| **MTN-033: Visit 4 (Sampling) & Visit 6 (Sampling/Early Termination) Checklist** | | |
| --- | --- | --- |
| **Procedures:** | | **Staff Initials** |
|  | Confirm identity and PTID |  |
|  | Check for co-enrollment in other studies:   * NOT enrolled in another study 🡪 CONTINUE. * Enrolled in another study 🡪 STOP. Immediately contact PSRT and Management Team for further guidance. |  |
|  | Explain procedures to be performed at today’s visit. |  |
|  | Review elements of informed consent, as needed. |  |
|  | Review/update locator information. |  |
|  | Provide available test results from previous visit. Treat and/or refer for care as required (includes treatment for RTI, UTI, or STI(s), *if indicated*). Document in chart notes. |  |
|  | Review/update participant’s medical/medications history to verify and update all information recorded at previous visit. Document all updates as needed on relevant source documents, **Baseline Medical History Log CRF**, **Concomitant Medications Log CRF**. |  |
|  | As needed, assess AEs and document on **Adverse Event Summary** and **Adverse Event Log** CRFs. |  |
|  | *If indicated*, perform a targeted physical exam and complete the **Vital Signs CRF** and **Physical Exam CRF**. |  |
|  | *If indicated*, administer pharyngeal swab for GC/CT. Document collection on [add site-specific laboratory testing source document] and complete **STI Test Results CRF** upon receipt of lab results. |  |
|  | *If indicated*, collect urine (15-60 mL) and perform tests:   * Dipstick urinalysis * NAAT for GC/CT   Document collection on [add site-specific laboratory testing source document] and complete **STI Test Results CRF** upon receipt of lab results. |  |
|  | *At Visit 6/early termination only*, provide and document HIV pre-test and HIV/STI risk reduction counseling using **HIV Pre/Post Test and Risk Reduction Counseling Worksheet**. |  |
| 13. | Collect blood samples:   * Plasma for PK \_\_\_\_ mL [tube type] \*   Document collection on **Specimen Storage CRF** and **LDMS Tracking Sheet**.  \*Reference the MTN-033 SSP Manual for additional details regarding the appropriate procedures to complete for an Early Termination Visit.  *Required at Visit 6/early termination:*   * Creatinine \_\_\_ mL [tube type], *at Visit 4 only if indicated* * AST, ALT \_\_\_ mL [tube type], *at Visit 4 only if indicated* * HIV 1/2 \_\_\_ mL [tube type]   *If clinically indicated*:   * CBC with differentials and platelets \_\_\_ mL [tube type] * Syphilis \_\_\_ mL [tube type]   Document collection on [add site-specific laboratory testing source document], **LDMS Tracking Sheet** and **Specimen Storage CRF**. When results are ready, document on the **Hematology, STI Test Results,** and **Local Laboratory Results CRFs**, as applicable. |  |
|  | Perform and document rectal exam using the **Genital Exam Checklist** and complete the **Anorectal Exam CRF** and **Anorectal Specimen Storage CRF**. |  |
|  | *If indicated*, perform and document genital exam using the **Genital Exam Checklist** and complete the **Genital Exam CRF**. |  |
|  | Provide and explain all available findings and results. Treat and/or refer for care as required (includes treatment for RTI, UTI, or STI(s), *if indicated*). |  |
|  | Conduct protocol counseling and document on **Protocol Counseling Worksheet**. |  |
|  | Complete the **Follow-up Visit Y/N and Follow-up Visit Summary CRFs**. |  |
|  | Offer condoms. |  |
|  | *If* applicable, confirm/schedule next study visit and advise participant of potential length of the visit. Provide contact information and instructions to report symptoms and/or to request information and/or counseling before next visit.  **NOTE:** Participants should be instructed to call in to the clinic to report any issues related to the collection of samples via the flexible sigmoidoscopy for up to 72 hours following Visits 4 and 6. See SSP Manual for additional details. |  |
|  | Perform QC1: With participant still present, review the following for completion, if done:   * Adverse Event Summary and Adverse Event Log CRFs * Anorectal Exam CRF * Baseline Medical History Summary/Log CRFs * Chart Notes * Concomitant Medications Log CRF * Follow-up Visit Y/N and Follow-up Visit Summary CRFs * Genital Exam Checklist * Genital Exam CRF * Hematology CRF * HIV Pre/Post Test and Risk Reduction Counseling Worksheet * LDMS Specimen Tracking Sheet * Physical Exam CRF * Specimen Storage CRF * Visit 4 & 6 Checklist * Vital Signs CRF * Supporting chart notes, as needed |  |
|  | Provide reimbursement |  |
| **POST-VISIT PROCEDURES** | | |
|  | Ensure that data is entered into Medidata Rave (and perform QC2 review, if applicable) ensuring all data entered is accurate and complete.  Required CRFs:   * Anorectal Exam * Anorectal Specimen Storage * Follow-up Visit Y/N * Follow-up Visit Summary * Specimen Storage   Required at Visit 6/Early Termination only:   * HIV Test Results * Local Laboratory Results   If Indicated CRFs:   * Additional Study Procedures * Genital Exam * Hematology * Missed Visit * Participant Replacement Assessment * Physical Exam * Product Discontinuation * Study Discontinuation * Vital Signs * STI Test Results |  |
|  | Log CRFs (if newly-completed or updated):   * Adverse Event Summary/Log * Baseline Medical History Log * Concomitant Medications Log * Protocol Deviations Summary/Log   Paper Forms   * Genital Exam Checklist * HIV Pre/Post Test and Risk Reduction Counseling Worksheet * LDMS Tracking Sheet * Protocol Counseling Worksheet |  |

**Additional Notes/Comments/Referrals:**