**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)
 |  |  |
|  | ***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.* |  |  |
|  | 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 (for calculated creatinine clearance – take height measurement as well)\*
	+ 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 (for calculated creatinine clearance – take height measurement as well)\*
* 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 **Site-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 **Site-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 **Site-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 **Site-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 on PEP and non-study PrEP

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.
* **Site-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
* Site-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
 |  |  |