**Instructions:** Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why (if not self-explanatory); initial and date this entry. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section.

| **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
|  | Confirm identity and PTID |  |  |
|  | Check for co-enrollment in other studies per site SOPs:* NOT enrolled in another study ⇒ CONTINUE.
* Enrolled in another study ⇒ STOP. Consult the PSRT regarding on-going product use and safety considerations.
 |  |  |
|  | Review elements of informed consent/assent as needed. Explain procedures to be performed at today’s visit. |  |  |
|  | Review/update locator information using site-specific form. |  |  |
|  | Provide available test results from previous visit. Treat and/or refer for care as required. |  |  |
|  | Log into the MTN-034 Medidata Rave database and select the appropriate PTID. Open the applicable visit folder. Complete the **Follow-up Visit Yes/No** **CRF**. |  |  |
|  | Collect mid-stream urine (15-60 mL) catch and perform tests:* Urine hCG (pregnancy)
* Dipstick urinalysis and/or culture per site SOP (if indicated)
 |  |  |
|  | Review pregnancy test results:* NOT pregnant ==> CONTINUE. Complete **Pregnancy Test Results CRF.**
* Pregnant: pregnancy newly identified at today’s visit ==> HOLD. (Refer to MTN-034 Pregnancy Participant Procedure Guide for complete instructions)
	+ Complete **Pregnancy Test Results CRF**.
	+ Complete the **Pregnancy Report, Pregnancy History,** and **Pregnancy Outcome Log CRFs *(if applicable)****.*
	+ Complete **Study Product Request Slip** indicating HOLDand the **Product Hold Summary/Log CRF** documentation regardless of which, if any product is being used.
	+ Administer the Early PUEV/Discontinuers ACASI
	+ Administer the **Product Preference and Acceptability CRF**
	+ Collect blood for CBC with platelets, PK and serum creatinine
	+ Collect vaginal samples for biomarkers\*
	+ HIV testing and associated counseling \*
	+ If applicable, arrange to collect product not returned today within 24 hours.
	+ Complete **Pregnancy Case Worksheet** and submit
	+ If participant is selected for Serial IDIs, alert the Qualitative Management Team (mtn034qmt@mtnstopshiv.org).

\**Perform if procedures have not already been done as required for this visit. These samples will not be collected at visits following pregnancy confirmation.* |  |  |
|  | **At Visits 6, 9, 13, 16 and 20 ONLY**, administer the Follow-Up ACASI and document on the **ACASI Summary CRF** and **ACASI Tracking CRFs** per the participant’s visit number and the product she has been using prior to this visit:* Ring
* Tablet
* No Product *(option for Visit 20 ONLY)*

Run the “Need Counseling” report and refer participant to counselor if requested. |  |  |
|  | **At Visits 9 and 16 ONLY**, administer the **Product Preference and Acceptability CRF** |  |  |
|  | Review/ update **Social Impact/ Social Benefits Log CRF(s).****At Visits 6, 9, 13, 16 and 20 ONLY**,\* administer the **Social Benefits and Impacts CRF** and **Social Impact/ Social Benefits Log CRFs**, as applicable.*\*if indicated at all other visits.*  |  |  |
|  | Collect follow-up medical/contraceptive/medications history and document any Adverse Events; review/update: * **Adverse Event Summary/ Log CRF**
* **Concomitant Medications Log CRF**
* **Family Planning Log CRF**
 |  |  |
|  | ***If indicated*,** provide contraceptive counseling and prescribe contraceptives as necessary. Document in chart notes and/or on **Contraceptive Counseling Worksheet.***Note: Counsel in case the participant is found to have stopped using or is concerned with current method; refer to Family Planning Log.* |  |  |
|  | Administer and document HIV pre-testing and HIV/STI risk reduction counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet**.*Note: Site can modify risk reduction counseling if necessary* |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* HIV-1
	+ [X] mL [color] top [additive] tube
* Dried blood spot (DBS) for PK (UTC Lab)
* *N/A if participant did not use Truvada during the previous month.*
	+ 10 mL [color] top (no additive) tube

**Required at Visits 6, 9, 13, 16 and 20 ONLY:*** Plasma storage
	+ 10 mL [color] top (no additive) tube
* HSV-2 antibody\*
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology\*
	+ [X] mL [color] top [additive/no additive] tube

**Required at Visits 9 and 16 ONLY:*** Complete blood count (CBC) with platelets\*
	+ [X] mL [color] top [additive] tube
* Blood creatinine (and calculated creatinine clearance)\*
	+ [X] mL [color] top [additive/no additive] tube

Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet.**\* if indicated at non-required visits.*Note: Label all required tubes with a SCHARP-provided PTID label at the time of collection. For MTN LC bound specimens, store frozen at site while awaiting shipping request.* |  |  |
|  | Perform and document two different rapid HIV tests per site SOPs.  |  |  |
|  | Complete HIV test results and post-testing actions:* Provide testing results and referrals if needed/requested per site SOPs.
* If both tests negative = UNINFECTED ==> CONTINUE.
* If both tests positive = INFECTED ==> STOP ***or****,*
* If one test positive and one test negative = DISCORDANT ==> STOP. (Refer to MTN-034 HIV Confirmation and Seroconversion Procedure Guide for complete instructions.)
* Complete **Product Hold Summary/Log CRF** documentation, if any product is being used.
	+ Complete **Study Product Request Slip** indicating HOLDdocumentation, if any product is being used.
* Collect blood for HIV Confirmatory Testing (sample 2) and to perform Geenius confirmatory, RNA, and CD4 testing per SSP.
* Collect blood for CBC with platelets, PK and serum creatinine
* Collect vaginal samples for biomarkers\*
* Follow Protocol HIV Testing Algorithm for confirmation testing and follow-up actions based on test results.
* If participant is selected for Serial IDIs, alert the Qualitative Management Team (mtn034qmt@mtnstopshiv.org).
* Provide and document HIV post-test counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet\*\***
* Offer condoms
* Document test results onto **HIV Test Result CRF** and **HIV Confirmatory Results CRF**, if applicable.

\* *Perform if samples have not already been collected as required for this visit. These samples will not be collected at visits following HIV confirmation.**\*\*Modify HIV risk reduction counseling if necessary.* |  |  |
|  | Perform and document targeted physical exam. Complete **Vital Signs CRF** and **Physical Exam CRF**. |  |  |
|  | Collect study product from last month’s use as applicable:* N/A (if not using tablet or ring)

**If ring used last month:** * N/A (if not using ring)

Have participant (or clinician/designee) remove used ring, if applicable. Collect used ring, send to lab for storage, and document on **Participant-Specific Clinic Study Product Accountability Log,** and **Ring Insertion and Removal CRF***NOTE: Ring should be removed prior to performing a pelvic exam.***If tablet used last month:*** N/A (if not using tablet)

Collect study tablet bottle with any unused tablets and send back to pharmacy, if applicable. Document on **Participant-Specific Clinic Study Product Accountability Log** and **PrEP Provisions and Returns CRF.** |  |  |
|  | **At Visits 6, 9, 13, 16 and 20**,\* perform and document a pelvic exam per the Pelvic Exam Checklist, including sample collection. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.***\*if indicated at all other visits.* |  |  |
|  | If no pelvic exam is conducted, have participant collect vaginal fluid for **biomarker analyses** at MTN LC. * 1 swab from lateral vaginal wall.

Complete **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet** for all applicable collected specimens.*NOTE: Refer to self-collection instructions sheet* |  |  |
|  | If not vaccinated against HPV and/or HBV, offer. If accepted, provide or refer for HBV and/or HPV vaccine series. Document on in **chart notes** and confirm provision of each dose on the **Concomitant Medications Log CRF.***NOTE: The vaccine series may be initiated at any time during follow-up.* |  |  |
|  | When all lab results are available, enter data on the **Local Laboratory Results** and **STI Test Results CRFs,** if applicable. |  |  |
|  | Evaluate findings identified during pelvic and physical examinations and medical and menstrual history review. Document in chart notes and update **Concomitant Medications Log, AE Summary/Log** **CRFs**, if applicable. Document ongoing conditions on **AE Log**.  |  |  |
|  | Provide and explain all available findings and results to participant. Refer for other findings as indicated. ***If indicated****,* treat for STI/RTI/UTI per site SOP. |  |  |
|  | **FOR START OF PRODUCT USE PERIOD 2: At Visit 9,** confirm study product (Ring or Tablet) to be provided for study use period 2 (2nd 24 weeks) based on randomized group assignment (opposite product of period 1).* Ring
* Study Tablet

Complete the **Product Discontinuation Log CRF** for study product used in Period 1. |  |  |
|  | **FOR PRODUCT USE PERIOD 3 (product choice): At Visit 16, and 18-22,** confirm study product (Ring, Tablet, or none) to be provided for following four weeks (until next monthly visit) based on participant choice.* Ring
* Study Tablet
* NONE

**At Visit 16:** Administer the **Product Choice CRF** and complete the **Product Discontinuation Log CRF** for study product used in Period 2.**At Visits 18-22: *if the participant changes product use*,** administer the **Product Change CRF**and complete a **Product Discontinuation Log CRF*** N/A (no change)
 |  |  |
|  | Conduct product adherence counseling. Administer the **Adherence Counseling CRF** and document on the **Adherence Counseling Worksheet.****At Visits 5, 8, 12, 15, 19 and 22 ONLY**, provide drug level feedback with adherence counseling**.\****\* In the case of delayed drug level laboratory results, provide results with associated adherence counseling session when available.* |  |  |
|  | **At initial product use period 2 & 3 visits (V 9 & 16), and for a product switch during period 3 (V 18-22):** complete the **MTN-034** **Prescription** per the participant’s product use assignment/choice for the current study product use period being initiated * Deliver the top (white) copy along to the pharmacy.
* Retain yellow copy of prescription in participant’s binder.

*NOTE: prescription is completed even if the participant declines product use.* |  |  |
|  | **At product re-supply visits (V 4-8, 11-15, 18-22), as applicable:** complete the **Study Product Request Slip** per the participant’s product use assignment/choice for the following 4 weeks. * Deliver the top (white) copy to the pharmacy.
* Retain yellow copy of prescription in participant’s binder.

NOTE: The slip is completed even if the participant declines product use. |  |  |
|  | **For participants assigned to the ring**:* N/A (if not assigned to ring)
 |  |  |
| * Retrieve study ring and white return bag (for used ring) from pharmacy
 |  |  |
| * Provide ring use instructions and review important information. Give participant white return bag to take home.
 |  |  |
| * Have participant (or clinician/designee, if necessary) insert ring.
 |  |  |
| * Perform digital (bimanual) exam to check ring placement.
 |  |  |
| * Complete entry on the **Participant-Specific Clinic Study Product Accountability Log,** **Ring Insertion and Removal CRF,** and **Ring Assessment CRF,** if applicable.
 |  |  |
|  | **For participants using the study tablet:*** N/A (if not using tablet)
 |  |  |
| * Provide study tablet use instructions and review important information.
 |  |  |
| * Provide participant with one month’s supply of study tablets
 |  |  |
| * Instruct participant to self-administer one tablet by mouth and observe dose administration
 |  |  |
| * Complete entry on the **Participant-Specific Clinic Study Product Accountability Log, PrEP Provisions and Returns CRF** and **Tablet Assessment CRF,** if applicable.
 |  |  |
|  | Provide protocol adherence counseling by instructing participant of the following: * For 72 hrs (3 days) prior to study visits:
	+ Abstain from non-study vaginal products and/or practices including but are not limited to spermicides, diaphragms, vaginally applied medication, menstrual cups, cervical caps, douches, lubricants, sex toys, etc.
	+ Stay sexually abstinent i.e. no receptive intercourse (vaginal, anal, oral and finger stimulation).
* For entire study:
	+ Refrain from using non-study PrEP.
	+ If PEP is used, study product will be temporarily held. Note that participants should be offered PEP if they have a known or potential HIV exposure during the study, as soon as possible and within 72 hours of exposure.

Participants should be encouraged to inform study staff if they have not been able to follow the above guidelines.Document any questions or issues on this checklist or in chart notes. |  |  |
|  | Refer to **Qualitative Participation Log (QPL)** to see if participant is to participate in an upcoming IDI or FDG.* If **yes**, either:
	+ Schedule next interview or confirm interview if already scheduled.
	+ Conduct IDI if scheduled during this study visit. Refer to and complete the **IDI Visit Checklist or FDG Group/Individual Checklist,** as applicable.
* Not participating in an IDI or FDG
 |  |  |
|  | Complete the **Follow-up Visit Summary CRF.** |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation:* Follow-Up ACASI and recorded in **ACASI Summary and ACASI Tracking CRFs** *(V 6, 9, 13, 16, and 20)*
* **Adherence Counseling CRF**
* **Social Benefits and Impacts CRF** (V 6, 9, 13, 16 & 20)
* **Product Preference and Acceptability CRF** (V 9 and 16)
* **LDMS Specimen Tracking Sheet**, **Specimen Storage CRF**
* **Baseline Medical History Logs, AE Logs,** **Family Planning Logs, and Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Participant-Specific Clinic Study Product Accountability Log** and **Ring Insertion and Removal** or **PrEP Provisions and Returns CRF** are constantly completed.
* **Ring Assessment** or **Tablet Assessment are completed**, as applicable.
* **Chart notes**
* **Physical, Pelvic, Vital Signs, HIV Test, Pregnancy Test Results, STI Test Results CRFs**
 |  |  |
|  | Schedule next visit. * Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring/tablets, or condoms before next visit.
 |  |  |
|  | Provide reimbursement. |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:Required CRFs* Adherence Counseling
* Social Benefits and Impacts *(V 6, 9, 13, 16, 20)*
* Follow-up Visit Yes/No
* Follow-up Visit Summary
* ACASI Summary/Tracking (*for Follow-Up ACASI at V 6, 9, 13, 16, 20)*
* Product Preference and Acceptability *(V 9 and 16)*
* Specimen Storage
* HIV Test Result
* Vital Signs
* Physical Exam
* Pelvic Exam *(V 6, 9, 13, 16, and 20; and if indicated at other visits)*
* STI Test Results *(V 6, 9, 13, 16, 20; and if indicated at other visits*)
* Laboratory Results *(V 9 & 16*; *and if indicated at other visits*)
* Pregnancy Test Result
* Product Choice *(V 16 only)*
* Ring Insertion and Removal, or PrEP Provisions and Returns *(per participant’s study arm)*
* Product Discontinuation Log *(V 9 & 16; and if indicated at other visits)*

*As needed* * Pregnancy Report
* Pregnancy History
* Pregnancy Outcome
* HIV Confirmatory Results
* Social Impacts Log
* Social Benefits Log
* Family Planning Log
* Adverse Events Log
* Concomitant Medications Log
* Product Hold Log
* Product Change

Paper Forms:* Pelvic Exam Diagrams *(V 6, 9, 13, 16, and 20 and if indicated)*
* LDMS Specimen Tracking Sheet
* Participant-Specific Clinic Study Product Accountability Log
* HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet
* Adherence Counseling Worksheet

*If indicated/applicable* * Contraceptive Counseling Worksheet
* Qualitative Participation Log (QPL)
* Study Product Request Slip
* MTN-034 Prescription
* Pregnancy Case Worksheet
 |  |  |