**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 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/or **INFANT**  \* If exiting at an interim visit, instead add an Interim Visit folder. |  |  |
|  | **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 CRF**  **If 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 **Discontinuation of Study Product Log CRF.** Complete Study Product Supply Slip as “Permanent Discontinuation” for the reason of early termination/withdrawal and send to pharmacy. |  |  |
|  | **MOTHER**: collect urine (15-60 mL) and perform tests:   * Pregnancy * Dipstick urinalysis and/or culture per site SOP, ***if indicated***   + N/A   Document on **Pregnancy Test Results CRF** and **Urine Test Results CRF, if applicable.** |  |  |
|  | **MOTHER:** Administer **Behavioral Assessment – Month 3 Follow Up CRF** 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 & TFV-DP (Truvada group) * *N/A (ring group)*    + 4 mL purple top (EDTA) 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   ***If indicated:***   * Syphilis serology   + [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 |  |  |
|  | Provide PrEP counseling to discuss current local policies and access to PrEP following study exit for interested participants. Document in chart notes. |  |  |
|  | **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.** |  |  |
|  | **MOTHER**: perform and document targeted physical exam. Complete **Vital Signs CRF** and **Physical Examination CRF**. |  |  |
|  | **MOTHER**: perform and document a pelvic exam and sample collection per the *Pelvic Exam Checklist*. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.** |  |  |
|  | **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 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** |  |  |
|  | Complete Permission to Contact Log [and or sites specific tool].  *For pregnant participants:* As indicated per protocol, confirm permission to contact participant upon pregnancy outcome and at the infant’s 1-year birthday, if born alive, to capture outcome information after study exit (tick all that apply):   * Participant permits contact upon pregnancy outcome and infant’s 1-year birthday for outcome information after study exit * Participant permits capture of outcome information for pregnancy and infant from medical records * **No,** participant does not permit any contact or capture of outcome information after study exit   Note: Contacts after study termination should be documented in the chart notes only with the exception of completion of the Pregnancy Outcome CRF and 1-Year Infant Assessment CRF, if termination was due to a pregnancy. Do not update any AE CRFs after participant termination. |  |  |
|  | Document reason for early termination in chart notes. |  |  |
|  | Complete the **Follow-up Visit Summary CRF** for **MOTHER** and **Infant Follow-up Visit Summary CRF INFANT,** or **Interim Visit Summary CRF**, as applicable. |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation (for both mother and infant unless otherwise noted):   * **LDMS Specimen Tracking Sheet**, **Specimen Storage CRF** * **AE Logs, Vaginal Practices (mother), Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated. * **Edinburgh Postnatal Depression Scale CRF (Mother)** * **Infant Ages and Stages CRF (Infant)** * **Behavioral Assessment, Ring/Tablet Adherence, Social Impacts CRFs (mother)** * **Feeding Assessment/Inventory (Mother)** * **Chart notes** |  |  |
|  | 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 Impacts * Behavioral Assessment– Month 3 Follow Up * Ring Adherence Y/N, Ring Adherence or Tablet Adherence Y/N, Tablet Adherence *(per participant’s study arm)* * HIV Test Results * Pregnancy Test Results * Hematology \* * Chemistry Panel\* * Vital Signs * Physical Examination * Pelvic Exam * Ring Insertion and Removal, or PrEP Provisions and Returns *(per participant’s study arm)* * *Study Termination*   *As needed*   * HIV Confirmatory Results * Adverse Events Log * Concomitant Medications Log * STI Test Results\* * Vaginal Practices * Urine Test Results\* * IDI Tracking * Discontinuation of Study Product   Paper Forms:   * LDMS Specimen Tracking Sheet * HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet * Contraceptive Counseling Worksheet * Participant-Specific Clinic Study Product Accountability Log * Pelvic Exam Diagrams   **INFANT**  Required CRFs   * Follow-up Visit Y/N, Infant Follow-up Visit Summary * Infant Specimen Storage * Physical Examination * Infant Vital Signs * Infant Ages and Stages Assessment   *As needed*   * Concomitant Medications YN/Log (if medications are reported) * Adverse Events log (if AEs reported)   Paper form:   * Ages and Stages Questionnaire   *\*CRFs/Tools to be completed when lab results are available* |  |  |