**Instructions: For a seroconverter participant who remains in MTN-034, use this visit checklist in place of the regular study visit checklist for all subsequent follow-up visits through study exit.** 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** and **Follow-up Visit Summary CRF.** |  |  |
|  | **At next visit following HIV confirmation,** administer the end of product use behavioral assessments: (All behavioral assessment discontinued hereafter)* Administer **Early PUEV/Discontinuers ACASI** and complete **ACASI Summary** and **ACASI Tracking CRF.** The choice of ACASI survey (ring, tablet, or no product) should be based on the product used at the time of the first positive HIV test.
* Run the “Need Counseling” report and refer participant to counselor if requested.
 |  |  |
| * Administer **Product Preference and Acceptability 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)
 |  |  |
|  | **Except at phone contacts (Visits 3, 10 & 17),** collect mid-stream urine (15-60 mL) catch and perform tests:* Urine hCG (pregnancy)
* Dipstick urinalysis and/or culture per site SOP (if indicated)
 |  |  |
|  | Collect follow-up medical/contraceptive/medications history and document any Adverse Events; review/update: * **Adverse Event Summary/ Log CRF**
* **Concomitant Medications Log CRF**
* **Family Planning Log CRF**
 |  |  |
|  | ***If indicated*,** provide contraceptive counseling and prescribe contraceptives as necessary. Document in chart notes and/or on **Contraceptive Counseling Worksheet.***Note: Counsel in case the participant is found to have stopped using or is concerned with current method; refer to Family Planning Log.* |  |  |
|  | **Except at phone contacts (Visits 3, 10 & 17),** Review pregnancy test results:* NOT pregnant ==> CONTINUE.
* Pregnant: pregnancy newly or identified at a previous visit. **Follow steps on Pregnancy Guide.**
 |  |  |
|  | 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*.**\* If indicated at phone contacts (Visits 3, 10 & 17)* |  |  |
|  | **At next clinic visit following HIV confirmation and visits every 3 months thereafter,** collect the following amounts of blood and send to lab for testing:* Post HIV Seroconverter Plasma storage – EDTA
	+ [X] mL [color] top [additive/no additive] tube
* CD4+T – EDTA
	+ [X] mL [color] top [additive/no additive] tube
* HIV RNA PCR – EDTA
	+ [X] mL [color] top [additive/no additive] tube

 Document on the **Seroconverter Laboratory Results CRF, Local Laboratory Results** and **STI Test Results CRFs,** as applicable. *Note: Refer to Seroconverter Schedule Tool to confirm collection schedule.* |  |  |
|  | **Required at Visit 6, 9, 13, 16, 20, and 23/Early Termination\***Collect the following amounts of blood and send to lab for testing:* HSV-2 antibody
	+ [X] mL [color] top [additive/no additive] tube
* Syphilis serology
	+ [X] mL [color] top [additive/no additive] tube

**Required at Visit 9, 16, and 23/Early Termination\**** 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

*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.**\*if indicated at all other visits.* |  |  |
|  | **Except at phone contacts (Visits 3, 10 & 17),** perform and document physical exam. Complete **Vital Signs CRF** and **Physical Exam CRF**.* Targeted Exam (Monthly visits)
* Full Exam (V23)
 |  |  |
|  | **At Visits 6, 9, 13, 16, 20**, **and 23/Early Termination**\* perform and document a pelvic exam per the Pelvic Exam Checklist. Document on **Pelvic Exam Diagrams** and **Pelvic Exam CRF.**The following specimens should be collected as part of the pelvic exam: gram stain, pH, vaginal swabs for microbiota (except at visit 20) and cervical swabs for flow cytometry (if applicable)**DO NOT COLLECT** specimens for PK or biomarkers, including blood PK, vaginal and cervical swabs for biomarkers, and CVL.*\*if indicated at all other visits.* |  |  |
|  | If not vaccinated against HPV and/or HBV, offer. If accepted, provide or refer for HBV and/or HPV 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.* |  |  |
|  | 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**
* Complete **Study Exit Worksheet** and **Permission to Contact Log**. As indicated per protocol, arrange future contact for follow-up on ongoing AEs.
 |  |  |
|  |  |  |  |
|  | 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)
* **Product Preference and Acceptability**
* **LDMS Specimen Tracking Sheet**, **Specimen Storage CRF**
* **Baseline Medical History Logs, AE Logs,** **Family Planning Log, and Concomitant Medications Logs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Chart notes** to ensure complete and accurate
* **Physical, Pelvic Exam Diagrams form (Non Rave), Vital Signs, Seroconverter Test Results, Pregnancy Test Results, STI Test Results CRFs** completed for Physical and 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* ACASI Summary and ACASI Tracking (*for next follow-up visit after HIV confirmation)*
* Product Preference and Acceptability (*for next follow-up visit after HIV confirmation)*
* Social Benefits and Impacts (V 6, 9, 13, 16, 20, & 23)
* Follow-up Visit Yes/No
* Follow-up Visit Summary
* Specimen Storage
* Seroconverter Laboratory Results *(required at visit 1 month after seroconversion, then every 3 months thereafter)*
* 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, and 23;* *and if indicated at other visits*)
* Laboratory Results *(V 9 & 16;* and *if indicated at other visits)*
* Pregnancy Test Result
* Study Discontinuation CRF*(at scheduled or early study exit only)*

*As needed* * Pregnancy Report
* Pregnancy History
* Pregnancy Outcome
* Social Impacts Log
* Social Benefits Log
* Family Planning Log
* Adverse Events Log
* Concomitant Medications Log

Paper Forms:* Pelvic Exam Diagrams *(V 6, 9, 13, 16, and 20 and if indicated)*
* LDMS Specimen Tracking Sheet
* HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet

*If indicated/applicable* * Contraceptive Counseling Worksheet
* Pregnancy Case Worksheet
* Study Exit Worksheet
* Permission to Contact Log
 |  |  |