**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 |  |  |
|  | 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 Exit CASI assessment and document on the **Behavioral Summary CRF** and **CASI Tracking CRF**. |  |  |
|  | ***If participant was invited and agreed to an IDI at enrollment:\**** Administer IDI or schedule for another time between this visit or at the final contact visit. First confirm her verbal willingness to participate, including being audio recorded. Document on **Behavioral Summary** **CRF.*** AGREES TO IDI
* DECLINES TO PARTICIPATE
* N/A (not invited)

\*Only for subset of participants randomly selected at Enrollment. *NOTE: May be scheduled at a different date due to visit length and/or to accommodate participant availability.* |  |  |
|  | Administer and document HIV pre-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. NOT ELIGIBLE.

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

Document collection on [add site-specific laboratory testing source document], **Specimen Storage CRF** and **LDMS Tracking Sheet.** 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 proximity as possible (within 30 minutes) and immediately prior to VR removal.* |  |  |
|  | Perform and document a pelvic exam per the Pelvic Exam Checklist, including pelvic and rectal specimen collection. Document on **Pelvic Exams Diagram** and **Pelvic Exam CRF.** |  |  |
|  | Remove VR and document on the **Site-Specific Clinic Study Product Accountability Log, Product Discontinuation CRF, VR Request Slip** and **Ring Insertion and Removal CRF.** |  |  |
|  | Collect blood for DPV level testing at following time-points after VR removal (For MTN LC): **□** 1 hr **□** 2 hrs **□** 4 hrs* Each blood draw:10 mL lavender top EDTA tube

Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Tracking Sheet.***Note: For each time-point, collect blood and CVF samples (below procedure) in as close time proximity as possible to one another (within 30 minutes).* |  |  |
|  | Collect cervical fluid (CVF) for DPV level testing at following time-points after VR removal (For MTN LC): **□** 1 hr **□** 2 hrs **□** 4 hrs\* * 1 swab near the site of the VR

Document stored specimen collection on the **Cervical Specimen Storage CRF** and **LDMS Tracking Sheet.***Note: For each time-point, collect blood and CVF samples (above procedures) in as close time proximity as possible to one another (within 30 minutes).* |  |  |
|  | **At 4 hours after VR removal,** collect cervicovaginal lavage (CVL) for PK, PD and biomarker analysesat MTN LC. * Insert Speculum
* Sample from cervix/ upper-end of vagina using syringe technique.
* Remove speculum

Document storage on the **Cervical Specimen Storage CRF** and **LDMS Specimen Tracking Sheet**.*Note: must be taken after 4-hr CVF sample.* |  |  |
|  | Provide HIV test results in the context of post-test counseling and document on **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet.** Provide referrals if needed/requested per site SOPs. * If negative ==> UNINFECTED ==> CONTINUE.
* If positive or indeterminate ==> STOP. Perform HIV confirmation test actions per HIV testing algorithm to determine eligibility

Document HIV test results on **HIV Test Results 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 Y/N and Summary** **CRFs.** |  |  |
|  | **FOR EARLY TERMINATION ONLY:** Complete the **Study Discontinuation CRF** and complete permission to contact or [site specific log]. As indicated per protocol, arrange future contact for follow-up on ongoing AEs.  |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and clear documentation:* Visit checklist to ensure all required procedures were completed
* Exit Behavioral Assessment and IDI are complete and documented on CASI CRF
* **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 CRF** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Chart notes** to ensure complete and accurate
 |  |  |
|  | Schedule the Final Contact visit between 24-72 hours after the PUEV visit, using the participant’s **Visit Calendar** **Tool**.* 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
* Local Laboratory Results
* Behavioral Summary
* CASI Tracking
* Pelvic Exam
* HIV Test Results
* Hematology
* Cervical Specimen Storage
* Specimen Storage
* Pregnancy Test Results
* Follow-up Visit Y/N and Summary
* Ring Insertion and Removal
* Product Discontinuation

*If indicated/applicable CRFs** Adverse Events Summary/ Log
* Baseline Medical History Summary/ Log
* Concomitant Medications Summary/ Log
* STI Test Results
* Vital Signs
* Physical Exam
* Study Discontinuation (for early termination)

Paper Forms:* Protocol Counseling Worksheet
* HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet
* Pelvic Exam Diagrams
* LDMS Specimen Tracking Sheet
* Site-Specific Clinic Study Product Accountability Log
* Visit Calendar Tool
 |  |  |