**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.

**NOTE:** The 4-week visit procedure schedule varies for the 1st 4-week visit and for 4-week visits corresponding to a specific gestational age. Gestational age at the current visit in weeks should be documented in item 2 below and visit procedures completed on the following schedule:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **1st 4-week visit** | **4-week Visit Corresponding to a Gestational Age of:** | | | | | | | | |
| **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** |
| **Follow-up BA CRF and Ring/Tablet Adherence CRFs** | X |  |  |  |  |  | X | | | |
| **Social Impact CRFs** | X |  |  |  |  |  | X | | | |
| **EPDS CRF** |  |  |  | X | | | |  |  |  |
| **Urine Dipstick (and/or culture, per SOC)** | X | X | | | |  |  |  |  |  |
| **AST/ALT** | X | X | | | |  |  |  |  |  |
| **CBC** | X | X | | | |  |  |  |  |  |
| **Creatinine/CrCl** | X | X\*\*\*  \*\*\*At Week 16 (V18.0) for participants who enrolled between 12-20 weeks gestation only | | | | | | | | |

| **Procedure** | | **Staff Initials** | **Comments:** |
| --- | --- | --- | --- |
|  | Confirm identity and PTID |  |  |
|  | Verify the participants gestational age in weeks at this visit (the visit calendar can be referenced for this information). Complete procedures required for this 4-week visit based on gestational age as outlined in the table above  **Participant Gestational Age at this visit (weeks): \_\_\_\_\_\_\_** |  |  |
|  | Check for co-enrollment in other studies per site SOPs:   * NOT enrolled in another study Þ CONTINUE. * Enrolled in another study Þ 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- Pre-PO CRF** |  |  |
|  | ***At 1st 4-week visit (v6.0) and the 4-week visit corresponding to a gestational age of 33, 34, 35, or 36 weeks:*** Complete **Tablet Adherence Y/N** and **Tablet Adherence CRF** (if applicable) or **Ring Adherence Y/N** and **Ring Adherence CRF** (if applicable), per product assignment |  |  |
|  | ***At 1st 4-week visit (v6.0) and the 4-week visit corresponding to a gestational age of 33, 34, 35, or 36 weeks:*** Administer **Follow-up Behavioral Assessment CRF** |  |  |
|  | ***At 1st 4-week visit (v6.0) and the 4-week visit corresponding to a gestational age of 33, 34, 35, or 36 weeks:*** Administer **Social Impact CRF** and complete **Social Impact Y/N and Log CRFs**, as applicable. |  |  |
|  | ***At the 4-week visit that corresponds with a gestational age of 30, 31, 32, or 33 weeks:*** Administer **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 the **Adverse Event Log.** |  |  |
|  | Have participant self-collect swabs for:   * Microbiota analysis – qPCR (MTN LC) (2 swabs) * Gram stain (MTN LC)   + 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. Ring should remain in place during collection, unless participant has been put on clinical hold. If pelvic exam is done during the visit, collect all swabs during the exam.* |  |  |
|  | ***At 1st 4-week visit (v6.0) and the 4-week visit corresponding to a gestational age of 28, 29, 30 or 31 weeks\*:*** collect urine (15-60 mL) and perform tests.   * Dipstick urinalysis * Culture per site SOP   Document on **Urine Test Results CRF.**  \*if indicated at any other visit |  |  |
|  | Collect follow-up medical/ultrasound/antenatal/obstetric/medications (including medicated vaginal products) history and document any AEs; review update:   * **Adverse Event Y/N and Adverse Event Log CRFs** * **Concomitant Medications Y/N and Concomitant Medications Log CRFs** * **Ultrasound Results CRF** |  |  |
|  | 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 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:  **Required at all visits** **(select one):**   * **Ring group:** Plasma for DPV - 5 mL Purple top (EDTA) tube   **OR**   * **Truvada group:** Dried blood spot (DBS) for PK **-** 4 mL purple top (EDTA) tube   **Required at all visits (all participants):**   * HIV-1   + [X] mL [color] top [additive] tube   ***Required at* *1st 4-week visit (v6.0) and the 4-week visit corresponding to a gestational age of 28, 29, 30 or 31 weeks\*:***   * AST/ALT   + [X] mL [color] top [additive/no additive] tube * Complete blood count (CBC) with platelets   + [X] mL [color] top [additive] tube   ***Required at* *1st 4-week visit (v6.0) and at week 16 (v18.0) for participants who enrolled between 12-20 weeks gestation only\*:***   * Blood creatinine (and calculated creatinine clearance) [weight must be taken for CrCl calculation]   + [X] mL [color] top [additive/no additive] tube   **If indicated at all visits:**   * Syphilis serology   + [X] mL [color] top [additive/no additive] tube   Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet.**  \*if indicated at any other visit type |  |  |
|  | 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 à CONTINUE. * If both tests positive = INFECTEDà STOP ***or****,* * If one test positive and one test negative = DISCORDANTà 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 |  |  |
|  | Perform and document targeted physical exam. Complete **Vital Signs CRF** and **Physical Examination CRF**. |  |  |
|  | Perform obstetric abdominal exam and complete **Obstetric abdominal Exam 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 any pelvic, obstetric 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. Document ongoing conditions on **AE Log**. |  |  |
|  | 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**.** |  |  |
|  | Collect study product from last month’s use:   * **If 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:** 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.** |  |  |
|  | Complete the **Study Product Request Slip** per the participant’s product use assignment.   * Deliver the top (white) copy to the pharmacy. * Retain yellow copy of the slip in participant’s binder. |  |  |
|  | **For participants assigned to 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/review ring use instructions and 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* * Complete entry on the **Participant-Specific Clinic Study Product Accountability Log** and **Ring Insertion and Removal CRF,** and **Ring Assessment CRF** |  |  |
|  | **For participants assigned to oral Truvada:**   * N/A (if not using or not receiving new oral Truvada) * Provide/review study oral Truvada use instructions and 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**.** * Complete entry on the **Participant-Specific Clinic Study Product Accountability Log** and **PrEP Provisions and Returns CRF,** and **Tablet Assessment CRF** |  |  |
|  | Provide protocol counseling using the *MTN-042 Protocol Counseling Guide.* Document any questions or issues on this checklist or in chart notes. |  |  |
|  | If participant has been selected for an IDI (check **Enrollment CRF**) or may be invited to a special case IDI, ensure relevant qualitative team members are aware and confirm if interview has been scheduled. NOTE: For Cohort 3, the IDI should be scheduled near 36 weeks gestation and after a minimum of 4 weeks of product use. Complete **IDI Tracking CRF** once interview is done. |  |  |
|  | Complete the **Follow-up Visit Summary CRF.** |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation:   * **LDMS Specimen Tracking Sheet**, **Specimen Storage CRF** * **AE Logs, and Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated. * **Participant-Specific Clinic Study Product Accountability Log** and **Ring Insertion and Removal** or **PrEP Provisions and Returns CRF** are consistently completed, if needed. * **Chart notes** * **Obstetric abdominal Exam** |  |  |
|  | 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:  Required CRFs   * Follow-up Visit Y/N – Pre-PO * Follow-up Visit Summary * Chemistry Panel (at v6.0 (all participants), at gestational age of 28, 29, 30 or 31 weeks (AST/ALT), AND at v18.0/Week 16 for participants enrolled between 12-20 weeks only (Creatinine) * Edinburgh Postnatal Depression Scale (at gestational age of 30, 31, 32, or 33 weeks) * Follow-up Behavioral Assessment (at v6.0 (all participants) AND at gestational age of 33, 34, 35, or 36 weeks) * Hematology (at v6.0 (all participants), at gestational age of 28, 29, 30 or 31 weeks) * HIV Test Results * Obstetric Abdominal Exam * Physical Exam * Ring Adherence Y/N OR Tablet Adherence Y/N (at v6.0 (all participants) AND at gestational age of 33, 34, 35, or 36 weeks) * Ring Assessment OR Tablet Assessment * Ring Insertion and Removal OR PrEP Provisions and Returns * Social Impact (at v6.0 (all participants) AND at gestational age of 33, 34, 35, or 36 weeks) * Specimen Storage * Vital Signs * Urine Test Results (at v6.0 (all participants) AND at gestational age of 28, 29, 30 or 31 weeks)   *As needed:*   * Social Impact Log * HIV Confirmatory Results * Adverse Events Log * Concomitant Medications Log * Pelvic Exam * STI Test Results * Discontinuation of Study Product * Product Hold Log * IDI Tracking * Vaginal Practices * Ultrasound Results   Paper Forms:   * LDMS Specimen Tracking Sheet * HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet * Study Product Request Slip * Participant-Specific Clinic Study Product Accountability Log * Pelvic Exam Diagrams (If indicated/applicable) * Pelvic Exam Checklist (If indicated/applicable) |  |  |