**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.

| **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
|  | Confirm identity and PTIDs |  |  |
|  | Check for co-enrollment in other studies per site SOPs:* NOT enrolled in another study ⇒ CONTINUE.
* Enrolled in another study ⇒ STOP. Consult the PSRT regarding on-going product use and safety considerations.
 |  |  |
|  | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
|  | Review/update locator information using site-specific form. |  |  |
|  | Provide available test results from previous visit. Treat and/or refer for care as required. |  |  |
|  | Complete the **Follow-up Visit Y/N CRFs** for **MOTHER** and **INFANT** |  |  |
|  | **MOTHER**: ***If indicated,*** collect urine (15-60 mL) and perform tests:* Pregnancy
* Dipstick urinalysis
* Culture per site SOP

Document on **Pregnancy Test Results CRF** and **Urine Test Results CRF.** |  |  |
|  | **MOTHER:** Administer **Behavioral Assessment CRF - Follow-up** per the participant’s visit number and the product she has been assigned:* Ring
* Tablet

Refer participant to counselor if requested. |  |  |
|  | **MOTHER:** Administer the **Ring Adherence Y/N, Ring Adherence CRFs** OR **Tablet Adherence Y/N, Tablet Adherence CRFs** per product assignment. |  |  |
|  | **MOTHER:** Administer the **Social Impact Y/N CRF.** Review/update **Social Impact Log CRFs**, as applicable. |  |  |
|  | **MOTHER**: Administer the **Feeding Assessment – Follow-up CRF** and complete the **Feeding Inventory** **CRF**, if applicable. |  |  |
|  | Collect follow-up medical/medications (including medicated vaginal products for mother) history, review pediatric care records and document any AEs; review update:* **Adverse Event Y/N and Adverse Event Log CRFs** for **MOTHER** and **INFANT**
* **Concomitant Medications Y/N and Log CRFs, if applicable** for **MOTHER** and **INFANT**
 |  |  |
|  | **MOTHER**: Administer **Edinburgh Postnatal Depression Scale CRF.** Calculate score using online tool (see SSP 7.9 for link). 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 **AE 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: 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) should be recorded on the* ***Concomitant Medications Log.*** |  |  |
|  | Provide contraceptive counseling. Document in chart notes and/or on **Contraceptive Counseling Worksheet.** |  |  |
|  | Administer and document HIV pre-testing and HIV/STI risk reduction 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:* HIV-1
	+ [X] mL [color] top [additive] tube
* Plasma for DPV (ring group)
* *N/A (Truvada group)*
	+ 4 mL Purple top (EDTA) tube
* Dried blood spot (DBS) for FTC-TP (Truvada group)
* *N/A (ring group)*
	+ 4 mL purple top (EDTA) tube

***If indicated:**** AST/ALT
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology
	+ [X] mL [color] top [additive/no additive] tube
* Complete blood count (CBC) with platelets
	+ [X] mL [color] top [additive] tube
* Blood creatinine (and calculated creatinine clearance) [weight must be taken for CrCl calculation]
	+ [X] mL [color] top [additive/no additive] tube

Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet.** |  |  |
|  | **MOTHER**: 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 ***or****,*
* If one test positive and one test negative = DISCORDANT ==> STOP. (Refer to MTN-043 HIV Confirmation and Seroconversion Procedure Guide for complete instructions.)

Document test results onto **HIV Test Results CRF** and **HIV Confirmatory Results CRF**, if applicable. |  |  |
|  | * Provide and document HIV post-test counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet**
* Offer condoms
 |  |  |
|  | **INFANT:** Collect the following amounts of blood and send to lab for testing:* Plasma for DPV (ring group)
* *N/A (Truvada group).*
	+ 2 mL Purple top (EDTA) tube
* Dried blood spot (DBS) for FTC-TP (Truvada group)
* *N/A (ring group)*
	+ 2 mL purple top (EDTA) tube

Document stored specimen collection on the **Infant Specimen Storage CRF** and **LDMS Specimen Tracking Sheet.**  |  |  |
|  | **MOTHER**: Collect breastmilk sample from mother and prepare for drug level testing. * Have mother fully express milk from one breast by hand or manual pump in to a cup or designated container. Review the Breast Milk Expression Guide.
* In the presence of the mother, swirl the sample to mix and transfer 2 ml each into 4 cryovials (8mL total) and send to lab.
* Offer any leftover milk to the mother in a sealed container.
	+ If mother keeps leftover milk, review the Expressed Milk Factsheet.
	+ Dispose of milk in presence of mother if she declines the leftover milk, per site practices.

Document sample collection on the **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet.** |  |  |
|  | Complete the **Follow-up Visit Summary CRF** for **MOTHER** and **Infant Follow-up Visit Summary CRF INFANT.** |  |  |
|  | **MOTHER**: ***If indicated****,* perform and document targeted physical exam. Complete **Vital Signs CRF** and **Physical Examination CRF**. |  |  |
|  | **MOTHER**: ***If indicated****,* perform and document a pelvic exam per the *Pelvic Exam Checklist*. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.** |  |  |
|  | **INFANT:** ***If indicated****,* perform targeted physical exam and complete **Infant Vital Signs CRF** and **Physical Examination CRF.**  |  |  |
|  | Evaluate findings identified during pelvic and physical examinations and/or medical history review. Document in chart notes and update **Concomitant Medications Log, AE Y/N** and **Log** **CRFs**, and **Baseline Medical History CRF** if applicable, and document ongoing conditions on **AE Log** for **MOTHER** and **INFANT.** |  |  |
|  | Provide and explain all available findings and results to participant. Refer for other findings as indicated. ***If indicated****,* treat for STI/RTI/UTI per site SOP. |  |  |
|  | Conduct product adherence counseling using the Counseling Flipchart for the assigned study product. Document on Adherence Counseling Worksheet or in chart notes**.** |  |  |
|  | **MOTHER**: Collect study product from last month’s use as applicable: * N/A no product returned.

**If ring used last month:** * N/A (if not using ring)

Have participant (or clinician/designee) remove used ring. Collect used ring, send to lab for storage, and document on **Participant-Specific Clinic Study Product Accountability Log,** and **Ring Insertion and Removal CRFIf oral Truvada used last month:*** N/A (if not using oral Truvada)

Collect study oral Truvada bottle with any unused Truvada and send back to pharmacy, if applicable. Document on **Participant-Specific Clinic Study Product Accountability Log** and **PrEP Provisions and Returns CRF.** |  |  |
|  | **MOTHER**: complete the **Study Product Request Slip** per the participant’s product use assignment for the following 4 weeks. * Deliver the top (white) copy to the pharmacy.
* Retain yellow copy of the slip in participant’s binder.
 |  |  |
|  | **MOTHER**: **for participants assigned to the ring**:* N/A (if not assigned to ring or not receiving a new 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*, if indicated*
* 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.
 |  |  |
|  | **MOTHER**: **for participants using the oral Truvada:*** N/A (if not using or not receiving new oral Truvada)
* Provide study oral Truvada use instructions and review important information.
* 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.
 |  |  |
|  | Provide protocol counseling using the *MTN-043 Protocol Counseling Guide.* Document any questions or issues on this checklist or in chart notes. |  |  |
|  | At Month 2 Visit Only: Check QPL to determine if participant had been purposively selected for a IDI and accepted invitation. If yes, inform her the interview will take place between her Month 3 and SEV. Confirm her willingness to participant and document outcome in QPL. |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation (for both mother and infant unless otherwise indicated):* **LDMS Specimen Tracking Sheet**, **Specimen Storage CRFs**
* **AE Logs, Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Edinburgh Postnatal Depression Scale CRF (Mother)**
* **Behavioral Assessment, Ring/Tablet Adherence, Ring/Tablet Assessment, Social Impacts CRFs (Mother)**
* **Feeding Assessment/Inventory (Mother)**
* **Chart notes**
 |  |  |
|  | Schedule next visit. * Provide contact information and instructions to report symptoms or delivery and/or request information, counseling, a new ring/pills, or condoms before next visit.
* Offer condoms if not already done.
 |  |  |
|  | Provide reimbursement. |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:**MOTHER**Required CRFs* Follow-up Visit Y/N, Follow-up Visit Summary
* Specimen Storage
* Feeding Assessment – Follow-up
* Edinburgh Postnatal Depression Scale
* Social Impact
* Behavioral Assessment – Follow Up
* Ring Adherence Y/N, Ring Adherence or Tablet Adherence Y/N, Tablet Adherence *(per participant’s study arm)*
* Ring Assessment or Tablet Assessment *(per participant’s study arm)*
* HIV Test Results
* Ring Insertion and Removal or PrEP Provisions and Returns *(per participant’s study arm)*

*As needed* * HIV Confirmatory Results
* Adverse Events Log
* Concomitant Medications Log
* Feeding Inventory
* Vital Signs
* Physical Examination
* Pelvic Exam
* STI Test Results\*
* Hematology \*
* Chemistry Panel\*
* Vaginal Practices
* Urine Test Results\*
* Pregnancy Test Results

Paper Forms:* LDMS Specimen Tracking Sheet
* HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet
* Contraceptive Counseling Worksheet
* Study Product Request Slip
* Participant-Specific Clinic Study Product Accountability Log
* Pelvic Exam Diagrams *If indicated/applicable*

**INFANT**Required CRFs* Follow-up Visit Y/N, Infant Follow-up Visit Summary
* Infant Specimen Storage

*As needed** Physical Examination
* Infant Vital Signs
* Concomitant Medications YN/Log (if medications are reported)
* Adverse Events log (if AEs reported)

*\*CRFs/Tools to be completed when lab results are available* |  |  |