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, age, and PTID |  |  |
|  | Check for co-enrollment * NOT currently or recently enrolled in another study 🡪 CONTINUE.
* Currently or recently enrolled in another study 🡪 STOP. Assess eligibility to continue.

*NOTE: Participation in studies involving drugs, medical devices, genital or rectal products, or vaccines within 30 days of enrollment is exclusionary.*   |  |  |
|  | Confirm participant is within 45-day screening window* WITHIN 45 days from screening visit🡪 CONTINUE.
* OUTSIDE 45 days from screening visit 🡪 STOP. Not eligible to enroll during this screening attempt 🡪 If willing, schedule for rescreening (only one re-screen permitted per participant).
 |  |  |
|  | Review/update locator information and re-assess adequacy:* Adequate locator information 🡪 CONTINUE.
* Inadequate locator information 🡪 STOP. NOT ELIGIBLE.
 |  |  |
|  | 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.
 |  |  |
|  | Log into Medidata Rave database and select the appropriate PTID. Begin visit by opening the Enrollment Visit folder.  |  |  |
|  | Provide and explain all prior screening test results.  |  |  |
|  | Assess behavioral eligibility by administering the Enrollment Behavioral Eligibility Worksheet * ELIGIBLE thus far🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | Collect urine (15-60 mL) and perform tests:* Qualitative hCG (pregnancy), for participants of childbearing potential
* NAAT for GC/CT, *if indicated and pelvic GC/CT cannot be performed*
* Dipstick urinalysis and/or culture per site SOP*, if indicated*

Confirm and document pregnancy results:* NOT pregnant 🡪 CONTINUE.
* Pregnant 🡪 STOP. NOT ELIGIBLE.
* NA

Complete Pregnancy Test Results (if applicable) and STI Test Results CRFs upon receipt of lab test results.*NOTE: If symptomatic and diagnosed with a UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment.* |  |  |
|  | Provide contraceptive counseling (for participants of childbearing potential). Determine and document current contraceptive method and review study contraception requirements. Effective study methods per study protocol include: * hormonal methods
* Intrauterine device (IUD) inserted\*
* sterilization of participant or partner
* abstinent from penile-vaginal intercourse (including self-identified as having sex with women exclusively)\*\*

[Prescribe/provide/refer for] contraception as needed; if applicable, document current contraceptive method on Concomitant Medications Log orin **chart notes (abstinence or sterilization)** or *[add site-specific form if desired]*.* NA (participant is not of childbearing potential)

*\*To occur at least 30 days prior to Enrollment.**\*\*To occur at least* 90 days prior to Enrollment  |  |  |
|  | 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
* Plasma for PK
	+ 10 mL lavender top EDTA tube
* Plasma for archive

***Sites to confirm and update tube type and aliquots per local requirements.**** + 10 mL lavender top EDTA tube

*If indicated:** 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

Document collection on Specimen Collection and Storage CRF and LDMS Tracking Sheet. If indicated, document results on Chemistry Panel, Hematology or STI Test Results CRFs |  |  |
|  | 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.  |  |  |
|  | Review participant’s medical and current medications, to verify and/or update all information recorded at the Screening Visit. Document all updates as needed on:* Relevant source documents
* Baseline Medical History Summary/Log CRF
* Concomitant Medications Summary/Log CRF
 |  |  |
|  | Perform full 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 on STI Test Results CRF when available.  |  |  |
|  | Perform and document the following, including specimen collection, per the Genital Exam Checklist.* Rectal exam
* Pelvic Exam*, if applicable* *and if indicated*
* Male genital exam*, if applicable and if indicated*
 |  |  |
|  | Determine whether participant has current RTI/STI/UTI symptoms:* No symptoms 🡪 CONTINUE.
* Symptom(s) present ⇒ evaluate per site SOPs. Treat or refer for treatment if required\* 🡪 STOP. MAY BE INELIGIBLE.

Document provision of results, treatment and/or referrals in chart notes.*\* If symptomatic and/or diagnosed with BV, candida or a UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment. Treat if indicated per site SOP. If diagnosed with an STI, the participant is not eligible.* |  |  |
|  | Evaluate findings identified during genital and physical examinations and medical history review. Document in chart notes and update Concomitant Medications Log CRF and Baseline Medical History Log CRF, if applicable. Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
|  | Conduct confirmation and final determination of eligibility status by review/completion of Eligibility Checklist. * ELIGIBLE 🡪 CONTINUE 🡪 sign the Eligibility Checklist and proceed to eligibility verification.
* NOT ELIGIBLE 🡪 STOP. DO NOT enroll. 🡪 Pause and evaluate whether participant is:
	+ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt 🡪 PAUSE🡪perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible.
* NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt 🡪 STOP. Provide clinical management as needed.

Complete the Inclusion Exclusion Criteria CRF. |  |  |
|  | Verify participant eligibility by review of Eligibility Checklist [must be different staff member from above step]: * ELIGIBLE 🡪 CONTINUE
* NOT ELIGIBLE 🡪 STOP. DO NOT RANDOMIZE. Provide clinical management as needed. Complete the Inclusion Exclusion Criteria CRF with ineligibility status.
 |  |  |
|  | Administer the Baseline CASI assessment and document on the Behavioral Assessment CRF and CASI Tracking CRF. |  |  |
|  | Randomize the participant to sample collection schedule by completing the Randomization CRF. ONCE THE RANDOMIZATION DATE AND TIME AUTO-POPULATE ON THE CRF, THE PARTICIPANT IS OFFICIALLY ENROLLED IN THE STUDY. |  |  |
|  | Complete the Enrollment CRF. |  |  |
|  | Complete Home Saline Enema Kit Request Slip to obtain enema kit for administration prior to dosing visit. Deliver the top (white) copy to the pharmacy. Retain yellow copy of prescription in participant’s binder. Review content of kit and use instructions with participant and address any questions or concerns. |  |  |
|  | Conduct and document protocol counseling on Protocol Counseling Worksheet.  |  |  |
|  | 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.
* Baseline CASI to ensure completion and documentation on Behavioral Assessment and CASI Tracking CRFs.
* LDMS Specimen Tracking Sheet and Specimen Collection and Storage CRFs
* Baseline Medical History Log and Concomitant Medications Log to ensure all conditions and medications are captured consistently.
* Enrollment CRF, Chart notes, Eligibility Checklist and Enrollment Behavioral Eligibility Worksheet, and Inclusion Exclusion Criteria CRF to ensure all items are complete and accurate.
* All CRFs for completeness and accuracy based on participant response and clinical findings
 |  |  |
|  | 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]* |  |  |
|  | Update Screening and Enrollment Log.  Generate participant visit calendar if not done already, or update calendar with 48-hr Post-Dose Visit assignment. Review study schedule including the assigned rectal collection schedule using participant visit schedule tool. Schedule first doing visit (to occur at least 7 days after Enrollment) and advise participant of potential length of visit. |  |  |
|  | Provide reimbursement |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Vital Signs
* Physical Exam
* Anorectal Exam
* Behavioral Assessment
* CASI Tracking
* HIV Test Results
* Randomization
* Specimen Collection and Storage
* Inclusion Exclusion Criteria
* Enrollment

*If indicated/applicable:** Pregnancy Test Result
* STI Test Results
* Pelvic Exam
* Hematology
* Chemistry Panel
* Baseline Medical History Summary/ Log
* Concomitant Medications Summary/ Log

Paper Forms:* Screening and Enrollment Log
* Home Saline Enema Kit Request Slip
* Enrollment Behavioral Eligibility Worksheet
* HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet
* Protocol Counseling Worksheet
* LDMS Tracking Sheet
* Pelvic Exam Diagrams, *if applicable*
* Eligibility Checklist
* Participant Visit Calendar Tool, *if applicable*
* Genital Exam Checklist

For failed screening attempts, the only CRF that requires completion is the Inclusion Exclusion CRF. Other CRFs that were completed during the failed screening attempt up until the point that ineligibility was determined may remain in the study database. |  |  |