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. Use a new Screening Visit Checklist if a second screening attempt is needed.

| Procedure | Staff Initials | Comments: |
| --- | --- | --- |
|  | Confirm identity and age per site SOPs. * 18 years or older 🡪 CONTINUE.
* Under 18 years old 🡪 STOP. NOT ELIGIBLE.
 |  |  |
|  | 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.*   |  |  |
|  | Determine screening attempt (verify if an MTN-039 PTID has previously been assigned)* First attempt 🡪 Document recruitment source, CONTINUE.
* Re-screen attempt 🡪 CONTINUE.

*Note: Only one re-screen permitted per participant.* |  |  |
|  | Explain, conduct, and document the informed consent process. Complete Informed Consent Coversheet and ICComprehension Assessment, per site SOP:* Willing and able to provide written informed consent 🡪 CONTINUE.
* NOT willing and able to provide written informed consent 🡪 STOP. NOT ELIGIBLE.
 |  |  |
|  | Log into Medidata and generate PTID (if not done during a previous screening attempt). Open the Screening Visit folder to begin CRF data entry.Complete new entry on Screening and Enrollment Log and PTID Name Linkage Log.  |  |  |
|  | Complete Screening Date of Visit CRF. |  |  |
|  | Explain procedures to be performed at today’s visit. |  |  |
|  | Obtain and record locator information per site SOP and determine adequacy:* Adequate locator information 🡪 CONTINUE.
* Inadequate locator information 🡪 PAUSE and re-assess:
	+ Adequate information likely to be available prior to enrollment 🡪 CONTINUE.
	+ Adequate information NOT likely to be available 🡪 STOP. NOT ELIGIBLE.
 |  |  |
|  | Administer Demographics CRF. |  |  |
|  | Assess behavioral eligibility by administering the Screening Behavioral Eligibility Worksheet: * ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | Collect baseline medical and medications history using the Baseline Medical History Guide and complete:* Baseline Medical History Summary/Log CRFs
* Concomitant Medications Summary/Log CRFs
 |  |  |
|  | Collect urine (15-60 mL) and perform tests:* Qualitative hCG (pregnancy) (for participants of childbearing potential)
* NAAT for GC/CT (if 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-testing 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
* Hepatitis B surface antigen (HBsAg)
* [4] mL [red] top [no additive] tube
* Complete blood count (CBC) with platelets and differentials
	+ [4] mL [lavender] top [EDTA] tube

***Sites to confirm and update tube type and aliquots per local requirements.**** Creatinine, AST, ALT
	+ [4] mL [green] top [Na Hep] tube
* Syphilis serology
	+ [4] mL [red] top [no additive] tube
* Coagulation (PT/INR)
	+ [4] mL [light blue] top [Na Citrate] tube

Document results on STI Test Results, Chemistry Panel and Hematology 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 results on HIV Test Results CRF.  |  |  |
|  | Perform full physical exam and complete the Vital Signs CRF and Physical Exam CRF. |  |  |
|  | Collect pharyngeal sample for NAAT for GC/CT and send to lab. Document results on STI Test Results CRF.  |  |  |
|  | Perform and document the following, including specimen collection, per the Genital Exam Checklist (as applicable). * 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 indicated\** 🡪 STOP. MAY BE INELIGIBLE.

Document provision of results, treatment and/or referrals in chart notes.*\* If symptomatic and 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, pelvic and/or physical examinations and medical history review. Document in chart notes and update Concomitant Medications Log CRF, if applicable. Document ongoing conditions on the Baseline Medical History Log CRF. Provide and explain all available findings and results. Refer for other findings as indicated. |  |  |
|  | Assess participant’s current eligibility status:* ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt 🡪 PAUSE. Perform and document relevant outcomes of all clinically indicated procedures. Schedule 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 and referrals as needed.
 |  |  |
|  | Perform QC1 review while participant is still present, review the following for completion and clear documentation:* This visit checklist and genital exam checklist to ensure all required procedures were completed
* Screening Behavioral Eligibility Worksheet ensure all items are complete and to verify participant eligibility.
* All CRFs for completeness and accuracy, based on participant response and clinical findings
* Baseline Medical History Log and Concomitant Medications Log to ensure all conditions and medications are captured consistently.
* Chart notes to ensure completeness and accuracy.
 |  |  |
|  | 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]* |  |  |
|  | Determine last possible enrollment date for this screening attempt (within 45 days) using the Participant Visit Calendar Tool.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |
| Mon |  | Day |  | Year |

 Schedule next visit and advise of potential length of next visit.  |  |  |
|  | Provide reimbursement |  |  |
|  | If participant will proceed to Enrollment, leave the Eligibility Checklist blank and complete form along with the Inclusion Exclusion Criteria CRF *at Enrollment Visit*.If participant will not proceed to Enrollment, complete and submit Inclusion Exclusion Criteria CRF. Other CRFs that were completed during the failed screening attempt may remain in the study database and will not undergo QC review. |  |  |
|  | Perform QC2 review. Review participant chart contents and EDC data: Required CRFs* Screening Date of Visit
* Demographics
* Vital Signs
* Physical Exam
* Anorectal Exam
* Hematology
* Chemistry Panel
* STI Test Results
* HIV Test Result
* Pregnancy Test Result *(if applicable)*

*If indicated/applicable:** Pelvic Exam
* Baseline Medical History Summary/ Log *(if pre-existing conditions are reported)*
* Inclusion Exclusion Criteria
* Concomitant Medications Summary/ Log *(if medications are reported)*

Paper Forms:* Informed Consent Coversheet
* Informed Consent Comprehension Assessment
* PTID Name Linkage Log
* Screening and Enrollment Log
* Screening Behavioral Eligibility Worksheet
* Baseline Medical History Guide
* HIV Pre/Post-Test and HIV/STI Risk Reduction Counseling Worksheet
* Protocol Counseling Worksheet
* Pelvic Exam Diagrams, *if applicable*
* Participant Visit Calendar Tool, *if applicable*
* Genital Exam Checklist
 |  |  |