**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 in other studies per site SOPs:* NOT enrolled in another study ⇒ CONTINUE.
* Enrolled in another study ⇒ STOP. ASSESS ELIGIBILITY.
 |  |  |
|  | Confirm participant is within 70-day screening window* WITHIN 70 days from screening visit ⇒CONTINUE.
* OUTSIDE 70 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 assent/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.
 |  |  |
|  | Provide and explain all prior screening visit test results.  |  |  |
|  | Log into Medidata Rave database, and select the appropriate PTID. Open the Enrollment Visit folder.  |  |  |
|  | Assess behavioral eligibility by administering the **Enrollment Behavioral Eligibility Worksheet.*** ELIGIBLE ⇒ CONTINUE.
* NOT ELIGIBLE ⇒ STOP.
 |  |  |
|  | Administer the Baseline A/CASI and document on the **ACASI Summary** and **ACASI Tracking 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.
 |  |  |
|  | Review study contraception requirements and provide contraceptive counseling. Effective study methods per study protocol include: * hormonal methods (except contraceptive ring)
* intrauterine device (IUD)
* Meets contraceptive requirements ⇒ CONTINUE.
* DOES NOT meet contraceptive requirements ⇒ STOP. NOT ELIGIBLE.

[Prescribe/provide/refer for] contraception if needed; complete/update **Family Planning Summary/ Log CRF**, as applicable. Document in chart notes and/or on the **Contraceptive Counseling Worksheet.***Note: Participant must be on the same contraceptive method for at least the 60 days prior to Enrollment.* |  |  |
|  | Administer and document HIV pre-test counseling 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 Rapid (local lab)
	+ [X] mL [color] top [additive/no additive] tube
* HSV-2 antibody (MTN LC)
	+ 4 mL [color] top [additive/no additive] tube
* Plasma archive (MTN LC)
	+ 10 mL [color] top EDTA tube

*If indicated:** Syphilis serology (local lab)
	+ [X] mL [color] top [additive/no additive] tube
* Complete blood count (CBC) with platelets (local lab)
	+ [X] mL [color] top [additive/no additive] tube
* Blood creatinine (and calculated creatinine clearance) (local lab)
	+ [X] mL [color] top [additive/no additive] tube

Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Tracking Sheet**.*Note: Label all required tubes with a SCHARP-provided PTID label at the time of collection. For MTN LC bound specimens, store frozen at site while awaiting shipping request.* |  |  |
|  | Perform and document 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
* 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
 |  |  |
|  | Review participant’s baseline medical and menstrual history, and current medications, to verify and/or update all information recorded at the Screening Visit. Complete the **Enrollment Menstrual History CRF.**Document all updates as needed on:* **Relevant source documents**
* **Baseline Medical History Questions Form (non-CRF Form)**
* **Baseline Medical History Log CRF(s)**
* **Concomitant Medications Log CRF(s)**
 |  |  |
|  | **If indicated*,*** perform physical exam*.* As applicable 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** and **Pelvic Exam CRF.** |  |  |
|  | Determine whether participant has current RTI/STI/PID/UTI 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/PID/UTI, she must complete treatment and all symptoms must resolve before she is eligible for enrollment. Treat if indicated per site SOP* |  |  |
|  | If not vaccinated against HPV and/or HBV, offer. If accepted, provide or refer for HPV and/or HBV vaccine series. Document in chart notes and confirm provision of each dose on the **Concomitant Medications Log CRF.***NOTE: For enrolled participants who decline vaccination at enrollment, the vaccine series may be initiated at any time during follow-up.* |  |  |
|  | Evaluate findings identified during pelvic and physical examinations and medical and menstrual history review. Document in chart notes and update **Concomitant Medications Log** as needed. Document ongoing conditions on the **Baseline** **Medical History Log** **CRF.**  |  |  |
|  | Provide and explain all available findings and results to participant. Refer for other findings as indicated.  |  |  |
|  | Provide protocol adherence counseling by instructing participant of the following: * For 72 hrs (3 days) prior to study visits:
	+ Abstain from non-study vaginal products and/or practices including but are not limited to spermicides, diaphragms, vaginally applied medication, menstrual cups, cervical caps, douches, lubricants, sex toys, etc.
	+ Stay sexually abstinent i.e. no receptive intercourse (vaginal, anal, oral and finger stimulation).
* For entire study: Refrain from using on PEP and non-study PrEP

Document any questions or issues on this checklist or in chart notes. |  |  |
|  | 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** (must be different staff member than who confirmed eligibility) and either the IoR or designee sign: * ELIGIBLE ⇒ CONTINUE
* NOT ELIGIBLE ⇒ STOP. DO NOT RANDOMIZE. Provide clinical management as needed.
 |  |  |
|  | Randomize the participant as follows: * Complete the **Eligibility Criteria CRF** (within the Screening Visit Rave Folder).
* Complete the **Randomization CRF**.

Once the participant’s randomization date and time auto-populates on the Randomization CRF, the participant is randomized. ONCE A PARTICIPANT IS RANDOMIZED, SHE IS OFFICIALLY ENROLLED IN THE STUDY. |  |  |
|  | Confirm study product (Ring or Tablet) to be provided for product use period 1 (1st 24 weeks) based on randomized group assignment.* DPV Ring
* Truvada Tablet

Complete the **MTN-034** **Prescription** for the participant’s first product use period per study randomization. * Deliver the top (white) copy along with the [site-specific form] to the pharmacy.
* Retain yellow copy of prescription in participant’s binder.
 |  |  |
|  | Check the **Enrollment CRF** for if the participant is randomized for serial In-depth Interviews (SIDI). Then refer to the **Qualitative Participation Log (QPL)** to determine whether she should be invited to participate in the IDIs.If yes, inform her of being randomly invited to participate and explain the IDI process and schedule. Confirm her verbal willingness to participate. Document selection outcome on the Enrollment CRF and QPL, as applicable. |  |  |
|  | Complete **Enrollment CRF.**  |  |  |
|  | Conduct product adherence counseling. Administer the **Adherence Counseling CRF** and document on the **Adherence Counseling Worksheet.** |  |  |
|  | **For participants assigned to the ring**:* N/A (if not assigned to ring)
* Retrieve study ring and white return bag (for used ring) from pharmacy
 |  |  |
| * Provide ring use instructions and review important information. Give participant white return bag to take home.
 |  |  |
| * Have participant (or clinician/designee, if necessary) insert ring.
 |  |  |
| * Perform digital (bimanual) exam to check ring placement.
 |  |  |
| * Document the provision of the vaginal ring to the participant using the **Site-Specific Clinic Study Product Accountability Log,** the **Ring Insertion and Removal CRF,** and the **Ring Assessment CRF,** if applicable.
 |  |  |
|  | **For participants assigned to the study tablet:*** N/A (if not assigned to tablet)
* Provide study tablet use instructions and review important information
 |  |  |
| * Provide participant with one month supply of study tablets
 |  |  |
| * Instruct participant to self-administer one tablet by mouth and observe dose administration**.**
 |  |  |
| * Document the provision of tablets to the participant on the **Site-Specific Clinic Study Product Accountability Log, PrEP Provisions and Returns CRF,** and the **Tablet Assessment CRF**, if applicable.
 |  |  |
|  | Generate participant visit calendar if not done already. |  |  |
|  | Schedule the one-week post-product initiation visit using **Visit Calendar Tool*** Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring/tablets (if applicable), or condoms before next visit.

Note: Visit may take place in-person or by phone. |  |  |
|  | Update **Screening and Enrollment Log.** |  |  |
|  | For enrolled participants, perform QC1: while participant is still present, review the following for completion and clear documentation:* **Enrollment Behavioral Eligibility Checklist** to ensure all items are complete.
* **Baseline A/CASI** is completed.
* **LDMS Specimen Tracking Sheet** and **Specimen Storage CRF**
* **Baseline Medical History Log, Family Planning Log, Enrollment Menstrual History CRF,** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently
* **Clinic Study Product Accountability Log** and **PrEP Provisions and Returns/Ring Collection and Insertion CRFs** are complete and match
* **Eligibility Checklist** and **Eligibility Criteria CRF** and complete and match.
* **Chart notes** to ensure complete and accurate
 |  |  |
|  | Provide reimbursement. |  |  |
|  | For enrolled participants, perform QC2 of all required CRFs into Medidata Rave.Required CRFs* ACASI Summary/ Tracking *(for Baseline ACASI)*
* Enrollment
* Enrollment Menstrual History
* Pelvic Exam
* Eligibility Criteria
* Specimen Storage
* STI Test Results
* Family Planning Summary
* Randomization
* Adherence Counseling
* Ring Insertion and Collection, or PrEP Provisions and Returns Log *(per participant’s study arm)*

*As needed:** Ring Assessment or Tablet Assessment *(per participant’s study arm)*
* Vital Signs
* Physical Exam
* Social Impacts Log
* Social Benefits Log
* Concomitant Medications Log
* Baseline Medical History Log
* Laboratory Results
* Family Planning Log

Paper Forms:* Eligibility Checklist
* Enrollment Behavioral Eligibility Worksheet
* HIV Pre-/Post-Test and Risk Counseling Worksheet
* Contraceptive Counseling Worksheet
* Adherence Counseling Worksheet
* Pelvic Exam Diagrams
* Safety Labs Calculator
* MTN-034 Prescription
* Participant-Specific Clinic Study Product Accountability Log
* LDMS Specimen Tracking Sheet
* Qualitative Participation Log (QPL)
* Clinic Study Product Destruction Log (as applicable)
* Visit Calendar Tool
 |  |  |