Instructions: Complete staff initials next to procedures completed. Do not initial for other staff members. 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. |  |  |
|  | 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*, provide and document HIV pre-testing and HIV/STI risk reduction counseling using the HIV Pre/Post Test and Risk Reduction Counseling Worksheet. |  |  |
|  | *If indicated*, collect urine and perform tests/send to lab for pregnancy (as applicable), NAAT for GC/CT (if pelvic GC/CT cannot be performed) and/or Dipstick urinalysis/culture per site SOP. Complete Pregnancy Test Results and STI Test Results CRFs upon receipt of lab test results. |  |  |
|  | *If indicated,* collect the following amounts of blood and send to lab for testing. Document results on Hematology, Chemistry Panel and STI Test Results CRFs when available.* HIV-1/2
* [4] mL [red] top [no additive] tube

***Sites to confirm and update tube type and aliquots per local requirements.**** CBC with platelets and differentials
* [4] mL [lavender] top [EDTA] tube
* Creatinine, AST, ALT
* [4] mL [green] top [Na Hep] tube
* Syphilis serology
* [4] mL [red] top [no additive] tube
 |  |  |
|  | *If indicated,* 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. Document test results on HIV Test Results CRF. * If negative 🡪 UNINFECTED 🡪 CONTINUE.
* If positive or indeterminate 🡪 STOP. Perform HIV confirmation test actions per HIV testing algorithm.
 |  |  |
|  | Review participant’s medical history and current medications, to verify and/or update all information recorded at previous visit. Assess/document any adverse events. Document all updates as needed on:* Relevant source documents
* Concomitant Medications Log CRF
* AE Summary/ Log CRFs
 |  |  |
|  | *If indicated,* perform a targeted physical exam and complete the Vital Signs CRF and Physical Exam CRF. |  |  |
|  | *If indicated,* collect pharyngeal sample for NAAT for GC/CT and send to lab. Document results on STI Test Results CRF.  |  |  |
|  | *If indicated and applicable*, perform and document the following per the Genital Exam Checklist.* Rectal exam
* Genital exam
* Pelvic Exam
 |  |  |
|  | *If indicated,* 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

Document test results on HIV Test Results CRF.  |  |  |
|  | Evaluate findings and assess for AEs identified during genital, rectal and physical examinations (if done) and medical history review. Document in chart notes and update/complete Concomitant Medications Log CRFs and AE Log CRFs, as applicable. |  |  |
|  | Provide and explain all available findings and results to participant. Treat and/or refer for care as required (includes treatment for RTI, UTI, or STI(s), *if indicated*). |  |  |
|  | Complete the Study Discontinuation CRF and document permission to contact on [site specific log]. As indicated per protocol, arrange future contact for follow-up on ongoing AEs.  |  |  |
|  | Complete the Follow-up Visit Yes/No and Follow-up Visit Summary CRFs. |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and clear documentation:* Visit checklist and genital exam checklist to ensure all required procedures were completed
* AE Log and Concomitant Medications Log CRFs to ensure all medications and AEs are captured consistently and updated.
* Chart notes to ensure completeness and accuracy
 |  |  |
|  | *If indicated,* confirm/schedule next visit. |  |  |
|  | Provide reimbursement |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs,* Follow-up Visit Yes/No and Summary
* Study Discontinuation

*if indicated/applicable* Hematology* Adverse Events Summary/Log
* Medical History Summary/Log
* Concomitant Medications Summary/Log
* Chemistry Panel
* Hematology
* Vital Signs
* Physical Exam
* HIV Test Results
* STI Tests
* Pregnancy Test Results
* Pelvic Exam (for females)
* Anorectal Exam

Paper Forms *(ALL if indicated/if applicable)** Protocol Counseling Worksheet
* HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet
* Pelvic Exam Diagrams
* Genital Exam Checklist
 |  |  |