SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

AE-1 (460)

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

Participant ID

Site ID – Participant Number – Chk

Adverse Experience Log

Date reported to site

dd MMM yy

1. Adverse Experience (AE) _____

Record diagnosis (in English), if available. Include anatomical location, if applicable.

2. Onset Date dd MMM yy

3. Severity Grade *grade 1 (mild)* ☐ *grade 2 (moderate)* ☐ *grade 3 (severe)* ☐ *grade 4 (potentially life-threatening)* ☐ *grade 5 (death)* ☐

4. Relationship to Study Product *related* ☐ *not related* ☐ *If not related, record rationale or alternative etiology in Comments.*

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

6. Status/Outcome
- ☐ continuing
- ☐ resolved
- ☐ death
- ☐ severity/frequency increased *Report as new AE.*
- ☐ continuing at end of study participation

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

7. Treatment *Mark "none" or all that apply.*
- ☐ none
- ☐ medication(s) *Report on Concomitant Medications Log.*
- ☐ new/prolonged hospitalization *Comment below.*
- ☐ procedure/surgery *Comment below.*
- ☐ other *Comment below.*

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

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

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

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

Comments:

Adverse Experience Log (AE-1)

Purpose:	To document all Adverse Experiences (AEs) required to be reported per protocol.
General Information/Instructions:	
	Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate AE on separate AE Log pages as applicable. If a cluster of symptoms reported on separate AE Log page is later attributed to a single diagnosis, change the earliest reported symptom page to the diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE Log pages (insert page #s)."
Page:	Number pages for this Log sequentially throughout the study for each PTID, starting with 001. Do not repeat page numbers on this log. If an AE Log page is marked for deletion, do not change the page number or re-assign that page number to another AE Log page.
Date Reported to Site:	Record the date the site became aware of the AE. For lab AEs, record the date the lab result was received.
Item-specific Instructions:	
Item 1:	Use medical terminology to describe the AE. Do not include text on the relationship to study product or timing of AE onset with regard to product use. For lab abnormalities, record the lab name with the direction (i.e., increased or decreased). For example, "increased ALT."
Item 2:	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE (onset of first symptom if diagnosis has multiple associated symptoms); date of the study visit/study exam (for physical or pelvic exam findings); specimen collection date (for lab abnormality AEs).
Item 3:	Record the severity grade using the current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums).
Item 4:	Mark "related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "not related" if there is not a reasonable possibility that the AE is related to the study agent. If "not related" is marked, record an alternative etiology or explanation in Comments.
Item 5:	• *no change:* Mark if there is no change in the participant's planned use of study product as a result of the AE. That is, the participant is still in the product use period and the AE does not result in a clinician initiated product hold or permanent discontinuation of study product. • *held:* Mark if the AE results in a clinician initiated product hold. If multiple AEs are reported at the same visit, mark "held" for each AE contributing to the hold. A Product Hold/Discontinuation (PH) Log should be completed for each AE page with "held" marked. If an AE results in a hold, then a permanent discontinuation, update this item to "permanently discontinued" at the time of permanent discontinuation. • *permanently discontinued:* Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark "permanently discontinued" for each AE contributing to the permanent discontinuation. For each AE page with this box marked, there should be a PH Log page with item 4 marked "no–permanently discontinued." • *N/A (not applicable):* Mark if the AE's onset date (item 2) is on or after the participant's Final Clinic Visit/early termination visit date. Also mark this box if the AE's onset date is on or after the date of permanent discontinuation.
Item 6:	• *continuing:* AE is continuing at the time it is first reported. • *resolved:* AE is no longer present or has returned to baseline severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated. • *death:* Mark only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation." • *severity/frequency increased:* If an AE increases in severity or frequency after it has been first reported on this form, line through the "continuing" box and mark "severity/frequency increased." Record the date of increase as the "Status/Outcome Date." Report the increase in severity/frequency as a new AE on a new AE Log page. For this new AE, the "Onset Date" (item 2) will be the same as the "Status/Outcome Date" (item 6a) of the AE Log page used to first report the AE. Note that decreases in severity (AE improvements) are not recorded as new AEs. • *continuing at end of study participation:* Mark this box whenever an AE is continuing at the time of participant termination.
Item 6a:	At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports no longer experiencing the AE or associated symptoms; or the date of the study visit or specimen collection at which it is first noted the AE has resolved or returned to baseline status.
Item 7:	Mark "medication(s)" only if participant reports taking the medication. If medication indicated but not yet used, mark "other" and describe the medication indicated; mark "medication(s)" once the medication has been used.
Items 8 and 9:	For questions about ICH guidelines and EAE reporting, refer to the current *Manual for Expedited Reporting of Adverse Events* to DAIDS. If item 9 is "yes," be sure to make any subsequent updates made to this form on the applicable EAE form.
Item 10:	Record the visit code that corresponds to the "Date Reported to Site." For lab AEs, record the visit code that matches the "Onset Date."

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

BMH-1 (051)

Participant ID ___ - ___ - ___
Site ID | Participant Number | Chk

Baseline Menstrual History

Visit Date ___ ___ ___
dd | MMM | yy

1. Age of first menses (menarche) ___ *years*

2. Usual menstrual cycle *regular* ☐ *irregular* ☐ *amenorrheic for past 6 months* ☐ → *Specify:* _____

3. Usual number of days between menses (1st day to 1st day) *minimum* ___ *# of days* TO *maximum* ___ *# of days*

4. Usual number of bleeding days (record range) *minimum* ___ *# of days* TO *maximum* ___ *# of days*

5. First day of last menstrual period dd ___ MMM ___ yy ___

6. Last day of last menstrual period dd ___ MMM ___ yy ___ OR *ongoing* ☐

7. Usual type of menstrual flow (at heaviest day of menses) *light* ☐ *moderate* ☐ *heavy* ☐

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

_____

_____

_____

_____

_____

_____

_____

_____

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

Baseline Menstrual History (BMH-1)	
Purpose:	This form is used to document information on the participant's menstrual history at the Screening Visit. This form is faxed to SCHARP only if the participant enrolls in the study.
Item-specific Instructions:	
Item 3:	Record the usual number of days that the participant experiences between menses starting on the first day of her menstrual period up to and including the day before the first day of her next menstrual period.
Item 4:	Record the range (minimum and maximum) of the usual number of bleeding days of the participant's menses. For example, if a participant reports that she has experienced menses that have lasted for a minimum of 3 days and a maximum of 6 days, record "03" for minimum of days and "06" for maximum number of days.
Item 5:	Record the first day of the participant's most recent menstrual period.
Item 7:	This item is based on how the participant describes her heaviest flow day during menses.
Item 8:	During follow-up, occurrences of genital bleeding will be compared to the participant's baseline bleeding pattern (as documented on this form) in order to determine if the episode requires reporting as an AE. With this in mind, use this space to describe as best possible the participant's usual genital bleeding pattern. Include details such as number of sanitary pads typically used, any spotting that is experienced, and any additional details on amount/heaviness of flow. Update with additional details as needed at the Enrollment Visit.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PH-1 (410)

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

Participant ID

Site ID – Participant Number – Chk

Clinical Product Hold/ Discontinuation Log

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

2. Why is study product being held? *Mark only one per page.*

- ☐ positive HIV test result
- ☐ adverse experience → *AE Log page #*
- ☐ allergic reaction to the study product → *AE Log page #*
- ☐ pregnancy
- ☐ breastfeeding
- ☐ use of PEP for HIV exposure
- ☐ use of PrEP for HIV prevention
- ☐ non-therapeutic injection drug use
- ☐ report of HIV-positive partner
- ☐ other, specify: _____

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

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

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

Comments

Clinical Product Hold/Discontinuation Log (PH-1)	
Purpose:	This log is used to document temporary clinical holds and clinical permanent discontinuations of study product use as instructed by study site staff. This log is completed each time a participant is instructed by study staff to temporarily stop (hold) or permanently discontinue study product use. If, at the same visit, a product hold/ discontinuation is initiated for more than one reason, complete one Clinical Product Hold/Discontinuation Log page for each reason. The same visit code should be used on each Log page.
General Information/Instructions:	
	Do not complete this log in cases where a participant has decided on her own to stop using study product.
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
Item-specific Instructions:	
Item 2:	Note that participant decline or refusal of study product is not documented as a product hold. Do not record this as a reason in "other, specify."
Item 3:	Record the last date the participant used study product. Use a best estimate if the actual date cannot be determined. *Note: Do not wait for information about product resumption or permanent discontinuation to fax the form—fax this form to SCHARP DataFax as soon as items 1 through 3 have been completed. Refax the page once item 4 has been completed.*
Item 4:	If "no – hold for another reason" is marked, record the date that the participant would have been instructed to resume study product use based on resolution of the reason indicated in item 2. If "no – permanently discontinued" is marked, record the date the permanent discontinuation was initiated.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

CM-1 (423)

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

Page

Participant ID

Site ID – Participant Number – Chk

Concomitant Medications Log

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

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

End of form. Fax to SCHARP DataFax.

1.

Medication Name	Staff Initials/Log Entry Date
Indication	Taken for a reported AE? ☐ yes ☐ no
Date Started: dd / MMM / yy — Date Stopped: dd / MMM / yy — OR ☐ Continuing at end of study	AE Log page(s):
Frequency (Mark only one.): *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* ☐ _____	
Dose/Units	Route (Mark only one.): *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify:* ☐ _____

2.

Medication Name	Staff Initials/Log Entry Date
Indication	Taken for a reported AE? ☐ yes ☐ no
Date Started: dd / MMM / yy — Date Stopped: dd / MMM / yy — OR ☐ Continuing at end of study	AE Log page(s):
Frequency (Mark only one.): *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* ☐ _____	
Dose/Units	Route (Mark only one.): *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *SC* ☐ *other, specify:* ☐ _____

Concomitant Medications Log (CM-1)

Purpose:	All medication(s) that are used by the participant during the study, other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.
General Information/Instructions:	
	When to fax this form: • once the participant has enrolled in the study; • when pages have been updated or additional Log pages have been completed (only fax updated or new pages); • when the participant has completed study participation; and/or • when instructed by SCHARP.
Item-specific Instructions:	
Page:	Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
No medications taken at Screening/ Enrollment:	Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01.
No medications taken throughout study:	Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study.
Medication Name:	Record the medication name. Refer to the protocol or study specific procedures manual (SSP) for guidance on whether trade name or generic name should be used.
Indication:	For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). For recreational drugs, record “recreation.”
Date Started:	If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.
Date Stopped:	At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year are required.
Frequency:	Below is a list of common frequency abbreviations: prn: as needed; qd: every day; tid: three times daily; qhs: at bedtime once: one time; bid: twice daily; qid: four times daily; other, specify: alternative dosing schedules
Dose/Units:	If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).
Route:	Below is a list of common route abbreviations: PO: oral; IV: intravenous; IHL: inhaled; REC: rectal; other, specify: alternative routes IM: intramuscular; TOP: topical; VAG: vaginal; SC: subcutaneous

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

DEM-1 (001)

Participant ID

Site ID – Participant Number – Chk

Demographics

Form Completion Date

dd MMM yy

1. What is your date of birth?	dd MMM yy OR *If unknown, record age:* ___ *years*
2. What was your sex at birth?	☐ *male* ☒ *female*
3. Do you consider yourself to be Latina or of Hispanic origin?	☐ *yes* ☐ *no*
4. What is your race? *Mark all that apply.*	☐ 4a. American Indian or Alaska Native ☐ 4b. Asian ☐ 4c. Black or African American ☐ 4d. Native Hawaiian or other Pacific Islander ☐ 4e. White ☐ 4f. Other, specify: _____

Demographics (DEM-1)	
Purpose:	This form is interviewer-administered and is used to collect participant's demographic information.
General Information/Instructions:	
	This form is faxed to SCHARP DataFax only if the participant enrolls in the study. This form is completed at the Screening Visit. Read each item aloud, except item 2, and record the participant's response.
Item-specific Instructions:	
Item 3:	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 4:	Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background. Per NIH policy, Latina is considered an ethnic group and not a race and should not be entered in item 4f.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

ECI-1 (023)

Participant ID

Site ID – Participant Number – Chk

Eligibility Criteria

Form Completion Date

dd MMM yy

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

1a. Obtain signature _____

Signature of Principal Investigator (or designee) *Date*

1b. Obtain signature _____

Signature of second staff member verifying eligibility *Date*

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

3. Why was the participant not enrolled?

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

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

- ☐ 4a. <15 or >17 years old
- ☐ 4b. not Tanner stage 4 or 5 at Screening
- ☐ 4c. HIV infected at Screening or Enrollment
- ☐ 4d. no reported history of penile-vaginal intercourse at Screening
- ☐ 4e. positive pregnancy test at Screening or Enrollment
- ☐ 4f. does not agree to use effective method of contraception during protocol-specified time period
- ☐ 4g. plans to become pregnant during the study participation period
- ☐ 4h. plans to relocate from study site during the study participation period or plans to travel away from site for more than 4 consecutive weeks
- ☐ 4i. diagnosed with urinary tract infection (UTI) and/or reproductive tract infection (RTI) at Screening or Enrollment, which has not resolved
- ☐ 4j. diagnosed with pelvic inflammatory disease (PID) or STI within 60 days of Enrollment
- ☐ 4k. has grade 2 or higher pelvic exam finding at Enrollment
- ☐ 4l. participant report of 3 or more penile-vaginal sexual partners in the month prior to Screening
- ☐ 4m. does not meet laboratory eligibility criteria
- ☐ 4n. does not meet other clinical eligibility criteria
- ☐ 4o. other reason, including investigator decision. Specify: _____

Eligibility Criteria (ECI-1)	
Purpose:	This form is used to document participant eligibility for enrollment in this study or reasons for participant ineligibility.
General Information/Instructions:	
	• Complete this form for each participant screened for this study. Complete and fax this form once it is determined whether the participant will enroll in the study. If not enrolled, this is the only form that is faxed for the participant. • If the participant has a second screening attempt, update this form with data from the second screening attempt and refax. Do not complete a new form for the second attempt.
Item-specific Instructions:	
Items 1a and 1b:	Local site Standard Operating Procedures (SOPs) must specify staff members designated to affirm eligibility.
Item 3:	Mark “participant did not complete all screening procedures” when a participant begins the screening process and is eligible, but does not return to the clinic to complete screening procedures within the 56-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 “other reason, including investigator decision,” and specify ineligibility reason on the line provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

ENR-1 (070)

Participant ID

Site ID – Participant Number – Chk

Enrollment

1. Date the participant marked or signed the assent/consent form for study participation:	dd MMM yy
2. Date the first parent or guardian marked or signed the assent/consent form for study participation:	dd MMM yy
3. Date the second parent or guardian marked or signed the assent/consent form for study participation:	dd MMM yy OR *N/A* ☐
4. Did the participant assent to long-term specimen storage and future testing?	*yes* ☐ *no* ☐
5. Plasma for archive:	Collection Date dd MMM yy ☐ *stored* ☐ *not stored* → *Reason:* _____
6. Randomization envelope number assigned:	☐☐☐
7. Randomization date and time:	dd MMM yy hr : min *24-hr clock*
8. Was the participant randomized to the in-depth interview?	*yes* ☐ *no* ☐
9. Was a Baseline ACASI questionnaire completed at this visit?	*yes* ☐ *no* ☐
10. Were there any problems or QC issues related to the administration or completion of the ACASI questionnaire?	*yes* ☐ *no* ☐ → *If no, end of form.*
10a. Describe: _____	

Enrollment (ENR-1)	
Purpose:	This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for the randomized participant.
General Information/Instructions:	
	Fax this form to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a randomization envelope).
Item-specific Instructions:	
Item 3:	If a second parent or guardian was not required to mark or sign the assent/consent form, leave the date blank and mark "N/A."
Item 4:	Assent for long-term specimen storage can be changed if the participant changes her decision after enrollment. Update as needed if the participant changes her decision during the study.
Item 5:	If the specimen is required to be stored, but for some reason it is not stored, mark "not stored" and record the reason on the line provided.
Item 6:	This item must match the randomization envelope number printed on the label of this participant's randomization envelope, and on the Randomization document contained inside the envelope. It must also match the randomization envelope number recorded for this participant on the Randomization Envelope Tracking Record.
Item 7:	These items must match the "date assigned" and "time assigned" recorded for this randomization envelope on the Randomization Envelope Tracking Record.
Item 8:	Record whether the participant has been randomized to complete the in-depth interview that takes place at the 12-Week Final Clinic Visit.
Items 9–10:	The Baseline ACASI questionnaire is required at the Enrollment Visit. If it was not done, mark item 10 "yes" and provide a brief explanation in item 10a.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

FCT-1 (153)

Visit Code ☐.☐ 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site ID | Participant Number | Chk

Follow-up ACASI Tracking

Visit Date

☐☐ dd ☐☐☐ MMM ☐☐ yy

1. Was a ACASI 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

☐☐☐☒ 19-FEB-14

N:\hivnet\forms\MTN_023\forms\m023_FCT.fm

01 English

Staff Initials/Date

Follow-up ACASI Tracking (FCT-1)	
Purpose:	This form is used to document participant completion of the Audio Computer-assisted Self Interview (ACASI) computerized questionnaires during follow-up.
Item-specific Instructions:	
Item 2a:	If there were any unusual details related to the ACASI questionnaire administration or completion, describe them on the line provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

FVS-1 (121)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Follow-up Visit Summary

Visit Date

dd MMM yy

1. Is this an interim visit? *yes* ☐ *no* ☐ → *If no, go to item 2.*

1a. Reason for interim visit *Mark all that apply.*

☐ *AE report or follow-up*

☐ *return of product or need new product*

☐ *other, specify:* _____

1b. Which forms, besides this form, were newly completed for this interim visit? *Mark all that apply.*

- ☐ Adverse Experience Log
- ☐ Clinical Product Hold/Discontinuation Log
- ☐ Pharmacokinetics
- ☐ Specimen Storage
- ☐ Laboratory Results
- ☐ Pelvic Exam
- ☐ STI Test Results
- ☐ HIV Confirmatory Results
- ☐ Ring Collection and Insertion
- ☐ Physical Exam
- ☐ Vaginal Practices
- ☐ Vaginal Ring Storage
- ☐ other, specify: _____

→ *Go to statement above item 4.*

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

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

Item 4 to be completed only at 12-Week Final Clinic Visit or early termination visit. For all other visits, end of form.

4. Was an in-depth interview completed? ☐ *yes* ☐ *no* ☐ *not required*

Comments:

Follow-up Visit Summary (FVS-1)

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

General Information/Instructions:

- This form is completed for each scheduled visit. This form is also completed for interim visits/contacts where a new form (other than the Follow-up Visit Summary) is completed. Note that there is no Interim Visit form for this study—instead, this form is completed to document interim visits.
- Record the Visit Code assigned to the visit. For required visits, the Visit Code will end in 0 (X.0). If the visit is an interim visit/contact, use an interim code for the Visit Code. Start with the Visit Code of the last required visit and add "1" to the right of the decimal point for each interim visit conducted. For example, if the participant's last required visit was the 4-Week Study Visit, the interim visit would be assigned Visit Code 4.1. If the participant has a second interim visit before the 8-Week Study Visit, this would be assigned a code of 4.2.
- If procedures for a required visit are split over 2 or more days, and all days are within the same visit window, assign all forms completed for the split visit the same Visit Code (ending in 0). For example, if a participant completes all 8-Week Study Visit procedures except pelvic exam procedures on 08-OCT-14, and completes the pelvic exam procedures on 09-OCT-14, assign a Visit Code of 5.0 to all forms.

Item-specific Instructions:

Item 1b:	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 acronym(s) in the space provided.
Item 2:	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 3:	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 4:	Record whether the participant completed the in-depth interview at the 12-Week Final Clinic Visit or early termination visit. Mark "not required" if the participant was not randomized to complete the in-depth interview.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

HCR-1 (330)

Visit Code . 1

Participant ID

Site ID – 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*

SAMPLE 2

2. HIV Confirmation Test — Not done/ Not collected — Specimen Collection Date: dd MMM yy — Visit Code .

2a. Western Blot — Not done | *negative* | *positive* | *indeterminate*

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

3. Final HIV Status — *HIV-uninfected* | *HIV-infected* | *pending*

Comments:

HIV Confirmatory Results (HCR-1)	
Purpose:	This form is used to document results from local lab confirmatory HIV testing once a participant has a positive or indeterminate EIA test result.
General Information/Instructions:	
	Complete this form for each visit where the participant has a positive or indeterminate EIA test result.
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-specific Instructions:	
Item 2:	Record the specimen collection date and visit code which corresponds to Sample 2.
Items 1a, 1b and 2a, 2b:	If the result is “negative,” “indeterminate,” or “invalid,” consult the Lab Center.
Item 3:	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.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

LR-1 (144)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Laboratory Results

Initial Specimen Collection Date

dd MMM yy

1. hCG for pregnancy	Not done/ Not collected ☐	*negative* ☐	*positive* ☐ →	*not required* ☐	*If newly positive, complete Clinical Product Hold/ Discontinuation Log and Pregnancy Report and History form.*
2. HIV	Not done/ Not collected ☐	*negative* ☐	*positive* ☐ →	*indeterminate* ☐ →	*If positive at Screening participant is ineligible. If positive during follow-up, complete HIV Confirmatory Results form and Clinical Product Hold/ Discontinuation Log. If indeterminate, consult Network Lab.*

	Not done/ Not collected	Alternate Collection Date (dd MMM yy)	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
3. HEMOGRAM	☐ → *Go to item 4.*				
3a. Hemoglobin	Not reported ☐	☐☐.☐ *g/dL*	☐	☐☐☐	OR ☐
3b. Hematocrit	☐	☐☐.☐ *%*			
3c. MCV	☐	☐☐☐.☐ *fL*	Severity Grade *If applicable* ☐	AE Log Page # ☐☐☐	Not reportable as an AE OR ☐
3d. Platelets	☐	☐☐☐☐.☐ *x10^3/mm^3*	☐	☐☐☐	OR ☐
3e. WBC	☐	☐☐☐.☐ *x10^3/mm^3*	☐	☐☐☐	OR ☐

	Not done/ Not collected	Alternate Collection Date (dd MMM yy)	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
4. SERUM CHEMISTRIES	☐ → *End of form.*				
4a. AST (SGOT)	Not reported ☐	☐☐☐☐ *U/L*	☐	☐☐☐	OR ☐
4b. ALT (SGPT)	☐	☐☐☐☐ *U/L*	☐	☐☐☐	OR ☐
4c. Creatinine	☐	☐☐.☐ *mg/dL* OR ☐☐☐.☐ *µmol/L*	☐	☐☐☐	OR ☐

Comments:

☐ ☐ ☐ ☒ 19-FEB-14

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Staff Initials/Date

Laboratory Results (LR-1)

Purpose:	This form is used to provide data on the participant's baseline and follow-up laboratory test results.
General Information/Instructions:	
	Use this form to report the hCG for pregnancy, HIV serology, hematology, and liver and renal function test results as they become available. Do not fax the form to SCHARP DataFax until all results are available and the participant has enrolled in the study.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form.
Not done/Not collected:	Mark this box in the event that a specimen was not collected or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available in Comments.
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 LR 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-023/IPM 030 Management Team. Note that the following units are equivalent: IU/L = U/L l/l x 100 = % 10^9/L = 10^3/mm^3 = 10^3/μL For creatinine, only record the result in the units listed on the source document. • If the site lab does not report results to the same level of precision allowed on the form, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the form. For example, a lab-reported hemoglobin value of 11.05 g/dL would be recorded as 11.1 g/dL. A lab-reported hemoglobin value of 11.04 g/dL would be recorded as 11.0 g/dL. - If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary.
Severity Grade:	• If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the result. If value is below Grade 1, leave the severity grade box blank. • Always compare the severity grade range to the value that was recorded on the form (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade. • Record any Grade 1 or higher lab values on the Pre-existing Conditions form or Adverse Experience Log, as applicable.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

MV-1 (463)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Missed Visit

Form Completion Date

dd MMM yy

1. Target Visit Date dd MMM yy

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

- ☐ 2a. unable to contact participant
- ☐ 2b. unable to schedule appointment(s) within allowable window
- ☐ 2c. participant refused visit
- ☐ 2d. participant incarcerated
- ☐ 2e. participant admitted to a health care facility
- ☐ 2f. participant withdrew from the study *Complete Termination form.*
- ☐ 2g. participant deceased *Complete Termination form. Complete Adverse Experience Log.*
- ☐ 2h. other, specify: _____

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

Comments

Missed Visit (MV-1)	
Purpose:	Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP).
General Information/Instructions:	
	If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a Missed Visit form. Fax this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the Visit Code of the visit that was missed. Record the date that the form was completed. This will not necessarily be the date of the missed visit. A complete date is required.
Item-specific Instructions:	
Item 1:	Record the target date of the visit. A complete date is required.
Item 2:	Record the reason the participant missed the visit.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PRC-1 (466)

Participant Receipt

Participant ID

Site ID – Participant Number – Chk

Form Completion Date

dd MMM yy

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 the participant marked or signed the assent/consent form for study participation:	dd MMM yy
4. Date the first parent or guardian marked or signed the assent/consent form for study participation:	dd MMM yy
5. Date the second parent or guardian marked or signed the assent/consent form for study participation:	dd MMM yy OR *N/A*
6. Did the participant assent to long-term specimen storage and future testing?	*yes* *no*
6a. Date informed consent for specimen storage signed	dd MMM yy

Comments

Participant Receipt (PRC-1)	
Purpose:	Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site.
General Information/Instructions:	
	• The Participant Receipt form is completed by the receiving site (the site at which the participant will be continuing his or her study visits). • For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP), 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.
Items 3, 4, and 6a:	A complete date is required.
Item 5:	If a second parent or guardian was not required to mark or sign the assent/consent form, leave the date blank and mark "N/A."

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PT-1 (465)

Participant ID

Site ID – Participant Number – Chk

Participant Transfer

Form Completion Date

dd MMM yy

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

☐☐☐☒ 19-FEB-14

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Staff Initials/Date

Participant Transfer (PT-1)

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

General Information/Instructions:

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

Item-specific Instructions:

Item 4: A complete date is required.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PE-1 (138)

Visit Code ☐.☐ 1

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

Pelvic Exam

Visit Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

1. Vaginal pH — *not done* ☐ ☐.☐ *If > 4.5, mark positive.* → *positive* ☐

2. Pelvic exam assessment: *not done* ☐ *abnormal findings* ☐ *no abnormal findings* ☐ → *If no abnormal findings, go to item 3.*
   → *If not done, 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)*	☐ adnexal masses *(based on bimanual exam; not pregnancy or infection-related)*
☐ vulvar tenderness	☐ vaginal abrasions or lacerations	☐ cervical motion tenderness	☐ uterine masses *(based on bimanual exam)*
☐ Bartholin's or Skene's gland abnormality	☐ vaginal tenderness	☐ cervical discharge	☐ uterine tenderness
Vulvar lesions	Abnormal vaginal discharge	Cervical lesions	☐ adnexal tenderness
☐ ulcer	☐ slight	☐ ulcer	☐ observed blood or bleeding; describe:
☐ blister	☐ moderate	☐ blister	_____
☐ pustule	☐ pooling	☐ pustule	_____
☐ peeling	Vaginal lesions	☐ peeling	_____
☐ ecchymosis	☐ ulcer	☐ ecchymosis	_____
	☐ blister		_____
	☐ pustule		
	☐ peeling		
	☐ ecchymosis		

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

Complete or update Pre-existing Conditions or AE Log as applicable.

3. Were any new pelvic finding AEs reported at this visit? *yes* ☐ *no* ☐ → *If no, go to item 4.*

3a. AE Log page (#)s: ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

4. Cervical ectopy: *0%* ☐ *1–25%* ☐ *26–50%* ☐ *51–75%* ☐ *76–100%* ☐ OR *not done* ☐

☐ ☐ ☐ ☒ 19-FEB-14

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Staff Initials/Date

Pelvic Exam (PE-1)	
Purpose:	This form is used to document the participant's pelvic exam assessment.
General Information/Instructions:	
	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, 4-Week and 8-Week Visit and the 12-Week 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. If an observed abnormal finding is not listed, mark "other abnormal findings, specify" and describe the abnormal finding on the line provided, including anatomical location. In general, for abnormal findings reported as adverse events on an AE Log, use text from item 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. Per Study-specific Procedures (SSP) manual section 7, all bleeding occurring during follow-up that is different from the participant's baseline bleeding pattern is an AE. This may include unusually heavy or prolonged menses, as well as non-menstrual bleeding different from baseline. • Each instance of observed blood/bleeding should be assessed for severity grade per the applicable rows of the *Division of AIDS Table for Grading the Severity of Adult and Pediatric Adverse Events Addendum 1: Female Genital Grading Table for Use in Microbicide Studies (FGGT)*. Refer to SSP manual section 8 for more information/guidance as needed.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

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

Participant ID

Site ID – Participant Number – Chk

Pelvic Exam Diagrams

Exam Date

dd MMM yy

☐ no normal variants or abnormal findings observed

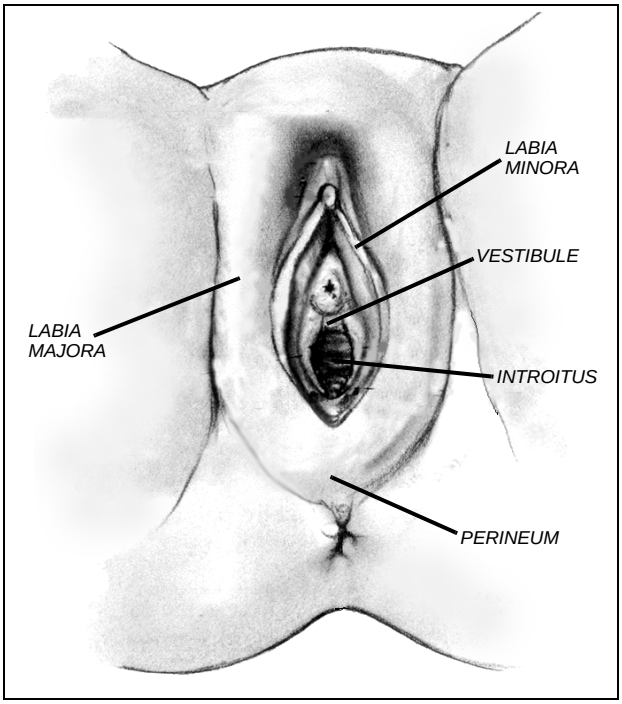
Speculum Type (screening only)

Pederson ☐ *plastic, single use* ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only)

small ☐ *medium* ☐ *large* ☐

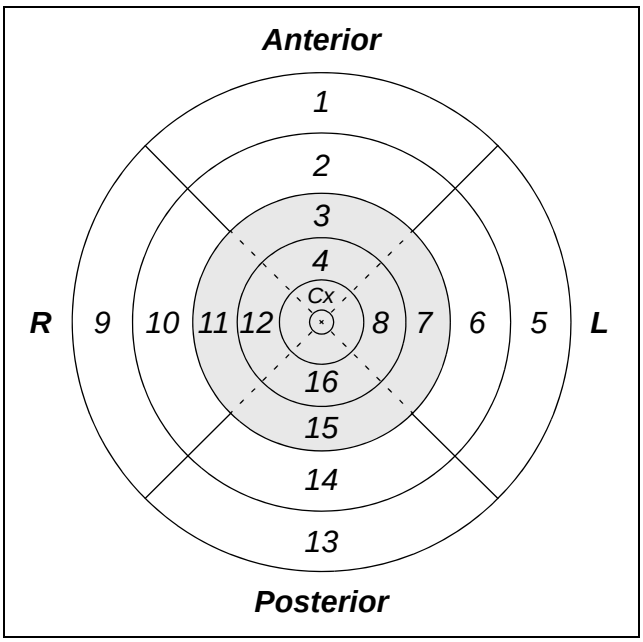
External Genitalia



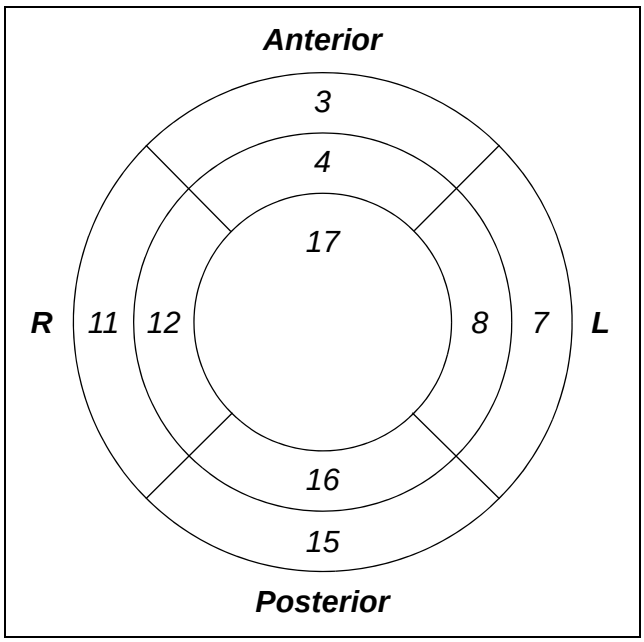
Legend for Vagina/Cervix

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

Vagina



Cervix



Pelvic Exam Diagrams (non-DataFax)

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

General Information/Instructions:

	This form is completed at the Screening Visit, the Enrollment Visit, the 4-Week and 8-Week Visits, the 12-Week Final Clinic Visit, and whenever a pelvic exam is clinically indicated during the study. This is a non-DataFax form and should not be faxed to SCHARP DataFax. Transcribe information onto the appropriate Pelvic Exam DataFax form for submission to DataFax and store this form in the participant's chart notes.

Item-specific Instructions:

Findings:	All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the Pelvic Exam DataFax forms. The following findings are considered normal variants: • anatomic variants • gland openings • Nabothian cysts • mucus retention cysts • Gartner's duct cysts • blood vessel changes other than disruption • skin tags • scars If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.
Documenting findings on the cervix:	If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PK-1 (161)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Pharmacokinetics

Specimen Collection Date

dd MMM yy

Not done/ Not collected

1. Plasma for PK

Alternate Collection Date

dd MMM yy

stored *not stored*

Reason not stored

Not done/ Not collected

2. Vaginal fluid

Alternate Collection Date

dd MMM yy

stored *not stored*

Reason not stored

Comments

Pharmacokinetics (PK-1)	
Purpose:	This form is used to document pharmacokinetics and stored specimen collection.
General Information/Instructions:	
Specimen Collection Date:	Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form). A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form.
Not done/Not collected:	Mark this box in the event that a specimen was not collected. If Not done/Not collected is marked and specimen is required, record item number and reason in Comments.
Stored/Not Stored:	Mark “stored” for specimens that are collected and sent to the lab for processing. If specimens are not stored, mark “not stored” and record the reason why on the line provided.
Item-specific Instructions:	
Item 1:	Record for all participants for the 2-Week, 4-Week, and 8-Week Visits and the 12-Week Final Clinic Visit/Early Termination Visit.
Item 2:	Record for all participants for the 4-Week and 8-Week Visits and the 12-Week Final Clinic Visit/Early Termination Visit.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PX-1 (036)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Physical Exam

Form Completion Date

dd MMM yy

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

FINDINGS *Items 10–16 may be omitted from assessment after the Enrollment Visit.*

	not done	*normal*	*abnormal*	*Notes*
7. General appearance	☐	☐	☐	
8. Abdomen/Gastrointestinal	☐	☐	☐	
9. Head, eye, ear, nose, and throat (HEENT)	☐	☐	☐	
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:

Physical Exam (PX-1)	
Purpose:	This form is used to document the participant's vital signs and physical exam findings.
General Information/Instructions:	
	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 the evaluation was required, but not done, mark "not done" and record the reason in the 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."

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PRE-1 (012)

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

Participant ID

Site ID – Participant Number – Chk

Pre-existing Conditions

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

Staff Initials/ Date: _____

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

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

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

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

Pre-existing Conditions (PRE-1)

Purpose:	The Pre-existing Conditions form serves as the "starting point" or baseline from which study clinicians must determine whether conditions identified during follow-up are adverse events (AEs).

General Information/Instructions:

- At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing. This includes, but is not limited to, history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions occurring prior to Enrollment.
- At the Enrollment Visit, review and update as needed.
- Do record pre-existing conditions if identified during follow-up. Add a chart note to explain why the PRE entry was added after Enrollment.

Item-specific Instructions:

Page:	Number pages sequentially throughout the study, starting with "01." Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
Condition:	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
Onset Date:	If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required.
Comments:	This field is optional. Use it to record any additional relevant information about the condition, including any associated signs/symptoms.
Severity Grade:	For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark "not gradable". Review and update as needed for conditions ongoing at the Enrollment Visit.
Ongoing at Enrollment?	Mark "yes" for chronic conditions, as well as any other conditions, ongoing at the Enrollment Visit. If a condition resolves or increases in severity or frequency after the Enrollment Visit, document this in chart notes and/or another document other than this form.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PO-1 (442)

Visit Code ☐.☐ Outcome Number ☐

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site ID | Participant Number | Chk

Pregnancy Outcome

☐ Outcome unobtainable → *Go to page 2.*

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

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

2. Outcome Date — dd ☐☐ MMM ☐☐☐ yy ☐☐

3. Place of delivery/outcome
   - ☐ home
   - ☐ 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: _____

Pregnancy Outcome (PO-1)	
Purpose:	This form is used to report pregnancy outcome information for a pregnancy reported post-enrollment. Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that pregnancy outcome is unobtainable.
General Information/Instructions:	
	A Pregnancy Outcome form is required for each Pregnancy Report and History form that is completed for a participant.
Visit Code:	Record the visit code of the participant's corresponding Pregnancy Report and History form.
Outcome Number:	A pregnancy outcome can be an infant or fetus. The conception of twins, for example, will result in reporting of two outcomes. For a pregnancy resulting in one outcome, record "1" here. For a pregnancy with multiple outcomes, record the outcome number corresponding to the outcome data recorded on the form.
Item-specific Instructions:	
Outcome unobtainable:	If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and fax both pages of this form to SCHARP DataFax.
Item 1:	If the pregnancy results in two or more outcomes, complete a Pregnancy Outcome form for each outcome. Each Pregnancy Outcome form will have the same visit code, but different outcome numbers (for example, one Pregnancy Outcome form will have an outcome number =1 and the second form will have an outcome number =2, and so on).
Item 4:	If the outcome is spontaneous fetal death, still birth, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an adverse experience (AE). If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under item 7, "Treatment." If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-specific Procedures (SSP) manual, and *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2* for guidance on AE and expedited AE reporting requirements.
Item 4a1:	"Operative vaginal" delivery includes delivery with forceps and/or vacuum.
Item 5:	Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PO-2 (443)

Visit Code ☐.☐ Outcome Number ☐

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site ID | Participant Number | Chk

☐ No data recorded on this page.

Pregnancy Outcome

7. Were any fetal/infant congenital anomalies identified? *yes* ☐ *no* ☐ *unknown* ☐ → *If no or unknown, go to the statement above item 8.*

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

- ☐ central nervous system, cranio-facial
- ☐ central nervous system, spinal
- ☐ cardiovascular
- ☐ renal
- ☐ gastrointestinal
- ☐ pulmonary
- ☐ musculoskeletal/extremities
- ☐ physical defect
- ☐ skin
- ☐ genitourinary
- ☐ chromosomal
- ☐ cranio-facial (structural)
- ☐ hematologic
- ☐ infectious
- ☐ endocrine/metabolic
- ☐ other

7b. Describe the congenital anomaly/defect: _____

_____

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

8. Infant gender — *male* ☐ *female* ☐

9. Infant birth weight — ☐☐.☐ *kg* OR *unavailable* ☐

10. Infant birth length — ☐☐.☐ *cm* OR *unavailable* ☐

11. Infant birth head circumference — ☐☐.☐ *cm* OR *unavailable* ☐

12. Infant birth abdominal circumference — ☐☐.☐ *cm* OR *unavailable* ☐

13. Infant gestational age by examination — *weeks* ☐☐ *days* ☐ OR *unavailable* ☐ → *If unavailable, end of form.*

13a. Method used to determine gestational age — *Ballard* ☐ *Dubowitz* ☐ *other, specify:* _____

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

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PR-1 (440)

Visit Code ☐.☐ 1

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site ID | Participant Number | Chk

Pregnancy Report and History

Pregnancy Report

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

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

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

	yes	*no*
3a. last menstrual period	☐	☐
3b. initial ultrasound < 20 weeks	☐	☐
3c. initial ultrasound ≥ 20 weeks	☐	☐
3d. physical examination	☐	☐
3e. conception date by assisted reproduction	☐	☐
3f. other, specify: _____	☐	☐

Pregnancy History

	yes	*no*	
4. Has the participant ever been pregnant before?	☐	☐ →	*If no, end of form.*
4a. Is this the participant's first pregnancy since enrollment in this study?	☐	☐ →	*If no, go to item 5.*
4b. Number of full term live births (≥ 37 weeks)	☐☐		
4c. Number of premature live births (< 37 weeks)	☐☐		
4d. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks)	☐☐		
4e. Number of spontaneous abortions (< 20 weeks)	☐☐		
4f. Number of therapeutic/elective abortions	☐☐		
4g. Number of ectopic pregnancies	☐☐		

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

5a. If yes, specify: _____

_____

_____

Pregnancy Report and History (PR-1)	
Purpose:	Complete this form when reporting a pregnancy of a study participant post enrollment through termination.
General Information/Instructions:	
	A Pregnancy Report and History form is required for each new pregnancy that the participant experiences during the study.
Visit Code:	Record the visit code at which study staff became aware that the participant is/was pregnant.
Item-specific Instructions:	
Item 1:	A complete date is required. Record best estimate if date not known.
Item 2:	A complete date is required.
Item 3d:	Physical examination includes fundal height, uterine size by pelvic exam, and/or fetal heart rate.
Item 5:	Include information on pregnancy complications and fetal/infant congenital anomalies experienced prior to enrolling in the study as well as any conditions experienced/reported during the study.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

PDL-1 (495)

Page ☐☐

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site ID | Participant Number | Chk

Protocol Deviation Log

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd | MMM | yy

1. Site awareness date:	dd ☐☐ MMM ☐☐☐ yy ☐☐
2. Deviation date:	dd ☐☐ MMM ☐☐☐ yy ☐☐
3. Has or will this deviation be reported to local IRB/EC?	*yes* ☐ *no* ☐
4. Has or will this deviation be reported to DAIDS as a critical event?	*yes* ☐ *no* ☐
5. Type of deviation:	☐☐ *deviation code (See back of form for code listing.)*

6. Description of deviation:

_____

_____

7. Plans and/or action taken to address the deviation:

_____

_____

8. Plans and/or action taken to prevent future occurrences of the deviation:

_____

_____

9. Deviation reported by: ☐☐☐☐ *staff code*

Protocol Deviation Log (PDL-1)

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

General Information/Instructions:

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

Item-specific Instructions:

Page:	Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.
Item 2:	Record the date the event occurred (start date).
Item 5:	Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6.
Item 6:	Briefly describe the specific details of the deviation.
Item 9:	Record staff code of the site staff person who completed the form. Sites will need to assign a four-digit staff code to each site staff person who will be completing this form. This list is created, maintained, and kept at the study site.

Code	Description
01	Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
02	Failure to follow trial randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
03	Study product management deviation: Site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
04	Study product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. Do not include any information related to study product assignment (product codes) on this form. Pharmacy staff must follow up with the MTN Pharmacist separately.
05	Study product 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.
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.

Code	Description
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 assent/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

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

RA-1 (133)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Ring Adherence

Visit Date

dd MMM yy

1. Did the participant have access to a vaginal ring during the past month?	*yes* ☐ *no* ☐	*If no, end of form.*
2. How many times in the past month has the participant had the vaginal ring out, in total?	☐☐ *times*	*If 00, end of form.*
3. How many of these times was the vaginal ring out for more than 12 hours continuously?	☐☐ *times*	*If 00, go to item 5.*
4. In the past month, what is the longest number of days in a row the vaginal ring was out?	☐☐ *days*	

5. In the past month, why was the vaginal ring out? *Record all codes that apply. See back of form for code listing.*

Reason Code

5a. ☐☐

5b. ☐☐

5c. ☐☐

5d. ☐☐

5e. ☐☐

5f. ☐☐

5g. ☐☐

If there is a reason that is not represented in the Reason Code list, mark item 5h or 5i, as applicable, and record the reason on the adjacent specify lines. Otherwise, leave items 5h and 5i blank.

☐ 5h. Other reason ring removed by participant or clinician, specify: _____

_____

☐ 5i. Other reason ring came out on its own, specify: _____

_____

Comments:

Ring Adherence (RA-1)

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

General Information/Instructions:

- Complete this form at each visit, as applicable. Complete even if the participant has been on product hold or has been permanently discontinued from ring use.
- All items on this form refer to ring access and use during the past month only, regardless of whether or not the participant missed her last monthly visit.

Item-specific Instructions:

Item 1: Mark "no" if the participant did not have a ring in her possession during the past month. Mark "yes" if the participant had access to a vaginal ring, regardless of how long ago the ring was dispensed, and regardless of whether or not the participant used the ring. For example, a participant is dispensed a ring at her 4-Week Study Visit. She misses her 8-Week Study Visit, but returns for her 12-Week Final Clinic Visit. At her 12-Week Final Clinic Visit, mark "yes" since the participant had in her possession for the past month the ring that was dispensed at her 4-Week Study Visit.

Item 2: The purpose of this question is to capture all instances in the past month when the ring was expelled, or was removed other than at regularly scheduled study visits. Do not count instances when the ring was removed at a regularly scheduled visit to insert a new ring.

Item 4: When determining the longest number of days in a row, include partial days as a day. For example, if a participant reports she removed the ring on a Wednesday and re-inserted it on a Friday, count this as 3 days (Wednesday, Thursday, Friday). This item should be an over-estimate rather than an exact or under-estimate.

Item 5: Refer to the list of Reason Codes below. Record the two-digit code that corresponds to each reason the vaginal ring was out during the past month (because the participant or clinician removed the ring, or ring expulsion occurred). Up to seven Reason Codes may be recorded (items 5a–5g). A Reason Code is required for item 5a. Record any additional reason codes in items 5b–5g; leave any unused items blank. For example, if three Reason Codes apply, record the codes in items 5a–5c and leave items 5d–5g blank.

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; includes ring removals at Day 35
31	Product permanently discontinued: Participant permanently discontinued from product
32	Procedure: Ring removed for clinical procedure (e.g., IUCD insertion, pelvic exam) that was *not* conducted at a regularly scheduled study visit
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

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

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

RCI-1 (135)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Ring Collection and Insertion

Visit Date

dd MMM yy

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* *2* *3* → *If 1, 2, or 3, 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
   - ☐ 12-Week Final Clinic Visit
   - ☐ other, specify: _____

   → *Go to item 6.*

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

   4a. Who inserted the new ring? *participant* *study staff*

5. Was a ring in place at the end of the visit? *yes* *no* → *If yes, go to item 6.*

   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: _____

6. Appearance of most recently-used ring: ☐ *used* ☐ *not used* ☐ *not sure* ☐ *no ring*

Ring Collection and Insertion (RCI-1)	
Purpose:	This form is used to document rings that are inserted and collected for each participant for the duration of the study.
General Information/Instructions:	
	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.
Item 6:	Document the clinic staff’s assessment of the appearance of the participant’s most recently-used ring. Base this assessment only on the appearance of the ring, do not factor in the participant’s reported use of the ring or other information when marking a response. If no ring was returned (item 2 of this form is “none”), mark “no ring” to indicate no ring was available for this assessment at this visit. Record the appearance of the ring most recently used by the participant.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

SS-1 (149)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Specimen Storage

Initial Specimen Collection Date

dd MMM yy

Not done/ Not collected

1. Vaginal smear for gram stain

Alternate Collection Date dd MMM yy

stored *not stored* *Reason not stored*

Not done/ Not collected

2. Quantitative vaginal culture

Alternate Collection Date dd MMM yy

stored *not stored* *Reason not stored*

Not done/ Not collected

3. Vaginal swab for biomarkers

Alternate Collection Date dd MMM yy

stored *not stored* *Reason not stored*

If not stored, go to item 4.

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

Not done/ Not collected

4. Cervicovaginal lavage for biomarkers

Alternate Collection Date dd MMM yy

stored *not stored* *Reason not stored*

If not stored, end of form.

4a. Cell pellet *stored* *not stored*

Comments:

Specimen Storage (SS-1)	
Purpose:	This form is used to document collection and storage of vaginal and cervical specimens by the local site laboratory.
General Information/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. A complete date is required.
Not done/Not collected:	Mark this box in the event that a specimen was not collected. If Not done/Not collected is marked and specimen is required, record item number and reason in Comments.
Stored/Not Stored:	Mark “stored” for specimens that are collected and sent to the lab for processing. If specimens are not stored, mark “not stored” and record the reason why on the line provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

STI-1 (190)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

STI Test Results

Initial Specimen Collection Date

dd MMM yy

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

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

Comments:

STI Test Results (STI-1)	
Purpose:	This form is used to document Vaginal Wet Prep and STI Test Results by the local site laboratory.
General Information/Instructions:	
	Complete this form at the Screening Visit and at other visits where these tests are performed during follow-up.
Initial Specimen Collection Date:	Record the date that the first specimen was collected (NOT the date the results were reported or recorded on the form) for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if the specimen was collected on a date after the Initial Specimen Collection Date. A specimen collected for the same visit but on a different date should be recorded on the same form.
Not done/Not collected:	Mark this box in the event that a specimen was not collected or if the specimen was collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available in Comments.
Visit Code:	Record the visit code assigned to this visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
Item-specific Instructions:	
Items 1–4:	If a test result(s) recorded on this form indicates that the participant has a new (or increased severity) laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on an Adverse Experience (AE) Log.
Item 1:	If a vaginal wet prep was performed but not all assays were completed, mark “Not done” 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 more than 20% 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.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

TM-1 (490)

Participant ID

Site ID – Participant Number – Chk

Termination

1. Termination date — dd / MMM / yy — *Date the site determined that the participant was no longer in the study.*

2. Reason for termination *Mark only one.*

- ☐ 2a. scheduled exit visit/end of study *End of form.*
- ☐ 2b. death *Indicate date and cause if known.*
  - 2b1. Date of death (dd / MMM / yy) OR ☐ date unknown
  - 2b2. Cause of death _____ OR ☐ cause unknown

  → *Complete or update Adverse Experience Log.*
- ☐ 2c. participant refused further participation, specify:
- ☐ 2d. participant unable to adhere to visit schedule
- ☐ 2e. participant relocated, no follow-up planned
- ☐ 2f. investigator decision, specify:
- ☐ 2g. unable to contact participant
- ☐ 2h. NOT APPLICABLE FOR THIS PROTOCOL.
- ☐ 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. participant's parent or guardian refused further participation of participant

3. Was termination associated with an adverse experience? *yes* ☐ *no* ☐ *don't know* ☐ → *If no or don't know, end of form.*

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

Comments:

☐ ☐ ☐ ☒ 19-FEB-14

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0 1 English

Staff Initials/Date

Termination (TM-1)	
Purpose:	This form should be completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.
Item-specific Instructions:	
Item 1:	A complete date is required.
Item 2:	Mark only the primary reason for termination.
Item 2a:	Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
Item 2b1:	If date is recorded, at a minimum, the month and year are required.
Item 2l:	Early study closure: Only mark 2l when instructed by SCHARP.
Item 3a:	Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the “specify” line.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

VP-1 (185)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Vaginal Practices

Visit Date

dd MMM yy

		yes	no	
1.	In the past month, have you had any vaginal bleeding or spotting?	☐	☐ →	*If no, go to statement above item 5.*
2.	Did you have the ring in place during vaginal bleeding or spotting?	☐	☐ →	*If no, go to item 4.*

3. How did you like wearing the vaginal ring during vaginal bleeding or spotting?

- ☐ you like wearing it during vaginal bleeding or spotting
- ☐ you don't like wearing it during vaginal bleeding or spotting
- ☐ you don't have any preferences about wearing it during vaginal bleeding or spotting

4. In the past month, what have you used to control or manage vaginal bleeding or spotting?

		yes	no
4a.	tissue, toilet paper placed in underwear/clothing	☐	☐
4b.	tampon	☐	☐
4c.	sanitary pad	☐	☐
4d.	water without soap, inside the vagina	☐	☐
4e.	water with soap, inside the vagina	☐	☐
4f.	anything else? Specify: _____	☐	☐

Please tell me about things you have put in your vagina in the past 1 month. These are things other than normal washing of the external vagina and other than to control or manage vaginal bleeding or spotting. Even though we ask participants not to put things in the vagina while they are in the study, we know that this is not possible for all women. For example, things may be inserted inside the vagina to prepare for sex, to clean inside the vagina before or after sex, or to treat or heal the vagina. Please feel free to answer openly. I'll read a list and ask you to tell me what you used.

5. In the past month, have you put any of the following inside your vagina?

		yes	no
5a.	water only	☐	☐
5b.	water plus soap	☐	☐
5c.	materials such as paper, cloth, or cotton wool	☐	☐
5d.	fingers, to clean or insert something	☐	☐
5e.	anything else? Specify: _____	☐	☐

		yes	no	
6.	Have you abstained from inserting anything into your vagina for 72 hours (3 days) prior to this visit, including having penile-vaginal intercourse?	☐	☐	
		→		*If yes, end of form.*
6a.	Have you had penile-vaginal intercourse within 72 hours (3 days) prior to this visit?	☐	☐	

Vaginal Practices (VP-1)	
Purpose:	This form is used to document a participant's vaginal practices during study follow-up.
General Information/Instructions:	
	This is an interviewer-administered form. Read each item aloud and record the participant's response.

SAMPLE: DO NOT FAX TO DATAFAX

MTN-023/IPM 030 (211)

VRS-1 (131)

Visit Code . 1

Participant ID

Site ID – Participant Number – Chk

Vaginal Ring Storage

Initial Specimen Collection Date

dd MMM yy

Not done/ Not collected		*stored*	*not stored*	*Reason not stored*
☐	1. Most recently used vaginal ring	☐	☐ →	_____
Not done/ Not collected		Alternate Collection Date dd MMM yy		Visit Code .
☐	2. Used vaginal ring	*stored* ☐	*not stored* ☐ →	*Reason not stored* _____
Not done/ Not collected		Alternate Collection Date dd MMM yy		Visit Code .
☐	3. Used vaginal ring	*stored* ☐	*not stored* ☐ →	*Reason not stored* _____

Comments:

☐ ☐ ☐ ☒ 19-FEB-14

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Staff Initials/Date

Vaginal Ring Storage (VRS-1)	
Purpose:	This form is used to document collection and storage of used vaginal rings by the local site laboratory.
General Information/Instructions:	
Initial Specimen Collection Date:	Record the date that the most recently used vaginal ring (i.e., last dispensed) was collected for this visit. A complete date is required.
Alternate Collection Date:	This date is to be completed ONLY if an additional used ring(s) was/were collected on a date after the Initial Specimen Collection Date. A complete date is required.
Not done/Not collected:	Mark this box in the event that a used ring(s) was/were not collected. If Not done/Not collected is marked and collection of the used ring is required, record item number and reason in Comments.
Stored/Not Stored:	Mark “stored” for used ring(s) that are collected and sent to the lab for processing. If used ring(s) are not stored, mark “not stored” and record the reason why on the line provided.
Item-specific Instructions:	
Items 2 and 3:	If more than one vaginal ring is collected at a visit, document the collection and storage of the additional ring(s). Record the Visit Code that corresponds to the visit when the ring(s) should have initially been collected. If the visit code is unknown, leave blank and record reason in Comments.