| **Visits 4-6 (PK Visits) 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. Provide and document treatment and/or referral as needed. |  |
|  | If clinically indicated, perform and document targeted physical examination on the Physical Exam CRF. |  |
|  | Obtain vitals (if indicated) and document on Vital Signs CRF. |  |
|  | Review/update medical, medication, and for female participants, menstrual history. 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. |  |
|  | 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:   * Blood for PK\_\_\_ mL [tube type]   Document PK blood collection on Specimen Storage CRF and LDMS Tracking Sheet  If clinically indicated:   * CBC with differentials and platelets \_\_\_ mL [tube type] * AST, ALT \_\_\_ mL [tube type] * Creatinine \_\_\_ mL [tube type] * Syphilis \_\_\_ mL [tube type]   Enter results onto Hematology and/or Local Laboratory Results CRF and/or STI Tests CRF once available. |  |
|  | Based on participant’s PK/PD assignment, perform and document anorectal exam. Collect rectal samples (See Genital Exam Checklist). |  |
|  | For female participants, based on PK/PD assignment: Perform and document pelvic exam. Collect pelvic samples (See 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 per Protocol Counseling worksheet |  |
|  | 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 6, when scheduling next visit (Visit 7), the washout period is a minimum of 14 days and a maximum of 28 days. For female participants, the washout period should be timed to coincide with menses.* |  |
|  | At Visit 6: Provide study condoms |  |
|  | Perform QC1: while participant is still present, review the following for completion if completed:   * Visit checklist * Follow-up Visit Summary * Anorectal Exam * Pelvic Exam * Pelvic Exam Diagrams * Cervical Specimen Storage (LMP items) * LDMS Specimen Tracking Sheets and Specimen Storage CRF * Concomitant Medications Log (as applicable) * Adverse Event Log (if, at this visit, new AEs are reported or previously reported AEs are updated) * Supporting chart notes, as needed |  |
|  | Provide reimbursement |  |
| **POST-VISIT PROCEDURES** | | |
|  | Perform QC2 review for all applicable forms, 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 4, 5, or 6):   + Anorectal Exam   + Pelvic Exam and Pelvic Exam Diagram (female participants only)   + Cervical Specimen Storage (female participants only)   If Indicated:   * Physical Exam * Vital Signs * Local Laboratory Results * Hematology * STI Tests * Study Discontinuation * Treatment Discontinuation * Participant Replacement Assessment * Additional Study Procedures * Missed Visit |  |
| 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:**