**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, 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
 |  |  |
|  | 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.
 |  |  |
|  | Administer the Baseline WSI assessment and document on the **Behavioral Summary CRF** and **WSI Tracking CRF**. |  |  |
|  | Collect urine (15-60 mL) and perform tests/send to lab:* **FOR FEMALES:** Qualitative hCG (pregnancy)
* NAAT for GC/CT, ***if indicated***
* Dipstick urinalysis and/or culture per site SOP, ***if indicated***

*NOTE: If symptomatic and diagnosed with a UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment.* |  |  |
|  | **FOR FEMALES:** Confirm pregnancy results:* NOT pregnant ⇒ CONTINUE.
* Pregnant ⇒ STOP. NOT ELIGIBLE.

Complete **Pregnancy Test CRF** upon receipt of lab test results. |  |  |
|  | Conduct protocol counseling with participant, including contraceptive counseling with female participants, and document on **Protocol Counseling Worksheet**. Offer Study Adherence Guide to take home.**FOR FEMALES:** Confirm contraceptive method, review study contraception requirements, and provide contraceptive counseling. Effective study methods per study protocol include: * hormonal methods (except contraceptive ring)
* intrauterine device (IUD) inserted\*
* sterilization of participant or partner\*
* self-identifies as having sex with women exclusively.
* Meets contraceptive requirements ⇒ CONTINUE.
* DOES NOT meet contraceptive requirements ⇒ STOP. NOT ELIGIBLE.

[Prescribe/provide/refer for] contraception if needed; document in chart notes and **Protocol Counseling Worksheet.***\*To occur at least 42 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 Risk Reduction Counseling Worksheet**. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* HIV-1/2
	+ [X] mL [color] top [additive/no additive] tube
* Plasma for archive
	+ [X] mL [color] top [additive/no additive] tube

***If indicated:**** CBC with platelets and differentials
	+ [X] mL [color] top [additive/no additive] tube
* Blood creatinine, AST, and ALT
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology
	+ [X] mL [color] top [additive/no additive] tube

Document collection on **Specimen Storage CRF** and **LDMS Tracking Sheet.** |  |  |
|  | 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 baseline 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.  |  |  |
|  | Perform and document the following, including specimen collection, per the **Genital Exam Checklist.*** Rectal exam
* Male genital exam***, if indicated***
* **FOR FEMALES:** Pelvic Exam***, 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 is diagnosed with an RTI/STI/UTI, the participant must complete treatment and all symptoms must resolve to be eligible for enrollment. Treat if indicated per site SOP.* |  |  |
|  | Evaluate findings identified during genital/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 **Eligibility Criteria CRF**  |  |  |
|  | Verify participant eligibility by review of **Eligibility Checklist** (done by IoR or designee [must be different staff member from above step]): * ELIGIBLE ==> CONTINUE
* NOT ELIGIBLE ==> STOP. DO NOT RANDOMIZE. Provide clinical management as needed. Complete the **Eligibility Criteria CRF** with ineligibility status.
 |  |  |
|  | Randomize the participant to rectal tissue, rectal fluid, and vaginal fluid (if applicable) sampling schedule by completing the **Randomization CRF**. Note that the participant’s 48-hour visit will also be randomly assigned at this time.ONCE A PARTICIPANT’S RANDOMIZATION DATE AND TIME AUTO-POPULATE ON THE CRF, HE/SHE IS OFFICIALLY ENROLLED IN THE STUDY. |  |  |
|  | Complete the **Enrollment** **CRF.** |  |  |
|  | 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 procedure were completed
* **Baseline WSI** is completed and documented on **Behavioral Summary/WSI Tracking** CRFs.
* **LDMS Specimen Tracking Sheet** and **Specimen 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 **Eligibility Criteria CRF** to ensure all items are complete and accurate.
* All CRFs are completed and accurate 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 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 (in approx. 14 days) 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 and Sigmoidoscopy
* Behavioral Summary
* WSI Tracking *(*for Baseline WSI)
* HIV Test Results
* Pregnancy Test Result (for females)
* Randomization
* Specimen Storage
* Anorectal Specimen Storage Enrollment
* Pelvic Specimen Storage (for females)
* Eligibility Criteria
* Enrollment

*If indicated/applicable:** STI Test Results
* Pelvic Exam (for females)
* Hematology
* Local Laboratory Results
* Baseline Medical History Summary/ Log
* Concomitant Medications Summary/ Log

Paper Forms:* Screening and Enrollment Log Form
* 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 (for females)*
* Eligibility Checklist

For failed screening attempts, the only CRF that requires completion is the Eligibility Criteria 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. |  |  |