| **Follow Up Visit Checklist (Day 1, 2, 3, 7, 14 and 21)**  PTID: \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_\_ Date: \_\_\_ \_\_\_ -\_\_\_ \_\_\_ \_\_\_-\_\_\_ \_\_\_  Visit Type: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Visit Code: \_\_\_ \_\_\_ . \_\_\_\_ | |
| --- | --- |
| **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. |  |
| **Days 7, 14 and 21 only**: 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 (required at Day 14 only, if indicated at all other times)** * Dipstick urinalysis (if indicated) * urine culture (if indicated)   Document pregnancy results on ***Follow Up Visit Summary CRF*** and dipstick UA and urine culture results on the ***Safety Laboratory Results CRF***, if applicable.  **Pregnant**: 🞎 Not done 🞎 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 (single time point)**  ❒ HIV-1 serology (if indicated)  ❒ Syphilis serology (if indicated)  Document PK blood collection on **LDMS Tracking** ***Sheet*** and ***Pharmacokinetics Specimens—Days 1, 2, 3, 7, 21, 29, 30, 31, 35 CRF***.  If HIV and/or 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. Document collection on ***LDMS Tracking Sheet*** and ***Pharmacokinetics Specimens—Days 1, 2, 3, 7, 21, 29, 30, 31, 35 CRF***.  *Note: Vaginal swab for PK should be collected within one hour of blood draw for PK.* |  |
| Perform and document modified physical examination on the ***Physical Exam CRF***. |  |
| Perform pelvic examination and complete ***Pelvic Exam Checklist, Pelvic Exam Diagrams CRF,* *Pelvic Exam CRF***, and ***Pelvic Exam Ring Assessment 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***. |  |
| 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.*** |  |
| As needed, provide and document protocol and product use adherence counseling using ***Protocol and Product Adherence Counseling Worksheet.***  *Note to sites: Weekly review (i.e. Days 7, 14 and 21) of adherence requirements and counseling messages is recommended.* |  |
| Review study schedule using visit schedule tool. 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 (Days 7, 14, and 21 only) |
| Follow-up Visit Summary CRF |
| Pelvic Exam CRF |
| Pelvic Exam Diagrams (non-DataFax) CRF |
| Pelvic Exam Ring Assessment CRF |
| Pharmacokinetics Specimens—Days 1, 2, 3, 7, 21, 29, 30, 31, 35 CRF |
| Physical Exam CRF |
| Ring Adherence CRF |
| Specimen Storage CRF (Day 3 only) |
| **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 |
| Safety Laboratory 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 |
| 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: \_\_\_\_\_\_\_\_\_\_\_\_