**Instructions: For a participant who is pregnant or breastfeeding, or less than 8 weeks from a pregnancy outcome, that is remaining in MTN-034, use this visit checklist in place of the regular study visit checklist for all subsequent follow-up visits through study exit or until study product is resumed after a pregnancy outcome or cessation of breastfeeding.** Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.” 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. |  |  |
|  | Review elements of informed consent/assent 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. |  |  |
|  | Log into the MTN-034 Medidata Rave database, and select the appropriate PTID. Open the applicable visit folder. Complete the **Follow-up Visit Yes/No** **CRF**. |  |  |
|  | Review/update **Social Impact/ Social Benefits Log CRF(s).**  **At Visits 6, 9, 13, 16, 20, and 23/Early Termination\*,** administer the **Social Benefits and Impacts CRF** and **Social Impact/ Social Benefits Log CRFs**, as applicable.  *\*if indicated at all other visits.* |  |  |
|  | **At the applicable visit**, administer the **COVID-19 Behavioral Assessment CRF**   * Initial assessment (as soon as possible once approved: over the phone or during next study visit) * Follow-up assessment: ≥3 months post initial assessment (no later than PUEV) |  |  |
|  | Collect follow-up medical/medications history, pregnancy status/outcome information, and document any Adverse Events; review/update:   * **Adverse Event Summary/ Log CRF** * **Concomitant Medications Log CRF** * **Family Planning Log CRF** |  |  |
|  | *If participant has had a pregnancy outcome since the last visit*, refer to the Pregnant Participant Procedure Guide (Part III).  Complete a **Pregnancy Outcome Log CRF** for each reported outcome. |  |  |
|  | ***If indicated*,** provide contraceptive counseling and prescribe contraceptives as necessary. Document in chart notes and/or on **Contraceptive Counseling Worksheet.** Tailor as appropriate for pregnant participant. |  |  |
|  | Administer and document HIV/STI risk reduction counseling using the **HIV/STI Risk Reduction Counseling Worksheet**. Modify for seroconverter status for primary and secondary prevention. |  |  |
|  | Collect the following amounts of blood and send to lab for testing:   * HIV-1   + [X] mL [color] top [additive] tube   **Required at Visits 6, 9, 13, 16, 20 and 23 ONLY:**   * Plasma storage   + 10 mL [color] top (no additive) tube * HSV-2 antibody\*   + [X] mL [color] top [additive/no additive] tube * Syphilis serology\*   + [X] mL [color] top [additive/no additive] tube   **Required at Visits 9, 16, and 23 ONLY:**   * Complete blood count (CBC) with platelets\*   + [X] mL [color] top [additive] tube * Blood creatinine (and calculated creatinine clearance)\*   + [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 non-required visits.  *Note: Label all required tubes with a SCHARP-provided PTID label at the time of collection. For MTN LC bound specimens, store frozen at site while awaiting shipping request.* |  |  |
|  | Perform and document two different rapid HIV tests per site SOPs. |  |  |
|  | Complete HIV test results and post-testing actions:   * Provide testing results and 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-034 HIV Confirmation and Seroconversion Procedure Guide and Pregnant Participant Procedure Guide for complete instructions) * Collect blood for HIV Confirmatory Testing and to perform Geenius confirmatory, RNA, and CD4 testing per SSP. * Collect blood for CBC with platelets and serum creatinine * Follow Protocol HIV Testing Algorithm for confirmation testing and follow-up actions based on test results. * Provide and document HIV post-test counseling using the **HIV Pre/Post Test and HIV/STI Risk Reduction Counseling Worksheet\*\*** * Offer condoms * Document test results onto **HIV Test Result CRF** and **HIV Confirmatory Results CRF**, if applicable.   \* *If samples have not already been collected as required for this visit. These samples will not be collected at visits following HIV confirmation.*  *\*\*Modify HIV risk reduction counseling if necessary.* |  |  |
|  | Perform and document physical exam. Complete **Vital Signs CRF** and **Physical Exam CRF**.   * Targeted Exam (Monthly visits) * Full Exam (PUEV – V23) |  |  |
|  | **At Visits 6, 9, 13, 16, 20**, **and 23**\*, perform and document a pelvic exam per the Pelvic Exam Checklist. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.**  **DO NOT COLLECT specimens for PK or biomarkers, including blood PK, vaginal and cervical swabs for biomarkers, and CVL.** Note: the following specimens should still be collected if the participant accepts a pelvic exam: gram stain, pH, vaginal swabs for microbiota and flow cytometry (if applicable)  *\*if indicated at all other visits. Do not perform pelvic examination or associated procedures after 24 weeks of pregnancy, unless the participant indicates comfort with continuing vaginal procedures. Document participant acceptance of pelvic exam in chart notes, if applicable.* |  |  |
|  | If not vaccinated against HBV, offer. If accepted, provide or refer for HBV vaccine series. Document on in **chart notes** and confirmed provision of each dose on the **Concomitant Medications Log CRF.**  *NOTE: The vaccine series may be initiated at any time during follow-up.* |  |  |
|  | When all lab results are available, enter data on the **Local Laboratory Results** and **STI Test Results CRFs,** as applicable. |  |  |
|  | Evaluate findings identified during pelvic and physical examinations and medical and menstrual history review. Document in chart notes and update **Concomitant Medications Log, AE Summary/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. |  |  |
|  | **At scheduled study exit at Visit 24 OR for Early Termination,**   * Complete **Study Discontinuation CRF** and **Product Discontinuation Log CRF.** Complete **Study Exit Worksheet** and **Permission to Contact Log**. As indicated per protocol, arrange future contact for follow-up on ongoing AEs and pregnancy outcome. |  |  |
|  | Complete the **Follow-up Visit Summary CRF.** |  |  |
|  | Perform QC1: while participant is still present, review the following for completion and clear documentation:   * **Social Benefits and Impacts CRF** (V 6, 9, 13, 16, 20, 23) * **LDMS Specimen Tracking Sheet**, **Specimen Storage CRF** * **Baseline Medical History Log CRF, AE Logs CRFs,** **Family Planning Log, and Concomitant Medications Log** to ensure all conditions, medications, AEs are captured consistently and updated. * **Chart notes** to ensure complete and accurate * **Physical, Pelvic (if applicable), Vital Signs, HIV Test Results, Seroconverter Test Results, STI Test Results CRFs** completed for Physical and/or Pelvic exam and testing documentation. |  |  |
|  | Schedule next visit.\*   * Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit.     *\*If indicated after Visit 24/SEV.* |  |  |
|  | Provide reimbursement. |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:  Required CRFs   * Social Benefits and Impacts (V 6, 9, 13, 16, 20, 23; and if indicated at other visits) * Follow-up Visit Yes/No * Follow-up Visit Summary * Specimen Storage * HIV Test Results * Vital Signs * Physical Exam * Pelvic Exam *(V 6, 9, 13, 16, 20 and 23; and if indicated at other visits)* * STI Test Results (V 6, 9, 13, 16, 20, 23; and if indicated at other visits) * Laboratory Results *(required at V 9 & 16 only;* and if indicated at other visits*)* * Study Discontinuation CRF*(only at study exit visit, early termination, or as needed)*   *As needed*   * Pregnancy Outcome * Social Impacts Log * Social Benefits Log * Family Planning Log * Adverse Events Log * Concomitant Medications Log * Seroconverter Laboratory Results   Paper Forms:   * Pelvic Exam Diagrams *(V 6, 9, 13, 16, and 20, and if indicated) \*If pelvic exam performed* * LDMS Specimen Tracking Sheet * HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet   *If indicated/applicable*   * Contraceptive Counseling Worksheet |  |  |