**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. Complete **Follow-up Visit YN CRF.** |  |  |
|  | **At Visits 6 & 8 ONLY,** administer **Ring Adherence YN CRF** and **Ring Adherence CRF.** |  |  |
|  | **At Visits 6 & 8 ONLY,** Administer the CASI assessment for the applicable visit day and document on the **Behavioral Assessments Summary CRF** and **CASI Tracking CRF**.* Visit 6/Day 28 Follow-up CASI *or*
* Visit 8/Day 56 Follow-up CASI
 |  |  |
|  | ***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**.\*if indicated and/or per local standard of care  |  |  |
|  | Collect urine (15-60 mL) and perform tests:* Qualitative hCG (pregnancy), ***required at Visits 6 & 8, if indicated at Visit 7.***
* Dipstick urinalysis and/or culture per site SOP, ***if indicated***
 |  |  |
|  | ***Required at Visits 6 & 8, if indicated at Visit 7,*** 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 CRFs**
* **AE CRF**
 |  |  |
|  | ***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:* TFV levels (For MTN LC), **at** **Visits 6 & 8 only**
* 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
* Serum creatinine
* [X] mL [color] top [additive/no additive] tube
* HIV-1/2
* [X] mL [color] top [additive/no additive] tube
* Syphilis serology
* [X] mL [color] top [additive/no additive] tube

*\* Collect blood, rectal fluid, and CVF samples for TFV level testing in as close time proximity as possible to one another (within 30 minutes).* |  |  |
|  | ***At Visits 6 & 8,*** 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 **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 for:* CVF for biomarkers

**At Visits 6 & 8 only:** * Vaginal swabs for microbiota
* Vaginal gram stain
* CVF anti-HSV-2 activity
* CVF for TFV levels
* CVL for PK, PD, and biomarkers
* Cervical biopsies for PK/ PD*– per sample collection schedule assignment*

Document on **Pelvic Exams Diagram,** **Pelvic Exam CRF,** and **Cervical Specimen Storage CRFs.** |  |  |
|  | 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** **CRF.** |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and accuracy:* Visit checklist, Pelvic Exam checklist, and **Follow Visit CRFs**
* **Behavioral Assessments Summary/CASI Tracking CRFs** for Day 28/56 Follow-up CASI
* **LDMS Specimen Tracking Sheet** and **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 next visit * For Visit 9/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* Pelvic Exam
* Cervical Specimen Storage
* Pregnancy Test Results
* Follow-up Visit YN
* Follow-up Visit Summary

*Only required at Visits 6 & 8* * Ring Adherence YN
* Ring Adherence
* Behavioral Assessments Summary
* CASI Tracking
* Pregnancy Test Results *(if indicated, otherwise)*
* Specimen Storage *(if indicated, otherwise)*

*If indicated/applicable CRFs** Hematology
* Chemistry Panel
* Adverse Events (YN/ Log)
* Concomitant Medications (YN/ Log)
* STI Test Results
* HIV Test Results
* Vital Signs
* Physical Exam
* Ring Insertion and Removal

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*
 |  |  |