SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

DEM-1 (001)

Participant ID

Unit ID – Participant Number – Chk

Demographics

Form Completion Date

dd MMM yy

1. Participant's sex at birth	☐ *male* ☒ *female*
2. What is your date of birth?	dd MMM yy OR *If unknown, record age:* ☐☐ *years*
3. Are you currently married?	☐ *yes* ☐ *no*
4. What is your highest level of education?	☐ no schooling ☐ primary school, not complete ☐ primary school, complete ☐ secondary school, not complete ☐ secondary school, complete ☐ attended college or university
5. Do you consider yourself to be Latina or of Hispanic origin?	☐ *yes* ☐ *no*
6. What is your race? *Mark all that apply.*	☐ 6a. American Indian or Alaska Native ☐ 6b. Asian ☐ 6c. Black or African American ☐ 6d. Native Hawaiian or other Pacific Islander ☐ 6e. White ☐ 6f. Other, specify: _____
7. Do you earn an income of your own?	☐ *yes* ☐ *no* *If no, go to statement below item 7a.*
7a. How do you earn income? *Mark all that apply.*	☐ *formal employment* ☐ *self-employment* ☐ *other*

I will ask questions about you and your sexual behaviors. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential. None of your answers will affect your ability to participate in the study. There are no right or wrong answers, and every answer is important, so please be as honest and as accurate as you can.

The next questions are about your recent sexual partners.

8. Do you currently have a primary sex partner? By primary sex partner we mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner?	☐ *yes* ☐ *no* ☐ *not applicable* *If no or not applicable, go to item 13 on page 2.*
9. Do you currently live with your partner?	☐ *yes* ☐ *no*
10. Does your primary partner know that you are taking part in this study?	☐ *yes* ☐ *no* ☐ *don't know*

Demographics (DEM-1)	
Purpose:	This form is interviewer-administered and is used to collect participants' demographic and socioeconomic information.
General Information/Instructions:	
	This form is faxed to SCHARP DataFax only if the participant enrolls in the study. This form is completed at the Screening Visit. Read each item aloud, except item 1, and record the participant's response.
Item-specific Instructions:	
Item 2:	If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant's estimate of their age. Do not complete both answers.
Item 3:	Mark "yes" if the participant is in a legally-binding marriage and has obtained a marriage certificate.
Item 4:	If the participant is currently attending, has ever attended, or has completed college, university, a post-secondary diploma or certificate program, mark "attended college or university."
Item 5:	This item is based on self-definition. Per NIH policy, Latina or Hispanic includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
Item 6:	Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background. Per NIH policy, Latina is considered an ethnic group and not a race and should not be entered in item 6f.
Item 8:	Mark "not applicable" if the participant has a female primary sex partner.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

DEM-2 (002)

Participant ID

Unit ID – Participant Number – Chk

Demographics

11. In the **past 3 months**, has your primary sex partner had sex with another partner besides you?	☐ *yes* ☐ *no* ☐ *don't know*
12. In the **past 3 months**, have you had vaginal sex with your primary sex partner? By vaginal sex we mean when a man puts his penis inside of your vagina.	☐ *yes* ☐ *no*
13. In the **past 3 months**, with how many other male partners have you had vaginal sex? By other male partners, we mean any man who is not your primary sex partner.	☐☐ *partners*
14. During the **last act** of vaginal sex that you had, was a male or female condom used?	☐ *yes* ☐ *no* ☐ *not applicable*
15. When did you last have anal sex? By anal sex we mean when a man puts his penis inside your anus.	*day(s) ago* ☐☐ OR *week(s) ago* ☐☐ OR *month(s) ago* ☐☐ OR *never* ☐ → *If never, go to item 18.*
16. In the **past 3 months**, how many times have you had anal sex?	☐☐ *times*
17. During the **last act** of anal sex that you had, was a male condom used?	☐ *yes* ☐ *no*
The next few questions are about HIV/AIDS.	
18. Does anyone with HIV/AIDS live in your household?	☐ *yes* ☐ *no* ☐ *don't know* ☐ *not applicable*
19. As far as you know, does your primary sex partner have HIV/AIDS?	☐ *yes* ☐ *no* ☐ *don't know* ☐ *not applicable*
20. How worried are you that you may get infected with HIV in the **next year**?	*very worried* ☐ *somewhat worried* ☐ *not at all worried* ☐

Comments:

Demographics (DEM-2)	
General Information/Instructions:	
	Read each item aloud and record the participant's response.
Item-specific Instructions:	
Item 13:	If the participant has not had vaginal sex with a male partner or has had sex exclusively with women, in the past 3 months, record "00" for this item.
Item 15:	Record the last time the participant had anal sex. For example, if she reports having last had anal sex 2 months ago, mark '02' months ago and leave all other boxes blank for this item. If she has never had anal sex, mark "never." Only one response should be marked for this item.
Item 16:	Record the number times the participant has had anal sex in the past 3 months (90 days).
Item 17:	Record whether a male condom was used during the participant's last act of anal sex.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

PRE-1 (012)

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

Page

Participant ID

Unit ID – Participant Number – Chk

Pre-existing Conditions

☐ No pre-existing conditions reported or observed.
End of form. Fax to SCHARP DataFax.

Staff Initials/ Date: _____

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 and rectal 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*, the *DAIDS Rectal Grading Table for Use in Microbicide Studies (as appropriate),* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark "not gradable". Review and update as needed for conditions ongoing at the Enrollment Visit.
Ongoing at Enrollment?	Mark "yes" 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-014 (201)

ECI-1 (023)

Participant ID

Unit ID – Participant Number – Chk

Eligibility Criteria

Form Completion Date

dd MMM yy

1. Does this participant meet all eligibility criteria? *yes* ☐ *no* ☐ → *If no, go to item 2.*

1a. Obtain signature _____

Signature of Principal Investigator (or designee) *Date*

1b. Obtain signature _____

Signature of second staff member verifying eligibility *Date*

2. Was the participant enrolled? *yes* ☐ *no* ☐ → *If yes, end of form.*

3. Why was the participant not enrolled?

- ☐ participant did not complete all screening procedures → *End of form.*
- ☐ eligible but declined enrollment → *End of form.*
- ☐ not eligible

4. Reason(s) for ineligibility *Mark all that apply.*

- ☐ 4a. participant < 21 or > 45 years old
- ☐ 4b. inadequate locator information
- ☐ 4c. participant is pregnant or planning to become pregnant
- ☐ 4d. participant is breastfeeding
- ☐ 4e. participant has irregular menstrual cycles with 21 or more days between menses and does not use progestin-only contraceptive
- ☐ 4f. participant has enrolled in another research study in the last 42 days
- ☐ 4g. IUD inserted in the past 42 days or IUD replacement expected within the next 3 months
- ☐ 4h. PEP or PrEP exposure in the last 6 months
- ☐ 4i. participant is HIV-positive
- ☐ 4j. participant declines effective method of contraception
- ☐ 4k. participant has a grade 2 or higher pelvic or rectal exam finding
- ☐ 4l. participant does not meet laboratory eligibility criteria
- ☐ 4m. participant does not meet other clinical eligibility criteria
- ☐ 4n. other reason, including investigator decision. Specify: _____

Eligibility Criteria (ECI-1)	
Purpose:	This form is used to document participant eligibility for enrollment in this study or reasons for participant ineligibility.
General Information/Instructions:	
	• Complete this form for each participant screened for this study. Complete and fax this form once it is determined whether the participant will enroll in the study. If not enrolled, this is the only form that is faxed for the participant. • If the participant has a second screening attempt, update this form with data from the second screening attempt and refax. Do not complete a new form for the second attempt.
Item-specific Instructions:	
Items 1a and 1b:	Local site Standard Operating Procedures (SOPs) must specify staff members designated to affirm eligibility.
Item 3:	Mark “participant did not complete all screening procedures” when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 42-day screening window.
Item 4:	Mark all reasons for participant ineligibility. Refer to the Eligibility Checklist for the Screening and Enrollment Visit. If the reason for ineligibility is not listed, mark the “other reason, including investigator decision” box and specify ineligibility reason on the line provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

SPX-1 (035)

Participant ID

Unit ID – Participant Number – Chk

Screening Visit
Physical Exam

Visit Date

dd MMM yy

VITAL SIGNS

1. Weight	___ *kg*	4. Pulse	___ *beats per minute*
2. Body Temp	___ . ___ *°C*	5. Respirations	___ *breaths per minute*
3. BP	___ / ___ *mmHg*	6. Height	___ *cm*

FINDINGS

	not done	*normal*	*abnormal*	*Notes:*
7. General appearance	☐	☐	☐	
8. Abdomen/ Gastrointestinal	☐	☐	☐	
9. Neck	☐	☐	☐	
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 as applicable.

Screening Visit Physical Exam (SPX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings at the Screening Visit. This form is faxed to SCHARP only if the participant enrolls in the study.
General Information/Instructions:	
	Complete this form at the Screening Visit. If abnormal findings are found in items 7–18 transcribe information onto the Pre-existing Conditions DataFax form.
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 in Notes. If not evaluated, mark "not done" and record the reason in Notes. Normal findings may also be described in Notes, but is not required.
Item 18:	If abnormal, specify the body system being referenced and describe the findings in Notes.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

ARE-1 (041)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Unit ID – Participant Number – Chk)

Anorectal Exam

Exam Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

PERIANAL EXAMINATION

1. Findings from the perianal examination — *no abnormal findings* ☐ / *abnormal findings* ☐ / *not done* ☐ → *If not done, specify reason(s) in Comments. Go to item 2.*

If no abnormal findings, go to item 2.

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

- ☐ Warts
- ☐ Fissure
- ☐ Ulceration
- ☐ Pigmentation
- ☐ Hemorrhoids
- ☐ Skin tags
- ☐ Leukoplakia
- ☐ Fistula
- ☐ Petechiae (< 3 mm)
- ☐ Purpura (0.3–1 cm)
- ☐ Ecchymosis (> 1 cm)
- ☐ Discharge
- ☐ Erythema
- ☐ Bleeding
- ☐ Other abnormal findings, specify: _____

DIGITAL RECTAL EXAMINATION

2. Findings from the digital rectal examination — *no abnormal findings* ☐ / *abnormal findings* ☐ / *not done* ☐ → *If not done, specify reason(s) in Comments. Go to item 3.*

If no abnormal findings, go to item 3.

2a. Abnormal findings, specify:

ANOSCOPY

3. Was an anoscopy performed at this visit? — *yes* ☐ / *not required* ☐ / *no, specify:* _____

If not required or no, end of form.

4. Rectal mucosa findings — *no abnormal findings* ☐ / *abnormal findings* ☐

If no abnormal findings, end of form.

4a. Abnormal rectal mucosa findings *Mark all that apply.*

- ☐ Erythema
- ☐ Abnormal vessels
- ☐ Ulceration
- ☐ Friability
- ☐ Bleeding
- ☐ Discharge
- ☐ Polyps
- ☐ Hemorrhoids
- ☐ Other abnormal findings, specify _____

Comments:

Anorectal Exam (ARE-1)

Purpose:	This form is used to document the anorectal exam findings identified via perianal visual inspection, digital rectal examination, and anoscopy. An anorectal exam is required at Screening, Enrollment, and both initiate period visits and period end visits.

General Information/Instructions:

- At Screening and Enrollment, evaluate any abnormalities for eligibility.
- At Enrollment, update Pre-existing Conditions when applicable.
- During follow-up, complete or update Adverse Experience Log 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:

Item 1:	If the perianal visual examination was required but not done, mark “not done” and record the reason the visual examination was not done in Comments.
Items 1a and 4a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark “Other abnormal findings, specify” and describe the abnormal finding on the lines provided.
Item 2:	If a digital rectal examination was required but not done, mark “not done” and record the reason the digital rectal examination was not done in Comments.
Item 2a:	If an abnormal finding is observed, record the finding(s) on the line provided.
Item 3:	Mark “not required” only if anoscopy was not done and the visit was an interim visit or the Washout Visit. If anoscopy was required but not done, mark “no” and record the reason on the adjacent line.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

PK-1 (061)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Unit ID – Participant Number – Chk)

Pharmacokinetics

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

1. Last menstrual period: Start date ☐☐ dd ☐☐☐ MMM ☐☐ yy — Stop date ☐☐ dd ☐☐☐ MMM ☐☐ yy OR ☐ *ongoing*

SPECIMEN COLLECTION TIMES

Not done/ Not collected ☐

2. Cervicovaginal lavage — Alternate Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

stored *not stored* *Reason not stored*

Go to item 3.

2a. Supernatant ☐ ☐→ _____

2b. Cell pellet ☐ ☐→ _____

Not done/ Not collected ☐

3. Cervical cytobrush — Alternate Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

stored ☐ *not stored* ☐→ *Reason not stored* _____

Not done/ Not collected ☐

4. PBMC for PK — Alternate Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

stored ☐ *not stored* ☐→ *Reason not stored* _____

Not done/ Not collected ☐

5. Plasma for PK — Alternate Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

stored ☐ *not stored* ☐→ *Reason not stored* _____

Not done/ Not collected ☐

6. Rectal sponge for PK — Alternate Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

stored ☐ *not stored* ☐→ *Reason not stored* _____

Not done/ Not collected ☐

7. Vaginal swab for PK — Alternate Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

stored ☐ *not stored* ☐→ *Reason not stored* _____

End of form.

7a. Was blood visible on swab? ☐ *yes* ☐ *no*

Comments:

☐☐☐☒ 25-FEB-14

N:\hivnet\forms\MTN_014\forms\m014_PK.fm

0 1 English

Staff Initials/Date

Pharmacokinetics (PK-1)	
Purpose:	This form is used to document pharmacokinetics and stored specimen collection.
General Information/Instructions:	
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.
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.
Not done/Not collected:	Mark this box in the event that a specimen was not collected or not required.
Stored/Not Stored:	Mark “stored” for specimens that are collected and sent to the lab for processing. If specimens are not stored, mark “not stored” and record the reason why on the line provided.
Item-specific Instructions:	
Item 1:	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. If a participant is unable to recall the complete date, obtain the participant’s best estimate. At a minimum, the month and year are required.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

ENR-1 (070)

Participant ID

Unit ID – Participant Number – Chk

Enrollment

1. Date the participant marked or signed the study screening/ enrollment consent/long term storage form	dd MMM yy
2. Randomization envelope # assigned	*randomization envelope #*
3. Date randomization envelope # assigned	dd MMM yy
4. Time randomization envelope # assigned	hr : min *24-hr clock*
5. This participant is enrolling into which sequence?	*Sequence A Vaginal/Rectal* ☐ *Sequence B Rectal/Vaginal* ☐
6. Plasma archive storage	Collection Date dd MMM yy; *stored* ☐ *not stored* ☐ → *Reason not stored* _____

Comments:

Enrollment (ENR-1)	
Purpose:	This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants randomized.
General Information/Instructions:	
	Fax this form to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a randomization number).
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.
Item-specific Instructions:	
Item 3:	This item must match the "date assigned" date recorded for this randomization envelope on the MTN-014 Randomization Envelope Tracking Record.
Item 4:	This item must match the "time assigned" date recorded for this randomization envelope on the MTN-014 Randomization Envelope Tracking Record. When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12).
Item 6:	If specimens are not stored, mark "not stored" and record the reason why on the line provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

EDE-1 (075)

Participant ID

Unit ID – Participant Number – Chk

Enrollment DOD Experience Assessment

Visit Date

dd MMM yy

Study Treatment Period ☐ *vaginal* ☐ *rectal*

1. What are your feelings about being observed using the gel?

Response Code

1a. ☐☐ 1b. ☐☐ 1c. ☐☐ 1d. ☐☐ 1e. ☐☐ 1f. ☐☐

If there is a reason that is not represented in the Response Code list, mark 1g and record the reason on the adjacent specify line. Otherwise, leave item 1g blank.

☐ 1g. other, specify: _____

2. Why do you think we are observing you during daily use of the gel?

Response Code

2a. ☐☐ 2b. ☐☐ 2c. ☐☐ 2d. ☐☐ 2e. ☐☐ 2f. ☐☐

If there is a reason that is not represented in the Response Code list, mark 2g and record the reason on the adjacent specify line. Otherwise, leave item 2g blank.

☐ 2g. other, specify: _____

3. Will you insert the gel yourself or will study staff insert the gel for you?

☐ will insert gel herself

☐ study staff will insert gel for her

☐ don't know

☐ other, specify: _____

4. What are your feelings about having visits every day for 14 days in a row, including weekends?

Response Code

4a. ☐☐ 4b. ☐☐ 4c. ☐☐ 4d. ☐☐ 4e. ☐☐ 4f. ☐☐

If there is a reason that is not represented in the Response Code list, mark 4g and record the reason on the adjacent specify line. Otherwise, leave item 4g blank.

☐ 4g. other, specify: _____

Record other comments or suggestions in the participant's chart notes

Enrollment DOD Experience Assessment (EDE-1)

Purpose: This form is used to document the participant's feelings about directly observed dosing of tenofovir gel.

General Information/Instructions:

This is an interviewer-administered form and it is completed at the Enrollment/Study Product Administration/Period 1 Initiate Visit. Read each item aloud and record the participant's response. Record any notes, comments or suggestions in the participant's chart notes for reference.

Item-specific Instructions:

Items 1–2 and 4: Refer to the list of response codes below. Record the two-digit code that corresponds to the participant's response(s). Up to six response codes may be recorded. A response code is required for items 1a, 2a and 4a. Record any additional response codes in items 1b-1f, 2b-2f, or 4b-4f; leave any unused items blank. For example, if four response codes apply for item 1, record the codes in items 1a-1d and leave items 1e-1g blank. Record notes taken during the interview for these items in participant chart notes.

RESPONSE CODES

Study-related or Procedural Reasons	
Code	Description
10	**Proper gel use:** To make sure she inserts gel as instructed: in correct part of body/at correct time/every day
11	**Good data:** To make sure the study is done correctly and data are good
12	**Contribution:** Feels she is making a positive contribution to a good cause/science
13	**Store study product:** Convenient/comfortable to come to clinic because no need to store study product at home
14	**Short Visits:** Convenient to come to clinic because the visits will be/were short
15	**Incentives:** Will like/Liked getting paid for daily visits

Staff/Clinic-related experiences	
Code	Description
20	**Help/Assistance:** Provide(d) assistance: help her insert or remember to insert gel
21	**Trust:** Study Staff lacks trust/confidence in her
22	**Respect:** Study staff lacks respect for her
23	**Capability:** Study staff thinks she is incapable of inserting gel as instructed
24	**Comfortable with staff:** Felt/will feel comfortable with study staff
25	**Cared for:** Felt/will feel well-cared for by study staff
26	**Get Advice:** Will have/Had a chance to ask study staff questions/get advice from study staff
27	**Prolonged waiting time in clinic:** Did not like to wait while other participants were being seen
28	**Privacy at home:** Preferred to use gel at home because more privacy at home

Emotional/Physical experiences	
Code	Description
30	**Monitor Health:** Check for reactions to gel/ illness
31	**Monitor comfort level:** Emotional/psychological reactions to using gel
32	**Embarrassment:** Will feel/felt embarrassment/shame
33	**Guinea pig:** Will feel/felt like a "guinea pig"/dehumanizing
34	**Physical discomfort:** Inserting gel will be/was painful/uncomfortable
35	**Dislike pelvic exams:** Uncomfortable because it is similar to a pelvic exam
36	**Gel leaks out:** Did not like using/use gel because it leaks out
37	**Negative impact on sex:** Did not like using/use gel before sex
38	**Positive impact on sex:** Liked using gel before sex

Family/Partner/Community concerns	
Code	Description
40	**Privacy at clinic:** Convenient/comfortable to come to clinic because no family/ partner are there, more privacy
41	**Questions about clinic:** Inconvenient/uncomfortable to come to clinic because family/partner questioned why she will go/went to clinic everyday
42	**No questions at home:** Convenient/comfortable to use gel at home because family/partner did not question why she was going to clinic every day
43	**No privacy at home:** Inconvenient/uncomfortable to use gel at home because family members/partner are there/not enough privacy
44	**Curiosity from friends/neighbors:** Reaction to home visits
45	**Childcare:** Difficult to secure childcare during daily visits

DOD scheduling convenience	
Code	Description
50	**Time off work:** Inconvenient because she will have/had to take time off work
51	**Establish routine:** Coming to clinic will establish/established a routine/schedule
52	**Convenient to stay home:** Convenient/comfortable to use gel at home because saved her a trip to the clinic
53	**Convenient travel to clinic:** Convenient to come to clinic because it is/was on her way to other places and/or close to home
54	**Inconvenient travel to clinic:** Long travel time/expensive/too busy
55	**Remembers in clinic:** Coming to the clinic will make it/made it easier to remember to use gel
56	**Remembers at home:** Using gel at home will make it/made it easier to remember to use gel
57	**Convenient weekdays:** It was/will be easier to come in on weekdays
58	**Convenient weekends:** It was/will be easier to come in on weekends

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

PDR-1 (080)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Unit ID | Participant Number | Chk

Product Dispensation and Returns

Form Completion Date

dd ☐☐ MMM ☐☐☐ yy ☐☐

VAGINAL

1. Date product provided for non-observed home use — dd ☐☐ MMM ☐☐☐ yy ☐☐ — *not provided* ☐ → *Go to item 2.*

   1a. Number of applicators provided at this visit for home use — ☐☐ *# of applicators*

   If provided at a non-initiate period visit, record reason: _____

2. Date study product returned by participant — dd ☐☐ MMM ☐☐☐ yy ☐☐ — *not returned* ☐ → *Go to item 3.*

   2a. Number of **unused** applicators returned — ☐☐ *# of **unused** applicators*

RECTAL

3. Date product provided for non-observed home use — dd ☐☐ MMM ☐☐☐ yy ☐☐ — *not provided* ☐ → *Go to item 4.*

   3a. Number of applicators provided at this visit for home use — ☐☐ *# of applicators*

   If provided at a non-initiate period visit, record reason: _____

4. Date study product returned by participant — dd ☐☐ MMM ☐☐☐ yy ☐☐ — *not returned* ☐ → *End of form.*

   4a. Number of **unused** applicators returned — ☐☐ *# of **unused** applicators*

Comments:

☐☐☐☒ 25-FEB-14

N:\hivnet\forms\MTN_014\forms\m014_PDR.fm

0 1 English

Staff Initials/Date

Product Dispensation and Returns (PDR-1)	
Purpose:	This form is used to document when study product designated for non-observed home use is dispensed and/or collected from the participant during the study.
General Information/Instructions:	
	Complete this form at each visit when home-dosing applicators are dispensed or collected from the participant.
Item-specific Instructions:	
Items 1a and 3a:	Record the number of applicators dispensed to the participant in the event that home dosing is needed. If participants are dispensed applicators for insertion at home at a visit other than a period initiate visit, record the reason for product dispensation.
Items 2 and 4:	These items must be completed when a participant returns unused product from the previous dispensation.
Items 2a and 4a:	If a participant returns unused applicators to the clinic, specify the number of applicators returned.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

FVS-1 (121)

Visit Code ___ . ___ 1

Participant ID

___ ___ ___ - ___ ___ ___ ___ ___ - ___

Unit ID | Participant Number | Chk

Follow-up Visit Summary

Visit Date

dd ___ MMM ___ yy ___

1. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV? ☐ yes ☐ no → *If yes, complete Clinical Product Hold/Discontinuation Log, if applicable. Record on Concomitant Medications Log.*

2. Since the last visit, has the participant used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV? ☐ yes ☐ no *If no, go to item 3.*

   2a. Was oral or topical PrEP used? ☐ *oral* ☐ *topical* ☐ *both* → *Complete Clinical Product Hold/Discontinuation Log, if applicable. Record on Concomitant Medications Log.*

3. hCG for pregnancy

   ☐ Not done/ Not collected → *Go to item 4.*

   Alternate Collection Date dd ___ MMM ___ yy ___

   ☐ *negative* ☐ *positive* *If positive, complete the Pregnancy Report and History. Complete Clinical Product Hold/ Discontinuation Log, if applicable.*

4. Is this an interim visit? ☐ *yes* ☐ *no* *If no, go to item 5.*

   4a. Reason for interim visit *Mark all that apply.*

   ☐ *AE report or follow-up* ☐ *return of product or need new product* ☐ *other, specify:* _____

   4b. Which forms, besides this form, were newly completed for this interim visit? *Mark all that apply.*

   - ☐ Adverse Experience Log
   - ☐ Clinical Product Hold/Discontinuation Log
   - ☐ Pharmacokinetics
   - ☐ Specimen Storage
   - ☐ Safety Laboratory Results
   - ☐ Pelvic Exam
   - ☐ STI Test Results
   - ☐ Anorectal Exam
   - ☐ HIV Results
   - ☐ HIV Confirmatory Results
   - ☐ Product Dispensation and Returns
   - ☐ Abbreviated Physical Exam
   - ☐ other, specify: _____

   → *End of form.*

5. Were any **new** Adverse Experience Logs completed for this visit? ☐ *yes* ☐ *no*

6. Were any **new** Clinical Product Hold/Discontinuation Logs completed for this visit? ☐ *yes* ☐ *no*

Comments:

Follow-up Visit Summary (FVS-1)

Purpose:	This form is used to summarize information from each participant follow-up study visit (including interim visits).
General Information/Instructions:	
	This form is completed for each scheduled visit. This form is also completed for interim visits/contacts where a new form (other than the Follow-up Visit Summary) is completed. Note that there is no Interim Visit form for this study—instead, this form is completed to document interim visits.
Visit Code:	• Record the visit code assigned to the visit. For required visits, the Visit Code will end in 0 (XX.0). If the visit is an interim visit/contact, use an interim code for the Visit Code. Start with the Visit Code of the last required visit and add "1" to the right of the decimal point for each interim visit conducted. For example, if the participant's last required visit was the Period 1 End Visit, the interim visit would be assigned Visit Code 16.1. If the participant has a second interim visit before the Washout Visit, this would be assigned a code of 16.2. • If procedures for a required visit are split over 2 or more days, and all days are within the same visit window, assign all forms completed for the split visit the same Visit Code (ending in .0). For example, if a participant completes all Period 2 End/Final Clinic Visit procedures except rectal exam procedures on 08-OCT-13, and completes the rectal procedures on 09-OCT-13, assign a Visit Code of 32.0 to all forms.
Item-specific Instructions:	
Item 1:	If the participant has taken post-exposure prophylaxis (PEP) since her last visit, mark "yes" and update the Concomitant Medications (CM) Log. In addition, a Clinical Product Hold/Discontinuation (PH) Log must be completed, unless the participant has already permanently discontinued study product use at a previous visit or at the final clinic visit.
Item 2:	Record if the participant has used oral or topical medicine for pre-exposure prophylaxis (PrEP) against HIV and indicate whether oral or topical PrEP was used. If either or both were used, update the Concomitant Medications (CM) Log. In addition, a Clinical Product hold/Discontinuation (PH) Log must be completed, unless the participant has already permanently discontinued study product use at a previous visit or at the final clinic visit.
Item 4b:	Mark the newly completed forms (in addition to this form) that are being submitted for the interim visit/contact. If "other, specify" is marked, record the form acronyms in the space provided.
Item 5:	Mark "yes" if at least one Adverse Experience (AE) Log was newly completed for this visit (Visit Code in item 10 of the AE Log is the same as the Visit Code recorded on this form).
Item 6:	Mark "yes" if at least one Clinical Product Hold/Discontinuation (PH) Log was newly completed for this visit (Visit Code in item 1 of the PH Log is the same as the Visit Code recorded on this form).

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

BSS-1 (130)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Unit ID – Participant Number – Chk)

Biopsy Specimens

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

SIGMOIDOSCOPY

1. Was a sigmoidoscopy performed at this visit? ☐ *yes* ☐ *no, specify:* _____ → *Go to item 4.*

2. Sigmoidoscopy findings ☐ *no abnormal findings* ☐ *abnormal findings*
→ *If no abnormal findings, go to item 3.*

2a. Abnormal sigmoidoscopy findings *Mark all that apply.*

- ☐ Erythema
- ☐ Abnormal vessels
- ☐ Ulceration
- ☐ Friability
- ☐ Bleeding
- ☐ Discharge
- ☐ Polyps
- ☐ Hemorrhoids
- ☐ Other abnormal findings, specify: _____

At Screening, evaluate any abnormalities for eligibility. Complete Pre-existing Conditions when applicable.
During follow-up, complete or update AE Log when applicable.

3. Rectal biopsy specimens — Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

	not required	*stored*	*not stored*	*Reason not stored*
3a. Rectal biopsies for PK	☐	☐	☐ →	_____
3b. Rectal biopsies for gene expression	☐	☐	☐ →	_____
3c. Rectal biopsy for histology	☐	☐	☐ →	_____
3d. Rectal biopsy for proteomics	☐	☐	☐ →	_____

4. Vaginal biopsy specimens — Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

	not required	*stored*	*not stored*	*Reason not stored*
4a. Vaginal biopsies for PK	☐	☐	☐ →	_____
4b. Vaginal biopsies for gene expression	☐	☐	☐ →	_____

Comments:

Biopsy Specimens (BSS-1)	
Purpose:	This form is used to document collection and storage of rectal and vaginal biopsies by the local site laboratory. It is also used to document the findings identified via flexible sigmoidoscopy.
General Information/Instructions:	
	Complete this form only at Screening and at each end-of-period visit.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. 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.
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 2a:	Mark the box to the left of each abnormal finding observed. If an observed abnormal finding is not listed, mark “Other abnormal findings, specify” and describe the abnormal finding on the line provided.
Items 3a–3d and 4a–4b:	If the specimen was not required to be collected at this visit, mark “not required.” If the specimen was required to be stored, but for some reason it was not stored, mark “not stored” and record the reason on the line provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

APX-1 (136)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Unit ID – Participant Number – Chk)

Abbreviated Physical Exam

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

VITAL SIGNS

1. Weight ☐☐☐ *kg*
2. Body Temp ☐☐.☐ *°C*
3. BP ☐☐☐ / ☐☐☐ *mmHg*
4. Pulse ☐☐☐ *beats per minute*
5. Respirations ☐☐ *breaths per minute*

FINDINGS *Item 6 is a required assessment. Other items assessed if clinically indicated.*

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

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

Abbreviated Physical Exam (APX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings.
General Information/Instructions:	
	Complete this form at both initiate period visits, at each period end visit, and at an interim visit, as applicable.
Item-specific Instructions:	
Vital Signs:	Use leading zeros when needed.
Item 6:	This item is required to be assessed at both initiate period visits and both period end visits.
Items 7–17:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the findings in Notes. If not evaluated, mark "not done."
Item 17:	If abnormal, specify the body system being referenced and describe the findings in Notes. Normal findings may also be described in Notes, but is not required

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

PE-1 (138)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Unit ID – Participant Number – Chk)

Pelvic Exam

Visit 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 AE 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%* OR ☐ *not done*

Pelvic Exam (PE-1)

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

General Information/Instructions:

Complete this form at Screening, Enrollment, at each Period Initiate and End Visit, and early termination visit (as applicable), and when a clinically indicated pelvic exam is performed during follow-up. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to 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 "abnormal findings" and in item 1a, mark "observed blood or bleeding; describe" 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 "other abnormal findings, specify" and describe the abnormal finding on the line provided, including anatomical location. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 1a as 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 8, 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 8 for more information/guidance as needed.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

HIV-1 (140)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Unit ID | Participant Number | Chk

HIV Results

Initial Specimen Collection Date

☐☐ dd ☐☐☐ MMM ☐☐ yy

	Not done/ Not collected	*kit code*	Alternate Collection Date dd	MMM	yy	*negative*	*positive*	*indeterminate*
1. Rapid HIV test 1	☐	☐☐	☐☐	☐☐☐	☐☐	☐	☐	
2. Rapid HIV test 2	☐	☐☐	☐☐	☐☐☐	☐☐	☐	☐	
3. HIV-EIA	☐		☐☐	☐☐☐	☐☐	☐	☐	☐

If any are positive or indeterminate during follow-up, complete HIV Confirmatory Results form and Clinical Product Hold/Discontinuation Log.

Comments:

HIV Results (HIV-1)

Purpose:	This form is used to document the participant's HIV rapid test or EIA results, and plasma storage for HIV confirmatory testing as specified in the protocol.

General Information/Instructions:

Initial Specimen Collection Date:	Record the date that the first specimen 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.
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 in Comments.
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 and 2: Record the assigned two-digit rapid test kit code. *Note: More test kit codes may be added to the list as the study proceeds.*

Kit Code	Rapid Test
01	Determine
02	OraQuick
03	Uni-Gold Recombigen
04	Bioline
05	Clearview Statpak

Items 1, 2, 3: If item 1, 2, or 3 is positive (meaning the participant had at least one positive HIV test result) or indeterminate during follow-up, complete a new HIV Confirmatory Results (HCR) form and a Clinical Product Hold/Discontinuation (PH) Log.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

SLR-1 (144)

Visit Code . 1

Participant ID

Unit ID – Participant Number – Chk

Safety Laboratory Results

Initial Specimen Collection Date

dd MMM yy

	Not done/ Not collected	Alternate Collection Date dd MMM yy	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
1. HEMOGRAM	→ *Go to item 2.*				
1a. Hemoglobin	Not reported	. *g/dL*		OR	
1b. Hematocrit		. %			
1c. MCV		. *fL*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
1d. Platelets		. *x10^3/mm^3*		OR	
1e. WBC		. *x10^3/mm^3*		OR	

	Not done	Absolute Count *cells/mm3*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
DIFFERENTIAL	→ *Go to item 2.*				
1f. Neutrophils	Not reported			OR	
1g. Lymphocytes				OR	
1h. Monocytes					
1i. Eosinophils					
1j. Basophils					

	Not done/ Not collected	Alternate Collection Date dd MMM yy	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
2. SERUM CHEMISTRIES	→ *Go to item 3 on page 2.*				
2a. AST (SGOT)	Not reported	*U/L*		OR	
2b. ALT (SGPT)		*U/L*		OR	
2c. Creatinine		. *mg/dL*		OR	
		OR			
		. *µmol/L*			

Safety Laboratory Results (SLR-1)

Purpose:	This form is used to provide data on the participant's baseline and clinically indicated laboratory test results.
General Information/Instructions:	
	Use this form to report the hematology, differential, and liver and renal function test results as they become available. Do not fax the form to SCHARP DataFax until all results are available and the participant has enrolled in the study.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. 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.
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 in Comments on 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.
Repeat Testing:	If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same SLR form assigned Visit Code 1.0. Line through the original result(s), record the new result(s) and the Alternate Collection Date for each repeat test result.
Results Reporting:	• Results should be documented on the form using the units present on the source laboratory results document. If the units present on the form do not match your source results report, contact the MTN-014 Management Team. Note that the following units are equivalent: IU/L = U/L I/l x 100 = % 10^9/L = 10^3/mm^3 = 10^3/μL For creatinine, only record the result in the units listed on the source document. • If the site lab does not report results to the same level of precision allowed on the form, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.05 g/dL would be recorded as 11.1 g/dL. A lab-reported hemoglobin value of 11.04 g/dL would be recorded as 11.0 g/dL. - If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.
Severity Grade:	• If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the result. If value is below Grade 1, leave the severity grade box blank. • Always compare the severity grade range to the value that was recorded on the form (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade. - At Screening/Enrollment, record any Grade 1 or higher lab values on the Pre-existing Conditions form.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

SLR-2 (145)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Unit ID | Participant Number | Chk

Safety Laboratory Results

Alternate Collection Date: dd ☐☐ MMM ☐☐☐ yy ☐☐

3. DIPSTICK URINALYSIS TESTS	Not done/ Not collected ☐ → *End of form.*		
3a. Leukocyte esterase (LE)	Not done ☐	*negative* ☐	*positive* ☐
3b. Nitrates	Not done ☐	*negative* ☐	*positive* ☐

Comments:

Safety Laboratory Results (SLR-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.
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 in Comments on 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.
Repeat Testing:	If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same SLR form assigned Visit Code 1.0. Line through the original result(s), record the new result(s) and the Alternate Collection Date for each repeat test result.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

SS-1 (149)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Unit ID | Participant Number | Chk

Specimen Storage

Initial Specimen Collection Date

dd ☐☐ MMM ☐☐☐ yy ☐☐

Not done/ Not collected ☐ 1. Vaginal smear for gram stain

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

stored ☐ *not stored* ☐ → *Reason not stored* _____

Not done/ Not collected ☐ 2. Endocervical swab for biomarkers

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

stored ☐ *not stored* ☐ → *Reason not stored* _____

2a. Was blood visible on the swab? *yes* ☐ *no* ☐ → *If not stored, go to item 3.*

Not done/ Not collected ☐ 3. Vaginal swab for biomarkers

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

stored ☐ *not stored* ☐ → *Reason not stored* _____

3a. Was blood visible on the swab? *yes* ☐ *no* ☐ → *If not stored, go to item 4.*

Not done/ Not collected ☐ 4. Rectal Sponge for PD and Biomarkers

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

stored ☐ *not stored* ☐ → *Reason not stored* _____

Not done/ Not collected ☐ 5. Urine from hCG

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐

stored ☐ *not stored* ☐ → *Reason not stored* _____

Comments:

Specimen Storage (SS-1)	
Purpose:	This form is used to document collection and storage of vaginal, cervical, rectal, and urine specimens by the local site laboratory during follow-up.
General Information/Instructions:	
	Complete this form at Screening, both initiate period visits, the Washout Visit, at each period end visit and at early termination, as 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.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. 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 not required.
Stored/Not Stored:	Mark “stored” for specimens that are collected and sent to the lab for processing. If specimens are not stored, mark “not stored” and record the reason why on the line provided.
Item-specific Instructions:	
Items 1–5:	If the specimen is required to be stored, but for some reason it is not stored, mark “not stored” and record the reason on the line provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

DE-1 (175)

Visit Code ___ . ___ 1

Participant ID ___ - ___ - ___

Unit ID | Participant Number | Chk

DOD Experience Assessment

Visit Date ___ ___ ___

dd | MMM | yy

Study Treatment Period ☐ *vaginal* ☐ *rectal*

1. Did you insert the gel yourself or did study staff insert the gel for you?

   ☐ inserted gel herself

   ☐ study staff inserted gel for her

   ☐ other, specify: _____

2. Tell me about your experiences being observed using the gel or having the gel inserted. What did you like?

   Response Code 2a. ___ 2b. ___ 2c. ___

   If there is a reason not represented in the Response Code list, mark 2d and record the reason on specify line. Otherwise, leave item 2d blank.

   ☐ 2d. other, specify: _____

3. What did you dislike?

   Response Code 3a. ___ 3b. ___ 3c. ___

   If there is a reason not represented in the Response Code list, mark 3d and record the reason on specify line. Otherwise, leave item 3d blank.

   ☐ 3d. other, specify: _____

4. Why do you think we observed you using the gel or inserted gel for you?

   Response Code

   4a. ___ 4b. ___ 4c. ___ 4d. ___ 4e. ___ 4f. ___

   If there is a reason not represented in the Response Code list, mark 4g and record the reason on specify line. Otherwise, leave item 4g blank.

   ☐ 4g. other, specify: _____

5. Overall, how comfortable were you being observed using the gel or having gel inserted?

   ☐ very comfortable

   ☐ comfortable

   ☐ neutral

   ☐ uncomfortable

   ☐ very uncomfortable

DOD Experience Assessment (DE-1)

Purpose: This form is used to document the participant's feelings about directly observed dosing of tenofovir gel during the study.

General Information/Instructions:

This is an interviewer-administered form and it is completed at the Period 1 End Visit and the Period 2 End/Final Clinic Visit. Read each item aloud and record the participant's response. Record any notes taken during the interview, together with additional comments or suggestions that the participant may have, in the participant's chart notes.

Item-specific Instructions:

Items 2–4: Refer to the list of Response Codes below. Record the two-digit code that corresponds to the participant's response(s). Up to six Response Codes may be recorded. A response code is required for items 2a, 3a, and 4a. Record any additional response codes in items 2b–2c, 3b–3c, or 4b–4f; leave any unused items blank. For example, if two response codes apply for item 2, record the codes in items 2a–2b and leave items 2c–2d blank. Record notes taken during the interview for these items in participant chart notes.

RESPONSE CODES

Study-related or Procedural Reasons	
Code	Description
10	**Proper gel use:** To make sure she inserts gel as instructed: in correct part of body/at correct time/every day
11	**Good data:** To make sure the study is done correctly and data are good
12	**Contribution:** Feels she is making a positive contribution to a good cause/science
13	**Store study product:** Convenient/comfortable to come to clinic because no need to store study product at home
14	**Short Visits:** Convenient to come to clinic because the visits will be/were short
15	**Incentives:** Will like/Liked getting paid for daily visits

Staff/Clinic-related experiences	
Code	Description
20	**Help/Assistance:** Provide(d) assistance: help her insert or remember to insert gel
21	**Trust:** Study Staff lacks trust/confidence in her
22	**Respect:** Study staff lacks respect for her
23	**Capability:** Study staff thinks she is incapable of inserting gel as instructed
24	**Comfortable with staff:** Felt/will feel comfortable with study staff
25	**Cared for:** Felt/will feel well-cared for by study staff
26	**Get Advice:** Will have/Had a chance to ask study staff questions/get advice from study staff
27	**Prolonged waiting time in clinic:** Did not like to wait while other participants were being seen
28	**Privacy at home:** Preferred to use gel at home because more privacy at home

Emotional/Physical experiences	
Code	Description
30	**Monitor Health:** Check for reactions to gel/ illness
31	**Monitor comfort level:** Emotional/psychological reactions to using gel
32	**Embarrassment:** Will feel/felt embarrassment/shame
33	**Guinea pig:** Will feel/felt like a "guinea pig"/dehumanizing
34	**Physical discomfort:** Inserting gel will be/was painful/uncomfortable
35	**Dislike pelvic exams:** Uncomfortable because it is similar to a pelvic exam
36	**Gel leaks out:** Did not like using/use gel because it leaks out
37	**Negative impact on sex:** Did not like using/use gel before sex
38	**Positive impact on sex:** Liked using gel before sex

Family/Partner/Community concerns	
Code	Description
40	**Privacy at clinic:** Convenient/comfortable to come to clinic because no family/ partner are there, more privacy
41	**Questions about clinic:** Inconvenient/uncomfortable to come to clinic because family/partner questioned why she will go/went to clinic everyday
42	**No questions at home:** Convenient/comfortable to use gel at home because family/partner did not question why she was going to clinic every day
43	**No privacy at home:** Inconvenient/uncomfortable to use gel at home because family members/partner are there/not enough privacy
44	**Curiosity from friends/neighbors:** Reaction to home visits
45	**Childcare:** Difficult to secure childcare during daily visits

DOD scheduling convenience	
Code	Description
50	**Time off work:** Inconvenient because she will have/had to take time off work
51	**Establish routine:** Coming to clinic will establish/established a routine/schedule
52	**Convenient to stay home:** Convenient/comfortable to use gel at home because saved her a trip to the clinic
53	**Convenient travel to clinic:** Convenient to come to clinic because it is/was on her way to other places and/or close to home
54	**Inconvenient travel to clinic:** Long travel time/expensive/too busy
55	**Remembers in clinic:** Coming to the clinic will make it/made it easier to remember to use gel
56	**Remembers at home:** Using gel at home will make it/made it easier to remember to use gel
57	**Convenient weekdays:** It was/will be easier to come in on weekdays
58	**Convenient weekends:** It was/will be easier to come in on weekends

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

DE-2 (176)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Unit ID | Participant Number | Chk

DOD Experience Assessment

6. Tell me about your experience of having visits every day for 14 days in a row, including weekends. What did you like?

Response Code 6a. ☐☐ 6b. ☐☐ 6c. ☐☐

If there is a reason not represented in the Response Code list, mark 6d and record the reason on specify line. Otherwise, leave item 6d blank.

☐ 6d. other, specify: _____

7. What did you dislike?

Response Code 7a. ☐☐ 7b. ☐☐ 7c. ☐☐

If there is a reason not represented in the Response Code list, mark 7d and record the reason on specify line. Otherwise, leave item 7d blank.

☐ 7d. other, specify: _____

8. How much did you like having daily visits?

☐ strongly disliked ☐ neutral ☐ strongly liked

☐ disliked ☐ liked

9. If you ever used the gel at home by yourself what were the reasons for this?

9a. N/A ☐ Response Code 9b. ☐☐ 9c. ☐☐ 9d. ☐☐

If there is a reason not represented in the Response Code list, mark 9e and record the reason on specify line. Otherwise, leave item 9e blank.

☐ 9e. other, specify: _____

10. Did you ever miss a dose, and if so, why?

10a. N/A ☐ Response Code 10b. ☐☐ 10c. ☐☐ 10d. ☐☐

If there is a reason not represented in the Response Code list, mark 10e and record the reason on specify line. Otherwise, leave item 10e blank.

☐ 10e. other, specify: _____

TO BE ASKED AT PERIOD 2 END/FINAL CLINIC VISIT ONLY

11. In the future, would you be willing to join a research study similar to this one in which you were observed using a study product vaginally or rectally over a 2-week period?

☐ *yes* ☐ *no* *Specify reason:* _____

Record other comments or suggestions in the participant's chart notes.

DOD Experience Assessment (DE-2)

Item-specific Instructions:

Items 6–7, and 9–10:	Refer to the list of Response Codes below. Record the two-digit code that corresponds to the participant's response(s). Up to six Response Codes may be recorded. A response code is required for items 6a, 7a, 9a, and 10a. Record any additional response codes in items 6b–6c, 7b–7c, 9b–9c or 10b–10c; leave any unused items blank. For example, if only two response codes apply for item 6, record the code in items 6a and 6b leave item 6c blank. Record notes taken during the interview for these items in participant chart notes.
Items 9 and 10:	Mark "NA" if the participant did not use the gel at home by herself or if the participant did not miss a dose during the product period.
Item 11:	Complete item 10 at the Period 2 End/Final Clinic Visit only. At the Period 1 End visit, leave this item blank.

RESPONSE CODES

Study-related or Procedural Reasons	
Code	Description
10	**Proper gel use:** To make sure she inserts gel as instructed: in correct part of body/at correct time/every day
11	**Good data:** To make sure the study is done correctly and data are good
12	**Contribution:** Feels she is making a positive contribution to a good cause/science
13	**Store study product:** Convenient/comfortable to come to clinic because no need to store study product at home
14	**Short Visits:** Convenient to come to clinic because the visits will be/were short
15	**Incentives:** Will like/Liked getting paid for daily visits

Staff/Clinic-related experiences	
Code	Description
20	**Help/Assistance:** Provide(d) assistance: help her insert or remember to insert gel
21	**Trust:** Study Staff lacks trust/confidence in her
22	**Respect:** Study staff lacks respect for her
23	**Capability:** Study staff thinks she is incapable of inserting gel as instructed
24	**Comfortable with staff:** Felt/will feel comfortable with study staff
25	**Cared for:** Felt/will feel well-cared for by study staff
26	**Get Advice:** Will have/Had a chance to ask study staff questions/get advice from study staff
27	**Prolonged waiting time in clinic:** Did not like to wait while other participants were being seen
28	**Privacy at home:** Preferred to use gel at home because more privacy at home

Emotional/Physical experiences	
Code	Description
30	**Monitor Health:** Check for reactions to gel/ illness
31	**Monitor comfort level:** Emotional/psychological reactions to using gel
32	**Embarrassment:** Will feel/felt embarrassment/shame
33	**Guinea pig:** Will feel/felt like a "guinea pig"/dehumanizing
34	**Physical discomfort:** Inserting gel will be/was painful/uncomfortable
35	**Dislike pelvic exams:** Uncomfortable because it is similar to a pelvic exam
36	**Gel leaks out:** Did not like using/use gel because it leaks out
37	**Negative impact on sex:** Did not like using/use gel before sex
38	**Positive impact on sex:** Liked using gel before sex

Family/Partner/Community concerns	
Code	Description
40	**Privacy at clinic:** Convenient/comfortable to come to clinic because no family/ partner are there, more privacy
41	**Questions about clinic:** Inconvenient/uncomfortable to come to clinic because family/partner questioned why she will go/went to clinic everyday
42	**No questions at home:** Convenient/comfortable to use gel at home because family/partner did not question why she was going to clinic every day
43	**No privacy at home:** Inconvenient/uncomfortable to use gel at home because family members/partner are there/not enough privacy
44	**Curiosity from friends/neighbors:** Reaction to home visits
45	**Childcare:** Difficult to secure childcare during daily visits

DOD scheduling convenience	
Code	Description
50	**Time off work:** Inconvenient because she will have/had to take time off work
51	**Establish routine:** Coming to clinic will establish/established a routine/schedule
52	**Convenient to stay home:** Convenient/comfortable to use gel at home because saved her a trip to the clinic
53	**Convenient travel to clinic:** Convenient to come to clinic because it is/was on her way to other places and/or close to home
54	**Inconvenient travel to clinic:** Long travel time/expensive/too busy
55	**Remembers in clinic:** Coming to the clinic will make it/made it easier to remember to use gel
56	**Remembers at home:** Using gel at home will make it/made it easier to remember to use gel
57	**Convenient weekdays:** It was/will be easier to come in on weekdays
58	**Convenient weekends:** It was/will be easier to come in on weekends

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

VRP-1 (185)

Visit Code ___.___ 1

Participant ID ___ - ___ - ___

Unit ID | Participant Number | Chk

Vaginal and Rectal Practices

Visit Date ___ ___ ___

dd | MMM | yy

1. **Ask at all scheduled clinic visits, except period initiate visits:**
Since her last visit, has the participant inserted anything inside her vagina or rectum, other than study product?

yes ☐ *no* ☐ *If no, go to item 2.*

Ask at the Period 1 and 2 Initiate Visit only:
In the past 24 hours, has the participant inserted anything inside her vagina or rectum, other than study product?

What has the participant inserted? *Mark all that apply.*

	vaginally	*rectally*
1a. Spermicides	☐	☐
1b. Female condoms	☐	☐
1c. Diaphragm	☐	☐
1d. Contraceptive vaginal ring	☐	☐
1e. Vaginal medications	☐	☐
1f. Menstrual cup	☐	☐
1g. Cervical cap *(or any other vaginal barrier method)*	☐	☐
1h. Douche	☐	☐
1i. Enema	☐	☐
1j. Non-study approved lubricants	☐	☐
1k. Sex toys *(vibrators, dildos, etc.)*	☐	☐
1l. Tampons	☐	☐
1m. Soap *(with or without water)*	☐	☐
1n. Anything else? _____	☐	☐

2. Since her last visit, has the participant had vaginal or anal sex? *Mark all that apply.*

vaginal	*rectal*	*neither*
☐	☐	☐

Comments:

Vaginal and Rectal Practices (VRP-1)	
Purpose:	This form is used to collect participant vaginal and rectal practices.
General Information/Instructions:	
	Complete this form at Enrollment/Initiate Period 1 Visit, Period 2 Initiate and End Visits, and all Study Product Administration Visits.
Item-specific Instructions:	
Item 1n:	If the participant reports inserting anything other than what is listed on this form, mark the appropriate box and specify the practice on the line provided. Study-product applicators do not apply.
Item 2:	For study purposes, vaginal sex is defined as when a man puts his penis inside of the vagina. Anal sex is defined as when a man puts his penis inside the anus.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

STI-1 (190)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐

Unit ID | Participant Number | Chk

STI Test Results

Initial Specimen Collection Date ☐☐ ☐☐☐ ☐☐

dd | MMM | yy

1. VAGINAL WET PREP STUDIES	Not done/ Not collected ☐ → *Go to item 2.*	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐			
1a. Homogeneous vaginal discharge	Not done ☐		*negative* ☐	*positive* ☐	*Only required if assessment for BV performed.*
1b. pH	Not done ☐	☐.☐	*If > 4.5, mark positive.* →	*positive* ☐	
1c. Whiff test	Not done ☐		*negative* ☐	*positive* ☐	*Only required if assessment for BV performed.*
1d. Clue cells > 20%	Not done ☐		*negative* ☐	*positive* ☐	*Only required if assessment for BV performed.*
1e. *Trichomonas vaginalis*	Not done ☐		*negative* ☐	*positive* ☐	
1f. Buds and/or hyphae (yeast)	Not done ☐		*negative* ☐	*positive* ☐	
2. Trichomonas rapid test	Not done/ Not collected ☐	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐	*negative* ☐	*positive* ☐	
3. *N. gonorrhea (urine)*	Not done/ Not collected ☐	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐	*negative* ☐	*positive* ☐	
4. *C. trachomatis (urine)*	Not done/ Not collected ☐	Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐	*negative* ☐	*positive* ☐	

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

Comments:

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results by the local site laboratory.
General Information/Instructions:	
	Complete this form at both initiate period visits, at each period end visit, and at other visits where these tests are performed during follow-up.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. 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.
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 in Comments.
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 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 “Not done/Not collected” for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason in Comments.
Item 1a:	Mark “positive” if homogeneous vaginal discharge was observed.
Item 1b:	Vaginal fluid pH is required at Enrollment/Period 1 Initiate Visit, Period 1 End Visit, Period 2 Initiate and End Visits. If assessment for BV is not performed, complete 1b and mark “not done” for 1a, 1c, and 1d.
Item 1d:	Mark “positive” if 20% or more of the cells were clue cells.
Item 1e:	Mark “positive” if trichomonads were observed.
Item 1f:	Mark “positive” if yeast buds and/or hyphae were observed.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

DOD-1 (260)

Participant ID

Unit ID – Participant Number – Chk

Directly Observed Dosing

Form Completion Date

dd MMM yy

☐ Period 1 End Visit ☐ Period 2 End Visit

1. DOSING

Dose #	Was the gel application observed?				Dose #	Was the gel application observed?			
	not done	*yes, in clinic*	*yes, in home*	*no, in home not observed*		*not done*	*yes, in clinic*	*yes, in home*	*no, in home not observed*
Dose # 1	☐	☐	☐	☐	Dose # 8	☐	☐	☐	☐
Dose # 2	☐	☐	☐	☐	Dose # 9	☐	☐	☐	☐
Dose # 3	☐	☐	☐	☐	Dose # 10	☐	☐	☐	☐
Dose # 4	☐	☐	☐	☐	Dose # 11	☐	☐	☐	☐
Dose # 5	☐	☐	☐	☐	Dose # 12	☐	☐	☐	☐
Dose # 6	☐	☐	☐	☐	Dose # 13	☐	☐	☐	☐
Dose # 7	☐	☐	☐	☐	Dose # 14	☐	☐	☐	☐

2. Date and time of last three applications of tenofovir gel prior to this visit starting with the most recent

Not done/ Not collected	Dose #	dd	MMM	yy	hr	min (*24-hr clock*)	Is this dosing time an estimate? *yes*	*no*
☐	2a.					:	☐	☐
☐	2b.					:	☐	☐
☐	2c.					:	☐	☐

Comments:

☐ ☐ ☐ ☒ 25-FEB-14

N:\hivnet\forms\MTN_014\forms\m014_DOD.fm

0 1 English

Staff Initials/Date

Directly Observed Dosing (DOD-1)

Purpose: This form is used to document observed participant dosing and times for Period 1 and Period 2.

General Information/Instructions:

- Mark the box that corresponds to the current product period.
- Complete this form as each dose is observed at the study administration visits

Item-specific Instructions:

Item 1: For each dose, document mark "yes, in clinic" if the gel application was directly observed at the clinic, mark "yes, in home" if the gel application was directly observed at the participant's home, or mark "no, in home, not observed" if the gel applicator was inserted at home without the observation of clinic staff.

Item 2:

- Complete the dosing numbers, date and time for the last three gel applicators inserted for the current period. These three doses should correspond to the last three doses reported as actually inserted in item 1. The date must be transcribed using the SCHARP DataFax standard, dd MMM yy. The time must be transcribed using the 24-hour clock.
- For each day that dosing dates and times are recorded, mark "yes" if the dose was inserted at home and is per participant report.

Comments: Record any other relevant information (e.g., partial dosing). You may leave this space blank if there are no additional relevant comments.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

HCR-1 (330)

Visit Code ☐☐.☐ 1

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Unit ID – Participant Number – Chk)

HIV Confirmatory Results

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

1. HIV Western Blot — Not done/Not collected ☐ (*Go to item 3.*) | *negative* ☐ | *positive* ☐ | *indeterminate* ☐ → *If negative or indeterminate, notify Network Lab.*

2. HIV Western Blot band results — Band Interpretation

Western Blot Band	(-) Negative	(+/-) Indeterminate	(+) Positive	(++) High Positive
GP160	☐	☐	☐	☐
GP120	☐	☐	☐	☐
P65	☐	☐	☐	☐
P55/51	☐	☐	☐	☐
GP41	☐	☐	☐	☐
P40	☐	☐	☐	☐
P31	☐	☐	☐	☐
P24	☐	☐	☐	☐
P18	☐	☐	☐	☐

2a. Were any other bands present? ☐ *yes* ☐ *no*

3. HIV RNA PCR — Not done/Not collected ☐ (*Go to item 4.*)

Alternate Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

☐ > ☐ = ☐ < ☐☐☐☐☐☐☐☐ *viral copies/mL* OR ☐ *target not detected*

3a. RNA PCR kit lower limit of detection ☐ *20* ☐ *40* OR ☐☐☐ *viral copies/mL*

4. Absolute CD4+ — Not done/Not collected ☐ (*Go to item 5.*)

Alternate Collection Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

☐ *unable to analyze* OR ☐☐☐☐ *cells/mm³*

4a. CD4 % ☐ *not available* OR ☐☐.☐ %

5. Final HIV Status ☐ *HIV-uninfected* ☐ *HIV-infected* ☐ *pending*

HIV Confirmatory Results (HCR-1)	
Purpose:	This form is used to document results from local lab confirmatory HIV testing once a participant has a positive rapid HIV test result or a positive or indeterminate EIA test result. This form also documents the HIV RNA viral load and CD4+ count if instructed by the Network Lab.
General Information/Instructions:	
	Complete this form for each visit where the participant has at least one positive rapid HIV test or a positive or indeterminate EIA test result.
	Fax this form to SCHARP DataFax as soon as any results are available, leaving all pending items blank. Do not wait for all results before faxing. Faxing this form with items blank will not generate a QC.
Visit Code:	The visit code recorded on this form should be the same visit code recorded on the HIV Results form documenting the positive or a positive or indeterminate EIA test result.
Specimen Collection Date:	Record the date the specimen was collected (NOT the date results were reported or recorded on the form). The Specimen Collection Date should be the same date as the collection date of the plasma for HIV seroconversion confirmation (HIV Results, item 4a).
Item-specific Instructions:	
Items 3 and 4:	Complete items 3 and 4 for confirmatory testing when instructed by the Network Lab.
Item 3:	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay.
Item 4a:	If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 4. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark "not available."
Item 5:	Once a participant's HIV status has been determined, record the final HIV status. Once all results are available, if the final HIV status is not clearly negative or clearly positive, mark "pending."

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

PH-1 (410)

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

Page

Participant ID

Unit ID – Participant Number – Chk

Clinical 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.*

- ☐ positive HIV test result
- ☐ adverse experience → *AE Log page #*
- ☐ pregnancy
- ☐ breastfeeding
- ☐ report of PEP and PrEP use
- ☐ 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 Final Clinic Visit → Date:
- ☐ no—permanently discontinued → Date:

Clinical Product Hold/Discontinuation Log (PH-1)

Purpose:	This log is used to document temporary clinical holds and clinical permanent discontinuations of study product use as instructed by study site staff. This log is completed each time a participant is instructed by study staff to temporarily stop (hold) or permanently discontinue study product use. If, at the same visit, a product hold/ discontinuation is initiated for more than one reason, complete one Clinical Product Hold/Discontinuation Log page for each reason. The same visit code should be used on each Log page.
General Information/Instructions:	
	Do not complete this log in cases where a participant has decided on her own to stop using study product.
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers.
Item-specific Instructions:	
Item 2:	Note that participant decline or refusal of study product is not documented as a product hold. Do not record this as a reason in “other, specify.”
Item 3:	Record the last date the participant used study product. 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-014 (201)

CM-1 (423)

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

Participant ID

Unit ID – Participant Number – Chk

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.

Medication 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.

Medication 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: All medication(s) that are used by the participant during the study (starting at the Screening Visit),other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, 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 visit if no medications were taken by the participant throughout the entire study.

Medication 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.”

Date Started: If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.

Date Stopped: At the participant’s Termination 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 dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. 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:

PO: oral	IV: intravenous	IHL: inhaled	REC: rectal	**other, specify**: alternative routes
IM: intramuscular	TOP: topical	VAG: vaginal	SC: subcutaneous	

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

PR-1 (440)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Unit ID | Participant Number | Chk

Pregnancy Report and History

Pregnancy Report

1. First day of last menstrual period — dd ☐☐ MMM ☐☐☐ yy ☐☐ OR ☐ *amenorrheic for past 6 months*

2. Estimated date of delivery — dd ☐☐ MMM ☐☐☐ yy ☐☐

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

	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: _____	☐	☐

Pregnancy 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 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

MTN-014 (201)

PO-1 (442)

Visit Code ☐☐.☐ Outcome Number ☐

Participant ID ☐☐☐ - ☐☐☐☐☐ - ☐
Unit ID | Participant Number | Chk

Pregnancy Outcome

☐ Outcome unobtainable → *Go to page 2.*

If Outcome Number recorded is 2 or greater, go to item 2.

1. How many pregnancy outcomes resulted from this reported pregnancy? ☐

2. Outcome Date dd ☐☐ MMM ☐☐☐ yy ☐☐

3. Place of delivery/outcome
☐ home ☐ unknown
☐ hospital ☐ other, specify: _____
☐ clinic

4. Specify outcome. *Mark only one.*

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.

☐ 4a. full term live birth (≥ 37 weeks) → 4a1. Method:
☐ 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: _____

4a1. Method:
☐ C-section
☐ standard vaginal
☐ operative vaginal

If full term live birth, go to item 6.

5. Provide a brief narrative of the circumstances: _____

6. Were there any complications related to the pregnancy outcome? *yes* ☐ *no* ☐ *If no, go to item 7 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 and History form that is completed for a participant.
Visit Code:	Record the visit code of the participant's corresponding Pregnancy Report and History 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.
Item-specific Instructions:	
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 month, 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 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

MTN-014 (201)

PO-2 (443)

Visit Code ☐☐.☐ Outcome Number ☐

Participant ID ☐☐☐-☐☐☐☐☐-☐
Unit ID | Participant Number | Chk

☐ No data recorded on this page.

Pregnancy Outcome

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)	
General Information/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-specific Instructions:	
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 “unavailable” 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 “unavailable” if no medical record documentation of the infant’s gestational age is available.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

AE-1 (460)

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

Participant ID

Unit ID – Participant Number – Chk

Adverse Experience Log

Date reported to site

dd MMM yy

1. Adverse Experience (AE) _____

Record diagnosis (in English), 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* ☐ *If not related, record rationale or alternative etiology in Comments.*

5. Study Product Administration — *no change* ☐ *held* ☐ *permanently discontinued* ☐ *N/A* ☐

6. Status/Outcome
- ☐ continuing
- ☐ resolved
- ☐ death
- ☐ severity/frequency increased — *Report as 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 below.*
- ☐ procedure/surgery — *Comment below.*
- ☐ other — *Comment below.*

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

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

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

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

Comments:

Adverse Experience Log (AE-1)

Purpose:	To document all MTN-014 Adverse Experiences (AEs) required to be reported per protocol.
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 Log pages as applicable. If a cluster of symptoms reported on separate AE Log page is later attributed to a single diagnosis, change the earliest reported symptom page to the diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE Log pages (insert page #s)."
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-specific Instructions:	
Item 1:	Use medical terminology to describe the AE. Do not include text on the relationship to study product or timing of AE onset with regard to product use. 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 in Comments.
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 Final Clinic Visit/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 Follow-up Visit Summary form with this visit code should have item 5 = "yes" or (for interim visits) the AE Log page marked in item 4b.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

MV-1 (463)

Visit Code . 0 1

Participant ID

Unit ID – Participant Number – Chk

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 the study *Complete Termination form.*
- ☐ 2g. participant deceased *Complete Termination form. Complete Adverse Experience Log.*
- ☐ 2h. other, specify: _____

3. Steps taken to address the missed visit (corrective action plan):

Comments

Missed Visit (MV-1)	
Purpose:	Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP).
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 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-014 (201)

TM-1 (490)

Participant ID

Unit ID – Participant Number – Chk

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
  - 2b2. Cause of death _____ OR ☐ cause unknown

  → *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. pregnancy

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 ☐☐☐ OR Specify:

Comments

☐ ☐ ☐ ☒ 25-FEB-14

N:\hivnet\forms\MTN_014\forms\m014_TM.fm

0 1 English

Staff Initials/Date

Termination (TM-1)	
Purpose:	This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.
Item-specific Instructions:	
Item 1:	A complete date is required.
Item 2:	Mark only the primary reason for termination.
Item 2a:	Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
Item 2b1:	If date is recorded, at a minimum, the month and year are required.
Item 2l:	Early study closure: Only mark 2l when instructed by SCHARP.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

PDL-1 (495)

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

Page

Participant ID

Unit ID – Participant Number – Chk

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:** The 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 per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.
10	**Unreported AE:** Site staff become aware of an AE, but do not report it per protocol requirements.
11	**Unreported EAE:** Site staff become aware of an EAE, but do 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.
99	**Other**

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-014 (201)

THIS IS NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.

Participant ID

Unit ID – Participant Number – Chk

Pelvic Exam Diagrams

Exam Date

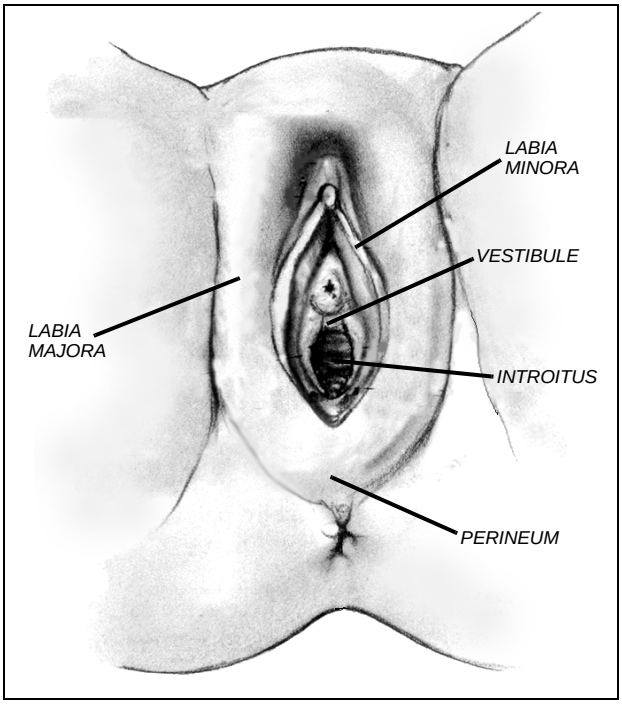
dd MMM yy

☐ no normal variants or abnormal findings observed

Speculum Type (screening only) *Pederson* ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only) *small* ☐ *medium* ☐ *large* ☐

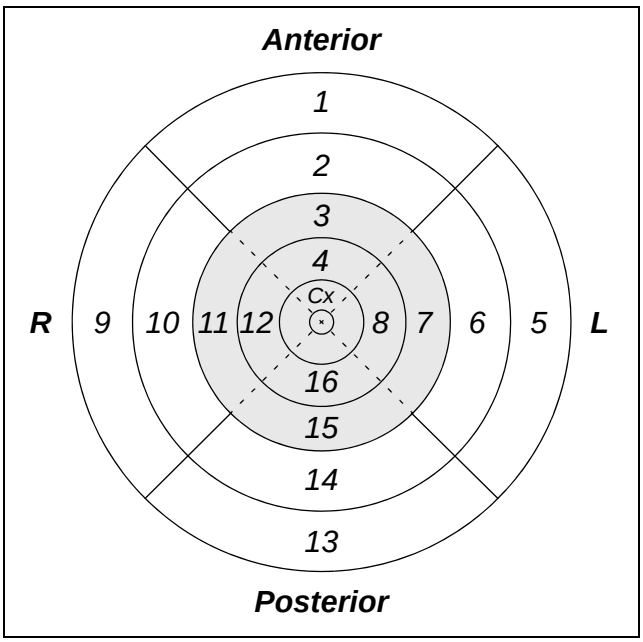
External Genitalia



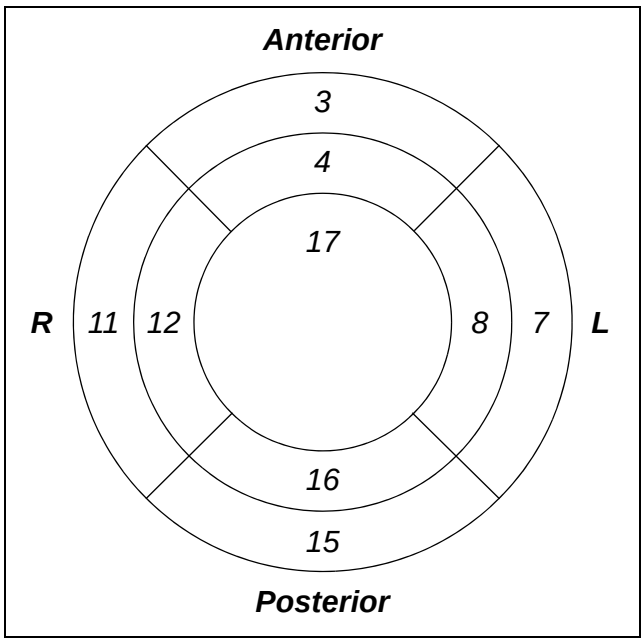
Legend for Vagina/Cervix

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



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 at the Screening Visit, each semi-annual visit, at the Product Use End Visit (PUEV), 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:

- expected menstrual and non-menstrual bleeding
- anatomic variants
- gland openings
- Nabothian cysts
- mucus retention cysts
- Gartner's duct cysts
- blood vessel changes other than disruption
- skin tags
- scars
- cervical ectopy

If there are no 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).

SAMPLE: DO NOT FAX TO DATAFAX

MTN-014 (201)

THIS IS NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.

Participant ID ☐☐☐ – ☐☐☐☐☐ – ☐
Unit ID | Participant Number | Chk

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, including missed menses, oligomenorrhea, and amenorrhea, 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.

Missed menses terminology: Use the table below to determine which term to use to describe a missed menses event (based on duration).

Missed menses duration	Term to use
1–3 months	Missed menses
4–5 months	Oligomenorrhea
6 or more months	Amenorrhea

MTN-014 Response Code List

CODE	DESCRIPTION
Study-related or Procedural Reasons	
10	Proper gel use: To make sure she inserts gel as instructed: in correct part of body/at correct time/every day
11	Good data: To make sure the study is done correctly and data are good
12	Contribution: Feels she is making a positive contribution to a good cause/science
13	Store study product: Convenient/comfortable to come to clinic because no need to store study product at home
14	Short Visits: Convenient to come to clinic because the visits will be/were short
15	Incentives: Will like/Liked getting paid for daily visits
Staff/Clinic-related experiences	
20	Help/Assistance: Provide(d) assistance: help her insert or remember to insert gel
21	Trust: Study Staff lacks trust/confidence in her
22	Respect: Study staff lacks respect for her
23	Capability: Study staff thinks she is incapable of inserting gel as instructed
24	Comfortable with staff: Felt/will feel comfortable with study staff
25	Cared for: Felt/will feel well-cared for by study staff
26	Get Advice: Will have/Had a chance to ask study staff questions/get advice from study staff
27	Prolonged waiting time in clinic: Did not like to wait while other participants were being seen
28	Privacy at home: Preferred to use gel at home because more privacy at home
Emotional/Physical experiences	
30	Monitor Health: Check for reactions to gel/ illness
31	Monitor comfort level: Emotional/psychological reactions to using gel
32	Embarrassment: Will feel/felt embarrassment/shame
33	Guinea pig: Will feel/felt like a “guinea pig”/dehumanizing
34	Physical discomfort: Inserting gel will be/was painful/uncomfortable
35	Dislike pelvic exams: Uncomfortable because it is similar to a pelvic exam
36	Gel leaks out: Did not like using/use gel because it leaks out
37	Negative impact on sex: Did not like using/use gel before sex
38	Positive impact on sex: Liked using gel before sex
Family/Partner/Community concerns	
40	Privacy at clinic: Convenient/comfortable to come to clinic because no family/partner are there, more privacy
41	Questions about clinic: Inconvenient/uncomfortable to come to clinic because family/partner questioned why she will go/went to clinic everyday
42	No questions at home: Convenient/comfortable to use gel at home because family/partner did not question why she was going to clinic every day
43	No privacy at home: Inconvenient/uncomfortable to use gel at home because family members/partner are there/not enough privacy
44	Curiosity from friends/neighbors: Reaction to home visits
45	Childcare: Difficult to secure childcare during daily visits
DOD scheduling convenience	
50	Time off work: Inconvenient because she will have/had to take time off work
51	Establish routine: Coming to clinic will establish/established a routine/schedule
52	Convenient to stay home: Convenient/comfortable to use gel at home because saved her a trip to the clinic
53	Convenient travel to clinic: Convenient to come to clinic because it is/was on her way to other places and/or close to home
54	Inconvenient travel to clinic: Long travel time/expensive/too busy
55	Remembers in clinic: Coming to the clinic will make it/made it easier to remember to use gel
56	Remembers at home: Using gel at home will make it/made it easier to remember to use gel
57	Convenient weekdays: It was/will be easier to come in on weekdays
58	Convenient weekends: It was/will be easier to come in on weekends

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