SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) DEM-1 (001)

Participant ID: Protocol | PTID | Chk | Cohort

Demographics

Visit Date: dd | MMM | yy

1.	Date of birth	dd / MMM / yy → *If unknown, record age:* years
2.	What is the participant's gender?	☐ male ☐ female
3.	Is the participant currently married?	☐ yes ☐ no
4.	Is the participant currently living with her/his partner?	☐ yes ☐ no
5.	Highest level of education	☐ no schooling ☐ primary school, not complete ☐ primary school, complete ☐ secondary school, not complete ☐ secondary school, complete ☐ attended college or university
6.	Does the participant earn an income of her/his own?	☐ yes ☐ no → *If no, go to item 7.*
6a.	What is her/his average monthly income?	☐☐☐☐☐☐☐
6b.	How does the participant earn her/his income?	☐ *formal employment* ☐ *self-employed* ☐ *other, specify:* _____
7.	How many children does the participant have?	☐ *# of children*
8.	Does the participant consider herself/himself to be Latina/o or of Hispanic origin?	☐ yes ☐ no
9.	What does the participant report as her/his race? *Mark all that apply.*	☐ American Indian or Alaskan Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or other Pacific Islander ☐ White ☐ other, specify: _____

Comments: _____

☐ ☐ ☐ ☒ 01-AUG-12

01 English

Staff Initials / Date

Demographics (DEM-1)	
Purpose:	This form is used to collect all participants' demographic and socioeconomic information.
General Information/ Instructions:	This form is faxed to SCHARP DataFax only if the couple enrolls in the study. This form is completed at the Screening Visit.
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 5:	If the participant attended or completed a post-secondary diploma or certificate program, mark the "attended college or university" box.
Item 8:	Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background. *NOTE: Latino is not a race.*

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135)

PRE-1 (012)

Note: Number pages sequentially (01, 02, 03) for each participant. Page

Participant ID

Protocol | PTID | Chk | Cohort (0)

Pre-existing Conditions

☐ No pre-existing conditions reported or observed.

Staff Initials/ Date _____ → *End of form. Fax to SCHARP DataFax.*

1. Condition	Onset Date *MMM* *yy*	Staff Initials/Date
Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	Severity Grade *grade* ☐ *not gradable* ☐

2. Condition	Onset Date *MMM* *yy*	Staff Initials/Date
Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	Severity Grade *grade* ☐ *not gradable* ☐

3. Condition	Onset Date *MMM* *yy*	Staff Initials/Date
Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	Severity Grade *grade* ☐ *not gradable* ☐

4. Condition	Onset Date *MMM* *yy*	Staff Initials/Date
Comments	Ongoing at Enrollment? *yes* ☐ *no* ☐	Severity Grade *grade* ☐ *not gradable* ☐

Pre-existing Conditions (PRE-1)	
Purpose:	The Pre-existing Conditions form serves as the "starting point" or baseline from which study clinicians must determine whether conditions identified during follow-up are adverse events (AEs).
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. This includes, but is 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 occurring prior to Enrollment. • At the Enrollment Visit, review and update as needed. • Do record pre-existing conditions if identified during follow-up. Add a chart note to explain why the PRE entry was added after Enrollment
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
Condition:	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 entry on the Pre-existing Conditions form. 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."
Onset Date:	If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required.
Comments:	This field is optional. Use it to record any additional relevant information about the condition, including any associated signs/symptoms.
Severity Grade:	For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark the "not gradable" box. Review and update as needed for conditions ongoing at the Enrollment Visit.
Ongoing at Enrollment?	Mark the "yes" box for chronic conditions, as well as any other conditions, ongoing at the Enrollment Visit. If a condition resolves or increases in severity or frequency after the Enrollment Visit, document this in chart notes and/or another document other than this form.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) PX-1 (036)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐ ☐☐☐☐-☐-0 (Protocol / PTID / Chk / Cohort)

Physical Exam

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

VITAL SIGNS

1.	Weight	☐☐☐ *kg* OR ☐ *not done*	4.	Pulse	☐☐☐ *beats per minute*
2.	Body Temp	☐☐.☐ *°C*	5.	Respirations	☐☐ *breaths per minute*
3.	BP	☐☐☐ / ☐☐☐ *mmHg*	6.	Height	☐☐☐ *cm* OR ☐ *not done*

FINDINGS

		not done	*normal*	*abnormal*	*Notes:*
7.	General appearance	☐	☐	☐	
8.	Genitourinary	☐	☐	☐	
9.	Abdomen	☐	☐	☐	
10.	Lymph Nodes	☐	☐	☐	
11.	Heart/ Cardiovascular	☐	☐	☐	
12.	Lungs/ Respiratory	☐	☐	☐	
13.	Extremities	☐	☐	☐	
14.	Neurological	☐	☐	☐	
15.	Skin	☐	☐	☐	
16.	Eyes	☐	☐	☐	
17.	Ears, Nose, Throat	☐	☐	☐	
18.	Other	☐	☐	☐	

Record abnormal findings on Pre-existing Conditions form or Adverse Experience Log, as applicable.

Physical Exam (PX-1)	
Purpose:	This form is used to document the female participant's vital signs and physical exam findings during screening, enrollment, and follow-up.
General Information/ Instructions:	If abnormal findings are found in items 7–18 transcribe information onto the Pre-existing Conditions form or Adverse Experience Log form, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Items 7–17:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings on the Notes line. If not evaluated, mark the "not done" box.
Item 18:	If no other abnormal findings are identified, mark the "normal" box. If abnormal, specify the body system being referenced and describe the findings on the Notes line.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN-011 (135) PK-1 (061)

Participant ID ☐☐☐ ☐☐☐☐-☐-0 (Protocol / PTID / Chk / Cohort)

Pharmacokinetics

Specimen Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

Not done/ Not collected			
☐	1.	Participant height	☐☐☐ *cm*
☐	2.	Participant weight	☐☐☐ *kg*

SPECIMEN COLLECTION TIMES

Not done/ Not collected				
☐	3.	Cervicovaginal lavage	☐☐:☐☐ *24-hour clock* (*hr* *min*)	
			stored *not stored*	*Reason not stored:*
Go to item 4.	3a.	Supernatant	☐ ☐→	_____
	3b.	Cell pellet	☐ ☐→	_____
☐	4.	Vaginal tissue biopsy	☐☐:☐☐ *24-hour clock*	
☐	5.	Cervical tissue biopsy	☐☐:☐☐ *24-hour clock*	
☐	6.	Cervical cytobrush	☐☐:☐☐ *24-hour clock*	
☐	7.	Blood draw	☐☐:☐☐ *24-hour clock*	
☐	8.	Rectal sponge	☐☐:☐☐ *24-hour clock*	

dry ☐☐☐.☐☐ *weight (grams)* — *wet with PBS* ☐☐☐.☐☐ *weight (grams)* — *after* ☐☐☐.☐☐ *weight (grams)*

BIOPSY WEIGHTS

PRE-COLLECTION *Note: Weight includes empty cryovial and screw lid*

Not done/ Not collected			
☐	9.	Vaginal biopsy for PK: Pre-collection	☐☐☐☐.☐ *weight (mg)*
☐	10.	Cervical biopsy for PK: Pre-collection	☐☐☐☐.☐ *weight (mg)*

POST-COLLECTION *Note: Weight includes cryovial, tissue biopsy, and screw lid*

Not done/ Not collected			
☐	11.	Vaginal biopsy for PK: Post-collection	☐☐☐☐.☐ *weight (mg)*
☐	12.	Cervical biopsy for PK: Post-collection	☐☐☐☐.☐ *weight (mg)*

Comments: _____

☐ ☐ ☐ ☒ 01-AUG-12

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0 1 English

Staff Initials / Date

Pharmacokinetics (PK-1)	
Purpose:	This form is used to document pharmacokinetics, stored specimen collection, as well as pre- and post-collection weights of vaginal tissue (biopsy) pharmacokinetic (PK) specimens for female participants.
	• Visit Code: Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes. • Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). 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.
Items 3a and 3b:	• These items must be completed after the lab has processed the primary specimen. If these specimens are not stored, mark the "not stored" box and record the reason why on the line provided.
Items 3–8:	• When recording time, use a 24-hour clock (e.g., 8:12pm is recorded as 20:12.
Item 8:	• Record the weights in grams. "Dry" refers to the weight of the sponge and insertion tube, dry (before insertion into the participant's anus). "Wet with PBS" refers to the weight of the sponge and insertion tube, wet with PBS (before insertion into the participant's anus). "After" refers to the weight of the sponge and insertion tube after removal from the participant's anus.
Items 9 and 10:	• Record the pre-collection weight in milligrams. Be sure to include all items listed in the "Note" section above this item when obtaining weights.
Items 11 and 12:	• Record the post-collection weight in milligrams. Be sure to include all items listed in the "Note" section above this item when obtaining weights.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) ENR-1 (070)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - ☐
Protocol PTID Chk Cohort

Enrollment

Form Completion Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1.	Does this couple meet all eligibility criteria?	*yes* ☐ *no* ☐ → *If no, couple is not eligible. Do not fax to SCHARP DataFax. Do not enroll couple.*
	1a. Obtain signature: _____ *Signature of Principal Investigator (or designee)*	
	1b. Obtain signature: _____ *Signature of Principal Investigator (or designee)*	
2.	Date the informed consent form for screening and enrollment was marked or signed:	☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*
3.	Date the couple was enrolled:	☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*
4.	This participant is enrolling into which Group?	☐ 4a. Group 1 Female ☐ 4c. Group 2 Female ☐ 4b. Group 1 Male ☐ 4d. Group 2 Male
5.	Has this participant enrolled previously?	*yes* ☐ *no* ☐ → *If no, go to item 6.*
	5a. Participant ID of previous enrollment:	☐☐☐ - ☐☐☐☐ - ☐ - ☐ Site Number Participant Number Chk Cohort
6.	Does the participant agree to long-term storage of biological specimens for future testing?	*yes* ☐ *no* ☐
7.	Was plasma archived for the participant?	*yes* ☐ *no* ☐
8.	Did the participant complete the CASI Baseline Questionnaire (BAQ)?	*yes* ☐ *no* ☐

Item 9 is for Female Participants only. Male Participants, go to item 10 on page 2.

9.	Did the participant complete the CASI Behavioral Questionnaire (BEH)?	*yes* ☐ *no* ☐

Enrollment (ENR-1)	
Purpose:	This form is used to document a couple's study enrollment, and is completed at the Enrollment Visit. An Enrollment form must be completed for each female participant (using the female Participant ID) and each male participant (using the male Participant ID).
General Information/ Instructions:	This form is faxed to SCHARP DataFax for enrolled couples only.
Item-specific Instructions:	
Items 1a and 1b:	Local site SOPs must specify staff members designated to affirm eligibility.
Item 2:	Record the date the informed consent for screening and enrollment was marked/signed.
Item 3:	Complete this item based on the definition of “enrollment” as defined in the Study Specific Procedures (SSP).
Item 6:	Complete this item based on the signed informed consents for long-term specimen storage. Update as needed if the participant changes her/his consent during the study.
Items 7 and 8:	Mark the “no” box if the procedure was not completed on the day of enrollment (date in item 3). Record the reason the item was not completed on the Comments lines on page 2.
Item 9:	For Female Participants only. Mark the “no” box if the questionnaire was not completed on the day of enrollment (date in item 3). Record the reason the item was not completed in Comments on page 2.Leave item blank for all other participants.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) ENR-2 (071)

Participant ID

Protocol | PTID | Chk | Cohort

Enrollment

Item 10 is for Male Participants only.

10. Date screening semen sample collected from the male participant: dd MMM yy → *End of form.*

Item 11 is for Group 2 Female Participants only.

11. Time of Enrollment Visit gel insertion: hr : min *24-hour clock* → *End of form.*

Item 12 is for Group 1 Female Participants only.

12. Did the couple complete coitus? *yes* *no* → *End of form.*

12a. Time of completion of coitus: *24-hour clock* hr : min

Comments: _____

_____

_____

☐ ☐ ☒ ☐ 25-SEP-12

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01 English

Staff Initials / Date

Enrollment (ENR-2)	
Item-specific Instructions:	
Item 10:	For Male Participants only. Leave blank for all other participants.
Item 11:	For Group 2 Female Participants only. Leave blank for all other participants.
Item 12:	For Group 1 Female Participants only. Leave blank for all other participants.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) FP-1 (075)

Visit Code ☐☐.☐ 1

Participant ID

Protocol ☐☐☐ PTID ☐☐☐☐ - Chk ☐ - Cohort 0

Family Planning

Visit Date

dd ☐☐ MMM ☐☐☐ yy ☐☐

1. What method(s) of contraception/family planning is the participant currently using? *Mark "none" or all that apply.*

- ☐ 1a. none
- ☐ 1b. spermicide
- ☐ 1c. diaphragm
- ☐ 1d. sponge
- ☐ 1e. intrauterine device (IUD)–levonorgestrel (Mirena)
- ☐ 1f. intrauterine device (IUD)–copper (Paraguard)
- ☐ 1g. vaginal ring
- ☐ 1h. oral contraceptives/birth control pills
- ☐ 1i. injectable contraceptives (such as Depo-Provera)
- ☐ 1j. (Ortho Evra) The Patch
- ☐ 1k. implants
- ☐ 1l. female condoms
- ☐ 1m. natural methods such as the withdrawal or rhythm method
- ☐ 1n. male condoms
- ☐ 1o. sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization)
- ☐ 1p. sex with partner who had a vasectomy
- ☐ 1q. other, specify: _____

Family Planning (FP-1)	
Purpose:	This form is used to document the methods of contraception/family planning used by the couple at baseline.
General Information/ Instructions:	Complete this form at the Screening Visit and at the Enrollment Visit. Only fax this form to SCHARP DataFax if the participant enrolls in the study. Complete during follow-up as indicated on the Visit Summary form (if/when the participant's method changes post-enrollment).
Item-specific Instructions:	
Item 1:	Mark the method(s) of contraception/family planning the couple reports currently using.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) MPI-1 (115)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 1

Protocol PTID Chk Cohort

Male Practices—Group 1

Visit Date ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1.	Did the male participant complete the self-administered MTN-011 Male Practices questionnaire?	*yes* ☐	*no* ☐ → *If no, end of form.*
2.	In the past 3 full days (72 hours),		*yes* / *no*
	2a.	did your partner perform oral sex on you?	☐ / ☐
	2b.	have you had anal sexual intercourse with your partner?	☐ / ☐
	2c.	have you had penile-vaginal sexual intercourse with your partner?	☐ / ☐
	2d.	have you masturbated?	☐ / ☐
3.	For any activity in item 2 marked "yes," did you ejaculate/come?	*yes* ☐	*no* ☐ *N/A* ☐
4.	In the past 3 full days (72 hours),		*yes* / *no*
	4a.	have you had any nocturnal emissions (wet dreams)?	☐ / ☐
	4b.	have you applied lubricants, spermicides, or any other products to your genital area?	☐ / ☐

Comments: _____

☐☐☐☒ 01-AUG-12

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0 1 English

Staff Initials / Date

Male Practices—Group 1 (MPI-1)	
Purpose:	This form is used to collect data on male behavior practices that could affect interpretation of key study data.
General Information/ Instructions:	This form is completed by transcribing responses present on the participant self-administered Male Practices Questionnaire onto this form. For Group 1 male participants, this form is required at visits 2a (02.0), 3a (03.0), 5a (05.0), and 7a (09.0).
Visit Date:	If the couple misses the visit, record the Target Visit Date recorded on the Missed Visit form for the female participant.
Item-specific Instructions:	
Item 1:	Complete for all Group 1 participants to indicate whether the required MTN-011 Male Practices Questionnaire was completed at the visit. Mark the “no” box if the questionnaire was not completed at a required visit. Record the reason(s) in Comments, leaving all other items blank.
Items 2–4:	Transcribe responses as they appear on the questionnaire document completed by the participant.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN-011 (135) MII-1 (117)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 1

Protocol PTID Chk Cohort

Male Practices—Group 2

Visit Date ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1.	Did the male participant complete the self-administered MTN-011 Male Practices questionnaire?	*yes* ☐	*no* ☐ → *If no, end of form.*
2.	During the duration of time your partner last used the gel (approximately 6-7 days),	2a. did your partner perform oral sex on you?	*yes* ☐ *no* ☐
		2b. have you had anal sexual intercourse with your partner?	*yes* ☐ *no* ☐
		2c. have you had penile-vaginal sexual intercourse with your partner?	*yes* ☐ *no* ☐
3.	In the past 3 full days (72 hours),	3a. did your partner perform oral sex on you?	*yes* ☐ *no* ☐
		3b. have you had anal sexual intercourse with your partner?	*yes* ☐ *no* ☐
		3c. have you had penile-vaginal sexual intercourse with your partner?	*yes* ☐ *no* ☐
		3d. have you masturbated?	*yes* ☐ *no* ☐
4.	For any activity in item 3 marked "yes," did you ejaculate/come?	*yes* ☐	*no* ☐ *N/A* ☐
5.	In the past 3 full days (72 hours),	5a. have you had any nocturnal emissions (wet dreams)?	*yes* ☐ *no* ☐
		5b. have you applied lubricants, spermicides, or any other products to your genital area?	*yes* ☐ *no* ☐

Comments: _____

☐ ☐ ☐ ☒ 01-AUG-12

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0 1 English

Staff Initials / Date

Male Practices—Group 2 (MII-1)	
Purpose:	This form is used to collect data on male behavior practices that could affect interpretation of key study data.
General Information/ Instructions:	This form is completed by transcribing responses present on the participant self-administered Male Practices Questionnaire onto this form. For Group 2 male participants, this form is required at visits 3a (23.0) and 7a (27.0).
Visit Date:	If the couple misses the visit, record the Target Visit Date recorded on the Missed Visit form for the female participant.
Item-specific Instructions:	
Item 1:	Complete for all Group 2 participants to indicate whether the required MTN-011 Male Practices Questionnaire was completed at the visit. Mark the “no” box if the questionnaire was not completed at a required visit. Record the reason(s) in Comments, leaving all other items blank.
Items 2–5:	Transcribe responses as they appear on the questionnaire document completed by the participant.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) VS-1 (121)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 0
Protocol PTID Chk Cohort

Visit Summary

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1.	What was the participant's last day of previous menses?	☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* OR ☐ *amenorrheic for past 6 months*
2.	hCG for pregnancy:	*not required* ☐ *negative* ☐ *positive* ☐ → *If positive, complete Pregnancy Report form and Product Hold/ Discontinuation Log.*
3.	Has participant's method of contraception/family planning changed since her last visit?	*yes* ☐ *no* ☐ → *If yes, complete Family Planning form.*
4.	How many **new** AE Log pages were completed for the female participant at this visit?	*# of pages* ☐☐
5.	How many **new** Product Hold/Discontinuation Log pages were completed for this visit?	*# of pages* ☐☐
6.	Did the female participant complete the CASI Behavioral Questionnaire (BEH)?	*yes* ☐ *no* ☐ OR *not required* ☐
7.	Time during visit of study product insertion:	*24-hour clock* ☐☐ : ☐☐ *hr* *min* OR *not required* ☐
8.	Did the couple complete coitus?	*yes* ☐ *no* ☐ *not required* ☐ → *If no or not required, go to instructions above item 9.*
8a.	Time of completion of coitus:	*24-hour clock* ☐☐ : ☐☐ *hr* *min*

Complete item 9 for Group 1 participants only, and only at Visit Code 09.0. For all other visits, leave item 9 blank.

9.	Time of post-coital study product insertion:	*24-hour clock* ☐☐ : ☐☐ *hr* *min* OR *not inserted* ☐

Visit Summary (VS-1)	
Purpose:	This form is used to document completion of all Follow-up Visits (required and interim) completed by female participants once enrolled.
Item-specific Instructions:	
Item 1:	If the participant is unable to recall the complete date, obtain participant's best estimate. At a minimum, the month and year are required. Only record dates of menstrual period bleeding. Do not record dates of episodes of expected breakthrough bleeding experienced while a participant is on Depo, Mirena, or other continuous contraceptive method where a woman does not experience a monthly menstrual period.
Item 4:	Record in item 4 how many new AE Log pages were completed for the female participant at this visit. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
Item 5:	Record how many new Product Hold/Discontinuation Log pages were completed for this visit. For example, if two new product holds/discontinuations were reported, record “02.” Note that the Visit Code recorded in item 1 of the Product Hold/Discontinuation Log pages should be the same as the Visit Code recorded on this form.
Items 8 and 8a:	Completion of coitus is defined as when the male partner ejaculates into the female partner’s vagina.
Item 9:	When recording time, use a 24-hour clock (e.g., 8:12pm is recorded as 20:12).

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN-011 (135) SEC-1 (128)

Participant ID ☐☐☐ ☐☐☐☐-☐-0 (Protocol / PTID / Chk / Cohort)

Study Exit CASI Tracking

Visit Date ☐☐ ☐☐☐ ☐☐ (*dd* / *MMM* / *yy*)

		yes	*no*
1.	Was a Female Exit Acceptability CASI questionnaire completed?	☐	☐
2.	Was a Male Exit Acceptability CASI questionnaire completed?	☐	☐

Comments: _____

☐☐☐☒ 01-AUG-12

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01 English

Staff Initials / Date

Study Exit CASI Tracking (SEC-1)	
Purpose:	This form is used to document completion of the Study Exit Acceptability Computer-Assisted Self-Interview (CASI) web-based questionnaires at study exit for female and male participants. Complete only one Study Exit CASI Tracking form per couple.
General Information/ Instructions:	Complete this form when the Study Exit Acceptability CASI questionnaire is completed.
Item-specific Instructions:	
Comments:	Use this space to record any unusual events regarding the administration of the CASI questionnaires during follow-up.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN-011 (135) PE-1 (138)

Participant ID ☐☐☐ ☐☐☐☐-☐-0 (Protocol / PTID / Chk / Cohort)

Pelvic Exam

Exam Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

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

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

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

☐ 1b. Other abnormal findings, specify (include anatomical location): _____

Complete or update Pre-existing Conditions or Adverse Experience Log as applicable.

2. Were any new pelvic finding AEs reported at this visit? ☐ *yes* ☐ *no* → *If no, go to item 3.*

2a. AE Log page (#)s: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

3. Cervical ectopy: ☐ *0%* ☐ *1–25%* ☐ *26–50%* ☐ *51–75%* ☐ *76–100%*

☐☐☐☒ 01-AUG-12

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01 English

Staff Initials / Date

Pelvic Exam (PE-1)	
Purpose:	This form is used to document the participant's required pelvic exam assessments.
General Information/ Instructions:	Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to SCHARP DataFax.
Item-specific Instructions:	
Item 1:	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark the "abnormal findings" box and in item 1a, mark the "observed blood or bleeding; describe" box and describe on the lines provided.
Item 1a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box 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 AE descriptive text finding (this does not apply to observances of blood or bleeding). Observed blood or bleeding; describe: If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for AE reporting purposes. Per Study-specific Procedures (SSP) manual section 10.6, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline. Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)*. Refer to SSP manual section 10.6 for more information/guidance as needed.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN-011 (135) PCI-1 (139)

Participant ID ☐☐☐ ☐☐☐☐-☐-0
Protocol PTID Chk Cohort

Pelvic Exam—Clinically-indicated

Exam Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

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

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

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

☐ 1b. Other abnormal findings, specify (include anatomical location): _____

Complete or update Adverse Experience Log as applicable.

2. Were any new pelvic finding AEs reported at this visit? ☐ *yes* ☐ *no* → *If no, end of form.*

2a. AE Log page (#)s: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

3. Cervical ectopy: ☐ *not assessed* ☐ *0%* ☐ *1–25%* ☐ *26–50%* ☐ *51–75%* ☐ *76–100%*

Pelvic Exam—Clinically-indicated (PCI-1)	
Purpose:	This form is used to document the participant's clinically-indicated pelvic exam assessments. This form must be used when two pelvic exams are done on the same day.
General Information/ Instructions:	Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to SCHARP DataFax.
Item-specific Instructions:	
Item 1:	Note that observation of any genital blood or bleeding is considered an abnormal finding, regardless of whether the blood is expected (menstrual blood, for example). If blood or bleeding is observed, mark the "abnormal findings" box and in item 1a, mark the "observed blood or bleeding; describe" box and describe on the lines provided.
Item 1a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box 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 AE descriptive text finding (this does not apply to observances of blood or bleeding). Observed blood or bleeding; describe: If blood or bleeding is observed, mark this item and in the space provided, briefly describe the color, amount, and location of the blood/bleeding. If known, specify if the blood was menstrual or non-menstrual. Assess the blood/bleeding for AE reporting purposes. Per Study-specific Procedures (SSP) manual section 10.6, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline. Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)*. Refer to SSP manual section 10.6 for more information/guidance as needed.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN-011 (135) LR-1 (151)

Participant ID ☐☐☐ ☐☐☐☐-☐-0 (Protocol / PTID / Chk / Cohort)

Laboratory Results

Initial Specimen Collection Date ☐☐ ☐☐☐ ☐☐ (dd / MMM / yy)

1. Hemogram	Go to item 2. ☐ Not done/ Not collected	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐	
Not reported ☐ 1a. Hemoglobin	☐☐.☐ g/dL	Severity Grade (if applicable) ☐	AE Log page # ☐☐☐ OR not reportable as an AE ☐
Not reported ☐ 1b. Hematocrit	☐☐.☐ %		
Not reported ☐ 1c. MCV	☐☐☐.☐ fL		
Not reported ☐ 1d. Platelets	☐☐☐☐.☐ $x10^3/mm^3$	Severity Grade (if applicable) ☐	AE Log page # ☐☐☐ OR not reportable as an AE ☐
Not reported ☐ 1e. WBC	☐☐☐.☐ $x10^3/mm^3$	Severity Grade (if applicable) ☐	☐☐☐ OR ☐
2. HIV Test Results	Go to item 3. ☐ Not done/ Not collected	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐	
2a. HIV EIA	negative ☐ positive ☐ indeterminate ☐	If positive or indeterminate, complete HIV Test Results.	
3. Hepatitis B			
3a. Hepatitis B Surface Antigen	☐ Not done/ Not collected	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐	non-reactive ☐ reactive ☐

Record abnormal findings on Pre-existing Conditions form or Adverse Experience Log, as applicable.

Laboratory Results (LR-1)	
Purpose:	This form is used to document laboratory results as required or clinically indicated during screening, enrollment, and follow-up for female participants.
	• Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. 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:	• If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the results are recorded on the form. • 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 CRF. 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 abnormal laboratory 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. • Always compare the severity grade range to the value that was recorded on the CRF (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. • There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.
AE Log Page #:	• If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.
Not Reportable as an AE:	• Only mark this box if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
Item 3:	• If a result is positive/reactive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log form.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) LR-2 (152) Visit Code . 1

Participant ID

Protocol PTID Chk 0 Cohort

Laboratory Results

4. Syphilis Serology — *End of form.* Not done/ Not collected ☐ Alternate Collection Date *dd* *MMM* *yy*

4a. Syphilis screening test — *non-reactive* ☐ *reactive* ☐ *equivocal* ☐

If non-reactive, end of form.

4a1. Was titer performed? — *yes* ☐ *N/A* ☐ → *If N/A, go to item 4b.*

4a2. Syphilis titer — **1:** ☐☐☐☐

4b. Syphilis confirmatory test #1: — *non-reactive* ☐ *reactive* ☐

If non-reactive, go to item 4c.

4b1. Was titer performed? — *yes* ☐ *N/A* ☐ → *If N/A, end of form.*

4b2. Syphilis titer — **1:** ☐☐☐☐

4c. Syphilis confirmatory test #2: — *non-reactive* ☐ *reactive* ☐ *inconclusive* ☐

Record abnormal findings on Pre-existing Conditions form or Adverse Experience Log, as applicable.

Comments: _____

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0 1 English

Staff Initials / Date

Laboratory Results (LR-2)	
	• Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. 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.
Item 4:	• If a result is positive/reactive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log form.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN-011 (135) STI-1 (190)

Participant ID ☐☐☐ (Protocol) ☐☐☐☐-☐-0 (PTID, Chk, Cohort)

STI Test Results

Initial Specimen Collection Date ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

1. Vaginal Wet Prep	*Go to item 2.*	Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐		
Not done ☐ 1a. Homogeneous vaginal discharge		*negative* ☐	*positive* ☐		
Not done ☐ 1b. pH ☐.☐	*If > 4.5, mark as positive.*		*positive* ☐		
Not done ☐ 1c. Whiff test		*negative* ☐	*positive* ☐		
Not done ☐ 1d. Clue cells ≥ 20%		*negative* ☐	*positive* ☐		
Not done ☐ 1e. *Trichomonas vaginalis*		*negative* ☐	*positive* ☐		
Not done ☐ 1f. Buds and/or hyphae (yeast)		*negative* ☐	*positive* ☐		
2. Trichomonas Rapid Test		Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*negative* ☐	*positive* ☐
3. *N. gonorrhoeae*		Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*negative* ☐	*positive* ☐
4. *C. trachomatis*		Not done/ Not collected ☐	Alternate Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*negative* ☐	*positive* ☐
5. Pre-coital pH:		Not done ☐	☐.☐		
6. Post-coital pH:		Not done ☐	☐.☐		

Complete or update Pre-existing Conditions or Adverse Experience Log, as applicable.

Comments: _____

☐ ☐ ☐ ☒ 01-AUG-12

0 1 English

Staff Initials / Date

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results during screening, enrollment, and follow-up for female participants.
General Information/ Instructions:	• Initial Specimen Collection Date: Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required. • Alternate Collection Date: This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form. 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 lines.
Item-specific Instructions:	
Items 1–4:	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.
Item 1:	If a vaginal wet prep was performed but not all assays were completed, mark the “Not done/Not collected” box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines.
Item 1a:	Mark the “positive” box if homogeneous vaginal discharge was observed.
Item 1d:	Mark the “positive” box if 20% or more of the cells were clue cells.
Item 1e:	Mark the “positive” box if trichomonads were observed.
Item 1f:	Mark the “positive” box if yeast buds and/or hyphae were observed.
Item 5:	Record the result of the pre-coital vaginal fluid pH.
Item 6:	Record the result of the post-coital vaginal fluid pH.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) PDC-1 (260)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 0
Protocol PTID Chk Cohort

Group 2—Participant-reported Dosing

Form Completion Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

HOME DOSING (*Any dosing given during clinic visit captured on the Visit Summary form.*)

Study Gel Not Inserted	Dose #	Dosing Date	Dosing Time *(24-hour clock)*	Was this dosing time provided from the source document?
☐	Dose # 2	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 3	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 4	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 5	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 6	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐
☐	Dose # 7	*dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐	*hr* ☐☐ : *min* ☐☐	*yes* ☐ *no* ☐

Comments: _____

Group 2—Participant-reported Dosing (PDC-1)	
Purpose:	This form is used to document home dosing dates and times for Group 2 participants.
General Information/ Instructions:	This form is completed for female participants in Group 2 only. Clinic staff will transcribe all relevant information from the participant's Home Dosing Log.
Item-specific Instructions:	
Dose # 2–7:	• Transcribe the date and time of each daily dosing recorded on the participant's Home Dosing Log form. The date must be transcribed using the SCHARP DataFax standard, dd MMM yy. The time must be transcribed using the 24-hour clock. • If the participant marked the "I did not insert study gel today" box on her log, mark the "Study Gel Not Inserted" box, and leave all other items for that specific day blank. • For each day that dosing information is recorded, mark "yes" if the time of dosing is provided on the source documentation (i.e., the Home Dosing Log form). If the source documentation is blank or not available, but the participant is able to report an estimated dosing date and time, record the estimated date and time, and mark the "no" box.
Dose #7:	• The "Study Gel Not Inserted" box should be marked for the first and second home dosing periods.
Comments:	• Any relevant information from the participant's log(s) may be transcribed here (e.g., partial doses). You may leave this space blank if there are no additional relevant comments.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN-011 (135) HTR-1 (351)

Participant ID

☐☐☐ ☐☐☐☐ - ☐ - 0

Protocol PTID Chk Cohort

HIV Test Results

Sample 1

1. HIV Western Blot or IFA

Not done/ Not collected ☐ Specimen Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

negative ☐ *positive* ☐ *indeterminate* ☐ → *If negative or indeterminate, notify Network Lab.*

Sample 2

2. HIV Western Blot or IFA

Not done/ Not collected ☐ Specimen Collection Date *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

negative ☐ *positive* ☐ *indeterminate* ☐ → *If negative or indeterminate, notify Network Lab.*

FINAL HIV STATUS

3. Final HIV status: *negative* ☐ *positive* ☐ *other, specify:* _____ ☐

Comments: _____

☐☐☐☒ 01-AUG-12

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0 1 English

Staff Initials / Date

HIV Test Results (HTR-1)	
Purpose:	This form documents confirmatory HIV test results and final HIV status during follow-up for female participants. This form is completed each time a female participant has a positive HIV EIA test result during study follow-up.
General Information/ Instructions:	Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for all required specimens are available and recorded and item 3 has been completed.
	• Visit Code: The visit code recorded on this form should be the same visit code recorded on the Local Laboratory Results form documenting the Sample 1 positive HIV EIA test result. • Specimen Collection Date: Record the date the specimen was collected (not the date results were reported or recorded on the form). For Sample 1, the Specimen Collection Date should be the same date as the collection date of the HIV EIA positive specimen. • Not done/Not collected: Mark the "Not done/Not collected" box in the event that a specimen is 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 lines at the bottom of the form.
Item-specific Instructions:	
Item 3:	Once a participant's HIV status has been determined, record the final HIV status. If, per the appropriate algorithm, the final HIV status is not clear, mark the "other, specify" box and provide a reason(s) on the line provided.
Comments:	Document any problems or reasons why expected results are not available (for example, if the sample was lost or damaged), on the lines provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) PH-1 (410)

Note: Number pages sequentially (01, 02, 03) for each participant. Page ☐☐

Participant ID

☐☐☐ ☐☐☐☐ - ☐ - 0

Protocol PTID Chk Cohort

Product Hold/Discontinuation Log

1. Date and visit code when study product hold was initiated: ☐☐ ☐☐☐ ☐☐ ☐☐.☐
   dd MMM yy visit code

2. Why is study product being held? *Mark only one per page.*
   - ☐ pregnancy
   - ☐ positive or indeterminate HIV test result
   - ☐ adverse experience → ☐☐☐ *AE Log page #*
   - ☐ participant report of non-monogamy
   - ☐ report of PEP use for HIV exposure
   - ☐ reported use of prohibited medications
   - ☐ IoR/designee decision
   - ☐ male partner–related, specify: _____
   - ☐ other, specify: _____

3. Date of last study product use: ☐☐ ☐☐☐ ☐☐
   dd MMM yy

4. Was the participant instructed to resume study product use?

		dd	*MMM*	*yy*
☐ yes →	Date:	☐☐	☐☐☐	☐☐
☐ no – hold continuing for another reason →	Date:	☐☐	☐☐☐	☐☐
☐ no – early termination →	Date:	☐☐	☐☐☐	☐☐
☐ no – hold continuing at scheduled termination →	Date:	☐☐	☐☐☐	☐☐
☐ no – permanently discontinued →	Date:	☐☐	☐☐☐	☐☐

Comments: _____

Product Hold/Discontinuation Log (PH-1)	
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 female 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 Product Hold/Discontinuation Log page for each reason. The same visit code should be used on each Log page. Do not complete this form in cases where a participant has decided herself to not use study product.
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers.
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 fax the form—fax this form to SCHARP DataFax as soon as items 1 through 3 have been completed. Refax the page once item 4 has been completed.*
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.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) SPA-1 (415)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 0
Protocol PTID Chk Cohort

Study Product Accountability

Form Completion Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1. Was study product given to the participant for clinic and/or home use? *yes* ☐ *no* ☐ → *If no, go to item 2.*

   1a. Date dispensed: ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

   1b. Number of study product applicators dispensed at this visit: *1* ☐ *2* ☐ *7* ☐ *8* ☐ *other, specify:* _____

2. Was study product returned by the participant? *yes* ☐ *no, specify:* _____ ☐ → *If no, end of form.*

   2a. Date study product was returned by participant: ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

   2b. Number of **used** applicators returned: ☐ *used applicators returned*

   2c. Number of **unused** applicators returned: ☐ *unused applicators returned*

Comments: _____

☐☐☐☒ 01-AUG-12

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0 1 English

Staff Initials / Date

Study Product Accountability (SPA-1)	
Purpose:	This form is used to document all study product dispensation, and used and unused product returns.
General Information/ Instructions:	This form should be completed at each visit when product is dispensed.
Item-specific Instructions:	
Item 1b:	Mark the box corresponding to the total number of applicators dispensed at this visit. For example, for Group 2 female participants at Visit 6 (26.0), the “8” box should be marked (1 applicator for clinic use, 6 applicators for home use, 1 applicator extra).
Item 2:	This item must be completed when participant returns product from the previous dispensation. For some visits, dispensation and returns will occur on the same day (e.g., Group 1, Visits 3a and 3b; Group 2, Visits 3a and 3b). For other visits, product returns will be several days after dispensation (e.g., Group 1, Visits 6a and 6b; Group 2, Visits 2 and 3a). Always record product returns on the SPA-1 form which documents that dispensation. If study product was not returned, record the reason on the line provided.
Item 2a:	Record the exact day, month, and year study product was returned by the participant.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) CM-1 (423)

Note: Number pages sequentially (001, 002, 003) for each participant. Page

Participant ID

Protocol | PTID | Chk | Cohort

Concomitant Medications Log

☐ No medications taken at Screening/Enrollment. Staff Initials/Date: _____

☐ No medications taken throughout study. Staff Initials/Date: _____

→ *End of form. Fax to SCHARP DataFax.*

1.

Trade Name | Staff Initials/Log Entry Date

Indication | Taken for a reported AE? ☐ *yes* ☐ *no*

Date Started: *dd* *MMM* *yy* | Date Stopped: *dd* *MMM* *yy* OR ☐ Continuing at end of study | *AE Log page(s):*

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:* ☐ _____

2.

Trade Name | Staff Initials/Log Entry Date

Indication | Taken for a reported AE? ☐ *yes* ☐ *no*

Date Started: *dd* *MMM* *yy* | Date Stopped: *dd* *MMM* *yy* OR ☐ Continuing at end of study | *AE Log page(s):*

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:* ☐ _____

Concomitant Medications Log (CM-1)

Purpose:	This form is used to document all medications taken by the participant starting at the Screening Visit. This form must be completed for each enrolled female and male participant. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive medications, intrauterine contraceptive devices, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.
General Information/ Instructions:	When to fax this form: • once the participant has enrolled in the study; • when pages have been updated or additional Log pages have been completed (only fax updated or new pages); • when the participant has completed study participation; and/or • when instructed by SCHARP.
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
No medications taken at Screening/ Enrollment:	Mark this box if no medications were taken by the participant from Screening through the Enrollment Visit. This box should only be marked on Page 01.
No medications taken throughout study:	Mark this box at the Termination/Study Exit Visit if no medications were taken by the participant throughout the entire study.
Trade Name:	Record the trade name of the medication (not the generic name) whenever possible.
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"). For recreational drugs, record "recreation."
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 schedules
Dose/Units:	If the participant does not know the exact dose or units (for example, "250 mg"), you may record an estimate (such as "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 tablespoon).
Route:	Below is a list of common route abbreviations: **IM:** intramuscular; **TOP:** topical; **VAG:** vaginal; **SC:** subcutaneous **IV:** intravenous; **IHL:** inhaled; **REC:** rectal; **other, specify:** alternative routes

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) PR-1 (440)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ ☐☐☐☐ - ☐ - 0

Protocol PTID Chk Cohort

Pregnancy Report and History

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?

	yes	*no*
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: _____	☐	☐

History

	yes	*no*	
4. Has the participant ever been pregnant before?	☐	☐	→ *If no, end of form.*
4a. Is this the participant's first pregnancy since enrollment in this study?	☐	☐	→ *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	☐☐		

	yes	*no*	
5. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	☐	☐	→ *If no, end of form.*

5a. If yes, specify: _____

_____

_____

Pregnancy Report and History (PR-1)	
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. • Visit Code: Record the visit code of the visit at which study staff became aware that the participant is/was pregnant.
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.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ Outcome Number ☐

MTN-011 (135) PO-1 (442)

Participant ID ☐☐☐ ☐☐☐☐-☐-0 (Protocol / PTID / Chk / Cohort)

Pregnancy Outcome

☐ Outcome unobtainable. *Go to page 2.*

If Outcome Number recorded above 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 ☐ unknown
☐ hospital ☐ other, specify: _____
☐ clinic

4. Specify outcome *Mark only one.*
☐ 4a. full term live birth (≥ 37 weeks) → 4a1. Method: ☐ C-section ☐ standard vaginal ☐ operative vaginal
☐ 4b. premature term live birth (< 37 weeks)
☐ 4c. stillbirth/intrauterine fetal demise (≥ 20 weeks)
☐ 4d. spontaneous abortion (< 20 weeks)
☐ 4e. ectopic pregnancy
☐ 4f. therapeutic/elective abortion
☐ 4g. other, specify: _____

If full term live birth, go to item 6.

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.

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 on page 2.*

6a. Delivery-related complications: *Mark "none" or all that apply.*
☐ 6a1. none
☐ 6a2. intrapartum hemorrhage
☐ 6a3. postpartum hemorrhage
☐ 6a4. non-reassuring fetal status
☐ 6a5. chorioamnionitis
☐ 6a6. other, specify: _____

6b. Non-delivery-related complications: *Mark "none" or all that apply.*
☐ 6b1. none
☐ 6b2. hypertensive disorders of pregnancy
☐ 6b3. gestational diabetes
☐ 6b4. other, specify: _____

Pregnancy Outcome (PO-1)	
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 form is required for each Pregnancy Report form that is completed for a participant.
Item-specific Instructions:	
Visit Code:	Record the visit code of the participant's corresponding Pregnancy Report form.
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 page and fax both pages of this form to SCHARP DataFax.
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 code, but different outcome numbers (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 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 experience (AE). If a therapeutic/ elective 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 7, "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.
Item 4a1:	"Operative vaginal" delivery includes delivery with forceps and/or vacuum.
Item 5:	Include 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.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ Outcome Number ☐

MTN-011 (135) PO-2 (443)

Participant ID ☐☐☐ ☐☐☐☐-☐-0 (Protocol / PTID / Chk / Cohort)

Pregnancy Outcome

☐ No data recorded on this page.

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
- ☐ musculoskeletal/extremities
- ☐ physical defect
- ☐ skin
- ☐ genitourinary
- ☐ chromosomal
- ☐ cranio-facial (structural)
- ☐ hematologic
- ☐ infectious
- ☐ endocrine/metabolic
- ☐ other

7b. 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:* _____

Pregnancy Outcome (PO-2)	
Item-specific Instructions:	
Visit Code:	Record the visit code that is present on page 1 of this form.
No data recorded on this page:	This box should only be marked if the “outcome unobtainable” box is marked on page 1. This box must only be marked if all items on the page are left blank.
Outcome Number:	Record the outcome number that is present on page 1 of this form.
Item 7a:	If a woman on study has a baby with a congenital anomaly, report the event on an Adverse Experience (AE) Log, if prior to termination. On the AE Log, record “Congenital Anomaly in Offspring” on 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 records. 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.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) AE-1 (460)

Note: Number pages sequentially (001, 002, 003) for each participant. Page ☐☐☐

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - ☐
Protocol PTID Chk Cohort

Adverse Experience Log

Date Reported to Site ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

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:* _____

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

6a. Status/Outcome Date *(Leave blank if Status/Outcome is "continuing.")*
dd ☐☐ *MMM* ☐☐☐ *yy* ☐☐

7. Treatment *Mark "none" or all that apply.*
☐ none
☐ medication(s) *Report on Concomitant Medications Log.*
☐ new/prolonged hospitalization *Comment:* _____
☐ procedure/Surgery *Comment:* _____
☐ other, specify: _____

8. Is this an SAE according to ICH guidelines? ☐ *yes* ☐ *no*

9. Has/will this AE be reported as an EAE? ☐ *yes* ☐ *no*

10. At which visit code was this AE first reported? ☐☐.☐ *Visit code is required (regular or interim)*

11. Was this AE a worsening of a pre-existing condition? ☐ *yes* ☐ *no*

Comments: _____

☐ ☐ ☐ ☒ 01-AUG-12

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0 1 English

Staff Initials / Date

Adverse Experience Log (AE-1)	
Purpose:	To document all MTN-011 Adverse Experiences (AEs) required to be reported on Log per protocol for female and male participants.
General Information/ 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/GAE Log pages as applicable. If a cluster of symptoms reported on separate AE/GAE Log page is later attributed to a single diagnosis, change the earliest reported symptom page to the diagnosis. In addition, mark the AE/GAE Log pages for the other symptoms with the words "Delete due to diagnosis on AE Log pages (insert page #s) and/or GAE Log pages (insert page #s)."
Item-specific Instructions:	
Page:	Number pages for this Log sequentially throughout the study for each PTID, starting with 001. Do not repeat page numbers on this log. If an AE Log page is marked for deletion, do not change the page number or re-assign that page number to another AE Log page.
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 minimum, 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. If "not related" is marked, record an alternative etiology or explanation on the line provided.
Item 5:	• *no change:* Mark if there is no change in the participant's planned use of study product as a result of the AE. That is, 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 Product Hold/Discontinuation (PH) Log should be completed for each AE page with "held" marked. If an AE results in a hold, then a permanent discontinuation, update this item to "permanently discontinued" at the time of permanent discontinuation. • *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 page with this box marked, there should be a PH Log page 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/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 of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation." • *severity/frequency increased:* If an AE increases in severity or 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 on a new AE Log page. For this new AE, the "Onset Date" (item 2) will be the same as the "Status/Outcome Date" (item 6a) of the AE Log page used to first report the AE. Note that decreases in severity (AE improvements) are not recorded as new AEs. • *continuing at end of study participation:* Mark this box whenever an AE is continuing at the time of participant termination.
Item 6a:	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports no longer experiencing 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 7:	Mark "medication(s)" only if participant reports taking the medication. If medication indicated but not yet used, mark "other" and describe the medication indicated; mark "medication(s)" once the medication has been used.
Items 8 and 9:	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," be sure to make any subsequent updates made to this form on the applicable EAE form.
Item 10:	Record the Visit Code that corresponds to the "Date Reported to Site." For lab AEs, record the Visit Code that matches the "Onset Date." Note that the Visit Summary form with this visit code should have item 6 = "yes" or (for interim visits) the AE Log page marked in item 5b.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.0

1

MTN-011 (135) MV-1 (463)

Participant ID

☐☐☐ ☐☐☐☐ - ☐ - 0

Protocol PTID Chk Cohort

Missed Visit

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

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
- ☐ 2f. participant withdrew from study → *Complete a Termination form.*
- ☐ 2g. participant deceased → *Complete a Termination form.* *Complete an Adverse Experience Log.*
- ☐ 2h. other, specify: _____

Comments: _____

☐ ☐ ☐ ☒ 01-AUG-12

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01 English

Staff Initials / Date

Missed Visit (MV-1)	
Purpose:	Complete this form whenever an enrolled female participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP) manual.
General Information/ Instructions:	If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a Missed Visit form. Fax 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 that the form was completed. This will not necessarily 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.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135)

PDL-1 (495)

Note: Number pages sequentially (01, 02, 03) for each participant.

Page ☐☐

Participant ID ☐☐☐-☐☐☐☐-☐-☐

Protocol PTID Chk Cohort

Protocol Deviation Log

Form Completion Date ☐☐ ☐☐☐ ☐☐

dd MMM yy

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*

Protocol Deviation Log (PDL-1)

Purpose:	This form documents and reports protocol deviations identified for study participants.
General 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 requires reporting as a deviation.

Item-specific Instructions:

Page:	Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.
Item 2:	Record the date the event occurred (start date).
Item 5:	Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.

Code	Description
01	Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
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.
03	Study product management deviation: Site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
04	Study product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. Do not include any information related to study product assignment (product codes) on this form. Pharmacy staff must follow up with the MTN Pharmacist separately.
05	Study product use/non-use deviation: Participant did not use the study product (including product refusals) or used it incorrectly (i.e., not in accordance with protocol requirements).
06	Study product sharing: Participant has shared study product with another person or study participant.
07	Study product not returned: Study product was not returned by the participant per protocol requirements.
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.
09	Improper AE/EAE follow-up: Use when an AE or EAE is not followed-upper protocol. For example, a clinical finding/ lab result that is not re-assessed as outlined in the protocol.
10	Unreported AE: Site staff become aware of an AE, but not report it per protocol requirements.
11	Unreported EAE: Site staff become aware of an EAE, but not report it per protocol and DAIDS EAE Manual requirements.

Code	Description
12	Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form.
13	Physical assessment deviation: Include missed or incomplete physical/pelvic/rectal exam assessments.
14	Lab assessment deviation: Include missed, or incomplete lab specimen collection.
15	Mishandled lab specimen: Include errors in the labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
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.
17	Questionnaire administration deviation: A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
18	Counseling deviation: Protocol-required counseling was not done and/or not documented correctly.
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.
20	Use of excluded concomitant medications, devices or non-study products
21	Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
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, use if Visit 3.0 procedures are done in the Visit 4.0 window.

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.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) ESI-1 (489)

Participant ID: ☐☐☐ ☐☐☐☐ - ☐ - 0
Protocol PTID Chk Cohort

End of Study Inventory

Form Completion Date: ☐☐ ☐☐☐ ☐☐
dd MMM yy

1. What is the **highest** visit code (scheduled or interim) for this participant, recorded on a form submitted via DataFax? ☐☐.☐ *visit code*

2. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax? ☐☐☐ *# of interim visits*

3. Indicate the **highest** page number submitted for this participant for each of the following forms:

3a.	Adverse Experience Log (AE) for female partner	☐☐☐ *page #*	OR	☐ *no pages submitted*
3b.	Concomitant Medications Log (CM) for female partner	☐☐ *page #*		
3c.	Pre-existing Conditions (PRE) for female partner	☐☐ *page #*		
3d.	Product Hold/Discontinuation Log (PH) for female partner	☐☐☐ *page #*	OR	☐ *no pages submitted*
3e.	Protocol Deviation Log (PDL) for female partner	☐☐ *page #*	OR	☐ *no pages submitted*
3f.	Adverse Experience Log (AE) for male partner	☐☐☐ *page #*	OR	☐ *no pages submitted*
3g.	Concomitant Medications Log (CM) for male partner	☐☐☐ *page #*		
3h.	Protocol Deviation Log (PDL) for male partner	☐☐ *page #*	OR	☐ *no pages submitted*

End of Study Inventory (ESI-1)	
Purpose:	This form is used to confirm that SCHARP has received all study data for a given couple.
General Information/ Instructions:	Complete this form once for each enrolled couple after the female participant has terminated from the study (as documented by a Termination form).
Item-specific Instructions:	
Form Completion Date:	A complete date is required.
Item 1:	Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.
Item 2:	Record the total number of interim visits documented on the Visit Summary DataFax forms submitted for this participant. If no interim visits were completed for the participant, record "000" in the boxes.
Items 3a–3e:	Only record the number of forms completed for the female participant.
Items 3f–3h:	Only record the number of forms completed for the male participant.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-011 (135) TM-1 (490)

Participant ID

Protocol | PTID | Chk | Cohort

Termination

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* — OR ☐ *cause unknown*
  - 2b2. cause of death: _____
  - → *Complete or update Adverse Experience Log.*
- ☐ 2c. participant refused further participation, specify: _____
- ☐ 2d. participant unable to adhere to visit schedule
- ☐ 2e. participant relocated, no follow-up planned
- ☐ 2f. investigator decision, specify: _____
- ☐ 2g. unable to contact participant
- ☐ 2h. 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.*
- ☐ 2m. permanent study product discontinuation
- ☐ 2n. self-reported non-monogamy → *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.*

3a. Record AE Log page number *AE Log page #* ☐☐☐ OR Specify: _____

Comments: _____

☐ ☐ ☐ ☒ 01-AUG-12

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Staff Initials / Date

Termination (TM-1)	
Purpose:	This form should be completed for every enrolled female and male participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.
General Information/ Instructions:	If a participant is terminated prior to completing all study product administration, complete a Product Hold/Discontinuation form.
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 3a:	Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the “specify” line.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN-011 (135)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 0
Protocol PTID Chk Cohort

Screening Menstrual History

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1.	Age of first menses (menarche)	☐☐ *years*
2.	Usual menstrual cycle	*regular* ☐ *irregular* ☐ *amenorrheic for past 6 months* ☐ → *Specify:* _____
3.	Usual number of days between menses (1st day to 1st day)	*minimum* ☐☐ *# of days* TO *maximum* ☐☐ *# of days*
4.	Usual number of bleeding days (record range)	*minimum* ☐☐ *# of days* TO *maximum* ☐☐ *# of days*
5.	First day of last menstrual period	☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*
6.	Last day of last menstrual period	☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* OR *ongoing* ☐
7.	Usual type of menstrual flow (at heaviest day of menses)	*light* ☐ *moderate* ☐ *heavy* ☐

8. Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern.

_____

_____

_____

_____

_____

_____

_____

_____

Record usual menstrual symptoms and any irregular bleeding on the Pre-existing Conditions form.

Screening Menstrual History (non-DataFax)	
Purpose:	This form is used to document information on the participant's menstrual history at the Screening Visit. Because this is a non-DataFax form, do NOT fax to SCHARP DataFax.
Item-specific Instructions:	
Item 3:	Record the usual number of days that the participant experiences between menses starting on the first day of her menstrual period up to and including the day before the first day of her next menstrual period.
Item 4:	Record the range (minimum and maximum) of the usual number of bleeding days of the participant's menses. For example, if a participant reports that she has experienced menses that have lasted for a minimum of 3 days and a maximum of 6 days, record "03" for minimum of days and "06" for maximum number of days.
Item 5:	Record the first day of the participant's most recent menstrual period.
Item 7:	This item is based on how the participant describes her heaviest flow day during menses.
Item 8:	During follow-up, occurrences of genital bleeding will be compared to the participant's baseline bleeding pattern (as documented on this form) in order to determine if the episode requires reporting as an AE. With this mind, use this space to describe as best possible the participant's usual genital bleeding pattern. Include details such as number of sanitary pads typically used, any spotting that is experienced, and any additional details on amount/heaviness of flow. Update with additional details as needed at the Enrollment Visit.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

Visit Code ☐☐.☐

MTN-011 (135)

Participant ID ☐☐☐ (Protocol) ☐☐☐☐-☐ (PTID, Chk) -1 (Cohort)

Genital Exam—Male

Examination Date ☐☐ (*dd*) ☐☐☐ (*MMM*) ☐☐ (*yy*)

	EXAM	FINDINGS
1.	Foreskin (internal and external)	☐ *N/A (circumcised)* ☐ *normal* ☐ *abnormal* → *If abnormal, specify type of finding. Mark all that apply.* ☐ vesiculation ☐ peeling ☐ bullous reaction ☐ erythema (with induration) ☐ ulceration ☐ erythema (without induration) ☐ bruising, petechiae or ecchymoses ☐ other, specify: _____
2.	Penile Shaft	☐ *normal* ☐ *abnormal* → *If abnormal, specify type of finding. Mark all that apply.* ☐ vesiculation ☐ peeling ☐ bullous reaction ☐ erythema (with induration) ☐ ulceration ☐ erythema (without induration) ☐ bruising, petechiae or ecchymoses ☐ other, specify: _____
3.	Glans	☐ *normal* ☐ *abnormal* → *If abnormal, specify type of finding. Mark all that apply.* ☐ vesiculation ☐ peeling ☐ bullous reaction ☐ erythema (with induration) ☐ ulceration ☐ erythema (without induration) ☐ bruising, petechiae or ecchymoses ☐ other, specify: _____
4.	Urethral Meatus	☐ *normal* ☐ *abnormal* → *If abnormal, specify type of finding. Mark all that apply.* ☐ vesiculation ☐ peeling ☐ bullous reaction ☐ erythema (with induration) ☐ ulceration ☐ erythema (without induration) ☐ bruising, petechiae or ecchymoses ☐ other, specify: _____

Genital Exam—Male (Non-DataFax--Page 1)	
Purpose:	This form is used to document the male participant's genital exams conducted during screening, enrollment, and follow-up. Because this form is a non-DataFax form, do NOT fax to SCHARP DataFax.
General Information/ Instructions:	For abnormal findings identified after enrollment, complete or update an Adverse Experience Log form when applicable.
Visit Code:	Record the visit code assigned to this visit. Refer to the Study Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
Item-specific Instructions:	
Items 1–4:	If an abnormal finding is observed, mark the appropriate finding(s) in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

Visit Code ☐☐.☐

MTN-011 (135)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 1

Protocol PTID Chk Cohort

Genital Exam—Male

	EXAM	FINDINGS
5.	Scrotum	*normal* ☐ *abnormal* ☐ → *If abnormal, specify type of finding. Mark all that apply.* ☐ vesiculation ☐ peeling ☐ bullous reaction ☐ erythema (with induration) ☐ ulceration ☐ erythema (without induration) ☐ bruising, petechiae or ecchymoses ☐ other, specify: _____
6.	Inguinal Lymph Nodes	*normal* / *enlarged and painless* / *enlarged and painful* 6a. Right ☐ ☐ ☐ 6b. Left ☐ ☐ ☐

Item 7 is only completed for visits AFTER Enrollment.

7. During this genital exam, was any dried product observed on the penile shaft, glans, urethral meatus, scrotum, or foreskin?
Mark "none observed" or all that apply.

- ☐ 7a. none observed
- ☐ 7b. penile shaft
- ☐ 7c. glans
- ☐ 7d. urethral meatus
- ☐ 7e. scrotum
- ☐ 7f. foreskin

Comments: _____

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Staff Initials / Date

Genital Exam—Male (Non-DataFax--Page 2)	
Visit Code:	Record the visit code assigned to this visit. Refer to the Study Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
Item-specific Instructions:	
Item 5:	If an abnormal finding is observed, mark the appropriate finding(s) in the space provided.
Item 7:	This item is only completed at follow-up visits. Leave this item blank at Screening and Enrollment.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN-011 (135)

Participant ID ☐☐☐ ☐☐☐☐ - ☐ - 1

Protocol PTID Chk Cohort

Physical Exam—Male

Exam Date ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

VITAL SIGNS

1.	Weight	☐☐☐ *kg* OR ☐ *not done*	4.	Pulse	☐☐☐ *beats per minute*
2.	Body Temp	☐☐.☐ *°C*	5.	Respirations	☐☐ *breaths per minute*
3.	BP	☐☐☐ / ☐☐☐ *mmHg*	6.	Height	☐☐☐ *cm* OR ☐ *not done*

FINDINGS

		not done	*normal*	*abnormal*	*Notes:*
7.	General appearance	☐	☐	☐	
8.	Genitourinary	☐	☐	☐	
9.	Abdomen	☐	☐	☐	
10.	Lymph Nodes	☐	☐	☐	
11.	Heart/ Cardiovascular	☐	☐	☐	
12.	Lungs/ Respiratory	☐	☐	☐	
13.	Extremities	☐	☐	☐	
14.	Neurological	☐	☐	☐	
15.	Skin	☐	☐	☐	
16.	Eyes	☐	☐	☐	
17.	Ears, Nose, Throat	☐	☐	☐	
18.	Other	☐	☐	☐	

Record abnormal findings on Adverse Experience Log as applicable.

Physical Exam—Male (Non-DataFax)	
Purpose:	This form is used to document the male participant's vital signs and physical exam findings.
General Information/ Instructions:	This form is completed each time a physical exam is performed. Because this is a non-DataFax form, do NOT fax to SCHARP DataFax.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed. The staff member who completes these items should initial and date in the space provided.
Findings:	The staff member who completes these items should initial and date in the space provided.
Item 18:	If no other abnormal findings are identified, mark the "normal" box. If abnormal, specify the body system being referenced and describe the findings on the Notes line.

SAMPLE: DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN-011 (135)

Participant ID

Protocol | PTID | Chk | Cohort (0)

Pelvic Exam Diagrams

Exam Date

dd MMM yy

☐ no normal variants or abnormal findings observed

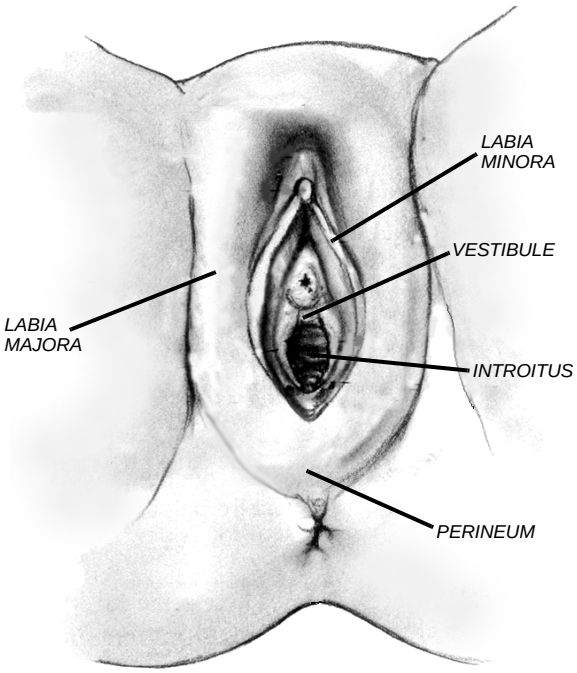
Speculum Type (screening only)

Pederson ☐ Graves ☐ Cusco ☐

Speculum Size (screening only)

small ☐ medium ☐ large ☐

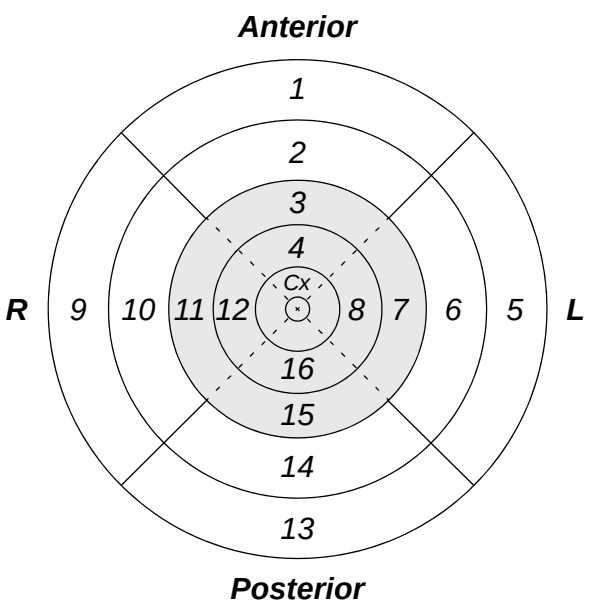
External Genitalia



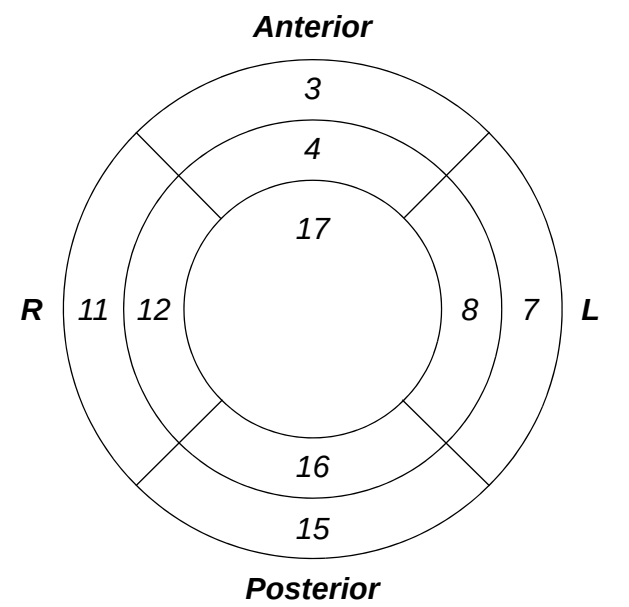
Legend for Vagina/Cervix

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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Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax)	
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 with each required pelvic exam, and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to SCHARP DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax 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 need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. 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 If there are no variants of normal or abnormal findings observed mark the "no normal variants or 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).