**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. |  |  |
|  | 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 and/or culture per site SOP   Document on **Pregnancy Test Results CRF** and **Urine Test Results CRF,** if applicable. |  |  |
|  | **MOTHER:** Administer the **Social Impact Y/N CRF.** Review/update **Social Impact Log CRF**, as 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.*** |  |  |
|  | Provide contraceptive counseling. Document in chart notes and/or on **Contraceptive Counseling Worksheet.** |  |  |
|  | Provide PrEP counseling to discuss current local policies and access to PrEP following study exit for interested participants. Document in chart notes. |  |  |
|  | ***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)*    + 5 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 * Syphilis serology   + [X] mL [color] top [additive/no additive] tube * AST/ALT   + [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:** 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.   + Destroy in presence of mother if she declines the leftover milk.   Document sample collection on the **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet.** |  |  |
|  | **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 and sample collection 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**, 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. |  |  |
|  | Complete **Study Termination CRF** for **MOTHER** and **INFANT.** |  |  |
|  | Complete **Study Exit Worksheet** and Permission to Contact Log [and or sites specific tool]. As indicated per protocol, arrange future contact for follow-up on ongoing AEs. |  |  |
|  | Complete the **Follow-up Visit Summary CRF** for **MOTHER** and **Infant Follow-up Visit Summary CRF INFANT.** |  |  |
|  | 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 CRF** * **AE Logs, Vaginal Practices, Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated. * **Social Impacts CRFs (Mother)** * **Chart notes** |  |  |
|  | Schedule next contact, as needed. 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 * Social Impacts * Study Termination   *As needed*   * HIV Test Results * Pregnancy Test Results * Hematology\* * Chemistry Panel\* * Vital Signs * Physical Examination * Pelvic Exam * HIV Confirmatory Results * Adverse Events Log * Concomitant Medications Log * STI Test Results\* * Vaginal Practices * Urine Test Results\*   Paper Forms:   * LDMS Specimen Tracking Sheet * HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet (if indicated) * Contraceptive Counseling Worksheet * Pelvic Exam Diagrams*, if indicated*   **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* |  |  |