**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 CRF** 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 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 CRF**, 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**: 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.*** |  |  |
|  | ***If indicated,*** provide contraceptive counseling. Document in chart notes and/or on **Contraceptive Counseling Worksheet.** |  |  |
|  | ***If indicated,*** 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:* 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:*** HIV-1
	+ [X] mL [color] top [additive] tube
* 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**: ***If indicated,*** 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. |  |  |
|  | ***If indicated**** Provide and document HIV post-test counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet**
* Offer condoms
 |  |  |
|  | **INFANT:** ***At Visit 4 only,*** collect the following amounts of blood and send to lab for testing:* Plasma for DPV (ring group only)
* *N/A (Truvada group).*
	+ 2 mL Purple top (EDTA) tube
* Dried blood spot (DBS) for PK (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 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 back 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.
 |  |  |
|  | 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 any pelvic and physical examinations and/or medical history review. Document in chart notes and update **Concomitant Medications Y/N and Log, and AE Y/N and Log** **CRFs**, 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**.** |  |  |
|  | Provide protocol counseling using the *MTN-043 Protocol Counseling Guide.* Document any questions or issues on this checklist or in chart notes. |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation:* **LDMS Specimen Tracking Sheet**, **Infant/Specimen Storage CRF**
* **AE Logs, Vaginal Practices, Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Ring/Tablet Adherence, Social Impacts CRFs**
* **Feeding Assessment/Inventory**
* **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
* Social Impact CRF
* Behavioral Assessment Follow-Up
* Ring Adherence Y/N, Ring Adherence *or* Tablet Adherence Y/N, Tablet Adherence

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

Paper Forms:* LDMS Specimen Tracking Sheet

*If indicated/applicable* * HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet
* Contraceptive Counseling Worksheet
* Pelvic Exam Diagrams

**INFANT**Required CRFs* Follow-up Visit Y/N, Infant Follow-up Visit Summary
* Infant Specimen Storage (Visit 4 only)

*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* |  |  |