(MTN 027) DF/Net 027 AE (460)

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

Participant ID

Site Number – *Participant Number* – *Chk*

Date AE Reported to Site

dd *MMM* *yy*

Adverse Experience Log

1 Adverse Experience (AE) *Record diagnosis (in English) if available. Include anatomical location, if applicable.*

2 Onset date *dd* *MMM* *yy*

3 At which visit was this AE first reported? . *visit code*

4 Severity
- ☐ *Grade 1—mild*
- ☐ *Grade 2—moderate*
- ☐ *Grade 3—severe*
- ☐ *Grade 4—potentially life-threatening*
- ☐ *Grade 5—death*

5 Relationship to study product ☐ *related* ☐ *not related* *Record rationale or alternative etiology in Comments.*

6 Study product administration ☐ *no change* ☐ *held* ☐ *permanently discontinued* ☐ *N/A*

7 Status or Outcome of AE
- ☐ *continuing*
- ☐ *resolved*
- ☐ *death*
- ☐ *severity/frequency increased (report as new AE)*
- ☐ *continuing at end of study participation*

7a. Status/Outcome Date *(Leave blank if item 7 is "continuing" or "continuing at end of study participation.")*

dd *MMM* *yy*

If severity/frequency increased, record the new AE page # *AE page #*

8 Treatment *Mark "none" or all that apply.*
- ☐ *none* → *If none, go to item 9.*
- ☐ *new/prolonged hospitalization* *Comment below.*
- ☐ *medication(s)* *(Report on CM)*
- ☐ *procedure/surgery* *Comment below.*
- ☐ *other, specify* *Comment below.* _____

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

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

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

Comments:

_____
Staff Initials/Date

Purpose:

To document any Adverse Experience (AE) reported by the participant or clinically observed as defined by the protocol.

General Instructions:

Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency. If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words “Delete due to diagnosis on AE page #” (specify page number of diagnosis AE).

Item-specific Instructions:

Page #	Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by DF/Net.
Item 1	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. 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.”
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; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected.
Item 4	To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *Addendum 1 (Female Genital Grading Table for Use in Microbicide Studies)*.
Item 5	Mark the assessment of the relationship between the AE and the study agent. 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. Record an alternative etiology, diagnosis, or explanation in Comments. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
Item 6	**no change:** Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation. **held:** Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark “held” for the AE(s) that contributed to the product hold. **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 the AE(s) that contributed to the permanent discontinuation. **N/A** (not applicable): Mark if the AE occurred after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is grade 5-death.
Item 7	**continuing:** AE is continuing at the time it is reported. **continuing at end of study participation:** Mark this box whenever an AE is continuing at the time of participant study termination. **resolved:** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved. **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 reported on the AE Log, line through the “continuing” box previously marked and mark “severity/frequency increased.” Record the date of increase in the “Status/Outcome Date.” Report the increase in severity or frequency as a new AE and record new AE Page # in space provided. If a new AE Page # is completed, an AE Log page with corresponding AE number must be received. For this new AE, the “Onset Date” will be the date that the severity or frequency increased. Update EAE form if applicable. Note that decreases in severity should not be recorded as new AEs.
Item 7a	At minimum, month and year are required. Record one of the following as appropriate: the date on which the participant no longer experienced the AE, or the date of the study visit or specimen collection at which the change in status/outcome is first noted.
Item 8	Indicate all treatments administered for this AE, including treatment provided by a health care professional and participant self-treatment. Do not indicate treatments that were clinically indicated or prescribed but not administered.
Items 9–10	For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2.*

(MTN 027) DF/Net 027 CM (423)

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

Page #

Participant ID

Site Number – *Participant Number* – *Chk*

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

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

→ *End of form. Submit to DF/Net.*

Concomitant Medications Log

1

Medication Name

Staff Initials/ Log Entry Date

Indication

Taken for a reported AE?

☐ *yes* ☐ *no*

AE Log page(s) ☐☐ ☐☐ ☐☐ ☐☐

Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*

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

Dose/Units

Frequency *Mark only one.*

prn ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify* ☐ _____

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*

AE Log page(s) ☐☐ ☐☐ ☐☐ ☐☐

Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*

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

Dose/Units

Frequency *Mark only one.*

prn ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify* ☐ _____

Route *Mark only one.*

PO ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify* ☐ _____

_____ *Staff Initials/Date*

Purpose:

All medication(s) that are used by the participant during the study [(including the protocol-defined screening period)], 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, and naturopathic preparations.

General 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 DF/Net.
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 generic name of medication. For combination generic medications, record the first three main active ingredients, if applicable.
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”).
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: IM: intramuscular; TOP: topical; VAG: vaginal; SC: subcutaneous; alternative routes

(MTN 027) DF/Net 027 DEM (001)

Participant ID ___ – ___ – ___
Site Number *Participant Number* *Chk*

Form Completion Date ___ ___ ___
dd *MMM* *yy*

Demographics

1. What is your date of birth? dd ___ MMM ___ yy ___

2. What was your sex at birth? ☐ *male* ☒ *female*

3. Are you currently married? ☐ *yes* ☐ *no*

4. Do you currently live with your partner? ☐ *yes* ☐ *no*

5. 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

6. Do you consider yourself to be Latino/a or of Hispanic origin? ☐ *yes* ☐ *no*

7. What is your race? *Mark all that apply.*
   - ☐ 7a. American Indian or Alaska Native
   - ☐ 7b. Asian
   - ☐ 7c. Black or African American
   - ☐ 7d. Native Hawaiian or other Pacific Islander
   - ☐ 7e. White
   - ☐ 7f. Other, specify: _____

8. Do you earn an income of your own? *yes* ☐ *no* ☐ → *If no, go to item 9.*

   8a. How do you earn income? *Mark all that apply.*
   ☐ *formal employment* ☐ *self-employment* ☐ *other*

9. How do you identify your gender? *Mark all that apply.*
   - ☐ 9a. male
   - ☐ 9b. female
   - ☐ 9c. transgender male (female to male)
   - ☐ 9d. additional category, specify: _____
   - ☐ 9e. decline to state

_____
Staff Initials/Date

Purpose:

This form is interviewer-administered and is used to collect participant's demographic and socioeconomic information.

General Instructions:

This form is faxed to DataFax only if the participant enrolls in the study. This form is completed at the Screening Visit. Read each item aloud, except item 2, and record the participant's response.

Item-specific Instructions:

Item 3	Mark "yes" if the participant is in a legally-binding marriage and has obtained a marriage certificate.
Item 5	If the participant attended or completed a post-secondary diploma or certificate program mark "attended college or university."
Item 6	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 7	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, Latino/a is considered an ethnic group and not a race and should not be entered in item 7f.
Item 9	This item must be self-reported by the participant. Site staff is encouraged to document in chart notes if the participant during study participation prefers to be referred to by a specific pronoun or gender.

(MTN 027) DF/Net 027 ECI (023)

Participant ID ☐☐☐ – ☐☐☐☐☐ – ☐
Site Number *Participant Number* *Chk*

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

Eligibility Criteria

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 < 18 or > 45 years old
- ☐ 4b. plans for relocation/travel
- ☐ 4c. participant is pregnant or planning to become pregnant within the next 3 months
- ☐ 4d. participant is breastfeeding
- ☐ 4e. participant unwilling to refrain from receptive sexual activity
- ☐ 4f. participant has enrolled in another research study in the last 60 days
- ☐ 4g. diagnosed with PID, RTI, or STI, which has not resolved
- ☐ 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 1 or higher pelvic exam finding
- ☐ 4l. participant does not meet laboratory eligibility criteria. Specify or provide test results: _____
- ☐ 4m. participant does not meet other clinical eligibility criteria
- ☐ 4n. other reason, including investigator decision. Specify: _____

Comments: _____

_____
Staff Initials/Date

Purpose:

This form is used to document participant eligibility for enrollment in this study or reasons for participant ineligibility.

General 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 45-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.

(MTN 027) DF/Net 027 ENR (070)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number *Participant Number* *Chk*

Enrollment

1. Date the participant marked or signed the consent form for study participation: dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

2. Did the participant consent to:

   2a. long-term specimen storage and future testing? *yes* ☐ *no* ☐

   2b. participate in Extra Samples Group (rectal fluid for PK collection)? *yes* ☐ *no* ☐

3. Plasma for archive: Collection Date dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] *stored* ☐ *not stored* ☐ → *Reason:* _____

4. Randomization number assigned: [ ][ ][ ]

5. Randomization date and time: dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] hr [ ][ ] : min [ ][ ] *24-hr clock*

6. Date and time vaginal ring inserted: dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ] hr [ ][ ] : min [ ][ ] *24-hr clock*

7. Was a Baseline CASI questionnaire completed at this visit? *yes* ☐ *no* ☐

8. Were there any problems or QC issues related to the administration or completion of the CASI questionnaire? *yes* ☐ *no* ☐ → *If no, end of form.*

   8a. Describe: _____

_____
Staff Initials/Date

Purpose:

This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for the randomized participant.

General Instructions:

Fax this form to DF/Net only if the participant is enrolled (that is, if she has been randomized).

Item-specific Instructions:

Item 2	Consent for long-term specimen storage or participation in the PK Subset can be changed if the participant changes her consent decision after enrollment. Update as needed if the participant changes her consent during the study.
Item 3	If the specimen for some reason is not stored, mark "not stored" and record the reason on the line provided.
Item 4	This item must match the randomization number provided within the randomization assignment confirmation email from FSTRF web-based system.
Item 5	These items must match the 'date assigned' and 'time assigned' recorded for this randomized participant within the randomization assignment confirmation email from the FSTRF web-based system.
Items 7–8	The Baseline CASI questionnaire is required at the Enrollment Visit. If it was not done, mark item 8 "yes" and provide a brief explanation in item 8a.

(MTN 027) DF/Net 027 FCT (153)

Visit Code ☐☐.☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Follow-up CASI Tracking

1. Was a CASI questionnaire administered at this visit? *yes* ☐ *no* ☐

2. Were there any problems or issues related to the administration or completion of the questionnaire? *yes* ☐ *no* ☐ → *If no, end of form.*

   2a. Describe:

   _____

   _____

   _____

Comments: _____

_____

_____

_____
Staff Initials/Date

Purpose:

This form is used to document participant completion of the Computer-assisted Self Interview (CASI) computerized questionnaires during follow-up.

General Instructions:

Complete this form at the Day 7, Day 14, Day 21, Day 28 and Day 35/Final Clinic Visit. Also complete this form at the participant's early termination visit.

Item-specific Instructions:

Item 2a	If there were any unusual details related to the CASI questionnaire administration or completion, describe them on the line provided.

(MTN 027) DF/Net 027 FVS (121)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐ (Site Number – Participant Number – Chk)

Visit Date ☐☐ ☐☐☐ ☐☐ (dd MMM yy)

Follow-up Visit Summary

1. Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV? ☐ *yes* ☐ *no* → *If yes, record on Concomitant Medications Log; complete Product Hold/Discontinuation 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* → *Record on Concomitant Medications Log; complete Product Hold/Discontinuation 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. Were any **new** Adverse Experience Logs completed for this visit? ☐ *yes* ☐ *no*

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

6. Is this an interim visit? ☐ *yes* ☐ *no* → *If no, go to statement above item 7.*

   6a. Reason for interim visit *Mark all that apply.* ☐ *AE report or follow-up* ☐ *return of product or need new product* ☐ *other, specify:* _____

   6b. Which forms, besides this form and the log forms, were newly completed for this interim visit? *Mark "None" or all that apply.*

   - ☐ None
   - ☐ Ring Collection and Insertion
   - ☐ Pharmacokinetics
   - ☐ Specimen Storage
   - ☐ Safety Laboratory Results
   - ☐ Pelvic Exam
   - ☐ STI Test Results
   - ☐ HIV Results
   - ☐ Physical Exam
   - ☐ other, specify: _____

Item 7 for Day 35/Final Clinic Visit or early termination visit. For all other visits, end of form.

7. Was an in-depth interview completed? ☐ *yes* ☐ *no*

Comments: _____

_____ *Staff Initials/Date*

Purpose:

This form is used to summarize information from each participant follow-up study visit (including interim visits).

General Instructions:

This form is completed for each scheduled visit. This form is also completed for interim visits/contacts where a new form (other than the Follow-up Visit Summary) is completed. Note that there is no Interim Visit form for this study—instead, this form is completed to document interim visits.

Item-specific Instructions:

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. • 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 more information on visit code assignments, please refer to Section 12 of the SSP.
Item 1	If the participant has taken post-exposure prophylaxis (PEP) since her last visit, mark "yes" and update the Concomitant Medications (CM) Log.
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.
Item 4	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 5	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).
Item 6b	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 7	Indicate whether an IDI was completed at the participant's Day 35/final clinic visit or early termination visit. At all other visits, leave this item blank.

(MTN 027) DF/Net 027 HIV (140)

Visit Code ☐☐.☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

HIV Results

	Not done/ Not collected	*negative*	*positive*	*indeterminate*	
1. HIV	☐	☐	☐	☐ →	*If any are positive or indeterminate, complete HIV Confirmatory Results form and complete Clinical Product Hold/Discontinuation Log.*

Comments: _____

_____

_____

_____

_____
Staff Initials/Date

Purpose:

This form is used to document the participant's HIV results.

General Instructions:

Record test results on this form as they become available. Fax this form into DF/Net DataFax once results for all collected specimens are recorded on the form. Complete this form at Day 35/Final Clinic Visit and if indicated during follow-up.

Item-specific Instructions:

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.
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 the Comments.

(MTN 027) DF/Net 027 HRS (331)

Visit Code ☐☐.☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

HIV Confirmatory Results

SAMPLE 1

1. HIV Confirmation Test — Not done/ Not collected ☐ → *Go to item 2.* — Specimen Collection Date: dd ☐☐ MMM ☐☐☐ yy ☐☐

1a. Western Blot — Not done ☐ *negative* ☐ *positive* ☐ *indeterminate* ☐

1b. Multispot — Not done ☐ *negative* ☐ *HIV-1 reactive* ☐ *HIV-2 reactive* ☐ *HIV-1/2 undifferentiated* ☐ *invalid* ☐

1c. 4th Generation HIV EIA — Not done ☐ *negative/ non-reactive* ☐ *positive/ reactive* ☐

1d. HIV RNA PCR — Not done ☐ > ☐ = ☐ < ☐ *viral copies/mL* ☐☐☐☐☐☐☐☐ OR *target not detected* ☐

1d1. RNA PCR kit lower limit of detection — *20* ☐ *40* ☐ OR *viral copies/mL* ☐☐☐

2. Final HIV Status — *HIV-uninfected* ☐ *HIV-infected* ☐ *pending* ☐

Comments: _____

_____

_____

_____

_____
Staff Initials/Date

Purpose:

This form is used to document results from local lab confirmatory HIV testing once a participant has a positive or indeterminate EIA test result.

General Instructions:

Complete this form for each visit where the participant has a positive or indeterminate EIA test result.

Item-specific Instructions:

Visit Code	The visit code recorded on this form should be the same visit code recorded on the Laboratory Results form documenting the 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.
Item 1	If confirmatory test is used, but is not listed, specify which test is used in the comments section of this form and contact the Lab Center for further guidance.
Items 1a, 1b, 1c, and 1d	If the result is “negative,” “indeterminate,” or “invalid,” consult the Lab Center.
Item 2	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.” If additional testing is done to determine final status, record details in Comments.

(MTN 027) DF/Net 027 MV (463)

Visit Code ☐☐.☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Missed Visit

1. Target Visit Date dd ☐☐ MMM ☐☐☐ yy ☐☐

2. Reason visit was missed. *Mark only one.*

- ☐ 2a. unable to contact participant
- ☐ 2b. unable to schedule appointment(s) within allowable window
- ☐ 2c. participant refused visit
- ☐ 2d. participant incarcerated
- ☐ 2e. participant admitted to a health care facility
- ☐ 2f. participant withdrew from study *Complete 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: _____

_____

_____

_____
Staff Initials/Date

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 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.

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.

(MTN 027) DF/Net 027 PDL (495)

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

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number *Participant Number* *Chk*

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Protocol Deviation Log

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*

_____
Staff Initials/Date

Purpose:
This form documents and reports protocol deviations identified for study participants.
General 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 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.

(MTN 027) DF/Net 027 PE (138)

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (*Site Number* – *Participant Number* – *Chk*)

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

Pelvic Exam

1 Vaginal pH: ☐ *Not done* ☐.☐ *If > 4.5, mark Positive* → ☐ *Positive*

2 Pelvic exam assessment: ☐ *Not done* → *End of form.* ☐ *Abnormal findings* ☐ *No abnormal findings* → *End of form.*

2a. 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)*	_____
☐ *Vulvar tenderness*	☐ *Vaginal abrasions or lacerations*	☐ *Cervical motion tenderness*	☐ *Adnexal masses (based on bimanual exam; not pregnancy or infection-related)*
☐ *Bartholin's or Skene's gland abnormality*	☐ *Vaginal tenderness*	☐ *Cervical discharge*	☐ *Uterine masses (based on bimanual exam)*
	☐ *Abnormal vaginal discharge* → *slight* ☐ *moderate* ☐ *pooling* ☐		☐ *Uterine tenderness*
			☐ *Adnexal tenderness*
Vulvar lesions	**Vaginal lesions**	**Cervical lesions**	☐ *Observed blood or bleeding, describe:*
☐ *Ulcer*	☐ *Ulcer*	☐ *Ulcer*	_____
☐ *Blister*	☐ *Blister*	☐ *Blister*	_____
☐ *Pustule*	☐ *Pustule*	☐ *Pustule*	_____
☐ *Peeling*	☐ *Peeling*	☐ *Peeling*	_____
☐ *Ecchymosis*	☐ *Ecchymosis*	☐ *Ecchymosis*	

☐ 2b. Other abnormal findings, specify (include anatomical location): _____

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

3 Are any new pelvic finding AEs reported at this visit? ☐ *Yes* ☐ *No* → *End of form.*

3a. AE Log page #(s): *Line through any unused boxes.*

☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

_____
Staff Initials/Date

Purpose:

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

General Instructions:

Complete this form at Screening, Enrollment, at all follow-up study visits, and early termination visit (as applicable), and when a clinically indicated pelvic exam is performed during interim visits. Transcribe information from the Pelvic Exam Diagrams form (non-DataFax) onto this form for submission to DataFax.

Item-specific Instructions:

Item 1	Vaginal fluid pH is required at Enrollment Visit, Day 3, Day 28, Day 29, Day 30, Day 31, and Day 35/Final Clinic Visit.
Item 2	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 2a, mark "observed blood or bleeding; describe" and describe on the lines provided.
Item 2a	• Mark the box to the left of each abnormal finding observed. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 2a 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. Please refer to Study-specific Procedures (SSP) manual section section 8 for AE reporting guidance for observed bleeding. • 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.
Item 2b	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.

(MTN 027) DF/Net 027

Participant ID

			–					–	

Site Number *Participant Number* *Chk*

Exam Date

dd *MMM* *yy*

☐ no normal variants or abnormal findings observed

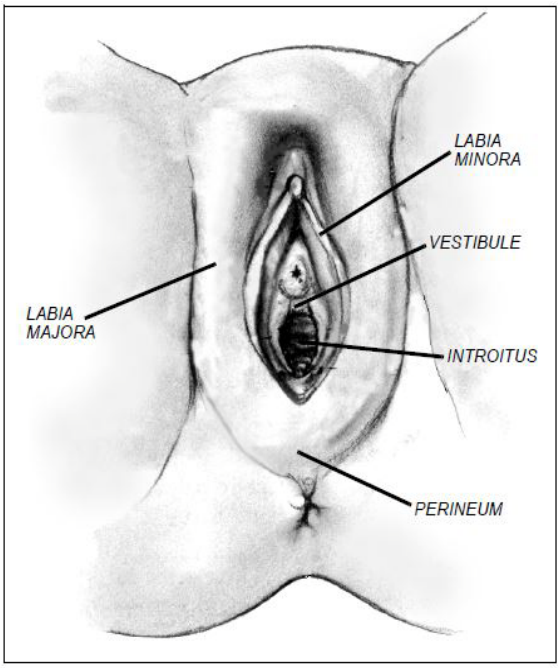
Speculum Type (screening only)

Pederson ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only)

small ☐ *medium* ☐ *large* ☐

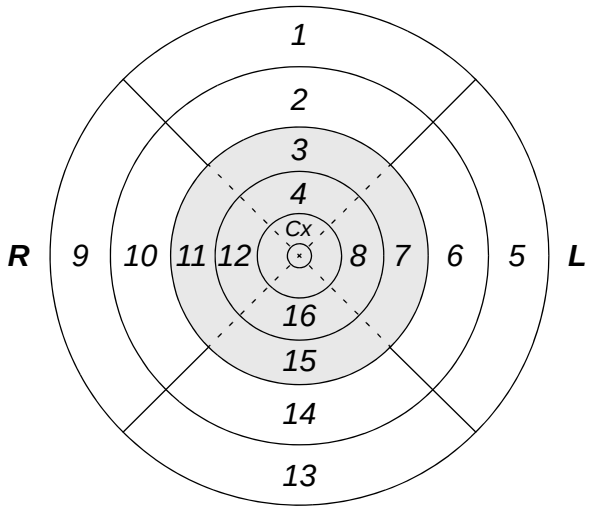
External Genitalia



Legend for Vagina/Cervix

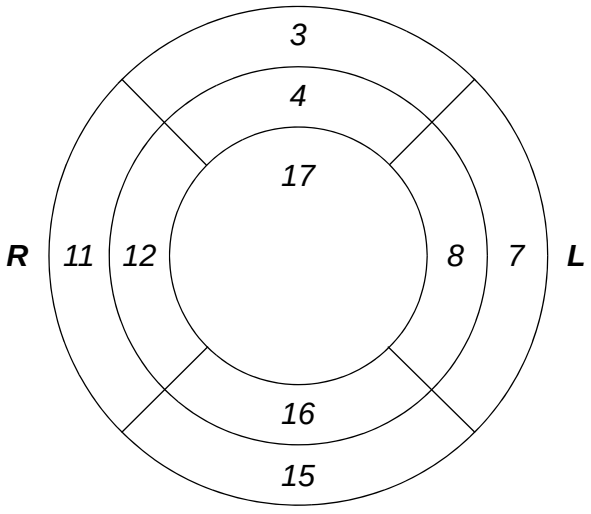
1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, 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: Anterior



Posterior

Cervix: Anterior



Posterior

Version 1.0, 01-APR-15

Staff Initials/Date

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 Instructions:

This form is completed at the Screening Visit, the Enrollment Visit, at all scheduled study visits, and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to DF/Net DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes..

Item-specific Instructions:

Findings	All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. The following findings are considered normal variants: • anatomic variants • gland openings • Nabothian cysts • mucus retention cysts • Gartner's duct cysts • blood vessel changes other than disruption • skin tags • scars • 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).

(MTN 027) DF/Net 027 PER (168)

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (*Site Number* – *Participant Number* – *Chk*)

Exam Date ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

Pelvic Exam Ring Assessment

1 Was the vaginal ring present in the vagina at the start of the exam? ☐ *Yes* ☐ *No* → *If no, go to item 3.*

2 Was the vaginal ring removed during the exam? ☐ *Yes* ☐ *No* → *If no, end of form.*

2a. If yes, how long was the vaginal ring removed from the vagina? ☐☐ *Hours* ☐☐ *Minutes*

3 Was the vaginal ring rinsed prior to reinsertion? ☐ *Yes* ☐ *No* ☐ *Not reinserted* → *If yes or no, end of form.*

3a. Specify reason ring not reinserted: _____

_____ *Staff Initials/Date*

Purpose:

The purpose of this form is to document presence/absence of the vaginal ring during pelvic exams.

General Instructions:

This form is completed for pelvic exams performed during the vaginal ring use period (post enrollment up through Day 28 Visit).

(MTN 027) DF/Net 027 PH (410)

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

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number *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
- ☐ use of prohibited medications → *Record on Concomitant Medications Log CRF.*
- ☐ breastfeeding
- ☐ report of PEP use for HIV exposure
- ☐ report of PrEP use for HIV exposure
- ☐ 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 the Day 28 visit	→ Date:	☐☐	☐☐☐	☐☐
☐ no—permanently discontinued	→ Date:	☐☐	☐☐☐	☐☐

Comments: _____

_____

_____

_____
Staff Initials/Date

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.

Do not complete this log in cases where a participant has decided on his/her own to stop using study product. This information will be documented on the Ring Collection and Insertion form.

Item-specific Instructions:

Page	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers.
Item 2	Note that participant decline or refusal of study product is not documented as a product hold. Do not record this as a reason in "other, specify."
Item 3	Record the last date the 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 DF/Net 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 reason in item 2 met criteria for permanent discontinuation. **Note:** *This date could fall anytime between enrollment through and including the date of termination.* If **"no-hold continuing at the Day 28 visit"** is marked, record the date the Day 28 visit was completed. If the Day 28 visit was missed, record the target date of the Day 28 visit. If the reason for the hold later meets criteria for permanent discontinuation between the Day 28 visit and the date of termination, update the response to "no-permanently discontinued" and record the date the reason first met criteria for permanent discontinuation.

(MTN 027) DF/Net 027 PKD (164)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐
Site Number *Participant Number* *Chk*

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

Pharmacokinetics Specimens—Days 1, 2, 3, 7, 14, 21, 29, 30, 31, 35

1. Last menstrual period: ☐ *None*

Start Date ☐☐ ☐☐☐ ☐☐ (dd MMM yy)

Stop Date ☐☐ ☐☐☐ ☐☐ (dd MMM yy) OR ☐ *ongoing*

Not done/ Not collected	Specimen	*Stored*	*Not Stored*	*If not stored, specify:*	Was blood visible on swab?
☐	2. Single time-point blood draw:	☐	☐		
☐	3. Single time-point vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
	3a. Number of vaginal swabs collected: ☐				

Comments:

Version 1.0, 01-APR-15

Staff Initials/Date _____

Purpose:

This form is used to document collection and timing of collection of pharmacokinetic (PK) laboratory specimens.

General Instructions:

Complete this form at Days 1, 2, 3, 7, 14, 21, 29, 30, 31, and 35.

Item-specific Instructions:

Item 1	If the participant has not had a period within the last 30 days, mark “none.”
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 by the lab, mark “not stored” and record the reason why on the line provided.

(MTN 027) DF/Net 027 PKS (162)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐
Site Number *Participant Number* *Chk*

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

Pharmacokinetics Specimens—Day 28

1. Last menstrual period: ☐ *None*
Start Date ☐☐ dd ☐☐☐ MMM ☐☐ yy
Stop Date ☐☐ dd ☐☐☐ MMM ☐☐ yy
ongoing OR ☐

Not done/ Not collected	Specimen	*Stored*	*Not Stored*	*If not stored, specify:*	Was blood visible on swab?
	Blood				
☐	2. 0-hour blood draw:	☐	☐		
☐	3. 1-hour blood draw:	☐	☐		
☐	4. 2-hour blood draw:	☐	☐		
☐	5. 4-hour blood draw:	☐	☐		
☐	6. 6-hour blood draw:	☐	☐		
	Vaginal Fluid	*Stored*	*Not Stored*	*If not stored, specify:*	Was blood visible on swab?
☐	7. 0-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	8. 1-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	9. 2-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	10. 4-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	11. 6-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
	Other				
☐	12. Rectal fluid for PK:	☐	☐		
☐	13. Cervical biopsy for PK:	☐	☐		
☐	14. Cervical biopsy for PD:	☐	☐		

Comments:

_____
Staff Initials/Date

Purpose:

This form is used to document collection and timing of collection of pharmacokinetic (PK) laboratory specimens.

General Instructions:

Complete this form at Day 28.

Item-specific Instructions:

Item 1	If the participant has not had a period within the last 30 days, mark “none.”
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 by the lab, mark “not stored” and record the reason why on the line provided.
Item 14	This item should be completed by the Pittsburgh site only. A cervical biopsy for PD is not required at the Alabama CRS and can be marked "not done/not collected".

(MTN 027) DF/Net 027 PKS (162)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐ (*Site Number* – *Participant Number* – *Chk*)

Specimen Collection Date ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

Pharmacokinetics Specimens—Enrollment

1. Last menstrual period: ☐ *None*
   Start Date ☐☐ (dd) ☐☐☐ (MMM) ☐☐ (yy)
   Stop Date ☐☐ (dd) ☐☐☐ (MMM) ☐☐ (yy)
   ongoing OR ☐

Not done/ Not collected	Specimen	*Stored*	*Not Stored*	*If not stored, specify:*	Was blood visible on swab?
	Blood				
	This row left intentionally blank.				
☐	3. 1-hour blood draw:	☐	☐		
☐	4. 2-hour blood draw:	☐	☐		
☐	5. 4-hour blood draw:	☐	☐		
☐	6. 6-hour blood draw:	☐	☐		
	Vaginal Fluid	*Stored*	*Not Stored*	*If not stored, specify:*	Was blood visible on swab?
☐	7. 0-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	8. 1-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	9. 2-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	10. 4-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
☐	11. 6-hour vaginal fluid for PK:	☐	☐		☐ *Yes* ☐ *No*
	Other				
☐	12. Rectal fluid for PK:	☐	☐		

Comments:

_____
Staff Initials/Date

Purpose:

This form is used to document collection and timing of collection of pharmacokinetic (PK) laboratory specimens.

General Instructions:

Complete this form at the Enrollment visit.

Item-specific Instructions:

Item 1	If the participant has not had a period within the last 30 days, mark “none.”
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 storedby the lab, mark “not stored” and record the reason why on the line provided.

(MTN 027) DF/Net 027 (PO-1) 442

Visit Code ☐☐.☐ Outcome Number ☐

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number *Participant Number* *Chk*

☐ Outcome unobtainable → *Go to page 2.*

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

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

2. Outcome Date dd ☐☐ MMM ☐☐☐ yy ☐☐

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

4. Specify outcome. *Mark only one.*

   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:
     - ☐ C-section
     - ☐ standard vaginal
     - ☐ operative vaginal

     If full term live birth, go to item 6.
   - ☐ 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: _____

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: _____

_____
Staff Initials/Date

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 Instructions:

A Pregnancy Outcome form is required for each Pregnancy Report and History form that is completed for a participant.

Item-specific Instructions:

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.
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 DF/Net.
Item 1	If the pregnancy results in two or more outcomes, complete a Pregnancy Outcome form for each outcome. Each Pregnancy Outcome form will have the same visit code, but different outcome numbers (for example, one Pregnancy Outcome form will have an outcome number =1 and the second form will have an outcome number =2, and so on).
Item 4	If the outcome is spontaneous fetal death, still birth, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an adverse experience (AE). If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under item 7, "Treatment." If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-specific Procedures (SSP) manual, and *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2* for guidance on AE and expedited AE reporting requirements.
Item 4a1	"Operative vaginal" delivery includes delivery with forceps and/or vacuum.
Item 5	Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.

(MTN 027) DF/Net 027 (PO-2) 443

Visit Code ☐☐.☐ Outcome Number ☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

☐ No data recorded on this page. → *End of form.*

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:* _____

_____
Staff Initials/Date

Item-specific Instructions:

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

(MTN 027) DF/Net 027 (PR) 440

Visit Code ☐☐.☐

Participant ID

☐☐☐–☐☐☐☐☐–☐

Site Number *Participant Number* *Chk*

Pregnancy Report and History

1	First day of last menstrual period	☐☐ ☐☐☐ ☐☐ *dd MMM yy* OR ☐ *amenorrhoeic for past 6 months*
2	Estimated date of delivery	☐☐ ☐☐☐ ☐☐ *dd MMM yy*
3	What information was used to estimate the date of delivery?	
	3a. last menstrual period	☐ *yes* ☐ *no*
	3b. initial ultrasound < 20 weeks	☐ *yes* ☐ *no*
	3c. initial ultrasound >= 20 weeks	☐ *yes* ☐ *no*
	3d. physical examination	☐ *yes* ☐ *no*
	3e. conception date by assisted reproduction	☐ *yes* ☐ *no*
	3f. other, specify: _____	☐ *yes* ☐ *no*
4	Has the participant ever been pregnant before?	☐ *yes* ☐ *no* → *If no, end of form.*
	4a. Is this the participant's first pregnancy since enrollment in this study?	☐ *yes* ☐ *no* → *If no, go to item 5.*
	4b. Number of full-term live births (≥ 37 weeks)	☐☐
	4c. Number of premature live births (< 37 weeks)	☐☐
	4d. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks)	☐☐
	4e. Number of spontaneous abortions (< 20 weeks)	☐☐
	4f. Number of therapeutic/elective abortions	☐☐
	4g. Number of ectopic pregnancies	☐☐
5	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before study enrollment?	☐ *yes* ☐ *no* → *If no, end of form.*
	5a. If yes, specify: _____	

_____
Staff Initials/Date

General Instructions:

Complete this form when reporting a pregnancy of a study participant post-enrollment through termination. Record the visit code of the visit at which study staff became aware that the participant is/was pregnant.

Item-specific Instructions:

Item 1	A complete date is required. Record best estimate if date not known.
Item 2	A complete date is required.

(MTN 027) DF/Net 027 PRC (466)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number *Participant Number* *Chk*

Form Completion Date

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

dd *MMM* *yy*

Participant Receipt

Instruction: Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.

1 Name of receiving study site _____

2 Name of transferring study site _____

3 Date informed consent signed at receiving study site [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

4 Did participant provide informed consent for specimen storage at receiving study site? ☐ *Yes* ☐ *No* → *If no, end of form.*

4a. Date informed consent signed at receiving study site [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

Comments:

_____

Staff Initials/Date

General Instructions:

- Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site.
- The **Participant Receipt** form is completed by the receiving site (the site at which the participant will be continuing his or her study visits).
- For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP), and/or Manual of Operations (MOP).

Item-specific Instructions:

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

(MTN 027) DF/Net 027 PRE (012)

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

Participant ID

Site Number – *Participant Number* – *Chk*

☐ No pre-existing conditions reported or observed.

Staff Initials/Date

→ *End of form. Submit to DF/Net.*

Pre-existing Conditions

1	Condition	Onset Date MMM yy	Staff Initials/Date
	Comments	Ongoing at Enrolment? *yes* ☐ *no* ☐	Severity Grade ☐ *or* ☐ *not gradable*
2	Condition	Onset Date MMM yy	Staff Initials/Date
	Comments	Ongoing at Enrolment? *yes* ☐ *no* ☐	Severity Grade ☐ *or* ☐ *not gradable*
3	Condition	Onset Date MMM yy	Staff Initials/Date
	Comments	Ongoing at Enrolment? *yes* ☐ *no* ☐	Severity Grade ☐ *or* ☐ *not gradable*
4	Condition	Onset Date MMM yy	Staff Initials/Date
	Comments	Ongoing at Enrolment? *yes* ☐ *no* ☐	Severity Grade ☐ *or* ☐ *not gradable*

Staff Initials/Date

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 Instructions:

- At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing. This includes, but is not limited to, history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions ongoing at screening and/or that occur between screening and 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 DF/Net.
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.
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.
Severity Grade	For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark "not gradable". Review and update as needed for conditions ongoing at the Enrollment Visit.

(MTN 027) DF/Net 027 (PT) 465

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number *Participant Number* *Chk*

Form Completion Date

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

dd *MMM* *yy*

Participant Transfer

1	Name of transferring study site _____	
2	Name of receiving study site _____	
3	Visit Code of last completed contact with participant	[ ][ ] . [ ] *visit code*
4	Date participant records were sent to receiving study site	[ ][ ] [ ][ ][ ] [ ][ ] *dd* *MMM* *yy*

Comments:

_____
Staff Initials/Date

General Instructions:

- Complete this form when a participant is transferring to another study clinic/site.
  The **Participant Transfer** form is completed by the transferring site (the site that the participant is leaving).
  For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP), and/or Manual of Operations (MOP).

Item-specific Instructions:

Item 4	A complete date is required.

(MTN 027) DF/Net 027 PX (036)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐
Site Number *Participant Number* *Chk*

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Physical Exam

Vital Signs

Not Required ☐

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

FINDINGS:
Items 8–16 may be omitted after Enrollment.

		Not Done	Normal	Abnormal	*Notes*
7	General appearance	☐	☐	☐	
8	Abdomen/Gastrointestinal	☐	☐	☐	
9	Head, eye, ear, nose, and throat	☐	☐	☐	
10	Neck	☐	☐	☐	
11	Lymph Nodes	☐	☐	☐	
12	Heart/Cardiovascular	☐	☐	☐	
13	Lungs/Respiratory	☐	☐	☐	
14	Extremities	☐	☐	☐	
15	Neurological	☐	☐	☐	
16	Skin	☐	☐	☐	
17	Other	☐	☐	☐	

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

Comments: _____

_____
Staff Initials/Date

Purpose:

This form is used to document the participant's vital signs and physical exam findings.

General Instructions:

Complete this form at the Screening, Enrollment, and all follow-up study visits. If abnormal findings are found, for items 7–17, transcribe the information onto the Pre-existing Conditions or Adverse Experience form(s).

Item-specific Instructions:

Vital Signs	Use leading zeros as applicable.
Item 1	This item is required at Screening and Enrollment only.
Items 7–16	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 17	If no other abnormal findings are identified, mark "not done."

(MTN 027) DF/Net 027 RA (170)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐
Site Number *Participant Number* *Chk*

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

Ring Adherence

1 Date and visit code this form was last completed for this participant? ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*) Visit Code ☐☐.☐

2 Since this form was last completed, has the ring been out at any time? ☐ *Yes* ☐ *No* → *If no, end of form.*

2a. How many times total has the ring been out? ☐☐ → *If 6 or more, add Comment after completing items 3a–3e.*

3 For each instance the vaginal ring was out, complete the information below on when the ring was out, how long it was out, and why it was out? Ring removals due to scheduled pelvic exams should not be recorded on this form.

	Date ring out *dd-MMM-yy*	Duration ring was out *days*	*hours*	*minutes*	Removal/ Expulsion code	If other, specify:
3a.	☐☐ ☐☐☐ ☐☐	☐☐	☐☐	☐☐	☐☐	
3b.	☐☐ ☐☐☐ ☐☐	☐☐	☐☐	☐☐	☐☐	
3c.	☐☐ ☐☐☐ ☐☐	☐☐	☐☐	☐☐	☐☐	
3d.	☐☐ ☐☐☐ ☐☐	☐☐	☐☐	☐☐	☐☐	
3e.	☐☐ ☐☐☐ ☐☐	☐☐	☐☐	☐☐	☐☐	

4 Has the vaginal ring stayed in place for at least the past 8 hours prior to this visit? ☐ *Yes* ☐ *No* → *If no, specify details in the Comments section.*

Comments: _____

_____

_____
Staff Initials/Date

Purpose:

This form is used to collect participant-reported information on ring use (adherence). This includes all instances where the participant reports the ring has not been used, regardless of reason for non-use.

General Instructions:

Complete this form at the Day 1, 2, 3, 7, 14, 21 and 28 visits only. This form is required at each of these visits, even if the participant has been on product hold. Do not complete this form at Interim Visits.

Item-specific Instructions:

Item 1	Record the date of enrollment and visit code “02.0” the first time this form is completed for each participant.
Item 2	Per participant report, if the ring has been out (not inserted) for any amount of time since the last time the form was completed for the participant, mark "yes" and continue with the form. If the participant reports the study vaginal ring has been in continuously since the last time this form was completed, mark "no" and end the form.
Item 2a	Record how many separate times the participant reports the ring has been out since the last time the form was completed.
Items 3a–3e	Complete one row for each separate time the participant reports the ring has been out. For example, if the participant reported that the ring has been out for two separate times since the last time this form was completed, complete rows 3a and 3b. In this case, item 2a of the form should be "02". When possible, complete items 3a–3e in ascending order by date, with item 3a being the earliest date the ring was out and item 3e the most recent date the ring was out.
Items 3a–3e: Removal/ Expulsion Codes	Select from the codes below and record the code that best describes why the vaginal ring was taken out or came out on its own.
Item 4	If the participant reports the ring has not been in place during the previous 8 hours prior to the visit, provide details in the comments section and include the time and duration of the outage(s), if possible.

REASONS RING REMOVED BY PARTICIPANT OR CLINICIAN

Hygienic or Physical Reasons	
Code	Description
10	**Discomfort/symptoms:** Ring caused discomfort/ participant experienced genital or other symptoms
11	**Ring falling out:** Ring was partially falling out
12	**Ring placement:** Didn’t feel the ring was correctly placed
13	**Ring presence:** Wanted to look at the ring or see if the ring was still in place
14	**Menses/Bleeding:** Had or was expecting menses/ any type of genital bleeding or spotting
15	**Cleaned ring:** Removed ring to clean it
16	**Cleaned vagina:** Removed ring to clean vagina

Study-related or Procedural Reasons	
Code	Description
30	**Product hold:** Participant placed on product hold
31	**Product permanently discontinued:** Participant permanently discontinued from product
32	**Procedure:** Ring removed for clinical procedure (e.g., IUCD insertion) that was *not* conducted at a regularly scheduled study visit
33	**Inserted new ring:** Ring removed to insert new ring between study visits or at an interim visit
34	**Missed visit:** Participant removed ring due to missed scheduled visit

Social or Sexual Reasons	
Code	Description
20	**Partner ring knowledge:** Did not want husband or primary sex partner to know about ring
21	**Partner concerns/objections:** Husband or any sex partner did not like the ring and/or wanted her to remove/stop using the ring
22	**Family concerns/objections:** Family member (other than husband/ primary sex partner) did not like the ring and/or wanted her to remove/ stop using the ring
23	**Friend or peer concerns/objections:** Friend or peer did not like the ring and/or wanted her to remove/stop using the ring
24	**Removal for sex:** Participant or partner did not want to have vaginal sex with the ring in place
25	**Discomfort during sex:** The ring feeling uncomfortable or painful during vaginal sex
26	**Partner felt ring during sex:** The sex partner feeling the ring during sex
27	**Showed ring:** Removed ring to show it to someone
28	**Not having sex:** Participant was not having sex so she decided to remove/stop using the ring
99	Other

REASONS RING CAME OUT ON ITS OWN

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

(MTN 027) DF/Net 027 RCI (135)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐ (*Site Number* – *Participant Number* – *Chk*)

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

Ring Collection and Insertion

1 Did the participant have a ring in place at the start of the visit? ☐ *Yes* ☐ *No*
→ *If yes, go to item 2.*

1a. When was the ring last in place? ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*) OR ☐ *Not applicable (ring not in place since last visit)*

2 Number of **used** rings collected: ☐ *None* ☐ *1* → *If "1," go to item 3.*

2a. If none, specify reason: _____

3 Number of **new** rings dispensed to participant: ☐ *None* ☐ *1* → *If "1," go to item 4.*

3a. Reason ring not dispensed:
- ☐ *participant on clinical hold*
- ☐ *participant has been permanently discontinued from product*
- ☐ *participant declined study ring, specify:* _____
- ☐ *early termination*
- ☐ *Day 28 ring removal visit*
- ☐ *Other, specify:* _____

→ *End of form.*

4 Was a new ring inserted at this visit? ☐ *Yes* ☐ *No* → *If no, go to item 5.*

4a. Time new ring was inserted: ☐☐ : ☐☐ (*hh* *mm*) *(24-hour clock)*

4b. Who inserted the new ring? ☐ *Participant* ☐ *Study staff*

5 Was a ring in place at the end of the visit? ☐ *Yes* ☐ *No*
→ *If yes, end of form.*

5a. Reason ring not in place at end of visit:
- ☐ *participant declined to have ring inserted*
- ☐ *participant had to leave before ring could be inserted*
- ☐ *Other, specify:* _____

_____
Staff Initials/Date

Purpose:

This form is used to document rings that are inserted and collected for each participant for the duration of the study.

General Instructions:

- Complete this form at the Day 28 visit, and at early termination visit, as applicable. Complete at interim visits as needed.
- If the participant has been permanently discontinued from study product, this form is not required to be completed at visits following the permanent discontinuation.

Item-specific Instructions:

Item 1a	If the vaginal ring was not in place at the start of the visit, record the date the vaginal ring was last in place over the past month. If the participant is unable to recall the exact date, obtain the participant's best estimate. At a minimum, the month and year are required. If the ring was not in place at any time since this form was last completed, mark "not applicable."
Item 2a	If no rings were collected (returned), specify the reason why (for example, participant forgot, or participant had no dispensed rings to return).
Item 3	Only document ring(s) dispensed and given to the participant.
Item 3a	If participant declined to have a ring dispensed to her, record a brief reason for her decline on the line provided. If the reason for her decline is due to or associated with an adverse event, document the adverse event on an Adverse Experience (AE) Log and note in the AE Log comments that the participant declined the ring because of the AE.

(MTN 027) DF/Net 027 SIL (151)

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

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number *Participant Number* *Chk*

Social Impact Log

Instructions: Fax this form to DataFax whenever a new social impact is recorded or information on this form is updated. Fax only pages with new entries or revisions

1 Concisely describe social impact:

_____

_____

2 Onset date: ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

3 Reported at visit: ☐☐ . ☐

4 Social impact code: ☐☐ *See back for codes and definitions.*

4a. Did this involve physical harm to the participant? ☐ *Yes* ☐ *No*

4b. Did this involve physical or other harm to participant's child(ren)? ☐ *Yes* ☐ *No*

5 What impact did this situation have on the participant's quality of life?

☐ Minimal disturbance

☐ Moderate disturbance; no significant impact

☐ Major disturbance with significant impact

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

6a. *Participant:*

_____

_____

6b. *Staff:*

_____

_____

7 Record current status:

☐ Unresolved

☐ Unresolved at end of study

☐ Unable to resolve; no further action taken

☐ Resolved

→ Closure Date: ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

_____
Staff Initials/Date

Purpose:

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

General Instructions:

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

Item-specific Instructions:

Page	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers/ Do not renumber any Social Impact Log pages after faxing, unless instructed by DF/Net.
Item 2	Record the date the negative experience first started. At minimum, a month and year are required.
Item 4	Use the Code List below to code the social impact. Use leading zeros when needed.
Item 5	• Minimal impact—no or little interference with usual social and/or functional activities • Moderate impact—greater than minimal interference with usual social and/or functional activities • Severe impact—inability to perform usual social and/or functional activities
Item 7	This item may be updated at subsequent follow-up visits.

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

(MTN 027) DF/Net 027 SLR-1 (144)

Visit Code ☐☐.☐

Participant ID ☐☐☐-☐☐☐☐☐-☐ (*Site Number* – *Participant Number* – *Chk*)

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

Safety Laboratory Results

	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*			
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	☐	☐☐☐☐			

Staff Initials/Date _____

Purpose:

This form is used to provide data on the participant's baseline and follow-up laboratory test results.

General 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 DF/Net until all results are available and the participant has enrolled in the study.

Item-specific Instructions:

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-027 Management Team. Note that the following units are equivalent: IU/L = U/L, I/I 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 thelab-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.

(MTN 027) DF/Net 027 SLR-2 (145)

Visit Code ____ . ____

Participant ID

___ – _____ – ___

Site Number *Participant Number* *Chk*

Safety Laboratory Results

	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.*	____ / _____ / ____			
2a. AST (SGOT)	Not reported ☐	_____ *U/L*	☐	_____	OR ☐
2b. ALT (SGPT)	☐	_____ *U/L*	☐	_____	OR ☐
2c. Creatinine	☐	____ . ____ *mg/dL*	☐	_____	OR ☐
2c1. Calculated creatinine clearance		_____ *mL/min*			

	Not done/ Not collected	Alternate Collection Date (dd / MMM / yy)
3. DIPSTICK URINALYSIS TESTS	☐ → *End of form.*	____ / _____ / ____

	Not done	*negative*	*positive*
3a. Leukocyte esterase (LE)	☐	☐	☐
3b. Nitrites	☐	☐	☐

	negative	*trace*	*1+*	*2+*	*3+*	*4+*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
3c. Protein	☐	☐	☐	☐	☐	☐	☐	_____	OR ☐
3d. Glucose	☐	☐	☐	☐	☐	☐	☐	_____	OR ☐

Comments: _____

_____

_____

_____
Staff Initials/Date

Purpose:

This form is used to provide data on the participant's baseline and follow-up laboratory test results.

General 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 DF/Net until all results are available and the participant has enrolled in the study.

Item-specific Instructions:

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.
Item 2c1	When calculating the participant's creatinine clearance use the age and weight of the participant at the time the blood specimen is drawn. If the participant was not weighed at the visit when the blood specimen was drawn, but was weighed at a previous visit (within the allowable window for creatinine clearance per the SSP Manual), record the weight from the previous visit. Also, record in the "Alternative Collection Date" boxes the date of the previous visit when the participant was weighed. If the participant has a creatinine value but cannot have her creatinine clearance calculated (due to missing weight data), line through the response boxes and initial and date.
Item 3	If a dipstick urinalysis was done, but a given result was not reported, mark the "not done" box.
Items 3a-3b	If the result is negative or trace, mark the 'negative' box. If the result is 1+ or greater, mark the 'positive' box.
Item 3d	Grade the severity of the urine glucose value according to the "Proteinuria, random collection" row of the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events.*

(MTN 027) DF/Net 027 SS (149)

Visit Code ☐☐.☐

Participant ID ☐☐☐–☐☐☐☐☐–☐
Site Number *Participant Number* *Chk*

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

Specimen Storage

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. Quantitative vaginal culture

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

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

3a. Was blood visible on the swab? *yes* ☐ *no* ☐

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

Not done/ Not collected ☐ 4. Cervical cytobrush

Alternate Collection Date dd ☐☐ MMM ☐☐☐ yy ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

Not done/ Not collected ☐ 5. Used vaginal ring

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

Collection Time *(24-hour clock)* *hh* ☐☐ : *mm* ☐☐ *stored* ☐ *not stored* ☐

Reason not stored _____

Comments: _____

_____

_____

_____
Staff Initials/Date

Purpose:

This form is used to document collection and storage of vaginal and cervical specimens by the local site laboratory.

General Instructions:

Complete this form at Enrollment, Day 3, Day 28 and Day 35/Final Clinic Visit, as applicable.

Item-specific Instructions:

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.
Stored/ Not Stored	Mark “stored” for specimens that are collected and sent to the lab for processing. If specimens are not stored by the lab, mark “not stored” and record the reason why on the line provided.

(MTN 027) DF/Net 027 STI (190)

Visit Code ____ . ____

Participant ID

Site Number – Participant Number – Chk

Initial Specimen Collection Date

dd MMM yy

STI Test Results

	Not done/ Not collected	Alternate Collection Date dd MMM yy	negative	positive	
1. VAGINAL WET PREP STUDIES	☐ → *Go to item 2.*				
1a. Homogeneous vaginal discharge	Not done ☐		☐	☐	*Only required if assessment for BV performed.*
1b. Whiff test	☐		☐	☐	*Only required if assessment for BV performed.*
1c. Clue cells >= 20%	☐		☐	☐	*Only required if assessment for BV performed.*
1d. *Trichomonas vaginalis*	☐		☐	☐	
1e. Buds and/or hyphae (yeast)	☐		☐	☐	

	Not done/ Not collected	Alternate Collection Date dd MMM yy	negative	positive
2. Trichomonas rapid test	☐		☐	☐
3. *N. gonorrhea*	☐		☐	☐
4. *C. trachomatis*	☐		☐	☐

	Not done/ Not collected	Alternate Collection Date dd MMM yy	non-reactive	reactive	
5. STI SEROLOGY	☐				
5a. Syphilis screening test			☐	☐ →	*If non-reactive, end of form.*
5a1. Syphilis titer:			1: ____		
			negative	*positive*	*indeterminate*
5b. Syphilis confirmatory test			☐	☐	☐

Complete Adverse Experience Log if applicable.

Comments: _____

_____
Staff Initials/Date

Purpose:

This form is used to document Vaginal Wet Prep and STI Test Results by the local site laboratory.

General Instructions:

Complete this form if indicated during follow-up.

Item-specific Instructions:

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.
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 1c	Mark “positive” if 20% or more of the cells were clue cells.
Item 1d	Mark “positive” if trichomonads were observed.
Item 1e	Mark “positive” if yeast buds and/or hyphae were observed.

(MTN 027) DF/Net 027 (TM) 490

Participant ID

___ – _____ – ___

Site Number *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
  - 2b1. Date of death (*dd* / *MMM* / *yy*) __ __ / ___ / __ __ *OR* ☐ date unknown
  - 2b2. Cause of death _____ *OR* ☐ cause unknown

  → *Complete or update AE 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 → *If HIV-1 infection, complete HIV Results CRF. End of form.*
- ☐ 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 event? *yes* ☐ *no* ☐ *don't know* ☐ → *If no or don't know, end of form.*

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

Comments:

_____ *Staff Initials/Date*

General Instructions:

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

Item-specific Instructions:

Item 1	A complete date is required.
Item 2	Mark only the primary reason for termination.
Item 2a	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	Only mark 2l when instructed by SCHARP.
Item 3a	Record the page number of the **Adverse Experience Log** on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the “specify” line.