**Instructions:** Complete staff initials next to procedures completed. 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** |
| --- | --- |
|  | Confirm identity and PTID. |  |
|  | Review elements of informed consent. Explain procedures to be performed at today’s visit. Confirm participant is still willing to participate:* Willing to participate →CONTINUE.
* NOT willing to participate →STOP. NOT ELIGIBLE.
 |  |
|  | Explain procedures to be performed at today’s visit. |  |
|  | Log into Medidata Rave database and use “Add Event” to create the Interim Visit folder, which will add an Interim Visit Summary CRF to the participant’s casebook. |  |
|  | Provide and document HIV pre-test and HIV/STI risk reduction counseling, including offering male condoms, using the HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet. |  |
|  | Collect the following amounts of blood and send to lab for testing.* HIV-1/2: 4 mL [red] top [no additive] tube

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 to determine eligibility

Document test results on HIV Test Results CRF.  |  |
|  | Prepare, perform and document specimen collection. * Prepare exam equipment, documentation, and specimen collection supplies; label as needed.
* Position and drape participant comfortably.
* *If indicated, palpate the inguinal lymph nodes to assess for enlargement and/or tenderness.*
* Perform naked eye examination and evaluate for abnormalities of the external genitalia (perineum and perianal area).
* Prepare and insert anoscope for rectal fluid collection and collect 1 rectal swab at the proximal rectal lumen fluid for GC/CT NAAT test at local lab.

Document all findings on Anorectal Exam and STI Tests CRFs. |  |
|  | Provide any other study informational materials, site contact information, and instructions to contact the site for additional information, condoms and/or counseling if needed before the next visit: *[add site-specific list if desired]* |  |
|  | Provide reimbursement |  |
|  | Confirm date/time of next scheduled visit.  |  |
|  | Perform QC2. Review participant chart contents, paper forms and EDC data: CRFs * Interim Visit Summary
* STI Tests
* HIV Test Results

Paper Forms:* HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet
* Protocol Counseling Worksheet

*If indicated/applicable:** Product Hold
* Adverse Event Y/N
* Adverse Event Log
* Study Termination
* Discontinuation of Study Product
* Participant Replacement Assessment
 |  |
| **Comments:** |
|  |