**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](mailto: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](mailto: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 |  |  |