**Instructions: For a participant who is pregnant 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.** 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.* |  |  |
|  | 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.**  *\*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.* |  |  |
|  | 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 |  |  |