**Instructions:** Complete staff initials next to procedures completed. 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 **MOTHER** identity and age per site SOPs. * ≥ 18 years of age 🡪CONTINUE.
* < 18 years of age 🡪STOP. NOT ELIGIBLE.
 |  |  |
|  | Confirm **INFANT** identity and age per site SOPs. * Between 6-12 weeks of age (inclusive) 🡪CONTINUE.
* Not between 6-12 weeks of age (inclusive)🡪 STOP. NOT ELIGIBLE.
 |  |  |
|  | Check for co-enrollment in other studies per site SOPs:* NOT enrolled in another study 🡪 CONTINUE.
* Enrolled in another study 🡪 STOP. ASSESS ELIGIBILITY.
 |  |  |
|  | Confirm participants are within 35-day screening window* WITHIN 35 days from screening visit 🡪 CONTINUE.
* OUTSIDE 35 days from screening visit 🡪STOP. Not eligible to enroll during this screening attempt 🡪 If willing and infant still within appropriate age window, 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 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.  |  |  |
|  | Assess behavioral eligibility by administering the **Enrollment Behavioral Eligibility Worksheet.*** ELIGIBLE 🡪 CONTINUE.
* NOT ELIGIBLE 🡪 STOP.
 |  |  |
|  | **MOTHER**: Collect urine (15-60 mL) and perform tests:* Pregnancy
* Dipstick urinalysis and/or culture per site SOP, ***if indicated***
	+ N/A

Document on **Urine Test Results CRF***, if indicated* |  |  |
|  | Administer and document HIV pre-test counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet**. |  |  |
|  | **MOTHER**: Collect the following amounts of blood and send to lab for testing/storage:* HIV-1 (local lab)
	+ [X] mL [color] top [additive] tube
* Plasma archive (MTN LC)
	+ 10 mL purple top EDTA tube
* DBS for baseline TFV-DP and FTC-TP drug levels (testing lab)
	+ 4 mL purple top EDTA tube

*If indicated:** Syphilis serology (local lab)
	+ [X] mL [color] top [additive/no additive] tube

Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Tracking Sheet**. |  |  |
|  | Perform and document two rapid HIV test(s) per site SOPs and complete HIV test results and post-testing actions (including 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. Per standard of care and if participant allows, collect blood and perform an HIV confirmation and refer participant to local treatment of care.
 |  |  |
|  | * 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
 |  |  |
|  | **MOTHER**: Review study contraception requirements, and provide contraceptive counseling. Effective study methods per study protocol include: * hormonal methods (except contraceptive ring)
* intrauterine device (IUD)
* surgical sterilization
* Meets contraceptive requirements🡪 CONTINUE.
* DOES NOT meet contraceptive requirements 🡪 STOP. NOT ELIGIBLE.

[Prescribe/provide/refer for] contraception if needed; document in chart notes and/or **Contraceptive Counseling Worksheet.** Document hormonal methods/IUDs on the **Concomitant Medications Log CRF.** |  |  |
|  | **MOTHER**: Administer the **Feeding Assessment – Screening and Enrollment CRF**. |  |  |
|  | Review/update baseline **MOTHER** medical, medications (including medicated vaginal products) history. Update **INFANT** baseline medical, medications history and review any available pediatric care records. Complete**:*** **Baseline Medical History Y/N and Log CRFs** for **MOTHER** and **INFANT**
* **Concomitant Medications Y/N and Log CRFs,** if applicable for **MOTHER** and **INFANT**
* **Relevant source documents**
 |  |  |
|  | **MOTHER**: Administer **Edinburgh Postnatal Depression Scale CRF.** Refer for counseling/support, if needed. If after further clinical assessment, diagnosis of depression and/or other mental health conditions are made, record on the **Baseline Medical History Log**.  |  |  |
|  | **MOTHER**: Assess whether the participant has inserted anything in her vagina since her last visit. Document use of non-medicated gels, water, soap, dry materials (such as paper, ashes, or powders), and any other materials inserted vaginally on a **Vaginal Practices CRF**.*Note: Use of vaginal medication(s) or other vaginal products within five days prior to enrollment is exclusionary. All medicated vaginal products (including prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations which are intended to function as medication) used outside of this window should be recorded on the* ***Concomitant Medications Log.*** |  |  |
|  | **MOTHER:** Perform targeted physical exam*.* As applicable complete **Vital Signs CRF** and **Physical Examination CRF**  |  |  |
|  | Perform and document a pelvic exam and collect pelvic specimens per the Pelvic Exam Checklist. Document on Pelvic Exam Diagrams and Pelvic Exam CRF. |  |  |
|  | Determine whether participant has current RTI/STI/cervicitis/UTI symptoms:* 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.
 |  |  |
|  | **INFANT:** Perform targeted physical exam and complete **Infant Vital Signs CRF** and **Physical Examination CRF.** |  |  |
|  | Administer the appropriate **Ages and Stages Questionnaire** and complete **Infant Ages and Stages Assessment CRF** for **INFANT** |  |  |
|  | Evaluate findings identified during pelvic (for mother), and physical examinations and medical history review. Document in chart notes and update **MOTHER** and **INFANT Concomitant Medications Log** **CRF**, if applicable. Document ongoing conditions on the **Baseline** **Medical History Log** **CRF** for **MOTHER** and **INFANT.** Provide and explain all available findings and results to participant. Refer for other findings as indicated. |  |  |
|  | Provide protocol adherence counseling using the *MTN-043 Protocol Counseling Guide.* 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 participants are:
	+ 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 **Inclusion/Exclusion Criteria CRF** for **MOTHER** and **Infant Inclusion/Exclusion Criteria CRF** for **INFANT**
 |  |  |
|  | Verify participant eligibility by review/sign-off on **Eligibility Checklist** (must be different staff member than who confirmed eligibility): * ELIGIBLE ⇒ CONTINUE
* NOT ELIGIBLE ⇒ STOP. DO NOT RANDOMIZE. Provide clinical management as needed.
 |  |  |
|  | Randomize the participants as follows: * Complete the **Inclusion/Exclusion Criteria CRF** for **MOTHER** and **Infant Inclusion/Exclusion Criteria CRF** for **INFANT** *(within the Screening Visit Folder).*
* Complete the **Randomization** for **MOTHER**.
* Return to the Participant Type CRF and complete for both **MOTHER** and **INFANT**

Once the mother randomization date and time auto-populates on the Randomization CRF, the mother is randomized. ONCE A THE MOTHER IS RANDOMIZED, SHE AND THE INFANT ARE OFFICIALLY ENROLLED IN THE STUDY. |  |  |
|  | Confirm study product to be provided based on randomized group assignment, as auto-populated on the **Enrollment CRF**:* DPV Ring
* Oral Truvada

Complete the **MTN-043** **Prescription** for the participant’s product 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.
 |  |  |
|  | Complete **Enrollment CRF** for **MOTHER** and **INFANT.** |  |  |
|  | Review the QPL Slot List along with the participant’s product assignment and EPDS score to determine if participant should be invited for an IDI. Invite and explain IDI process, if slot is available. Update outcome on Enrollment CRF and QPL. |  |  |
|  | Inform participant of product assignment. Administer **Baseline Behavioral Assessment CRF** and **COVID Behavioral Assessment CRF** before the participant receives study product**.**  |  |  |
|  | Conduct product adherence counseling using the Counseling Flipchart for the assigned study product. Document using the **Adherence Counseling Worksheet** or in chart notes**.** |  |  |
|  | **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
* Review and provide **Ring Use Instructions and Important Information Sheet**. 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 ring to the participant using Participant-Specific **Clinic Study Product Accountability Log,** the **Ring Insertion and Removal CRF,** and the **Ring Assessment CRF,** if applicable.
 |  |  |
|  | **For participants assigned to oral Truvada:*** N/A (if not assigned to oral Truvada)
* Review and provide **Oral Truvada Use Instructions and Important Information Sheet**.
* Provide participant with one month’s supply of oral Truvada
* Instruct participant to self-administer one pill by mouth and observe dose administration**.**
* Document the provision of oral Truvada to the participant on the **Participant-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. Print and file in participant binder. |  |  |
|  | Schedule the 1-week Visit (V3) and 2-Week Visit (V4) using **Visit Calendar Tool.*** Provide contact information and instructions to report symptoms, start of labor, and/or request information, counseling, a new ring/pills (if applicable), or condoms before next visit.
 |  |  |
|  | Update **Screening and Enrollment Log.** |  |  |
|  | For enrolled participants, perform QC1: while participant is still present, review the following for completion and clear documentation:**MOTHER**:* **Enrollment Behavioral Eligibility Checklist**, **Eligibility Checklist** and **Inclusion/Exclusion Criteria CRF** are complete and match.
* **LDMS Specimen Tracking Sheet** and **Specimen Storage CRF**
* **Baseline Medical History Log, Vaginal Practices,** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently
* **Feeding Assessment/Inventory CRFs, Behavioral Assessment – Baseline CRF**
* **Clinic Study Product Accountability Log** and **PrEP Provisions and Returns/Ring Collection and Insertion CRFs, Tablet/Ring Assessment CRF** are complete and match
* **Chart notes**

**INFANT*** **Infant Vital Signs CRF** and **Physical Examination CRF**
* **Baseline Medical History Log,** and **Concomitant Medications Log** **CRF**s to ensure all conditions and medications are captured consistently.
* **Infant Ages and Stages CRF**
* **Chart notes**.
 |  |  |
|  | Provide reimbursement. |  |  |
|  | For enrolled participants, perform QC2 of all required CRFs in Medidata Rave.**MOTHER**:Required CRFs* Enrollment
* Inclusion/Exclusion Criteria *(located in Screening Visit folder)*
* Feeding Assessment – Screening and Enrollment
* Edinburgh Postnatal Depression Scale
* Pelvic Exam
* Specimen Storage
* Vital Signs
* Physical Exam
* Baseline Behavioral Assessment
* COVID Behavioral Assessment
* Randomization
* Ring Insertion and Collection, or PrEP Provisions and Returns Log *(per participant’s study arm)*
* Ring Assessment or Tablet Assessment *(per participant’s study arm)*

*As needed:** Concomitant Medications Log
* Baseline Medical History Log
* Urine Test Results \*
* Vaginal Practices
* STI Test Results\*

Paper Forms:* Eligibility Checklist
* Screening and Enrollment Log
* Enrollment Behavioral Eligibility Worksheet
* HIV Pre-/Post-Test and Risk Counseling Worksheet
* Adherence Counseling Worksheet
* Contraceptive Counseling Worksheet
* Pelvic Exam Diagrams
* MTN-043 Prescription
* Participant-Specific Clinic Study Product Accountability Log
* LDMS Specimen Tracking Sheet
* Visit Calendar Tool
* EPDS Worksheet

**INFANT**Required CRFs* Enrollment
* Infant Inclusion/Exclusion Criteria *(located in Screening Visit folder)*
* Physical Examination
* Infant Vital Signs
* Infant Ages and Stages Assessment

*As needed** Concomitant Medications YN/Log (if medications are reported)
* Baseline Medical History YN/Log (if pre-existing conditions are reported)

Paper form: * Ages and Stages Questionnaire

*\*CRFs/Tools to be completed when lab results are available*For failed screening attempts, the only CRFs that requires completion are the Informed Consent (Mother and Infant) and the **Inclusion/Exclusion Criteria** and **Infant Inclusion/Exclusion Criteria CRFs**. Other CRFs that were completed during the failed screening attempt up until the point that ineligibility was determined may remain in the study database. |  |  |