**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 of eligibility and proceed accordingly. * Will be 16-21 years of age at time of enrollment 🡪CONTINUE.
* Will potentially turn 16 years old by time of enrollment (i.e., birthday within S&E window) 🡪 CONTINUE. Assess eligibility to continue
* Will be <16 or >21 years of age at time of enrollment🡪 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 MTN-034 PTID has previously been assigned)* First attempt 🡪 Document recruitment source, CONTINUE.
* Re-screen attempt 🡪 CONTINUE.
 |  |  |
|  | *\*For participants who are minors (16 and 17 years old)*Explain, conduct, and document the informed assent\* process for potential participant. Complete **Informed Assent Coversheet** and **IC****comprehension Checklist**, per site SOP:* Willing and able to provide written informed assent 🡪 CONTINUE.
* NOT willing and able to provide written informed assent 🡪 STOP. NOT ELIGIBLE.
* Not applicable
 |  |  |
|  | *\*For participants who are minors (16 and 17 years old), parental permission is required.* Explain, conduct, and document the parental permission \* process. Complete **Informed Consent Coversheet** and **IC****comprehension Checklist**, per site SOP:* Willing and able to provide written permission 🡪 CONTINUE.
* NOT willing and able to provide written permission 🡪 STOP. NOT ELIGIBLE.
* Not applicable
 |  |  |
|  | *\*For participants who are ≥18 yrs old.* Explain, conduct, and document the participant informed consent\* process. Complete **Informed Consent Coversheet** and **IC****comprehension Checklist**, per site SOP:* Willing and able to provide written informed consent 🡪CONTINUE.
* NOT willing and able to provide written informed consent 🡪 STOP. NOT ELIGIBLE.
* Not applicable
 |  |  |
|  | Log onto the MTN-034 Medidata database and generate PTID (if not done during a previous screening attempt).Complete new entry on **Screening and Enrollment Log** and **PTID Name Linkage Log**. Open the Screening Visit folder to begin CRF data entry. |  |  |
|  | 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.
 |  |  |
|  | Complete **Screening Date of Visit CRF.** |  |  |
|  | 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 Question Guide and complete:* **Screening Menstrual History CRF**
* **Baseline Medical History Summary/ Log CRFs**
* **Concomitant Medications Summary/ Log CRFs**
 |  |  |
|  | Collect mid-stream urine (15-60 mL) catch and perform tests:* Urine hCG (pregnancy)
* Dipstick urinalysis and/or culture per site SOP (if indicated)
 |  |  |
|  | Confirm and document pregnancy results:* NOT pregnant ⇒ CONTINUE.
* Pregnant ⇒ STOP. NOT ELIGIBLE.
 |  |  |
|  | Administer **Family Planning History CRF**, review study contraception requirements, and provide contraceptive counseling. Effective study methods per study protocol include: * hormonal methods (except contraceptive ring)
* intrauterine device (IUD)

[Prescribe/provide/refer for] contraception if needed; document in chart notes and/or **Contraceptive Counseling Worksheet,** and complete **Family Planning Summary/ Log CRF**,as needed. Document hormonal methods/IUDs on the **Concomitant Medications Log CRF.***Note: Participant must be on the same contraceptive method for at least two months prior to Enrollment.* |  |  |
|  | Provide and document HIV pre-testing counseling 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] tube
* Complete blood count (CBC) with platelets
	+ [X] mL [color] top [additive] tube
* Blood creatinine (and calculated creatinine clearance)
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology
	+ [X] mL [color] top [additive/no additive] tube
* Hepatitis B surface antigen (HBsAG)
	+ [X] mL [color] top [additive/no additive] tube
 |  |  |
|  | Perform and document two rapid HIV test (s) per site SOPs.  |  |  |
|  | Complete HIV test results and post-testing actions:* Provide testing results and referrals if needed/requested per site SOPs.
* If both tests negative = UNINFECTED 🡪 CONTINUE.
* If both tests positive = INFECTED🡪 STOP. NOT ELIGIBLE or
* If one test positive and one test negative = DISCORDANT 🡪 STOP. NOT ELIGIBLE.
* Submit HIV Query form to inform LC. If participant allows, collect blood and perform an HIV confirmation and refer participant to local treatment of care.
* Follow Protocol HIV Testing Algorithm for follow-up actions based on confirmation test results.
* Provide and document HIV post-test and HIV/STI risk reduction counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet**
* Offer condoms
 |  |  |
|  | Determine whether participant is positive for Hepatitis B:* Test negative for HBsAG ⇒ CONTINUE.
* Test positive for HBsAG ⇒ evaluate per site SOPs. If treatment is required ⇒ STOP. MAY BE INELIGIBLE.

Document results onto **STI Test Results CRF** when results are available.*NOTE: If tested negative, offer HBV vaccination at the Enrollment Visit.* |  |  |
|  | Perform full physical exam and complete* **Vital Signs CRF**
* **Physical Exam CRF**
 |  |  |
|  | Perform and document a pelvic exam per the Pelvic Exam Checklist, including sample collection. Document on **Pelvic Exam Diagrams (non Medidata form)** and **Pelvic Exam CRF.** |  |  |
|  | Determine whether participant has current RTI/STI/UTI/PID symptoms and document provision of results:* No symptoms 🡪 CONTINUE.
* Symptom(s) present 🡪 evaluate per site SOPs. If treatment is required 🡪 STOP. May be INELIGIBLE. Provide any clinically indicated treatment and/or referrals.

Document provision of results, treatment and/or referrals in chart notes.*NOTE: If participant is symptomatic and is diagnosed with an RTI/STI/UTI/PID, she must complete treatment and all symptoms must resolve before she is eligible for enrollment. Treat if indicated per site SOP.* |  |  |
|  | Evaluate findings identified during pelvic and physical examinations and medical and menstrual 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:* **Screening Behavioral Eligibility Worksheet**
* **Demographics CRF, Screening Menstrual History CRF, Pelvic Exam Diagrams, Pelvic Exam CRF, Vital Signs CRF,** and **Physical Exam CRF**
* **Baseline Medical History Log, Family Planning History, Family Planning Log,** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently.
* **Chart notes**
 |  |  |
|  | Provide study informational material (e.g., factsheets), 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 using the **Visit Calendar Tool, Last Day to Enroll.\*** DD MON YY Schedule next visit and advise her of potential length of next visit. *\*Enrollment visit should be no greater than 70 days from Screening, and, no less than 60 days from the day a new contraceptive method is initiated.* |  |  |
|  | Provide Reimbursement |  |  |
|  | If participant will proceed to the Enrollment Visit, leave the Eligibility Checklist blank and complete form at Enrollment Visit along with the Eligibility Criteria CRF.If participant will not proceed to the Enrollment Visit, complete and submit the **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* Eligibility Criteria (complete at Screening if participant is ineligible)
* Demographics
* Local Laboratory Results
* Baseline Medical History Summary
* Concomitant Medications Summary
* Family Planning History
* Pelvic Exam
* Physical Exam
* Screening Date of Visit
* Screening Menstrual History
* Vital Signs
* STI Test Results

*As needed** Concomitant Medications Log (if medications are reported)
* Family Planning Summary and Log (if current FP methods are reported)
* Baseline Medical History Log (if pre-existing conditions are reported)

Paper Forms/Tools:* Informed Consent/Assent 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
* Contraceptive Counseling Worksheet
* Pelvic Exam Diagrams
* Safety Lab Calculator
* Visit Calendar Tool, Last Day to Enroll
 |  |  |