**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. |  |  |
|  | ***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/send to lab for qualitative hCG (pregnancy) or dipstick urinalysis and/or culture per site SOPDocument 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. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* DPV testing (For MTN LC)
* 10 mL lavender top EDTA tube
* CBC with platelets and differentials, ***if indicated***
* [X] mL [color] top [additive/no additive] tube

Document on [add site-specific laboratory testing source document], **Specimen Collection CRF** and **LDMS Tracking Sheet.** *\* Collect blood, rectal fluid, and CVF samples for DPV level testing (procedures below) in as close time proximity as possible to one another (within 30 minutes).* |  |  |
|  | Collect rectal fluid for **DPV level testing** at MTN LC.* Prepare and insert anoscope.
* 1 swab held against rectal mucosa for 2 minutes
* Remove anoscope.

Document on **Specimen Collection CRF** and **LDMS Tracking Sheet;** record pre- and post-collection weights. |  |  |
|  | Collect cervicovaginal fluid (CVF) for **DPV level testing** at MTN LC. * 1 swab near the site of the VR

 Document storage on the **Cervical** **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet**. |  |  |
|  | ***If indicated*** (symptomatic), perform saline/KOH wet mount and pH. |  |  |
|  | 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.** |  |  |
|  | 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***). |  |  |
|  | 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.  |  |  |
|  | Complete the **Follow-up Visit Y/N and 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.
* **Baseline Medical History Log, AE Log,** and **Concomitant Medications Log CRFs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Chart notes** to ensure complete and accurate
 |  |  |
|  | ***If indicated,*** Confirm/schedule next visit. |  |  |
|  | Provide any other study informational materials, male condoms (as needed), site contact information, and instructions to contact the site for additional information and/or counseling if needed: *[add site-specific list if desired]* |  |  |
|  | Provide Reimbursement per site SOP |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Cervical Specimen Storage
* Specimen Storage
* Follow-up Visit Y/N and Summary
* Study Discontinuation

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

Paper Forms:* HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet, *if indicated*
* LDMS Tracking Sheet
 |  |  |