**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. |  |  |
|  | ***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,*** 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**
* **Baseline Medical History Log CRF**
* **Concomitant Medications Log CRF**
* **AE Summary/ Log 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:* DPV 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
* 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 (V 5, 6, and 7 ONLY), 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. Document on **Pelvic Exams Diagram** and **Pelvic Exam 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 **Follow-up Visit Summary** **CRFs.** |  |  |
|  | Perform QC1 review while participant is still present, review the following:* Visit checklist to ensure all required procedures were completed
* **LDMS Specimen Tracking Sheet** and **Cervical/Specimen Storage CRFs** for completeness, accuracy and consistencybetween forms.
* **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 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]*
 |  |  |
|  | Provide Reimbursement |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Pelvic Exam
* Cervical Specimen Storage
* Specimen Storage
* Follow-up Visit Y/N / Summary

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

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
 |  |  |