| **Visits 14-16 (PK Visits) Checklist** | | |
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| **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. Provide and document treatment and/or referral as needed. |  |
|  | At Visit 14:Administer appropriate Follow-up CASI Behavioral Questionnaire. Document administration on the CASI Summary and CASI Tracking CRFs. |  |
|  | At Visit 14:Have participant complete the in-depth interview with remote interviewer at the agreed upon time. Document administration on the CASI Summary and CASI Tracking CRFs. |  |
|  | At Visit 16: Provide and document HIV pre-test/post-test and risk reduction counseling, per site SOP and HIV Pre/Post Test and Risk Reduction Counseling Worksheet, if applicable. |  |
|  | Collect urine (if clinically indicated) for:   * Dipstick urinalysis * Urine culture * NAAT for GC/CT   Enter results onto STI Tests CRF once available |  |
|  | Collect blood samples for:   * Plasma for PK\_\_\_ mL [tube type]   Document plasma for PK on LDMS Tracking Sheet and Specimen Storage CRF.     * At Visit 16:   + AST, ALT \_\_\_ mL [tube type]   + Creatinine \_\_\_ mL [tube type]   + Plasma for storage \_\_\_ mL [tube type]   + HIV serology \_\_\_ mL [tube type]   Enter results onto Local Laboratory Results CRF and HIV Test Results CRF once available. Document Plasma for storage on Specimen Storage CRF. |  |
| 11. | If clinically indicated:   * CBC with differentials and platelets \_\_\_ mL [tube type] * Syphilis serology \_\_\_ mL [tube type] * AST, ALT \_\_\_ mL [tube type] * Creatinine \_\_\_ mL [tube type]   Enter results onto Local Laboratory Results CRF and/or Hematology CRF and/or STI Tests CRF once available. |  |
|  | Provide and document test results and post-test counseling HIV Pre/Post Test and Risk Reduction Counseling Worksheet; provide/document referrals if needed/requested. |  |
|  | Review/update medical, medication, and for female participants, menstrual histories. Complete/update AE Log CRF(s), and Concomitant Medications Log CRF, if applicable. Document menstrual information on Cervical Specimen Storage CRF at participant’s assigned PK/PD sampling visit. |  |
|  | Based on participant’s PK/PD assignment, perform and document genital exam per Genital Exam Checklist. |  |
|  | Provide and explain all available findings and results. Refer for findings as indicated. |  |
|  | If STI/RTI/UTI is diagnosed, provide or refer for treatment. Document in chart notes |  |
|  | Provide and document protocol counseling using Protocol Counseling Worksheet |  |
|  | At Visit 14, complete the MTN-026 Study Gel Management Slip. |  |
|  | Confirm/Schedule next visit and advise participant of potential length of the visit. Provide contact information and instructions to report symptoms and/or request information, counseling before next visit.    ***Please note:*** *At Visit 16, when scheduling next visit (Visit 17), discuss with participant preferred contact method (i.e. phone call or clinic visit). Visit 17 should be scheduled approximately 7 days after Visit 16.* |  |
|  | Perform QC1: while participant is still present, review the following for completion if completed:   * Follow-up Visit Summary * Anorectal Exam * LDMS Specimen Tracking Sheets and Specimen Storage * Adverse Event Log (if, at this visit, new AEs are reported or previously reported AEs are updated) * Concomitant Medications Log (as applicable) * Pelvic Exam and Pelvic Exam Diagrams   Supporting chart notes, as needed |  |
|  | Provide reimbursement |  |

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| **POST-VISIT PROCEDURES** | | |
|  | Ensure that data is entered into the study database (and perform QC2 review, if applicable) ensuring all data entered into the study database is accurate and complete.  Required Visit Forms:   * Follow-up Y/N * Follow-up Visit Summary * Specimen Storage * Required at participant’s assigned PK/PD sampling visit (Visit 14, 15, or 16):   + Anorectal Exam   + Pelvic Exam and Pelvic Exam Diagrams (female participants only)   + Cervical Specimen Storage (female participants only) * Required at Visit 14 Only:   + CASI Summary and CASI Tracking * Required at Visit 16 Only:   + Local Laboratory Results   + HIV Test Results   If Indicated:   * Physical Exam * Vital Signs * STI Tests * Local Laboratory Results * Missed Visit * Hematology * HIV Confirmatory ResultsPregnancy Test (female participants only) * Pregnancy Report and History (female participants) * Additional Study Procedures * Study Discontinuation   Log CRFs (if newly-completed or updated):   * Adverse Event Summary/Log * Concomitant Medications Summary/Log * Protocol Deviations Summary/Log * Pregnancy Outcome Summary/Log (female participants only) |  |

**Additional Notes/Comments/Referrals:**