**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 PTID |  |  |
|  | 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 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. |  |  |
|  | Confirm participant is   * Pre-pregnancy outcome 🡪 Complete the **Follow-up Visit Y/N- Pre-PO\*** * Post pregnancy outcome 🡪 Complete the **Follow-up Visit Y/N\***   \* If exiting at an interim visit, instead add an Interim Visit folder. |  |  |
|  | ***If Pre-PO,*** confirm plans to deliver at a hospital/delivery facility. Update [site-specific form or chart notes] with any changes. |  |  |
|  | ***If applicable,*** Collect all study product still in participant’s possession as applicable:   * N/A, no product returned at this visit*.*   **For ring users:** Collect used ring, send to lab for storage, and document on **Participant-Specific Clinic Study Product Accountability Log, Specimen Storage CRF**, and **Ring Insertion and Removal CRF.**  **If pill users:** Collect study pill bottle with any unused pills and send back to pharmacy, if applicable. Document on **Participant-Specific Clinic Study Product Accountability Log** and **PrEP Provisions and Returns CRF.** |  |  |
|  | ***If applicable,*** complete **Study Product Request Slip** by marking “Permanent Discontinuation” for the reason of early termination/withdrawal and send to pharmacy. Complete **Discontinuation of Study Product CRF.** |  |  |
|  | Have participant self-collect 5 swabs for:   * NAAT for GC/CT/Trich (local lab) * Microbiota analysis – qPCR (MTN LC) * pH assessment (local lab) * Gram stain (MTN LC) – *note: can be done from pH swab*   + Roll swab across two labeled slides and air dry. * Biomarker analysis (MTN LC)   *NOTE: Refer to self-collection instructions sheet as needed. May be done by clinician, if preferred by participant. If pelvic exam is done during the visit, collect all swabs during the exam.* |  |  |
|  | ***If Post-PO,*** offer pregnancy test.  Collect urine (15-60 mL) and perform tests:   * Dipstick urinalysis * Culture per site SOP * Pregnancy (optional)   + N/A *(declined test)*   Document on **Urine Test Results CRF.** |  |  |
|  | Collect/review medical, obstetric, medications (including medicated vaginal products) history, and AEs:   * **If pre-PO:** ultrasound, antenatal * **If post-PO:** delivery, postpartum care records including for infant health, anthropometry, feeding history. Complete **Pregnancy Outcome CRF,** *if first visit since PO.* * Document findings, including any AEs on **Adverse Event Y/N and Log CRFs, Non-enrolled Infant Adverse Event Y/N and Log CRFs** [for any newly reported AEs on non-enrolled infant], and **Concomitant Medications Log CRF,** as needed.   Does the participant have any AEs that meet protocol requirements for follow-up after study exit?   * Yes 🡪 document follow-up plan in chart notes * No |  |  |
|  | Since her last visit, has the participant inserted anything in her vagina? Please include non-medicated gels, water, soap, dry materials (such as paper, ashes, or powders), and any other materials inserted vaginally. If yes, complete 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*** |  |  |
|  | Administer the **Social Benefits CRF** and **Social Impact CRF** and complete **Social Impact Y/N and Log CRFs**, as applicable. |  |  |
|  | Administer Edinburgh Postnatal Depression Scale (**EPDS) workshee**t (in Excel) and calculate score. Print and sign worksheet and complete the **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 **AE Log**. |  |  |
|  | ***If Post-PO,*** provide contraceptive counseling and offer/prescribe contraceptives as necessary. 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**. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:   * 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 CCr calculation]   + [X] mL [color] top [additive/no additive] tube |  |  |
|  | Perform and document two rapid HIV test(s) per site SOPs and complete HIV test results and post-testing actions (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-042 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 |  |  |
|  | ***If indicated,*** perform and document targeted physical exam. Complete **Vital Signs CRF** and **Physical Examination CRF**. |  |  |
|  | ***If indicated****,* perform and document a pelvic exam per the Pelvic Exam Checklist. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.** |  |  |
|  | Evaluate findings identified during physical examinations and 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** and/or **Non-enrolled Infant AE Log** *(in respective infant and mother folders).* |  |  |
|  | Provide and explain all available findings and results of infant and herself to participant. Refer for other findings as indicated.  ***If indicated****,* treat for STI/RTI/UTI per site SOP. |  |  |
|  | Provide relevant protocol adherence counseling using the *MTN-042 Protocol Adherence Counseling Guide.* Document any questions or issues on this checklist or in chart notes. |  |  |
|  | Complete **Study Termination CRF** |  |  |
|  | Complete Permission to Contact Log [and or sites specific tool].  As indicated per protocol, confirm permission to contact participant upon PO (if terminating pre-PO) and periodically up to one year after their PO to obtain information about their pregnancy and their infant’s health may occur after study exit (tick all that apply):   * Participant permits periodic contact up to one year to capture PO and any information about infant’s health after study exit * Participant permits capture of health information from medical records * **No,** participant does not permit any contact or obtain pregnancy nor infant health 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. Do not update any AE CRFs after participant termination.  Confirm intent to enroll/or keep infant in study follow-up and provide contact information and instructions for further contact.   * Infant to enter study upon birth, or if already enrolled, to remain in follow-up * Infant will not enter study upon birth or, if already enrolled, also terminating early |  |  |
|  | Document reason for early termination in chart notes. |  |  |
|  | Complete the **Follow-up Visit Summary CRF, Interim Visit Summary CRF** or **Interim Visit Summary CRF,** as applicable. |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation:  **Mother:**   * **LDMS Specimen Tracking Sheet**, **Specimen Storage CRF** * **AE Logs** and **Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated. * **Chart notes** * **HIV results, Urine Test Results CRFs** * **Social Impact Log CRF** |  |  |
|  | Provide reimbursement. |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:  **MOTHER**  Required CRFs   * HIV Test Result * STI Test Results\* * Hematology Results \* * Chemistry Panel\* * Specimen Storage * Urine Test Results * Study Termination * Social Impacts * Social Benefits   *As needed*   * Follow-up Visit Y/N * Follow-up Visit Summary * Interim Visit Summary * HIV Confirmatory Results * Adverse Events Log or Non-Enrolled Infant Adverse Events Log * Concomitant Medications Log * Social Impact Log * Vital Signs * Physical Exam * Pelvic Exam * Ring Insertion and Removal, or PrEP Provisions and Returns *(per participant’s study arm)* * Discontinuation of Study Product   *\*CRFs to be completed when lab results are available*  Paper Forms:   * LDMS Specimen Tracking Sheet * HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet * Contraceptive Counseling Worksheet * EPDS Worksheet   *If indicated/applicable*   * Pelvic Exam Diagram * Study Product Request Slip * Participant-Specific Clinic Study Product Accountability Log |  |  |