| **Final Clinic (Day 35)/Early Termination** PTID: \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ \_\_\_ - \_\_ Date: \_\_\_ \_\_\_ -\_\_\_ \_\_\_ \_\_\_-\_\_\_ \_\_\_Visit Type: Visit Code: \_\_\_ \_\_\_ . \_\_\_\_ |
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| **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. |  |
| 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 (if indicated)

Document pregnancy results on the ***Follow Up Visit Summary CRF*.** If pregnant, make plan for obtaining pregnancy outcome with participant. |  |
| Provide and document HIV pre- test and risk reduction counseling *using* ***HIV Pre/Post Test and Risk Reduction Counseling Worksheet.*** |  |
| Collect blood: * Complete blood count (CBC) with differential and platelets (if indicated)
* **Chemistries (AST, ALT, creatinine)**

**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**
* Syphilis serology (if indicated)

*\*For early Termination visit, omit PK if the study ring has been out for 3 or more consecutive days.* Document results on ***Safety Laboratory Results CRF*.** Document PK blood collection on ***LDMS Tracking******Sheet*** and ***Pharmacokinetics Specimens—Days 1, 2, 3, 7, 21, 29, 30, 31, 35 CRF***. Provide and document HIV pre- test and risk reduction counseling using ***HIV Pre/Post Test and Risk Reduction Counseling Worksheet***. Document HIV-1 serology test results on the ***HIV Results CRF****.* If syphilis testing was done, provide available test results and document results on the ***STI Results CRF***. |  |
| 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.**\*For early Termination visit, omit PK if the study ring has been out for 3 or more consecutive days.*  |  |
| Perform and document modified physical examination on the ***Physical Exam CRF***.  |  |
| Perform pelvic examination and complete ***Pelvic Exam Checklist, Pelvic Exam Diagrams CRF,*** and ***Pelvic Exam 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***. |  |
| If early termination visit and ring has not been previously collected: 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 permanent discontinuation, and deliver white original copy to the pharmacist. |  |
| 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***. |  |
| Have participant complete in-depth interview with remote interviewer at the agreed upon time. Document administration on the ***Follow Up Visit Summary CRF.*** |  |
| As needed, provide and document protocol adherence counseling using the ***Protocol and Product Adherence Counseling Worksheet.*** |  |
| Review all AEs reported, confirm relationship status, AE grade and outcome are accurately documented. For ongoing AEs, update to “continuing at the end of study participation”. The following AEs, identified as continuing, must be re-assessed within 30 days from this visit:* All grade 3 and higher AEs
* All AEs deemed ‘related’
* Previously reported AEs found to have increased in severity at the termination visit
* All SAEs/EAEs.

Consult with the IoR/designee to establish a clinically appropriate follow-up plan for the participant and document the plan in the participant’s chart notes. |  |
| Reinforce site contact information and: * If applicable, schedule a final study contact for disclosure of all remaining exam and lab test results.
* If applicable, schedule clinically indicated follow-up for AEs that meet definitions above
* Determine and document whether participant is willing to be contacted about future studies.
* Inform the participant of planned methods and timeframes for dissemination of study results. Determine participant preference for post-study contact.
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| 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).**

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| **Required Case Report Forms** |
| Follow-up Visit Summary CRF  |
| Pelvic Exam CRF  |
| Pelvic Exam Diagrams (non-DataFax) CRF  |
| Pharmacokinetics Specimens—Days 1, 2, 3, 7, 21, 29, 30, 31, 35 CRF |
| Physical Exam CRF  |
| Safety Laboratory Results CRF |
| HIV Results CRF |
| Specimen Storage CRF |
| Termination CRF |
| **Log Case Report Forms (as needed)** |
| Social Impact Log CRF  |
| AE Log CRF  |
| Concomitant Medications Log CRF |
| Protocol Deviation Log CRF |
| **Other as needed CRFs** |
| HIV Confirmatory Results CRF |
| Ring Collection and Insertion  |
| Specimen Storage CRF |
| Pregnancy Report and History CRF |
| Pregnancy Outcome CRF |
| Missed Visit CRF |
| STI Test Results CRF  |
| **Other Tools and Worksheets** |
| LDMS Tracking Sheet |
| HIV Pre/Post Test and Risk Reduction Counseling Worksheet |
| Clinic Study Product Accountability Log (as needed) |
| Intravaginal Ring Request Slip (as needed) |
| Contraceptive Counseling Worksheet (as needed) |
| Protocol and Product Adherence Counseling Worksheet (as needed) |

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

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