**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, age, and PTID |  |  |
|  | Check for co-enrollment in other studies per site SOPs:   * NOT enrolled in another study 🡪 CONTINUE. * Enrolled in another study 🡪 STOP. ASSESS ELIGIBILITY. |  |  |
|  | Confirm participant is within 35-day screening window   * WITHIN 35 days from screening visit 🡪 CONTINUE. * OUTSIDE 35 days from screening visit 🡪STOP. Not eligible to enroll during this screening attempt 🡪 If willing and still within appropriate gestational age window, schedule for rescreening. |  |  |
|  | Review/update locator information and re-assess adequacy:   * Adequate locator information 🡪 CONTINUE. * Inadequate locator information 🡪 STOP. NOT ELIGIBLE. |  |  |
|  | Review elements of informed consent. Explain procedures to be performed at today’s visit. Confirm participant is still willing to participate:   * Willing to participate🡪⇒ CONTINUE. * NOT willing to participate 🡪 STOP. NOT ELIGIBLE. |  |  |
|  | [Sites to include if Infant IC is not completed at this visit]: Confirm that the participant intends and is willing to enroll her infant:   * Yes, the participant intends to and is willing to provide IC for their infant’s 🡪CONTINUE. * No, the participant does not intend to or is not willing to provide IC for their infant 🡪 STOP. NOT ELIGIBLE. |  |  |
|  | Provide and explain all prior screening visit test results. |  |  |
|  | Assess behavioral eligibility by administering the **Enrollment Behavioral Eligibility Worksheet.**   * ELIGIBLE 🡪 CONTINUE. * NOT ELIGIBLE 🡪 STOP. |  |  |
|  | Review/Update [site-specific form or chart notes] with any changes to delivery facility. |  |  |
|  | Collect urine (15-60 mL) and perform tests:   * Dipstick urinalysis * Culture per site SOP   Document on **Urine Test Results CRF.** |  |  |
|  | Administer and document HIV pre-test 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/storage:   * HIV-1 Rapid (local lab)   + [X] mL [color] top [additive] tube * AST/ALT (local lab)   + [X] mL [color] top [additive/no additive] tube * Complete blood count (CBC) with platelets (local lab)   + [X] mL [color] top [additive] tube * Blood creatinine (and calculated creatinine clearance) (local lab)   + [X] mL [color] top [additive/no additive] tube * Plasma archive (MTN LC)   + 10 mL purple top EDTA tube * DBS for baseline TFV-DP and FTC-TP drug levels (testing lab)   + 4 mL purple top EDTA tube   *If indicated:*   * Syphilis serology (local lab)   + [X] mL [color] top [additive/no additive] tube   Document stored specimen collection on the **Specimen Storage CRF** and **LDMS Tracking Sheet**. |  |  |
|  | 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. NOT ELIGIBLE *or* * If one test positive and one test negative = DISCORDANT 🡪 STOP. NOT ELIGIBLE. * Submit HIV Query form to inform LC. Per standard of care and if participant allows, collect blood and perform an HIV confirmation and refer participant to local treatment of care. |  |  |
|  | * Provide and document HIV post-test and HIV/STI risk reduction counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet** * Offer condoms |  |  |
|  | Review participant’s baseline medical, obstetric, antenatal care, ultrasound history/records and current medications (including medicated vaginal products), to verify and/or update all information recorded at the Screening Visit. Document all updates as needed on:   * **Relevant source documents** * **Ultrasound Results CRF** * **Baseline Medical History Log CRF(s)** * **Concomitant Medications Log CRF(s)** |  |  |
|  | 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 **Baseline Medical History Log**. |  |  |
|  | 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.*** |  |  |
|  | *If indicated,* perform targeted physical exam*. NOTE: Weight must be captured for calculation of CrCl.* As applicable complete **Vital Signs CRF** and **Physical Examination CRF** |  |  |
|  | Perform obstetric abdominal exam and complete **Obstetric abdominal Exam CRF.** |  |  |
|  | *If indicated,* perform ultrasound and/or review results and complete the **Ultrasound Results CRF.** [see SSP section 7.7 for required U/S elements for eligibility determination]   * N/A – results obtained prior to enrollment visit   *NOTE: Ultrasound results from ≤28 weeks gestation must be available to be eligible for enrollment* |  |  |
|  | Complete **Pregnancy Assessment CRF** including re-dating of gestational age as needed based on Ultrasound results and protocol section 7.13. <http://perinatology.com/calculators/Due-Date.htm> A gestational age redating tool is available on the MTN website.  Confirm gestational age is within 30 0/7 weeks – 35 6/7 weeks.   * WITHIN range day 🡪 CONTINUE. * Earlier than range 🡪STOP. Not eligible to enroll. If possible, reschedule enrollment visit within appropriate GA range during current screening window. If not eligible during this screening window schedule for rescreening if willing. * Later than range 🡪STOP. Not eligible |  |  |
|  | Determine whether participant has current RTI/STI/cervicitis/UTI symptoms:   * No symptoms ⇒ CONTINUE. * Symptom(s) present ⇒ evaluate per site SOPs. If treatment is required ⇒ STOP. May be INELIGIBLE. Provide any clinically indicated treatment and/or referrals. |  |  |
|  | Perform and document a pelvic exam and collect pelvic specimens per the ***Pelvic Exam Checklist.***  *Note: all required swabs should be collected during exam.* |  |  |
|  | Evaluate findings identified during pelvic, obstetric and physical examinations and medical history review. Document in chart notes and update **Concomitant Medications Log** as needed. Document ongoing conditions on the **Baseline** **Medical History Log** **CRF.** |  |  |
|  | Provide and explain all available findings and results to participant. Refer for other findings as indicated. |  |  |
|  | Provide protocol adherence counseling using the *MTN-042 Protocol Adherence Counseling Guide.* Document any questions or issues on this checklist or in chart notes. |  |  |
|  | Conduct confirmation and final determination of eligibility status by review/completion of **Eligibility Checklist.**   * ELIGIBLE ⇒ CONTINUE. Sign the Eligibility Checklist and proceed to eligibility verification. * NOT ELIGIBLE ⇒ STOP. DO NOT enroll. Pause and evaluate whether participant is:   + NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE. Perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible.   + NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Complete the **Inclusion/Exclusion Criteria CRF.** If infant PTID has been assigned, complete the **Infant Inclusion/Exclusion CRF** to indicate the infant will not enroll. |  |  |
|  | Verify participant eligibility by review/sign-off on **Eligibility Checklist** (must be different staff member than who confirmed eligibility):   * ELIGIBLE ⇒ CONTINUE * NOT ELIGIBLE ⇒ STOP. DO NOT RANDOMIZE. Provide clinical management as needed. |  |  |
|  | Randomize the participant as follows:   * Complete the **Inclusion/Exclusion Criteria CRF** *(within the Screening Visit Folder).* * Complete the **Randomization CRF**.   Once the participant’s randomization date and time auto-populates on the Randomization CRF, the participant is randomized. ONCE A PARTICIPANT IS RANDOMIZED, SHE IS OFFICIALLY ENROLLED IN THE STUDY. |  |  |
|  | Confirm study product to be provided based on randomized group assignment:   * DPV Ring * Oral Truvada   Complete the **MTN-042** **Prescription** for the participant’s product per study randomization.   * Deliver the top (white) to the pharmacy. * Retain yellow copy of prescription in participant’s binder. |  |  |
|  | Confirm if participant should be selected for an IDI based on criteria specified in SSP section 14. ***If yes,*** inform her of selection, explain the IDI process, confirm her verbal willingness to complete the IDI, and schedule (or inform participant that she will be contacted for scheduling by the qualitative team). Note that final eligibility for the IDI will be determined on the day of the interview.  Document IDI selection outcome on the **Enrollment CRF** and **Qualitative Participation Log (QPL),** as applicable.  *Note: IDI may be done anytime between* the 4-week Visit and pregnancy outcome*, after 2 weeks of product use has been confirmed.* |  |  |
|  | Complete **Enrollment CRF.** |  |  |
|  | Inform participant of product assignment. Administer **Baseline Behavioral Assessment CRF.** |  |  |
|  | Administer **COVID-19 Behavioral Assessment CRF** |  |  |
|  | Conduct product adherence counseling using the Counseling Flipchart for the assigned study product before the participant receives product. Document using the **Adherence Counseling Worksheet** or in chart notes**.** |  |  |
|  | **For participants assigned to the ring**:   * N/A (if not assigned to ring) * Retrieve study ring and white return bag (for used ring) from pharmacy * Review and provide **Ring Use Instructions and Important Information Sheet**. 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. * Document the provision of the ring to the participant using Participant-Specific **Clinic Study Product Accountability Log,** the **Ring Insertion and Removal CRF,** and the **Ring Assessment CRF,** if applicable. |  |  |
|  | **For participants assigned to oral Truvada:**   * N/A (if not assigned to oral Truvada) * Review and provide **Oral Truvada Use Instructions and Important Information Sheet**. * Provide participant with one month’s supply of oral Truvada * Instruct participant to self-administer one pill by mouth and observe dose administration**.** * Document the provision of oral Truvada to the participant on the **Participant-Specific Clinic Study Product Accountability Log, PrEP Provisions and Returns CRF,** and the **Tablet Assessment CRF**, if applicable. |  |  |
|  | Generate participant visit calendar if not done already. Print and file in participant binder. |  |  |
|  | Schedule next visit(s) using **Cohort 2** **Visit Calendar Tool.**   * Provide contact information and instructions to report symptoms, start of labor, and/or request information, counseling, a new ring/pills (if applicable), or condoms before next visit. |  |  |
|  | Update **Screening and Enrollment Log.** |  |  |
|  | For enrolled participants, perform QC1: while participant is still present, review the following for completion and clear documentation:   * **Enrollment Behavioral Eligibility Checklist**, **Eligibility Checklist** and **Inclusion/Exclusion Criteria CRF** are complete and match. * **LDMS Specimen Tracking Sheet** and **Specimen Storage CRF** * **Baseline Medical History Log, Pregnancy Assessment CRF,** and **Concomitant Medications Log** to ensure all conditions and medications are captured consistently * **Clinic Study Product Accountability Log** and **PrEP Provisions and Returns/Ring Collection and Insertion CRFs, Tablet/Ring Assessment CRF** are complete and match * **Chart notes** |  |  |
|  | Provide reimbursement. |  |  |
|  | For enrolled participants, perform QC2 of all required CRFs in Medidata Rave.  Required CRFs   * Enrollment * Inclusion/Exclusion Criteria *(located in Screening Visit folder)* * Pregnancy Assessment * Hematology\* * Chemistry Panel\* * Obstetric Abdominal Exam * Pelvic Exam * Specimen Storage * STI Test Results\* * Ultrasound Results * Urine Test Results\* * Randomization * Ring Insertion and Collection, or PrEP Provisions and Returns Log *(per participant’s study arm)* * Ring Assessment or Tablet Assessment *(per participant’s study arm)* * Edinburgh Postnatal Depression Scale * Baseline Behavioral Assessment * COVID-19 Behavioral Assessment   *As needed:*   * Vital Signs * Physical Exam * Concomitant Medications Log * Baseline Medical History Log * Vaginal Practices   Paper Forms:   * Eligibility Checklist * Enrollment Behavioral Eligibility Worksheet * HIV Pre-/Post-Test and Risk Counseling Worksheet * Adherence Counseling Worksheet * Pelvic Exam Diagrams * Pelvic Exam Checklist * MTN-042 Prescription * Participant-Specific Clinic Study Product Accountability Log * LDMS Specimen Tracking Sheet * Qualitative Participation Log (QPL) * Cohort 2 Visit Calendar Tool   *\*CRFs/Tools to be completed when lab results are available*  For failed screening attempts, the only CRFs that require completion are the **Inclusion/Exclusion Criteria CRF (or Infant Inclusion/Exclusion CRF), Informed Consent CRF,** and **Participant Type CRF**. Other CRFs that were completed during the failed screening attempt up until the point that ineligibility was determined may remain in the study database. |  |  |