**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-036 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 and complete:* **Baseline Medical History Questions Sheet**
* **Baseline Medical History Summary/ Log CRFs**
* **Concomitant Medications Summary/ Log CRFs**
 |  |  |
|  | 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 cis-women
* 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**. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:* HIV-1
	+ [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

Document collection on **Local Laboratory Results** [add site-specific laboratory testing source document]. When results are ready document on the **Hematology CRF, STI Test Results,** and **Local Laboratory Results CRF**, as applicable |  |  |
|  | 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 Log** **CRF**, if applicable. Document relevant 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:* This visit checklist and pelvic exam checklist to ensure all required procedures were completed
* **Screening Behavioral Eligibility Worksheet/ Eligibility Checklist** and **Demographics CRF** to ensure all items are complete and to verify participant eligibility.
* All CRFs are completed and accurate based on participant response and clinical findings
* **Baseline Medical History Questions, Baseline Medical History Log,** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently.
* **Chart notes** to ensure complete and accurate.
 |  |  |
|  | 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 6) |  |  |
|  | Provide Reimbursement |  |  |
|  | If participant will proceed to Enrollment, leave **Eligibility Checklist** blank and complete form at Enrollment Visit along with **Eligibility Criteria CRF**.If participant will not proceed to Enrollment, complete the **Eligibility Checklist.** Complete and submit **Eligibility 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
* Pelvic Exam
* Hematology
* Local Laboratory Results
* STI Test Results
* HIV Test Results
* Pregnancy Test Results

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

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