pregnancy Test Result

Participant ID: _____

1	hCG for pregnancy	Not done/not collected ☐	***Specimen Collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Negative ☐ Positive → ***If positive, complete a Clinical Product Hold/Discontinuation Log and Pregnancy Report CRF.***
2	First day of last menstrual period	dd MMM yy ☐☐ ☐☐☐ ☐☐ OR ☐ *amenorrheic for past 6 months* OR ☐ *no menses since participant's last visit* → *End of form*	
3	Last day of last menstrual period	dd MMM yy ☐☐ ☐☐☐ ☐☐ OR ☐ *ongoing*	

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Form Instructions – Pregnancy Test Result

Purpose:
This form is used to document pregnancy test results at Enrollment and at all scheduled study follow-up visits.

General Instructions:
Record specimen test results on this form as they become available from the local lab.

- **Specimen Collection Date**: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
- **Not done/Not collected:** Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines.

Item-specific Instructions:

Item 2	The first day of the last menstrual period is the first day of bleeding.
Item 3	The last day of the last menstrual period is the last day of bleeding.

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Specimen Storage

Participant ID: _____

1	Hair collection for PK	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Stored → *Go to Item 2.* ☐ Not stored
1a	Reason hair collection was not done. *Mark all that apply.*	☐ Not required ☐ Unable to obtain hair sample; specify reason: _____ ☐ Insufficient quantity of hair ☐ Participant declined hair collection after counseling; specify reason: _____ ☐ Other, specify reason: _____
2	Self-Collected Vaginal Fluid Swab	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Not required ☐ Stored ☐ Not stored → Reason not stored:_____ *If not required or not stored, go to item 3.*
2a	Was blood visible on the swab?	☐ Yes ☐ No
2b	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
3	Plasma Storage	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Not required ☐ Stored ☐ Not stored → Reason not stored:_____

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Form Instructions - Specimen Storage

Purpose:
This form is used to document collection and storage of vaginal, hair, and plasma specimens by the local site laboratory during follow-up.

General Instructions:
Complete this form at Enrollment, Month 1, 2, quarterly visits, the Product Use End Visit (PUEV), early termination (as applicable), and Termination/Study Exit visits.

- **Specimen Collection Date**: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.

Item-specific Instructions:

Items 1a, 2 and 3:	If the specimen is not required to be collected at this visit, mark the 'not required' box.
Items 2 and 3:	If the specimen is required to be stored, but for some reason it is not stored, mark the 'not stored' box and record the reason on the line provided.

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HIV Test Results

Participant ID: _____

1	Rapid HIV test 1 *(Alere HIV Combo or backup)*	Not done/not collected ☐	Kit Code ☐☐	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Antibody positive ☐ Antigen positive ☐ Antibody and antigen positive ☐ Negative ***If antibody positive, antigen positive, or antibody and antigen positive, complete Clinical Product Hold/Discontinuation Log.***
2	Rapid HIV test 2	Not done/not collected ☐	Kit Code ☐☐	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Negative ☐ Positive → *If positive, complete Clinical Product Hold/Discontinuation Log.*
3	Geenius HIV-1/2 Confirmatory test	Not done/not collected ☐	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ 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)	
4	Was plasma stored for HIV confirmatory testing?		☐ Yes ☐ No ☐ Not required → *If no or not required, go to item 5.*	
4a	Plasma for HIV confirmatory testing collection date		dd MMM yy ☐☐ ☐☐☐ ☐☐	
5	HIV RNA PCR	Not done/not collected ☐ → *Go to item 6*	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ > = < *viral copies/mL* ☐☐☐☐☐☐☐ OR ☐ *target not detected*	
5a	HIV RNA PCR kit lower limit of detection	Kit Code ☐☐	20 ☐ 40 ☐ OR *viral copies/mL* ☐☐☐	

6	Absolute CD4+	Not done/not collected ☐ →*Go to item 7.*	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ Unable to analyze ☐ OR ☐☐☐☐ *cells/mm3*
6a	CD4 %	Not available ☐ OR ☐☐.☐ %	
7	Final HIV Status	☐ HIV-1 and HIV-2 uninfected ☐ HIV-1 infected ☐ HIV-2 infected ☐ HIV-1 and HIV-2 infected ☐ Pending	
Comments:			

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Form Instructions – HIV Test Results

Purpose:
This form is used to document HIV rapid test results and confirmatory results from local lab confirmatory HIV testing.

General Instructions:
Record specimen test results on this form as they become available from the local lab.

- **Specimen Collection Date**: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
- **Not done/Not collected:** Mark this box in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines.

Item-specific Instructions:

<table>
<tr><td>Items 1 and 2:</td><td>Record the assigned two-digit test kit code. Note: More test kit codes may be added to the list as the study proceeds.

<table>
<tr><th>Kit Code</th><th>HIV rapid test</th></tr>
<tr><td>01</td><td>Alere™ HIV Combo</td></tr>
<tr><td>02</td><td>Oraquick ADVANCE® HIV-1/2</td></tr>
<tr><td>03</td><td>Uni-Gold™ Recombigen® HIV-1/2</td></tr>
</table>

Mark ‘not applicable’ if a 4th generation test was not available and a 3rd generation test was used and contact the MTN Laboratory Center.</td></tr>
<tr><td>Item 3:</td><td>Record the Geenius Confirmatory Assay result as determined by the Geenius reader and software.</td></tr>
<tr><td>Item 4:</td><td>If plasma was required but not stored for HIV confirmatory testing, record the reason in the Comments.</td></tr>
<tr><td>Item 4a:</td><td>Record the date the plasma was collected for HIV confirmatory testing.</td></tr>
<tr><td>Item 5:</td><td>Record the participant’s HIV RNA PCR result exactly as it appears on the lab report source documentation. Note that the “>” symbol is ‘greater than’ and the “<” symbol is “less than”</td></tr>
<tr><td>Item 5a:</td><td>Record the assigned two-digit test kit code. Note: More test kit codes may be added to the list as the study proceeds.

<table>
<tr><th>Kit Code</th><th>HIV rapid test</th></tr>
<tr><td>01</td><td>Gene Xpert</td></tr>
<tr><td>02</td><td>Abbott M2000</td></tr>
<tr><td>03</td><td>Roche TaqMan</td></tr>
</table></td></tr>
<tr><td>Item 6a:</td><td>If automatically calculated, record the CD4+ percentage that was reported for the specimen in item “6”. If the CD4 percentage is not available (was not reported and would have to be manually calculated), mark the ‘not available’ box.</td></tr>
<tr><td>Item 7:</td><td>Once a participant’s HIV status has been determined, record the final HIV status. If the participant’s final HIV status is determined to be positive (according to the protocol testing algorithm), update the Clinical Product Hold/Discontinuation Log to reflect permanent discontinuation of study product. If the participant status is not clearly negative or clearly positive, mark the “pending” box and updated this item once the participant’s final HIV status is known.</td></tr>
</table>

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Seroconverter Laboratory Results

Participant ID: _____

1	**Is the participant enrolled in MTN-015?**	☐ Yes → *If yes, end of form.* ☐ No	
2	**T CELL SUBSETS**	Not done/not collected ☐ →*Go to item 3.*	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Negative ☐ Positive
2a	Absolute CD4+	*Unable to analyze* ☐ OR	☐☐☐☐ *cells/mm3*
2a1	*CD4 %*	*Not available* ☐	☐☐.☐ *%*
3	**HIV RNA**		
3a	HIV RNA PCR	Not done/not collected ☐ →*Go to item 4.*	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ *target not detected* > = < *viral copies/mL* ☐☐☐ ☐☐☐☐☐☐☐ OR ☐
3b	HIV RNA PCR Kit Lower limit of detection	Kit Code ☐☐	20 ☐ 40 ☐ OR *viral copies/mL* ☐☐☐
4	**Seroconverter Plasma Storage**	***Specimen collection date*** dd MMM yy ☐☐ ☐☐☐ ☐☐ ☐ Stored ☐ Not stored → Reason not stored:_____	
Comments:			

Form Instructions - Seroconverter Laboratory Results

Purpose:
This form is used to document MTN-015 enrollment status as well as CD4+ and HIV RNA test results for participants who have been confirmed as HIV-1 infected.

General Instructions:
Complete this form for participants with a final HIV status of "HIV infected". Complete this form at each regularly scheduled MTN-025 visit after determination of HIV infection. Complete this form at each visit regardless of enrollment into MTN-015.

Record specimen test results on this form as they become available from the local lab.

- **Specimen Collection Date**: Record the date that the first specimen(s) was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
- **Not done/Not collected:** For every test, mark either the "Not done/Not collected" box or enter a test result.

Item-specific Instructions:

<table>
<tr><td>Item 2a1:</td><td>If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 2a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the 'not available' box.</td></tr>
<tr><td>Item 3a:</td><td>Record the participant's HIV RNA PCR results exactly as it appears on the lab report source documentation. Note that the ">" symbol is 'greater than' and the "<" symbol is "less than".</td></tr>
<tr><td>Item 3b:</td><td>Record the assigned two-digit test kit code. Note: More test kit codes may be added to the list as the study proceeds.
<table>
<tr><th>Kit Code</th><th>RNA PCR Test</th></tr>
<tr><td>01</td><td>Abbott M2000</td></tr>
<tr><td>02</td><td>Roche TaqMan</td></tr>
<tr><td>03</td><td>Gene Xpert</td></tr>
</table>
</td></tr>
</table>

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Behavioral Forms

Baseline Behavior Assessment

Participant ID: _____ Visit Date: _____

☐ Questionnaire not done

Is this participant enrolled in MTN-025 or taking part in 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 *If no, go to item 13.*
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?	☐☐ *years OR* ☐ *don't know*
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 → *If no, go to item 12.*
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
11c	Did he come to the study clinic for any other reason? 11c1. Specify: _____	☐ Yes ☐ No → *If no, go to item 12.*
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?	☐☐ *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
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?	☐☐ *# of times - → If 00, go to item 19.*
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?	☐☐ *# of acts - → If 00, go to item 19.*
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?	☐☐ *# 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 ☐ 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.	☐☐ *# of times - → If 00, go to instructions above item 22.*
21	During the last act of anal sex that you had, was a male condom used?	☐ yes ☐ no
The next questions are about HIV.		

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
28	[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. *Read each response aloud.*	a. You are not at risk for HIV b. It does not matter to you if you get HIV c. You are worried that the ring will harm your health d. The ring is not as good at preventing HIV as you thought e. You are worried people will think you are HIV positive f. You want to avoid side effects you experienced in ASPIRE g. You want to avoid side effects that you heard about in ASPIRE h. Waiting time at the clinic i. Having to return to the clinic frequently j. Having to keep the ring inserted all the time 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, specify:_____	yes ☐ no ☐ *If only one reason is marked, end of form.*

29	What is the **main** reason that you are not willing to participate in HOPE? *Mark the applicable sub-item number from item 28.* *IF PARTICIPANT IS PART OF THE DECLINER GROUP, END OF FORM.*	☐a ☐b ☐c ☐d ☐e ☐f ☐g ☐h ☐i ☐j ☐k ☐l ☐m ☐n ☐o ☐p ☐q ☐r	
30	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. *Read each response aloud.*	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, specify:_____	yes no ☐ *If only one reason is marked, end of form.*
31	What is the **main** reason that you are willing to participate in HOPE? *Mark the applicable sub-item number from item 30.*	☐a ☐b ☐c ☐d ☐e ☐f ☐g ☐h ☐i ☐j ☐k ☐l ☐m	

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Form Instructions – Baseline Behavior Assessment

Purpose:
This form is used to document participant sexual behavior, information on her male sex partners, risk perception, and her willingness to enroll in MTN-025 at baseline.

General Instructions:
This is an interviewer-administered form. Read each item aloud and record the participant's response. Complete this form if the participant enrolls in MTN-025 or participates in the MTN-025 Decliner Population.

Item-specific Instructions:

Item 9:	Complete this item even if the participant is unsure of her partner's HIV status
Item 10:	Complete this item regardless of the response to item 9. Having a primary sex partner who is taking ARVs could impact the participant's HIV risk, so we want this item answered by all participants who answered item 9.
11c:	If the participant's primary sex partner has come to clinic within the past month for a reason other than accompanying the participant to her study visit or to receive counseling or other services form the study clinic, mark the 'yes' box and record the reason in English on the line provided in item 11c1.

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Behavior Assessment

Participant ID: _____ Visit Date: _____

☐ Questionnaire not done

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, 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, 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? 8c1. Specify: _____	☐ yes ☐ no → *If no, go to item 9.*
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?	☐☐ *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:	
11a	Slapped you, hit you with a fist or something else, or beaten you?	☐ yes → *Complete a Social Impact Log, if applicable.* ☐ no
11b	Kicked, dragged, pushed, pulled your hair, choked or burnt you?	☐ yes → *Complete a Social Impact Log, if applicable.* ☐ no
12	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 → *Complete a Social Impact Log, if applicable.* ☐ no
13	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?	☐☐ *# of acts - → If 00, go to item 15.*
14	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?	☐☐ *# of acts with a condom*
15	During the last act of vaginal sex that you had, was a male and/or female condom used?	☐ yes -male condom ☐ yes - female condom ☐ none
16	During the last act of vaginal sex that you had, was the vaginal ring in place?	☐ yes ☐ no ☐ not applicable
17	Does it bother you to wear the ring every day?	☐ yes ☐ no ☐ not applicable (hasn't used ring)
18	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 *If yes, complete a Social Benefit Log*
19	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 *If yes, complete a Social Impact Log*
Complete Items 20-25 at PUEV or Early Termination Visit Only.		
20	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
21	How difficult was it to store the ring(s) at home?	☐ very difficult ☐ somewhat difficult ☐ not at all difficult ☐ not applicable - did not store ring(s) at home ☐ not applicable - never used the ring during HOPE → *If not applicable, skip to item 23.*

22	Have you noticed any of the following changes in your vagina while wearing the vaginal ring?	
	22a. vagina wetter	☐ yes ☐ no → *If no, skip to item 22b.*
	22a1. Was this change a problem for you?	☐ yes ☐ no
	22b. vagina drier	☐ yes ☐ no → *If no, skip to item 22c.*
	22b1. Was this change a problem for you?	☐ yes ☐ no
	22c. change in scent or smell from the vagina	☐ yes ☐ no → *If no, skip to item 23.*
	22c1. Was this change a problem for you?	☐ yes ☐ no
23	Do you prefer to receive one ring or three rings at a time?	☐ prefer receiving 1 ring at a time ☐ prefer receiving 3 rings at a time ☐ no preference
24	As a method to prevent HIV, which do you prefer to use?	☐ ring ☐ condom ☐ neither ☐ both equally
25	What does your primary partner prefer?	☐ ring ☐ condom ☐ neither ☐ both equally ☐ don't know

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Form Instructions – Behavior Assessment

Purpose:
This form is used to document participant sexual behavior, information on her male sex partners during follow-up.

General Instructions:
This is an interviewer-administered form and is completed at quarterly visits as well as the Product Use End Visit (PUEV), and at early termination visit, as applicable. Read each item aloud and record the participant's response.

Item-specific Instructions:

Item 6:	Complete this item even if the participant is unsure of her partner's HIV status
Item 7:	Complete this item regardless of the response to item 9. Having a primary sex partner who is taking ARVs could impact the participant's HIV risk, so we want this item answered by all participants who answered item 9.
Item 8c:	If the participant's primary sex partner has come to clinic within the past month for a reason other than accompanying the participant to her study visit or to receive counseling or other services form the study clinic, mark the 'yes' box and record the reason in English on the line provided in item c1.
Item 17:	If the participant has not yet used the ring, mark the 'not applicable (hasn't use ring)" box.
Items 20-25:	Complete these items if this visit is the participant's Product Use End Visit or her early termination visit, if applicable. For all other visits, leave these items blank.
Item 20:	Complete this item regardless of whether the participant used the ring or not.

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Study Exit Assessment

Participant ID: _____ Visit Date: _____

☐ Questionnaire not done

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 → *If never, go to item 2* ☐ 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?	☐☐ → *If 00, go to item 3.*
	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, 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?	☐☐ *# of acts* - → *If 00, go to item 5.*
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?	☐☐ *# of acts*
5	During the last act of vaginal sex that you had, was a male and/or female condom used? *Mark all that apply.*	☐ yes -male condom ☐ yes - female condom ☐ none
7	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 ☐ no ☐ not applicable

f. Having to use a contraceptive method throughout the study		☐ yes ☐ no
g. Having your blood drawn		☐ yes ☐ no
h. Having an HIV test done at all scheduled visits		☐ yes ☐ no
i. Having pelvic exams		☐ yes ☐ no
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, specify: _____		☐ yes ☐ no
8	Were any of the rings dispensed to you ever used by someone else?	☐ yes ☐ no ☐ not applicable
9	In the future, if a vaginal ring similar to the one you 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 Instructions – Study Exit Assessment

Purpose:
This form is used to document participant engagement is study group activities, sexual behavioral, vaginal hygiene practices, and impressions of participation in HOPE.

General Instructions:
This is an interviewer-administered form. It is completed once for each participant at her scheduled Study Exit Visit. It is not required at early termination visits.

Item-specific Instructions:

Item 1:	Provide site-specific examples of study organized group discussions, activities, or events that the participant might have participated in during HOPE, as applicable. Waiting room discussions with the participant should not be considered a study organized group discussion.
Item 2:	If the participant cannot recall an exact number, provide her best estimate.
Items 2a-2e:	The number of women reported in Items 2a-2e should add up to the total number of women reported in item 2. IF any discrepancies are noted, clarify these with the participant and update the item 2a-2e responses as appropriate. If a woman could belong to more than one category, choose the category that reflects the woman's primary or strongest relationship to the participant. For example, if the participant reports her sister, who is also a neighbor, the primary relationship is 'sister' and the woman should be counted in item 2b. As needed, ask the participant to clarify what the primary or strongest relationship is in her opinion.
Item 2e:	Record the participant's response in English on the line provided.

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Baseline Vaginal Practices

Participant ID: _____ Visit Date: _____

☐ Questionnaire not done

1	In the last 3 months, have you had any menstrual bleeding or spotting?	☐ Yes ☐ No *If no, go to statement above item 3.*
2	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? Specify: _____	☐ Yes ☐ No
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? Specify: _____	☐ Yes ☐ No

Form Instructions – Baseline Vaginal Practices

Purpose:
This form is used to document a participant's vaginal practices at baseline. Only complete this form if the participant enrolls in MTN-025.

General Instructions:
This is an interviewer-administered form. It is completed at the Enrollment Visit. Read each item aloud and record the participant's response.

Item-specific Instructions:

Item 3a:	Note that this question does not include instances where the participant has used her fingers to insert a study vaginal ring.

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Vaginal Practices

Participant ID: _____ Visit Date:_____

☐ Questionnaire not done

1	In the last 3 months, what have you used to control or manage the menstrual blood or spotting?	☐ NA (*participant has not had menses or spotting in the last three months*) **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? Specify: _____	☐ Yes ☐ No
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? Specify:_____	☐ Yes ☐ No

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Form Instructions – Vaginal Practices

Purpose:
This form is used to document a participant's vaginal practices during study follow-up.

General Instructions:
This is an interviewer-administered form and is completed at the Product Use End Visit (PUEV), or at early termination, as applicable. Read each item aloud and record the participant's response.

Item-specific Instructions:

Item 2a:	Note that this question does not include instances where the participant has used her fingers to insert a study vaginal ring.

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Demographics

Participant ID: _____ Visit Date: _____

Is this participant enrolled in MTN-025 or part of the Decliner Population?		☐ MTN-025 main study ☐ Decliner Population
1	Date of Birth	dd MMM yy ☐☐ ☐☐☐ ☐☐ *If unknown, record age :* ☐☐ years
2	Is the participant currently married?	☐ Yes ☐ No
3	Highest level of education?	☐ no schooling ☐ primary school, not complete ☐ primary school, complete ☐ secondary school, not complete ☐ secondary school, complete ☐ attended college or university
4	Ethnic group or tribe	☐☐ *ethnic tribe code* *If other, specify:* _____
5	Number of alcohol drinks per week	☐☐ *# of drinks*
6	Number of cigarettes per day	☐☐ *# of cigarettes*
7	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
8	Does the participant earn an income of her own?	☐ Yes ☐ No *If no, skip to item 9.*
8a	How does she earn her income?	☐ formal employment ☐ self-employment ☐ other
9	How many times has the participant been pregnant?	☐☐ → *If 00, got to item 10*
9a	How many live births have the participant had?	☐☐

10	What is the participant's religion?	☐ Christian ☐ Muslim ☐ Other specify:_____ ☐ None → *If none, go to item 11.*	
10a	How many times a week does the participant attend religious services?	☐ More than once a week ☐ Once a week ☐ Less than once a week ☐ Never	
11	In the past four weeks, how often was the participant worried that she will not have enough food?	☐ Never ☐ Rarely (once or twice) ☐ Sometimes (3-10 times) ☐ Often (more than 10 times)	
12	Does the participant's household have: …? R*ead options and indicate 'yes' or 'no' for all items*.	a. Electricity or solar panels b. A radio c. A cassette player d. A television e. A mobile telephone f. A non-mobile telephone g. A refrigerator h. A table i. A sofa j. A bed k. A CD or digital music player m. A VCR/DVD player n. A car o. A motorcycle p. A bicycle	☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No

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Form Instructions - Demographics

Purpose:
This form is used to document a participant's demographics and socioeconomic information.

General Instructions:
This form is completed for participants who enrolled in MTN-025 and who enroll in the Decliner Population. This form is completed at screening.

Item-specific Instructions:

Item 1:	If any portion of the date of birth is unknown, record age at time of Screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers.
Item 3:	If the participant attended or completed a post-secondary diploma or certificate program, mark the 'attended college or university' box.
Item 4:	This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant's ethnic group or tribe. If the participant identifies as 'other', record '99' and the participant's response.
Item 5:	Record the number of alcohol drinks the participant reports drinking, on average, per week. If the participant does not drink alcohol or has less than one drink per week, enter "00".
Item 6:	If the participant does not smoke cigarettes or smokes less than one cigarette per day, enter "00".
Item 7:	If the participant did not travel from home for this visit, ask her to estimate the travel time it will take her to get to the clinic. If this visit was completed as an off-site visit, mark "N/A".

MALAWI	SOUTH AFRICA	UGANDA		ZIMBABWE
01 - Chewa	07 - Zulu	11 - Black		16 - Shona
02 - Lomwe	08 - Xhosa	06 - White		17 - Ndebele
03 - Yao	09 - Indian	99 - Other		05 - Other African tribe
04 - Tumbuka	10 - Colored			06 - White
05 - Other African tribe	05 - Other African tribe			99 - Other
06 - White	06 - White			
99 - Other	99 - Other			

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Social Influences Assessment

Participant ID: _____

☐ Questionnaire not done

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?	☐☐ *If 00, end of form.*

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 Person 4 and Person 5 columns. If more than five people are indicated, ask participant to think of the five most important people to her among those reported in Item 1 and complete items 2-6 for them.

	Person 1	**Person 2** *Only complete this column if participant indicates 2 or more people in item 1.*	**Person 3** *Only complete this column if participant indicates 3 or more people in item 1.*	**Person 4** *Only complete this column if participant indicates 4 or more people in item 1.*	**Person 5** *Only complete this column if participant indicates 5 or more people in item 1.*
2 What is your relationship with this person? ***Enter the relationship code. Refer to codes on back. If 99 or 5, specify.***	☐☐ *If 99 or 5, specify: _____*	☐☐ *If 99 or 5, specify: _____*	☐☐ *If 99 or 5, specify: _____*	☐☐ *If 99 or 5, specify: _____*	☐☐ *If 99 or 5, specify: _____*
3 Is this person male or female?	☐ male ☐ female	☐ male ☐ female	☐ male ☐ female	☐ male ☐ female	☐ male ☐ female
4 Did this person participate in HOPE?	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown	☐ yes ☐ no ☐ unknown
5 How important to you is this person's view about the ring? ***Read each response aloud.***	☐ not important ☐ a little important ☐ very important	☐ not important ☐ a little important ☐ very important	☐ not important ☐ a little important ☐ very important	☐ not important ☐ a little important ☐ very important	☐ not important ☐ a little important ☐ very important
6 Overall, was this person in favour or against you using the ring? ***Read each response aloud.***	☐ in favour ☐ against ☐ neither (neutral) ☐ N/A	☐ in favour ☐ against ☐ neither (neutral) ☐ N/A	☐ in favour ☐ against ☐ neither (neutral) ☐ N/A	☐ in favour ☐ against ☐ neither (neutral) ☐ N/A	☐ in favour ☐ against ☐ neither (neutral) ☐ N/A

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Form Instructions – Social Influences Assessment

Purpose:
This form is used to identify the people in the participant's life who may have influenced her study participation and use of the study ring.

General Instructions:
This is an interviewer-administered form. It is completed once for each participant at her scheduled Product Use End Visit (PUEV). It is not required at early termination visits.

Item-specific Instructions:

<table>
<tr><td>Items 2-6:</td><td>Ask items 2-6 for the first person. If the participant identifies more than one person in item 1, ask items 2-6 for each subsequent person (up to 5).</td></tr>
<tr><td>Item 2:</td><td>Enter the relationship code from the list below. If Item 2 is 05 or 99 (other), specify the participant's response in English on the line provided. If a person could belong to more than one category, choose the category that reflects the person's primary or strongest relationship to the participant. For example, if the participant reports her sister, who is also a neighbor, the primary relationship is 'sister" and code "03" applies.
<table>
<tr><td>Code</td><td>Relationship</td></tr>
<tr><td>01</td><td>Husband or primary partner</td></tr>
<tr><td>02</td><td>Sex partner other than primary partner</td></tr>
<tr><td>03</td><td>Mother</td></tr>
<tr><td>04</td><td>Father</td></tr>
<tr><td>05</td><td>Other family member. Specify in English on the line provided.</td></tr>
<tr><td>06</td><td>Someone you met during the study</td></tr>
<tr><td>07</td><td>Neighbor</td></tr>
<tr><td>08</td><td>Friend</td></tr>
<tr><td>09</td><td>Co-worker</td></tr>
<tr><td>99</td><td>Other. Specify in English on the line provided.</td></tr>
</table></td></tr>
<tr><td>Item 4:</td><td>If this item is not applicable (for example, if this person is male), mark "no" for this item.</td></tr>
<tr><td>Item 6:</td><td>Mark "N/A" if the person was unaware that the participant was using the vaginal ring as part of her study participation.</td></tr>
</table>