**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 |  |  |
|  | Based on the participant’s visit calendar, is this their 2nd bi-weekly visit?* YES 🡪 note procedures throughout checklist that are required at the ***2nd bi-weekly visit***
* NO
 |  |  |
|  | 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. |  |  |
|  | Confirm plans to deliver at a hospital/delivery facility. Update [site-specific form or chart notes] with any changes. |  |  |
|  | 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**  |  |  |
|  | 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.* |  |  |
|  | ***If indicated,*** collect urine (15-60 mL) and perform tests:* Dipstick urinalysis
* Culture per site SOP

Document on **Urine Test Results CRF.** |  |  |
|  | 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..*** |  |  |
|  | ***At the 2nd bi-weekly visit\*,*** provide contraceptive counseling to discuss what methods the participant may want to initiate after delivery. Document in chart notes and/or on **Contraceptive Counseling Worksheet.**\*if indicated at other biweekly visits |  |  |
|  | ***At the 2nd bi-weekly visit\*,*** 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**.\*if indicated at other biweekly visits |  |  |
|  | Collect the following amounts of blood and send to lab for testing:**Required (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 *the 2nd biweekly visit\**** * HIV-1
* *N/A for other biweekly visits*
	+ [X] mL [color] top [additive] tube

**If indicated at all visits:*** Blood creatinine (and calculated creatinine clearance) [weight must be taken for CrCl calculation]
	+ [X] mL [color] top [additive/no 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

Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Specimen Tracking Sheet.**\*if indicated at other biweekly visits |  |  |
|  | ***At the 2nd bi-weekly visit\*,*** 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-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.\*if indicated at other biweekly visits |  |  |
|  | ***At the 2nd biweekly visit\*,*** Provide and document HIV post-test counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet*** Offer condoms

\*if indicated at other biweekly visits |  |  |
|  | ***If indicated****,* 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**.** |  |  |
|  | ***If indicated (e.g. participant is due for a resupply of product or a product hold has been initiated),*** collect study product from last month’s use as applicable: * N/A no product returned.
* **If ring used last month:** 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:** 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.**
 |  |  |
|  | ***If indicated (e.g. participant is due for a resupply of product),*** complete the **Study Product Request Slip** per the participant’s product use assignment for the following 4 weeks/until delivery. * Deliver the top (white) copy to the pharmacy.
* Retain yellow copy of the slip in participant’s binder.
 |  |  |
|  | ***If indicated (e.g. participant is due for a resupply of product),* for participants assigned to the 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**
 |  |  |
|  | ***If indicated, (e.g. participant is due for a resupply of product),* for participants using the 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**
 |  |  |
|  | Provide protocol adherence counseling using the *MTN-042 Protocol Adherence Counseling Guide.* Document any questions or issues on this checklist or in chart notes. |  |  |
|  |  |  |  |
|  | 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,Ring Insertion and Removal** or **PrEP Provisions and Returns CRF, and Ring Assessment or Tablet Assessment** 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
* Specimen Storage
* Obstetric abdominal Exam
* HIV Test Results *(2nd bi-weekly visit only, if indicated at other biweekly visits)*

*As needed* * HIV Confirmatory Results
* Adverse Events Log
* Concomitant Medications Log
* Vital Signs
* Physical Examination
* Pelvic Exam
* STI Test Results
* Chemistry Panel\*
* Hematology\*
* Ring Insertion and Removal, or PrEP Provisions and Returns *(per participant’s study arm)*
* Discontinuation of Study Product
* Product Hold Log
* IDI Tracking
* Ring Assessment or Tablet Assessment *(per participant’s study arm)*
* Ultrasound Results
* Urine Test Results\*
* Vaginal Practices

*\*CRFs/Tools to be completed when lab results are available*Paper Forms:* LDMS Specimen Tracking Sheet
* HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet *(V10.0 only, if indicated at other biweekly visits)*
* Contraceptive Counseling Worksheet *(V10.0 only, if indicated at other biweekly visits)*

*If indicated/applicable* * Pelvic Exam Diagrams
* Pelvic Exam Checklist
* Study Product Request Slip
* Participant-Specific Clinic Study Product Accountability Log
 |  |  |