| **Follow Up Visit Checklist (Day 28)**  PTID: \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ Date: \_\_\_ \_\_\_ -\_\_\_ \_\_\_ \_\_\_-\_\_\_ \_\_\_  Visit Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Visit Code: 9.0 | |
| --- | --- |
| **Procedure** | **Staff Initials** |
| Confirm participant’s identity and PTID |  |
| Confirm whether the participant is co-enrolled in another study.  🞎 No ==> CONTINUE.  🞎 Yes ==> STOP. Consult PSRT and the Management Team for further guidance. |  |
| Review elements of informed consent as needed. |  |
| Assess if participant has experienced a social harm as a result of study participation. If participant reports social harm occurrence, complete ***Social Impact Log CRF***. |  |
| Review/update locator information. |  |
| Explain procedures to be performed at today’s visit. |  |
| Provide available test results from previous visit. |  |
| Administer **Follow up CASI Questionnaire** and document administration on the ***Follow Up CASI Tracking CRF***. |  |
| Complete ***Ring Adherence CRF.*** |  |
| Review/update medical and medications history. Document on the appropriate tracking tool and/or chart notes and ***Concomitant Medications Log CRF*** and ***Follow-up Visit Summary CRF***, as appropriate. |  |
| *If indicated, provide and document contraceptive counseling using* ***Contraceptive Counseling Worksheet.*** |  |
| Collect urine (15-60 mL):   * **hCG** * **Dipstick urinalysis** * urine culture (if indicated)   Document pregnancy and dipstick UA results on ***Follow Up Visit Summary CRF*** and ***Safety Laboratory Results CRF***.  Pregnant: 🞎 NO==> CONTINUE 🞎 YES==> **STOP**. Permanently Discontinue Product Use and Study Participation. If pregnant, make plan for obtaining pregnancy outcome with participant. |  |
| *If clinically indicated, provide and document HIV pre- test and risk reduction counseling using* ***HIV Pre/Post Test and Risk Reduction Counseling Worksheet.*** |  |
| Collect blood:  **Testing is based on local lab requirements; tailor this item to reflect site-specific tube type and volume.**  **❒ PK (Hour 0)**  **❒ Complete blood count (CBC) with differential and platelets**  **❒ Chemistries (AST, ALT, creatinine)**  ❒ HIV-1 serology (if indicated)  ❒ Syphilis serology (if indicated)  Document results onto ***Safety Laboratory Results CRF*** once available. Document PK blood collection (Hour 0) on ***LDMS Tracking Sheet*** and ***Pharmacokinetics Specimens—Day 28 CRF***.  If HIV and Syphilis testing was done:   * Provide available test results and appropriate post-test counseling using ***HIV Pre/Post Test and Risk Reduction Counseling Worksheet***. Document results on the ***HIV Results CRF*** and ***STI Results CRF***, if indicated. * Reactive HIV Rapid Test: 🞎 NO==> CONTINUE 🞎 YES==> **STOP**. Permanently Discontinue Product Use and Study Participation. |  |
| Instruct participant to self-collect the vaginal swab for PK for the Hour 0 sample collection. Document collection on ***LDMS Tracking Sheet*** and ***Pharmacokinetics Specimens—Days 28 CRF***.  ***Note****: This Hour 0 collection should be taken* ***prior to*** *ring removal, and ideally within 5 minutes of hour 0 PK blood draw.* |  |
| Perform and document modified physical examination on the ***Physical Exam CRF***. |  |
| Perform pelvic exam and complete ***Pelvic Exam Checklist, Pelvic Exam CRF, Pelvic Exam Ring Assessment CRF,*** *and* ***Pelvic Exam Diagrams CRF*.** |  |
| Evaluate any abnormal findings. Explain test results and exam findings. If STI/RTI/UTI is diagnosed, document results on the ***STI Test Results*** ***CRF***, if applicable. Document provision of results, treatments and/or referrals in chart notes and on the ***Concomitant Medications Log CRF***. |  |
| Document collection of the vaginal ring on the ***Ring Collection and Insertion CRF***, ***Clinic Study Product Accountability Log, LDMS Tracking Sheet, Specimen Storage CRF,*** *and* ***Intravaginal Ring Request Slip*** *indicating participant’s product use period has completed, and deliver white original copy to the pharmacist.* |  |
| Collect blood for PK at 1, 2, 4, and 6 hours post-ring removal. Document collection times on the ***LDMS Tracking Sheet.*** Document collection and storage of required specimens on the ***Pharmacokinetics Specimens—Day 28 CRF.*** |  |
| Instruct participant to self-collect the vaginal swab for PK (post ring removal) for the Hours 1, 2, 4, and 6 hours. Document collection times, pre/post/net weights on the ***LDMS Tracking Sheet.*** Document collection and storage of required specimens on the ***Pharmacokinetics Specimens—Day 28 CRF***.  ***Note****: Vaginal swab for PK should ideally be collected within 5 minutes of PK blood draw*. |  |
| As needed, provide and document protocol adherence counseling using the ***Protocol and Product Adherence Counseling Worksheet*** |  |
| As needed, record all AEs reported or identified during the medical history review, during the conduct of the physical and pelvic examinations or during specimen collection on the ***AE Log CRF.*** |  |
| Update study schedule tool, entering the actual Day 28 visit date, to generate visit windows for remaining visits. Schedule next visit and advise participant of potential length of next visit. |  |
| Provide reimbursement. |  |

**Complete and assemble all required CRFs, forms and other tools and complete QC 1 to ensure all items are completed (while the participant is still in the clinic).**

|  |
| --- |
| **Required Case Report Forms** |
| Follow Up CASI Tracking CRF |
| Follow-up Visit Summary CRF |
| Pelvic Exam CRF |
| Pelvic Exam Ring Assessment CRF |
| Pelvic Exam Diagrams (non-DataFax) CRF |
| Pharmacokinetics Specimens—Day 28 CRF |
| Physical Exam CRF |
| Ring Adherence CRF |
| Ring Collection and Insertion CRF |
| Safety Laboratory Results CRF |
| Specimen Storage CRF |
| **Log Case Report Forms (as needed)** |
| Social Impact Log CRF |
| AE Log CRF |
| Concomitant Medications Log CRF |
| Clinical Product Hold/Discontinuation Log CRF |
| Protocol Deviation Log CRF |
| **Other as needed CRFs** |
| HIV Results CRF |
| HIV Confirmatory Results CRF |
| Pregnancy Report and History CRF |
| Pregnancy Outcome CRF |
| Missed Visit CRF |
| STI Test Results CRF |
| **Other Tools and Worksheets** |
| LDMS Tracking Sheet |
| Clinic Study Product Accountability Log |
| Intravaginal Ring Request Slip |
| Protocol and Product Adherence Counseling Worksheet (as needed) |
| HIV Pre/Post Test and Risk Reduction Counseling Worksheet (as needed) |
| Contraceptive Counseling Worksheet (as needed) |

QC1 (Staff Initial): \_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

QC2 (Staff Initial): \_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_