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

| **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
|  | Confirm identity per site SOPs. Assess age eligibility and proceed accordingly. * 18-45 years old (inclusive) 🡪 CONTINUE.
* <18 or >45 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, vaginal products, or vaccines within 60 days of enrollment is exclusionary.*   |  |  |
|  | Determine screening attempt (Verify if an MTN-038 PTID has previously been assigned)* First attempt 🡪 Document recruitment source, CONTINUE.
* Second attempt\* 🡪 CONTINUE.

*\* Participant may only re-screen once per protocol section 7.2* |  |  |
|  | Explain, conduct, and document the informed consent process. Complete **Informed Consent Coversheet** and **IC****Comprehension 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 locator information 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.

Record locator info on [add site-specific source document] |  |  |
|  | Administer **Demographics CRF**  |  |  |
|  | Assess behavioral eligibility by administering the **Screening Behavioral Eligibility Worksheet** * ELIGIBLE thus far 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | Collect baseline medical, menstrual, medications history using the Baseline Medical History Guide and complete:* **Medical History YN/ Medical History (Log) CRFs**
* **Concomitant Medications YN/ Concomitant Medications (Log) CRFs**

Record last menstrual period dates: **First day: \_\_\_\_\_\_\_\_ Last day: \_\_\_\_\_\_\_\_\_\_\_**  |  |  |
|  | Collect urine (15-60 mL) and perform tests:* Qualitative hCG (pregnancy)
* 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.* |  |  |
|  | Confirm pregnancy results:* NOT pregnant 🡪 CONTINUE.
* Pregnant🡪 STOP. NOT ELIGIBLE.

Complete [add site-specific laboratory testing source document] and **Pregnancy Test Results CRF** upon receipt of lab test results. |  |  |
|  | Determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling. Effective study methods per study protocol include: * hormonal methods (except contraceptive ring)
* IUD
* sterilization (of participant or partner, as defined in site SOPs)
* having sex exclusively with individuals assigned female sex at birth
* abstinence from PVI for 90 days prior to Enrollment and intending to remain abstinent from PVI during study participation

[Prescribe/provide/refer for] contraception if needed; document in chart notes and **Protocol Counseling Worksheet (contraceptive counseling section)**. |  |  |
|  | Administer 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**.\*if indicated and/or per local standard of care |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* HIV-1/2
	+ [X] mL [color] top [additive/no additive] tube
* Complete blood count (CBC) with platelets and differentials
	+ [X] mL [color] top [additive/no additive] tube
* AST and ALT
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology
	+ [X] mL [color] top [additive/no additive] tube
* Serum creatinine
	+ [X] mL [color] top [additive/no additive] tube
* Hep B surface antigen
	+ [X] mL [color] top [additive/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 HIV test results on **HIV Test Results CRF.**  |  |  |
|  | 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 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.* |  |  |
|  | Perform full physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF.** |  |  |
|  | Perform and document a pelvic exam per the Pelvic Exam Checklist, including pelvic specimen collection. Document on **Pelvic Exams Diagram** and **Pelvic Exam CRF.**  |  |  |
|  | Evaluate findings identified during pelvic and physical examinations and medical history review. Document in chart notes and update **Concomitant Medications** and **Medical History CRFs**, if applicable. 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 accuracy:* Visit checklist and pelvic exam checklist
* **Screening Behavioral Eligibility Worksheet** and **Demographics CRF** to ensure all items are complete and to verify participant eligibility.
* All CRFs based on participant response and clinical findings
* **Medical History** and **Concomitant Medications CRFs** to ensure all conditions and medications are captured consistently.
* **Chart notes**
 |  |  |
|  | 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]* |  |  |
|  | Determine last possible enrollment date for this screening attempt **(45 days)**, using the **Visit Calendar Tool.**

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

 Schedule next visit and advise of potential length of next visit. NOTE: Consider participant’s menstrual cycle when scheduling enrollment to avoid bleeding in the first 7 days of product use (i.e. Enrollment Visit thru Visit 4) |  |  |
|  | Provide Reimbursement |  |  |
|  | If participant will proceed to Enrollment, leave Eligibility Checklist blank and complete the checklist at Enrollment Visit along with Inclusion Exclusion Criteria CRF.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
* Medical History YN
* Demographics
* Vital Signs
* Physical Exam
* Pelvic Exam
* Hematology
* Chemistry Panel
* STI Test Results
* HIV Test Results
* Pregnancy Test Results
* Inclusion Exclusion Criteria

*If indicated/applicable:** Medical History (Log) *(if pre-existing conditions are reported)*
* Inclusion/Exclusion Criteria (*if participant is ineligible)*
* Concomitant Medications YN/Concomitant Medications (Log) *(if medications are reported)*
* HIV Confirmatory Test Results

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