**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 Y/N** **CRF.** |  |  |
|  | Administer the PUEV/Discontinuers ACASI and document on the **ACASI Summary** and **ACASI Tracking CRFs** per the participant’s visit type and the product she has been using prior to this visit:

|  |  |
| --- | --- |
| * Scheduled PUEV
* Ring
* Tablet
* No Product
 | * Early Study Discontinuation
* Ring
* Tablet
* No Product *(Period 3 only)*
 |

 Run the “Need Counseling” report and refer participant to counselor if requested. |  |  |
|  | Administer the **Product Preference and Acceptability CRF** |  |  |
|  | Review/ updateany **Social Impact Log** and **Social Benefits Log CRF(s).**Administer the **Social Benefits and Impact CRF** and complete new **Social Impact/ Social Benefits Log CRFs**, as applicable. |  |  |
|  | Administer the **COVID-19 Behavioral Assessment** if applicable* Initial assessment
* Follow-up assessment: ≥3 months post initial assessment (no later than PUEV)
 |  |  |
|  | Collect follow-up medical/contraceptive/medications history and document any Adverse Events; review/update: * **Adverse Event Log CRF**
* **Concomitant Medications Log CRF**
* **Family Planning Log CRF**
 |  |  |
|  | **For early termination ONLY:** * Complete **Study Termination CRF** and **Product Discontinuation Log CRF.**
 |  |  |
| * If participant is selected for Serial IDIs, alert the Qualitative Management Team (mtn034qmt@mtnstopshiv.org).
 |  |  |
| * Complete **Study Exit Worksheet** and **Permission to Contact Log**. As indicated per protocol, arrange future contact for follow-up on ongoing AEs.
 |  |  |
|  | Collect mid-stream urine catch (15-60 mL) and perform tests:* Urine hCG (pregnancy)
* Dipstick urinalysis and/or culture per site SOP (if indicated)
 |  |  |
|  | 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 not liking 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 Pregnant Participant Procedure Guide for complete instructions)
	+ Complete **Pregnancy Test Results CRF.**
	+ Complete the **Pregnancy Report, Pregnancy History,** and **Pregnancy Outcome Log CRFs *(if applicable)****.*
	+ Administer the 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 procedures have not already been done as required for this visit.*  |  |  |
|  | Administer and document HIV pre-testing using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**. |  |  |
|  | 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
* *N/A if participant did not use Truvada during the previous month.*
	+ [x]mL [color] top (no additive) tube
* 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
* 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

 *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 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 Seroconverter Procedure Guide for complete instructions.)
* Collect blood for CBC with platelets, PK and serum creatinine
* Collect vaginal samples for biomarkers\*
* Follow Protocol HIV Testing Algorithm for follow-up actions based on confirmation test results.
* Provide and document HIV post-test and HIV/STI risk reduction counseling using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**\*\*
* Offer condoms.
* Document test results onto **HIV Test Results** **CRF** and **HIV Confirmatory Results**, if indicated.

*\* If samples have not already been collected.**\*\*Modify HIV risk reduction counseling if necessary.* |  |  |
|  | Perform and document FULL physical exam. Complete **Vital Signs CRF** and **Physical Exam CRF**. |  |  |
|  | Complete **Study Product Request Slip** by marking “Product Use Complete” and send to pharmacy.  |  |  |
|  | **For participants using the ring**:* N/A (if not using ring)

Have participant (or clinician/designee) remove used ring. Collect used ring, send to lab for storage, and document on **Participant-Specific Clinic Study Product Accountability Log, Specimen Storage CRF,** **Ring Insertion and Removal CRF,** and **Product Discontinuation Log CRF** |  |  |
|  | **For participants using the study tablet:*** N/A (if not using tablet)

Collect study tablet bottle with any unused tablets and send back to pharmacy. Document on **Participant-Specific Clinic Study Product Accountability Log**, **PrEP Provisions and Returns CRF,** and **Product Discontinuation Log CRF** |  |  |
|  | Perform and document a pelvic exam per the Pelvic Exam Checklist, including sample collection. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.** |  |  |
|  | 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 the **AE Log CRF**.  |  |  |
|  | 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 confirmed provision of each dose on the **Concomitant Medications Log CRF.***NOTE: For enrolled participants who decline vaccination at enrollment, the vaccine series may be initiated at any time during follow-up.* |  |  |
|  | 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. |  |  |
|  | Complete the **Follow-up Visit Summary CRF.** |  |  |
|  | Perform QC1: while participant is still present, review the following for completion:* **Follow-Up Y/N and Follow-up Visit Summary**
* **Social Impact/Benefits related CRFs,** **Product Preference and Acceptability CRF** and **ACASI CRFs**
* **AE Logs CRFs,** **Family Planning Log, and Concomitant Medications Log** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Participant-Specific Clinic Study Product Accountability Log** and **Ring Collection and Insertion** or **PrEP Provisions and Returns CRF**
* **Chart notes**
* **Physical, Pelvic, Vital Signs, HIV Test, Pregnancy Test Results, STI Test Results, Specimen Storage CRFs**
 |  |  |
|  | **PUEV Only:** Schedule final contact/visit (V24).\* Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit.*\*May be conducted by phone.* |  |  |
|  | Refer to **Qualitative Participation Log (QPL)** to see if participant is to participate in a late FDG\** If **yes**, confirm availability or date of FDG if already scheduled (must occur prior to Visit 24)
* Late FDG already completed (permitted as early as Visit 20)
* Not participating in an FDG

*\*subset of participants only* |  |  |
|  | Provide reimbursement |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:Required CRFs* ACASI Summary/ Tracking
* Follow-up Y/N
* Follow-up Visit Summary
* HIV Test Results
* Local Laboratory Results
* Physical Exam
* Pelvic Exam
* Social Benefits and Impacts
* Product Preference and Acceptability
* Specimen Storage
* Vital Signs
* STI Test Results
* Pregnancy Test Result
* Product Discontinuation Log
* Ring Insertion and Removal, or PrEP Provisions and Returns Log *(per participant’s study arm)*

*As needed* * Social Impacts Log
* Social Benefits Log
* Adverse Events Log
* Concomitant Medications Log
* Study Termination
* Family Planning Log

Paper Forms:* Pelvic Exam Diagrams
* LDMS Specimen Tracking Sheet
* Participant-Specific Clinic Study Product Accountability Log
* HIV Pre-/Post-Test and Risk Counseling Worksheet
* Study Product Request Slip

*If indicated/applicable* * Contraceptive Counseling Worksheet
* Qualitative Participation Log (QPL)
* Pregnancy Case Worksheet
* Study Exit Worksheet
* Permission to Contact Log
 |  |  |