**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. Complete the **Follow-up Visit YN CRF.** |  |  |
|  | Administer **Ring Adherence YN CRF** and **Ring Adherence CRF** |  |  |
|  | Administer the Exit CASI assessment and document on the **Behavioral Assessment 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. Does not need to precede counseling.* |  |  |
|  | 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.**\*if indicated and/or per local standard of care |  |  |
|  | 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**
* **Concomitant Medications CRF**
* **AE CRF**
 |  |  |
|  | ***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:* TFV levels (For MTN LC)\*
* 10 mL lavender top EDTA tube
* HIV-1/2
	+ [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
* Serum creatinine
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology, ***if indicated***
	+ [X] mL [color] top [additive/no additive] tube

*\* Collect blood, rectal fluid, and CVF samples for TFV level testing (see Pelvic Exam Checklist) in as close proximity as possible (within 30 minutes) and immediately prior to VR removal.* |  |  |
|  | Collect rectal fluid for **TFV levels testing** (for MTN LC) * Prepare and insert anoscope.
* 1 swab held against rectal mucosa for 2 minutes
* Remove anoscope.

Record pre- and post-collection weights. Document on **Timed Specimen Storage CRF.***Note: Collect blood, rectal fluid, CVF samples for TFV level testing in as close time proximity as possible (within 30 minutes).* |  |  |
|  | Perform and document a pelvic exam per the Pelvic Exam Checklist, including pelvic specimen collection required prior to VR removal. * Vaginal swabs for microbiota
* Vaginal gram stain
* CVF for TFV levels
* CVF for biomarkers
* Cervical biopsies for PK andPD*– only if assigned to sample collection at this visit (randomized to Visit 6 & 9 biopsy schedule)*

Document on **Pelvic Exams Diagram,** **Pelvic Exam CRF,** and **Timed Cervical Specimen Storage CRF.** |  |  |
|  | Remove VR and document on the **Site-Specific Clinic Study Product Accountability Log, Discontinuation of Study Product CRF, VR Request Slip** and **Ring Insertion and Removal CRF.** |  |  |
|  | 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.**  |  |  |
|  | **At 4 hours (+/- 15min) after VR removal,** collect following blood, rectal fluid, and CVF for TVF levels. Document on the **Timed** **Cervical Specimen Storage CRF** and **Timed Specimen Storage CRF;** record pre- and post-collection weights.*Note: Collect blood, rectal fluid, CVF samples for TFV level testing in as close time proximity as possible (within 30 minutes).* |  |  |
| * Plasma - [10] mL [lavender] top [EDTA] tube
 |  |  |
| * Rectal fluid- 1 swab held against rectal mucosa for 2 minutes, using anoscope.
 |  |  |
| * CVF - 1 swab near the site of the VR
 |  |  |
|  | Evaluate findings identified during pelvic and physical examinations (if done) and medical history review. Document in chart notes and update **Concomitant Medications** and **AE 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** **CRFs.** |  |  |
|  | **FOR EARLY TERMINATION ONLY:** Complete the **Study Termination 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, Pelvic Exam Checklist, and **Follow-Up Visit CRFs**
* **Behavioral Assessments Summary/CASI Tracking** **CRFs** for Exit CASI, and IDI, if applicable.
* **LDMS Specimen Tracking Sheet** and **Timed Cervical/Specimen Storage CRFs** for consistencybetween forms.
* **AE** and **Concomitant Medications CRFs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Chart notes**
 |  |  |
|  | 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].
* Offer male condoms
 |  |  |
|  | Provide Reimbursement |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Ring Adherence YN
* Ring Adherence
* Chemistry Panel
* Behavioral Assessments Summary
* CASI Tracking
* Pelvic Exam
* HIV Test Results
* Hematology
* Timed Cervical Specimen Storage
* Timed Specimen Storage
* Pregnancy Test Results
* Follow-up Visit YN
* Follow-up Visit Summary
* Ring Insertion and Removal
* Discontinuation of Study Product (stored in Discontinuation folder)

*If indicated/applicable CRFs** Adverse Events (YN/ Log)
* Concomitant Medications (YN/ Log)
* STI Test Results
* Vital Signs
* Physical Exam
* Study Termination (for early termination)
* Confirmatory HIV Test Results

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
 |  |  |