**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 * NOT enrolled in another study 🡪 CONTINUE.
* Enrolled in another study 🡪 STOP. Consult the PSRT regarding on-going product use and safety considerations.
 |  |  |
|  | 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 Medidata Rave database, and select the appropriate PTID. Begin visit by opening the applicable Visit folder. |  |  |
|  | Administer **Ring Adherence Y/N and Ring Adherence CRFs** |  |  |
|  | Administer the CASI assessment for the applicable visit day and document on the **Behavioral Summary CRF** and **CASI Tracking CRF**.* Day 28 Behavioral Assessment *or*
* Day 56 Behavioral Assessment
 |  |  |
|  | ***If indicated,*** administer and document HIV pre-test, post-test and HIV/STI risk reduction counseling, including offering male condoms, using the **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**. |  |  |
|  | Collect urine (15-60 mL) and perform tests:* Qualitative hCG (pregnancy)
* Dipstick urinalysis and/or culture per site SOP, ***if indicated***
 |  |  |
|  | Confirm pregnancy results:* NOT pregnant 🡪 CONTINUE.
* Pregnant 🡪 STOP. Review protocol, SSP Manual and site-specific SOPs for next actions.

Complete [add site-specific laboratory testing source document] and **Pregnancy Test Results CRF** upon receipt of lab test results. |  |  |
|  | Review participant’s medical/menstrual/medications history and any Adverse Events, to verify and/or update all information recorded at previous visit. Document all updates as needed on:* **Relevant source documents**
* **Baseline Medical History Log CRF**
* **Concomitant Medications Log CRF**
* **AE Summary/ Log CRFs**
 |  |  |
|  | ***If indicated,*** perform a targeted physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF.** |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* DPV levels (For MTN LC)
* 10 mL lavender top EDTA tube

***If indicated****:** AST/ALT
* [X] mL [color] top [additive/no additive] tube
* CBC with platelets and differentials
* [X] mL [color] top [additive/no additive] tube
* HIV-1
* [X] mL [color] top [additive/no additive] tube
* Syphilis serology
* [X] mL [color] top [additive/no additive] tube

Document collection on the **Specimen Storage CRF, LDMS Tracking Sheet** and[add site-specific laboratory testing source document]. When results are ready document on the **Hematology, STI Test Results,** and **Local Lab Results CRFs**, as applicable.*\* Collect blood, rectal fluid, and CVF samples for DPV level testing (see Pelvic Exam Checklist) in as close time proximity as possible to one another (within 30 minutes).* |  |  |
|  | Perform and document a pelvic exam per the Pelvic Exam Checklist, including pelvic and rectal specimen collection, as applicable. Document on **Pelvic Exams Diagram** and **Pelvic Exam CRF.** |  |  |
|  | **For participants randomized to the 25mg Ring:*** N/A (if not using the 25mg ring)

Complete the **Study Product Request Slip** for re-supply for the next 4 weeks. * Deliver the top (white) copy along with the [site-specific form] to the pharmacy.
* Retain yellow copy of prescription in participant’s binder.
 |  |  |
| Have participant (or clinician/designee) remove used VR if applicable. Collect used VR, send to lab for storage, and document on **Site-Specific** **Clinic Study Product Accountability Log** and **Ring Insertion and Removal CRF.** |  |  |
| Retrieve study VR and white return bag (for used VR) from pharmacy |  |  |
| Provide VR use instructions and review important information. Give participant white return bag to take home. |  |  |
| Have participant (or clinician/designee, if necessary) insert VR. ***If indicated****,* perform digital (bimanual) exam to check VR placement. |  |  |
| Document the provision of the new VR to the participant using the **Site-Specific** **Clinic Study Product Accountability Log** and **Ring Insertion and Removal CRF.**  |  |  |
|  | Evaluate findings identified during pelvic and physical examinations (if done) and medical history review. Document in chart notes and update **Concomitant Medications Summary/Log, Baseline Medical History Log,** **AE Summary/Log** **CRFs**, as applicable.  |  |  |
|  | Provide and explain all available findings and results. Treat and/or refer for care as required (includes treatment for RTI, UTI, or STI(s), ***if indicated***). |  |  |
|  | Conduct protocol counseling with participant and document on **Protocol Counseling Worksheet**. Provide Study Adherence Guide hand-out, as needed. |  |  |
|  | Complete the **Follow-up Visit Summary** **CRF.** |  |  |
|  | Perform QC1 review while participant is still present, review the following:* Visit checklist and Pelvic Exam checklist to ensure all required procedures were completed
* Day 28/56 Behavioral Assessments are complete and documented on **Behavioral Summary/CASI Tracking CRFs**
* **LDMS Specimen Tracking Sheet** and **Cervical/Specimen Storage CRFs** for completeness, accuracy and consistencybetween forms.
* **Baseline Medical History Log, AE Log,** and **Concomitant Medications Log CRFs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Chart notes** to ensure complete and accurate
 |  |  |
|  | Schedule next visit * For PUEV, notify participant of expected visit length (PUEV will be longer for PK collection requirements)
* Off male condoms (if not done already)
* Provide any other study informational materials, site contact information, and instructions to contact the site for additional information and/or counseling if needed before the next visit: *[add site-specific list if desired]*.
 |  |  |
|  | Provide Reimbursement |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Ring Adherence Y/N and Ring Adherence
* Behavioral Summary
* CASI Tracking
* Pelvic Exam
* Cervical Specimen Collection
* Specimen Storage
* Pregnancy Test Results
* Ring Insertion and Removal *(For participants assigned to mg25 VR)*
* Follow-up Visit Y/N and Summary

*If indicated/applicable CRFs** Hematology
* Local Laboratory Results
* Adverse Events Summary/ Log
* Baseline Medical History Summary/ Log
* Concomitant Medications Summary/ Log
* STI Test Results
* HIV Test Results
* Vital Signs
* Physical Exam

Paper Forms:* Protocol Counseling Worksheet
* Pelvic Exam Diagrams
* LDMS Specimen Tracking Sheet
* HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet, *if applicable*
* Study Product Request Slip (yellow copy), (*For participants assigned to 25mg VR)*
* Site-Specific Clinic Study Product Accountability Log (F*or participants assigned to 25mg VR)*
 |  |  |