PTID: __ __ __- __ __ __ __ __- __ Date: _____ Visit Month:_____

Instructions: The "Required at visits" column indicates when the item is required during follow-up per-protocol. Procedures do not have to be conducted in the order in which they appear in the checklist. When an item is performed, complete "Staff Initials" cell. If not done but required, write "N/D" and staff initials in "Staff Initials" cell, and provide more details in the chart notes as needed. Do not initial for other staff members. If other staff members are not available to initial items themselves, write and initial/ date a note documenting who completed the procedure, e.g., "done by {name}" or "done by nurse." If visit procedures are split across more than one date, ensure the date is captured in the comments cell for procedures conducted on a date different than that provided above.

	Monthly, Quarterly, and/or Semi-annual Visit Procedure	Required at visits:	Staff Initials	Comments:
1	Confirm identity and PTID, check visit window.	All		
2	Check for co-enrollment in other studies: ❒ NOT enrolled in another study ==> CONTINUE ❒ Enrolled in another study ==> Consult PSRT	All		
3	Review elements of informed consent as needed	All		
4	Review/update locator information	All		
5	Complete Ring Adherence CRF	All		
6	Administer Behavior Assessment CRF (If indicated, complete Social Impact Log CRF)	Quarterly, Semi-ann		
7	Administer Vaginal Practices CRF.	Semi-ann		
8	Administer Prevention Study Experiences CRF.	Month 3, 12		
9	Administer Month 3 ACASI, and Ring Worries CRF	Month 3		
10	Conduct and document protocol/ring adherence counseling	All		
11	Provide and document: ❒ HIV pre-test counseling ❒ HIV/STI risk reduction counseling ❒ Condoms	All		
12	Perform and document two Finger Stick HIV tests *[Note to sites: if your site is not doing finger sticks, edit checklist as needed.]*	All		
13	Provide HIV test results in the context of post-test counseling. Provide referrals if needed/requested. ❒ If both tests negative ==> UNINFECTED ==> CONTINUE. ❒ If at least one test positive **==> HOLD study product. Collect blood sample for plasma storage, Western Blot, HIV viral load, and CD4+ testing**. **If operating under LoA#2, collect ring for laboratory storage and testing (otherwise dispose of ring per accountability SOP).** If ring not returned, arrange to collect ring within 24 hours as applicable.	All		
14	Collect urine (15-60 mL) and send to lab for: ❒ Urine hCG (pregnancy)	All		

PTID: __ __ __- __ __ __ __ __- __ Date: _____ Visit Month:_____

	Monthly, Quarterly, and/or Semi-annual Visit Procedure	Required at visits:	Staff Initials	Comments:
	❒ NAAT for GC/CT (first catch urine)	Semi-ann		
15	Collect vaginal fluid for archive (self-collection)	All		
16	Collect follow-up medical/menstrual/medications history: review/update AE Log, Grade 1 AE Log, Concomitant Medications Log CRFs.	All		
17	Determine amounts required and collect blood:: ❒ *X x X mL lavender top (EDTA) tube, for HIV testing [include on checklist only if not performing Finger Stick HIV rapids]*	All		
	❒ X x X mL lavender top (EDTA) tube, for plasma storage ❒ X x X mL lavender top (EDTA) tube, for CBC with platelets ❒ X x X mL red top (no additive) tube, for Serum Chemistries	Quarterly Semi-ann		
	❒ X x X mL red top (no additive) tube, for Syphilis	If ind.		
18	Provide contraceptive counseling and complete Family Planning CRF	All		
19	Prescribe contraceptives if indicated; document and update Concomitant Medication log if applicable.	All		
20	Review pregnancy test results: ❒ NOT pregnant ==> CONTINUE. ❒ Pregnant, pregnancy newly identified at today's visit: • HOLD study product. If applicable, arrange to collect product not returned today within 5 working days. • Initiate Pregnancy Management Worksheet *[site to delete if not using]* • Complete Pregnancy Report and History CRF ❒ Pregnant, pregnancy first identified at a previous visit: • Continue to HOLD study product • If applicable, refer to MTN-016; document in chart notes.	All		
21	Perform and document targeted physical exam. Complete Abbreviated Physical Exam CRF.	Quart, Semi-ann		
22	Perform and document pelvic exam per Pelvic Exam Checklist (semi-annual visits). If indicated at other visits, conduct targeted pelvic exam and document per site SOPs.	Semi-ann		
23	If STI/RTI/UTI is diagnosed, provide treatment.	All		
24	Provide and explain all available findings and results. Refer for findings as indicated.	All		

PTID: __ __ __- __ __ __ __ __- __ Date: _____ Visit Month:_____

	Monthly, Quarterly, and/or Semi-annual Visit Procedure	Required at visits:	Staff Initials	Comments:
25	Document any Adverse Events: Complete/update Grade 1 AE Log CRF and/or AE Log CRF(s) as needed	All		
26	Assess eligibility and participant's willingness to continue product use. Complete Vaginal Ring Request Slip as appropriate and send to pharmacy.	All		
27	Have participant (or clinician/designee) remove used vaginal ring. Collect, document on Ring Collection/Insertion CRF. Collect ring for disposal in biohazard container per site SOPs or for storage (see item 27). Send returned unused rings to pharmacy for quarantine. (NOTE: if pelvic conducted, used ring will have been removed prior to exam).	All		
28	Collect used ring for lab storage	All		
29	Provide new vaginal ring to participant for self-insertion. As needed, review any ring insertion instructions and address participant questions.	All		
30	Update Study Product Accountability Log accordingly	All		
31	Confirm placement of the vaginal ring through digital examination [required at M1 only, conduct if indicated at other visits]	Month 1		
32	*[Sites to insert as applicable per site practice]:* As needed, provide bottle of water for rinsing vaginal ring.	If ind.		
33	Schedule next visit. Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring, or condoms before next visit. Update the Participant Tracking Database (or site-specific tracking documents).	All		
34	Perform QC1 while participant is still present to ensure information is complete and accurate. **All visits:** Visit Summary (items 2 and 3), Ring Adherence, Family Planning, Follow-up LDMS Specimen Tracking Sheet, AE/GAE CRFs (and supporting chart notes) as needed **Additionally at Quarterly Visits:** Behavior Assessment, Abbreviated Physical Exam CRF, Prevention Study Experiences (Month 3 only) **Additionally at Semi-annual:** Behavior Assessment,	All, as required		

PTID: __ __ __- __ __ __ __ __- __ Date: _____ Visit Month:_____

	Monthly, Quarterly, and/or Semi-annual Visit Procedure	Required at visits:	Staff Initials	Comments:
	Prevention Study Experiences (Month 12 only), Vaginal Practices, Pelvic Exam Diagrams			
35	Provide reimbursement	All		
36	Review and fax all required DataFax forms to SCHARP DataFax. **All visits:** Visit Summary, Monthly Laboratory Results, Ring Adherence, Family Planning, Ring Collection/Insertion **Additionally at Quarterly Visits:** Quarterly Laboratory Results, Behavior Assessment, Abbreviated Physical Exam, Specimen Storage; *at Month 3, also Ring Worries and Follow-up ACASI Tracking, Prevention Study Experiences.* **Additionally at Semi-Annual Visits:** Pelvic Exam, Vaginal Practices, STI Test Results, Specimen Storage CRF; *at Month 12, also Prevention Study Experiences.* **Log CRFs (if newly-completed or updated):** Adverse Experience Log, Concomitant Medications Log, Product Hold/Discontinuation Log, Social Impact Log, Protocol Deviations Log **If participant had a positive rapid HIV test result:** HIV Confirmatory Results, Specimen Storage CRF **If participant had a newly-positive pregnancy test result or outcome:** Pregnancy Report, Pregnancy Outcome	All, as required All, as required		