| **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:**