**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 the **Follow-up Visit YN CRF.** |  |  |
|  | ***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 |  |  |
|  | ***If indicated,*** collect urine and perform tests for pregnancy test and/or dipstick urinalysis/culture per site SOP.  Document results on the [add site-specific laboratory testing source document] and **Pregnancy Test Results CRF,** as applicable. If pregnant: review protocol, SSP Manual, and site-specific SOPs for next actions. |  |  |
|  | 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 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:   * TFV levels (For MTN LC) * 10 mL lavender top EDTA tube   ***If indicated****:*   * 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 (Visits 3 & 5 ONLY), and CVF samples for TFV level testing (see Pelvic Exam Checklist) in as close time proximity as possible to one another (within 30 minutes).* |  |  |
|  | ***At Visits 3 & 5,*** 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 collection required for:   * CVF for TFV levels * CVF for biomarkers * Cervical biopsies for PK *- at Visit 5 only and if assigned to sample collection at this visit (randomized to Visit 5 & 8 biopsy schedule)*   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 and pelvic exam checklist * **LDMS Specimen Tracking Sheet** and **Cervical/Specimen Storage CRFs** for consistencybetween forms. * **AE** and **Concomitant Medications CRFs** to ensure all AEs and medications are captured consistently * **Chart notes** |  |  |
|  | Schedule next visit   * Offer 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]*   \*if indicated and/or per local standard of care |  |  |
|  | Provide Reimbursement |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data:  Required CRFs   * Pelvic Exam * Cervical Specimen Storage * Specimen Storage * Follow-up Visit YN * Follow-up Visit Summary   *If indicated/applicable CRFs*   * Adverse Events (YN/ Log) * Concomitant Medications (YN/ Log) * Chemistry Panel * Hematology * STI Test Results * HIV Test Results * Vital Signs * Physical Exam * Pregnancy Test Results * Ring Insertion and Removal   Paper Forms:   * Protocol Counseling Worksheet * HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet, *if applicable* * Pelvic Exam Diagrams * LDMS Specimen Tracking Sheet |  |  |