Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN-003 study visits. The checklists also specify the data collection forms that must be completed at each visit.

7.1 Use of Checklists

The visit checklists included in this section are designed to guide site staff in proper study procedures as well as to serve as source documentation of procedures performed at study visits. Note, however, that checklists alone may not be sufficient for documenting all procedures. For example, chart notes may be required to:

- Explain why procedures in addition to those listed on a checklist were performed
- Explain why procedures listed on a checklist were not performed
- Document procedures performed at interim visits
- Document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements)

See Section 3 of this manual for detailed information on source documentation requirements. Tips for completing visit checklists in accordance with these requirements are as follows:

- Enter the participant identification number (PTID) and visit date in the top section of each checklist. If information is written on the front and back of the checklist, enter the PTID and visit date on both sides.

- For screening visits, enter the screening attempt number in the top section of the checklist.

- For follow-up visits, enter the visit code in the top section of each checklist.

- Enter your initials only beside the procedures that you perform. Do not enter your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by lab staff.”

- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.

- If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why on the checklist (if not self-explanatory); initial and date this entry.

7.2 Sequence of Procedures

The sequence of procedures presented on the visit checklists is a suggested ordering. In consultation with the MTN CORE (FHI), site staff may modify the checklists included in this section to maximize the efficiency of site-specific study operations. Sites may alter the sequence of procedures to suit local staffing and logistical requirements, with the following exceptions:

- Informed consent for screening must be obtained before any screening procedures are performed. Screening procedures are listed in protocol Sections 7.2 and 7.3.

- Informed consent for enrollment must be obtained before any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in protocol Section 7.4. Follow-up procedures are listed in protocol Section 7.5.

- On the day of enrollment, random assignment must take place after administration of the Baseline Behavior Assessment form, Baseline Audio Computer Assisted Self-Interview (ACASI) Questionnaire, collection of blood for plasma archive, and administration of Hepatitis B vaccine, if applicable.

- Pelvic exam procedures must be performed in the sequence shown on the pelvic exam checklists.

- At follow-up visits, behavioral assessment forms and ACASI questionnaires must be administered prior to the delivery of HIV and adherence counseling.

PTID:	Visit Date:
Screening Attempt:	Visit Code: 1.0

Initials	Procedures
	1. Confirm identity per site SOPs and determine whether a VOICE PTID has previously been assigned to participant.
	2. Determine screening attempt number: Æ First attempt ⇒ determine recruitment source and document per site SOPs. Æ Second or other attempt ⇒ CONTINUE.
	3. Check for co-enrollment in other studies per site SOPs: Æ NOT enrolled in another study ⇒ CONTINUE. Æ Enrolled in another study ⇒ STOP. NOT ELIGIBLE.
	4. Determine whether participant is of legal age to provide informed consent for research per site SOPs: Æ Of legal age ⇒ CONTINUE. Æ NOT of legal age ⇒ STOP. NOT ELIGIBLE.
	5. Explain, conduct, and document screening informed consent process per site SOPs: Æ Willing and able to provide written informed consent ⇒ CONTINUE. Æ NOT willing and able to provide written informed consent ⇒ STOP. NOT ELIGIBLE.
	6. Assign a VOICE PTID (if not done during a previous screening attempt).
	7. Determine last possible enrollment date for this screening attempt: ☐☐ ☐☐☐ ☐☐ DD MON YY
	8. Explain procedures to be performed at today's visit.
	9. Administer Demographics form.
	10. Administer Screening Part 1 Eligibility form: Æ ELIGIBLE thus far ⇒ CONTINUE. Æ NOT ELIGIBLE ⇒ STOP.
	11. If applicable, refer participant for site medical officer review of tuberculosis status.
	12. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant ⇒ CONTINUE. Æ Pregnant ⇒ STOP. NOT ELIGIBLE.
	13. Perform dipstick urinalysis for protein, glucose, nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form: Æ If 2+ or greater for protein OR glucose ⇒ STOP. NOT ELIGIBLE. Æ If 1+ for protein OR glucose, dipstick must be repeated at Screening Part 2 ⇒ CONTINUE. Æ If positive for nitrites and LE, treat for UTI per site SOPs only if participant has urinary symptoms. Document in chart notes. Participant must complete treatment and be free of symptoms prior to enrollment ⇒ CONTINUE. Æ Otherwise ⇒ CONTINUE.

These items are structured for sites that perform urine testing in-clinic. Sites that perform testing in the lab should modify this item as needed.

PTID:	Visit Date:
Screening Attempt:	Visit Code: 1.0

Initials	Procedures
	14. Refrigerate remaining urine for gonorrhea and chlamydia SDA.
	15. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling Æ Provide HIV/STI risk reduction counseling and condoms Æ Collect blood: Æ 1 x 6 mL lavender top (EDTA) tube Æ 1 x 5 mL red top (no additive) tube Æ 1 x 10 mL red top (no additive) tube Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes. Æ Perform and document two rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results. Æ Provide test results and post-test counseling: Æ If both tests negative ⇒ UNINFECTED ⇒ ELIGIBLE ⇒ CONTINUE. Æ If both tests positive ⇒ INFECTED ⇒ STOP. NOT ELIGIBLE. Æ If one test positive and one test negative ⇒ DISCORDANT ⇒ PAUSE ⇒ WB is required ⇒ continue OR defer screening until HIV status is clarified. Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe results onto Screening and Enrollment HIV Test Results form. This item is structured for sites that perform HIV testing in clinic. Sites that perform in-lab testing should modify this item as needed.
	16. Prepare remaining blood for required testing: • Complete blood count (see protocol Section 7.11) • Liver and renal function tests (AST, ALT, phosphate, creatinine) • Syphilis serology • Hepatitis B surface antigen (HBsAg) • Hepatitis B surface antibody (HBsAb)
	17. Measure and document participant weight per site SOPs. Transcribe onto Safety Laboratory Results form.
	18. Determine whether participant has current RTI/STI symptoms: Æ No symptoms ⇒ CONTINUE. Æ Symptom(s) present ⇒ evaluate per site SOPs and document in chart notes ⇒ CONTINUE.
	19. Provide and explain all available findings and results.
	20. If RTI/STI is diagnosed, provide treatment and offer testing and/or treatment for partners if indicated; document in chart notes. Participant must complete treatment and be free of symptoms prior to enrollment. CONTINUE.
	21. Determine current contraceptive method, review study contraception requirements, and provide contraceptive counseling; document per site SOPs.
	22. [Prescribe/provide/refer for] contraception if indicated per site SOP; document in chart notes.

PTID:	Visit Date:
Screening Attempt:	Visit Code: 1.0

Initials	Procedures
	23. Obtain locator information and determine adequacy per site SOPs: Æ Adequate locator information ⇒ CONTINUE. Æ Inadequate locator information ⇒ PAUSE and re-assess: Æ Adequate information likely to be available prior to enrollment ⇒ CONTINUE. Æ Adequate information NOT likely to be available ⇒ STOP. NOT ELIGIBLE.
	24. Provide study informational material: [add site-specific list if desired]
	25. Provide contact information and instructions to contact the site for additional information and/or counseling if needed before the next visit.
	26. Schedule next visit.
	27. Provide reimbursement.
	28. Ensure chart notes, Screening Consent DataFax form, and all other required visit documentation is completed (hold all DataFax forms until enrollment).
	29. Review all visit documentation.
	30. Enter participant in co-enrollment database.

Between Screening Part 1 and Screening Part 2 Worksheet

PTID:	Screening Attempt:

Initials & Date	Procedures
	1. Review, grade, and assess clinical significance of Screening Part 1 lab results: Æ Complete blood count Æ Liver function tests (AST, ALT) Æ Renal function tests (phosphate, creatinine) Æ Calculated creatinine clearance rate Æ Syphilis serology Æ Gonorrhea SDA Æ Chlamydia SDA Æ If indicated, HIV WB
	2. Hepatitis B test results may not be available before Screening Part 2. If results are received, review, grade, and assess clinical significance and clinical status: Æ HBsAg+ and HBsAb- ⇒ not eligible for study ⇒ counsel and refer Æ HBsAg- and HBsAb- ⇒ Hep B susceptible ⇒ offer vaccine if enroll Æ HBsAg- and HBsAb+ ⇒ not Hep B susceptible ⇒ vaccine not indicated
	3. Complete laboratory test result case report forms (hold forms until enrollment): Æ Safety Laboratory Results Æ STI Laboratory Results If indicated: Æ Screening and Enrollment HIV Test Results (if HIV WB was done)
	4. Assess eligibility based on lab results: Æ Eligible Æ Not Eligible ⇒ specify:
	5. Assess clinical management and referral needs: Æ No action needed Æ Action needed ⇒ specify:
	6. Complete additional QC/QA review of Screening Part 1 and subsequent documentation per site SOPs.
	7. Perform eligibility review of all Screening Part 1 data per site SOPs: Æ Eligible Æ Not Eligible ⇒ specify:

PTID:	Visit Date:
Screening Attempt:	Visit Code: 2.0

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs.
	2. Check for co-enrollment in other studies per site SOPs: Æ NOT enrolled in another study ⇒ CONTINUE. Æ Enrolled in another study ⇒ STOP. NOT ELIGIBLE.
	3. Review previous visit documentation.
	4. Verify current screening attempt number and confirm last possible enrollment date for this attempt: ☐☐ ☐☐☐ ☐☐ DD MON YY
	5. Provide and explain all prior screening test results. Provide post-test counseling if HIV WB was performed at Screening Part 1.
	6. Explain current eligibility status and procedures to be performed at today's visit: Æ ELIGIBLE thus far ⇒ CONTINUE. Æ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ CONTINUE. Æ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.
	7. Review/update locator information and re-assess adequacy per site SOPs: Æ Adequate locator information ⇒ CONTINUE. Æ Inadequate locator information ⇒ PAUSE and re-assess: Æ Adequate information likely to be available prior to enrollment ⇒ CONTINUE. Æ Adequate information NOT likely to be available ⇒ STOP. NOT ELIGIBLE.
	8. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant ⇒ CONTINUE. Æ Pregnant ⇒ STOP. NOT ELIGIBLE.
	9. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis (see #10-12). Refrigerate remaining urine for possible additional testing (e.g., SDA).
	10. Review participant's Screening Part 1 dipstick urinalysis results and determine if participant has current urinary symptoms.
	11. If 1+ for protein or glucose was identified at Screening Part 1, perform dipstick urinalysis for these analytes; complete testing logs; transcribe results onto Safety Laboratory Results form: Æ If 2+ or greater for protein OR glucose ⇒ STOP. NOT ELIGIBLE. Æ If 1+ for protein at this visit and 1+ for protein at Screening Part 1 ⇒ STOP. NOT ELIGIBLE. Æ If 1+ for glucose at this visit and 1+ for glucose at Screening Part 1 ⇒ STOP. NOT ELIGIBLE. Æ Otherwise ⇒ ELIGIBLE ⇒ CONTINUE.

This item is structured for sites that perform urine testing in-clinic. Sites that perform in-lab testing should modify this item as needed.

PTID:	Visit Date:
Screening Attempt:	Visit Code: 2.0

Initials	Procedures
	12. If 1+ proteinuria detected at today's visit, or if participant has urinary symptoms, perform dipstick urinalysis for nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form: Æ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs. Participant must complete treatment and be free of symptoms prior to enrollment ⇒ CONTINUE. Æ Otherwise ⇒ CONTINUE.
	13. Collect baseline medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.
	14. Perform physical exam with measurement of height and weight; document per site SOPs.
	15. Perform and document pelvic exam per Screening Pelvic Exam Checklist.
Items 16-20 could be done while awaiting pelvic lab test results.	16. If indicated, collect and prepare blood for syphilis serology.
	17. If indicated, collect and prepare blood for other testing needed to determine eligibility (specify):
	18. If indicated, prepare urine for gonorrhea and chlamydia SDA.
	19. Verify current contraceptive method, review study contraception requirements, and provide contraceptive counseling; document per site SOPs.
	20. [Prescribe/provide] contraception if indicated per site SOPs. Update baseline reproductive history documentation and Contraceptives Log form if applicable.
	21. Provide and explain available exam findings and lab test results.
	22. If STI/RTI is diagnosed, provide treatment and offer testing and/or treatment for partners if applicable; document per site SOPs. Participant must complete treatment and be free of symptoms prior to enrollment. CONTINUE.
	24. Administer Screening Part 2/Enrollment Behavioral Eligibility form.
	25. Assess participant's current eligibility status: Æ ELIGIBLE thus far ⇒ CONTINUE. Æ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE ⇒ perform and document all clinically indicated procedures. Schedule Enrollment Visit when participant is likely to be eligible. Æ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.
	26. Provide HIV/STI risk reduction counseling and condoms. Offer HIV counseling and testing for partner(s).

PTID:	Visit Date:
Screening Attempt:	Visit Code: 2.0

Initials	Procedures
	27. Provide study informational material: [add site-specific list if desired]
	28. Provide contact information and instructions to contact the site for information and/or counseling if needed before the next visit.
	29. Schedule next visit.
	30. Provide reimbursement.
	31. Ensure chart notes and all other required visit documentation is completed (hold all DataFax forms until enrollment)
	32. Review all visit documentation.
	33. If applicable, update participant record in co-enrollment database.

Screening Pelvic Exam

PTID:	Exam Date:
Screening Attempt:	Visit Code:

Initials	Procedures
	Review relevant documentation from previous and current visits.
	Prepare exam equipment and specimen collection supplies; label as needed.
	Explain exam procedures to participant and answer any questions.
	Position and drape participant comfortably.
	Palpate inguinal lymph nodes; identify all normal and abnormal findings.
	Inspect external genitalia; identify all normal and abnormal findings.
	Insert speculum, using warm water as lubricant if needed.
	Inspect cervix and vagina; identify all normal and abnormal findings.
	If clinically indicated, collect vaginal fluid for rapid BV test. Using the cotton swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.
	Collect vaginal fluid for rapid trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.
	Collect vaginal fluid (1 swab) from lateral vaginal wall for Gram stain at MTN NL. Roll swab across two labeled slides and air dry.
	If clinically indicated, collect vaginal fluid (1 swab) from lateral vaginal wall for KOH wet mount for candidiasis. Place swab in labeled tube (saline) and cap tube.
	Collect vaginal fluid (1 dacron swab) from posterior fornix for biomarker analyses at MTN NL. After tip of swab is saturated, place in labeled cryovial (PBS) and cap vial.
	Collect vaginal fluid (1 swab) from lateral vaginal wall for pH assessment. Swab fluid onto pH strip. Record pH on Vaginal Test Results form.
	Collect endocervical cells for biomarker analyses at MTN NL: • Remove cervical mucus with large cotton swab to expose cell layer (discard swab). • Insert dacron swab ~1 cm into endocervical canal and rotate two full turns. • Withdraw swab, place in labeled cryovial (PBS), and cap vial.
	Collect ecto- and endocervical cells for Pap smear per site SOPs. ⇒ NOT required if documented normal Pap within 12 months prior to enrollment
	Remove speculum and perform bimanual exam.
	Document exam per site SOPs: • Record all exam findings on Pelvic Exam Diagrams form. • Record abnormal exam findings on Screening and Enrollment Pelvic Exam form. • Record all pelvic specimen test results on Vaginal Test Results form.
	Record slides and swabs collected for assessment at the MTN NL on LDMS Specimen Tracking Sheet and Specimen Storage/PK form.

Between Screening Part 2 and Enrollment Worksheet

PTID:	Screening Attempt:

Initials & Date	Procedures
	1. If applicable per site SOPs, verify participant's locator information and re-assess adequacy based on verifiable information; document per site SOPs.
	2. Based on the Screening Part 2/Enrollment Behavioral Eligibility form, and other associated documentation, review participant eligibility re: locator information, last pregnancy outcome, breastfeeding, and contraception: Æ Eligible Æ Not Eligible ⇒ specify:
	2. If Hepatitis B test results were not available before Screening Part 2, review, grade, and assess clinical significance and clinical status: Æ HBsAg+ and HBsAb- ⇒ not eligible for study ⇒ counsel and refer Æ HBsAg- and HBsAb- ⇒ Hep B susceptible ⇒ offer vaccine if enroll Æ HBsAg- and HBsAb+ ⇒ not Hep B susceptible ⇒ vaccine not indicated
	3. Review, grade, and assess the clinical significance of Pap test result (either result report from Pap collected at Screening Part 2 or documented Pap within 12 months prior to enrollment).
	4. Review, grade, and assess the clinical significance of the results of any clinically indicated lab tests performed at Screening Part 2: Æ No clinically indicated lab tests performed Æ Clinically indicated lab tests performed ⇒ specify:
	5. Complete laboratory test result case report forms (hold forms until enrollment): Æ Pap Test Result If indicated: Æ Safety Laboratory Results Æ STI Laboratory Results
	6. Complete Screening Part 2 Medical Eligibility form and assess eligibility based on all available clinical and laboratory findings and results: Æ Eligible Æ Not Eligible ⇒ specify:

Items related to Pap smears may be deleted at sites not doing these tests.

Between Screening Part 2 and Enrollment Worksheet

PTID:	Screening Attempt:

Initials & Date	Procedures
	7. Assess clinical management and referral needs: Æ No action needed Æ Action needed ⇒ specify:
	8. Complete additional QC/QA review of Screening Part 2 and subsequent documentation per site SOPs.
	9. Perform eligibility review of all Screening Part 1 and Screening Part 2 data per site SOPs: Æ Eligible Æ Not Eligible ⇒ specify:

PTID:	Visit Date:
Screening Attempt:	Visit Code: 3.0

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs
	2. Check for co-enrollment in other studies per site SOPs: Æ NOT enrolled in another study ⇒ CONTINUE. Æ Enrolled in another study ⇒ STOP. NOT ELIGIBLE.
	3. Review previous visit documentation.
	4. Verify current screening attempt number and confirm last possible enrollment date for this attempt: ☐☐ ☐☐☐ ☐☐ DD MON YY
	5. Provide and explain all prior screening test results.
	6. Explain current eligibility status and procedures to be performed at today's visit: Æ ELIGIBLE thus far ⇒ CONTINUE. Æ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE ⇒ perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible. Æ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.
	7. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant ⇒ CONTINUE. Æ Pregnant ⇒ STOP. NOT ELIGIBLE.
	8. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis (see #9-11). Refrigerate remaining urine for possible additional testing (e.g., SDA).
	9. Review participant's Screening Part 1 and Screening Part 2 dipstick urinalysis results and determine if participant has current urinary symptoms.
	10. If 1+ for protein or glucose was identified at Screening Part 1, repeat testing should have been done at Screening Part 2. If repeat testing was not done at Screening Part 2, or if 1+ for protein or glucose was newly identified at Screening Part 2, perform dipstick urinalysis for these analytes; complete testing logs and transcribe results onto Safety Laboratory Results form: Æ If 2+ or greater for protein OR glucose ⇒ STOP. NOT ELIGIBLE. Æ If 1+ for protein at this visit and 1+ for protein at either Screening Part 1 OR Screening Part 2 ⇒ STOP. NOT ELIGIBLE. Æ If 1+ for glucose at this visit and 1+ for glucose at either Screening Part 1 OR Screening Part 2 ⇒ STOP. NOT ELIGIBLE. Æ Otherwise ⇒ ELIGIBLE ⇒ CONTINUE.

These items are structured for sites that perform urine testing in-clinic. Sites that perform in-lab testing should modify these items as needed.

PTID:	Visit Date:
Screening Attempt:	Visit Code: 3.0

Initials	Procedures
	11. If 1+ proteinuria detected at today's visit, or if participant has urinary symptoms, perform dipstick urinalysis for nitrites and LE; complete testing logs; transcribe results onto Safety Laboratory Results form: Æ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Participant must complete treatment and be free of symptoms prior to enrollment ⇒ PAUSE. NOT ELIGIBLE. ⇒ Schedule another Enrollment Visit when participant is likely to be eligible. Æ Otherwise ⇒ CONTINUE.
	12. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling Æ Provide HIV/STI risk reduction counseling and condoms Æ Collect 4 mL blood in lavender top (EDTA) tube Æ Perform and document two rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results. Æ Provide test results and post-test counseling: Æ If both tests negative ⇒ UNINFECTED ⇒ ELIGIBLE ⇒ CONTINUE. Æ If both tests positive ⇒ INFECTED ⇒ STOP. NOT ELIGIBLE. Æ If one test positive and one test negative ⇒ DISCORDANT ⇒ PAUSE ⇒ WB is required ⇒ defer further screening until HIV status is clarified. Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe results onto Screening and Enrollment HIV Test Results form.
	13. Review/update locator information and re-assess adequacy per site SOPs: Æ Adequate locator information ⇒ CONTINUE. Æ Inadequate locator information ⇒ STOP. NOT ELIGIBLE.
	14. Actively review participant's baseline medical and menstrual history, current medications, and current contraceptives to verify and/or update all information recorded at Screening Part 2. Document all updates on relevant source documents and case report forms.
	15. If clinically indicated or otherwise required to confirm eligibility, perform pelvic exam and associated lab tests: Æ No exclusionary findings identified ⇒ CONTINUE. Æ Exclusionary finding(s) identified but likely to resolve within this screening attempt ⇒ PAUSE. NOT ELIGIBLE. ⇒ Perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible. Æ Exclusionary finding(s) identified and NOT likely to resolve within this screening attempt ⇒ NOT ELIGIBLE. STOP. Provide clinical management as needed. Document in chart notes.
	16. Provide and explain available exam and lab test results.

4 mL is approximate. Tailor to reflect site-specific volume.

This item is structured for sites that perform HIV testing in clinic. Sites that perform in-lab testing should modify this item as needed.

PTID:	Visit Date:
Screening Attempt:	Visit Code: 3.0

Initials	Procedures
	17. Provide any clinically indicated treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	18. Review study contraception requirements and provide contraceptive counseling; document per site SOPs.
	19. [Prescribe/provide] contraception if indicated per site SOPs. Update baseline reproductive history documentation and Contraceptives Log form if applicable.
	20. Administer Screening Part 2/Enrollment Behavioral Eligibility form: Æ ELIGIBLE ⇒ CONTINUE. Æ NOT ELIGIBLE ⇒ STOP.
	21. Reinforce co-enrollment guidelines and provide associated information and counseling as needed; document in chart notes.
	22. Review all screening documentation, complete Enrollment Medical Eligibility form, and determine eligibility: Æ ELIGIBLE ⇒ CONTINUE ⇒ proceed to eligibility verification per site SOPs. Æ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ⇒ PAUSE ⇒ perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible. Æ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ⇒ STOP. Provide clinical management as needed. Document in chart notes.
	23. Verify participant eligibility per site SOPs: Æ ELIGIBLE ⇒ CONTINUE ⇒ proceed to enrollment informed consent process. Æ NOT ELIGIBLE ⇒ STOP. Provide clinical management as needed. Document in chart notes.
	24. Explain, conduct, and document enrollment informed consent process per site SOPs: Æ Willing and able to provide written informed consent ⇒ CONTINUE. Æ NOT willing and able to provide written informed consent ⇒ STOP. NOT ELIGIBLE.
	25. Explain, conduct, and document specimen storage informed consent process per site SOPs.
	26. Administer Baseline Behavior Assessment form.
	27. Administer Enrollment ACASI Questionnaire.
	28. Collect 10 mL blood in lavender top (EDTA) tube; refrigerate pending delivery to lab for plasma archive.
	29. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.
	30. If participant is susceptible (HBsAg- and HBsAb-), offer Hepatitis B vaccine: Æ Participant accepted; vaccine was administered; document per site SOPs and record on Concomitant Medications Log form. Æ Participant refused; refusal was documented.
	31. Verify documentation of enrollment informed consent and assign next sequential Clinic Randomization Envelope to participant per site SOPs. **PARTICIPANT IS NOW ENROLLED IN THE STUDY.**

This item refers to verification of eligibility and should be completed by a staff member other than the person who determines eligibility per the previous item.

PTID:	Visit Date:
Screening Attempt:	Visit Code: 3.0

Initials	Procedures
	32. Open the assigned envelope and confirm that the envelope number printed on the prescription contained in the envelope corresponds with the number on the outside of the envelope. Inform participant of her assignment (gel or tablets).
	33. Complete prescription.
	34. Give completed white original prescription to participant to bring to pharmacy to obtain study product. Retain envelope and yellow copy of prescription in participant's study notebook.
	35. Verify participant received study product. Review product use instructions with participant in detail, using visual aids as needed.
	36. Ask participant if she has any questions about the product use instructions. If so, address each question.
	37. Ask participant if she is ready to [insert her gel] / [take her tablets] now. Æ If yes, proceed. Æ If no, note and address all questions and concerns, then proceed. _____ _____ _____ _____
	38. First product use: Æ For participants assigned to gel, provide a private space for gel insertion, while standing by in case participant needs assistance; remind participant to discard the wrapper and applicator in the bin provided. Æ For participants assigned to tablets, a private space is not required; remind participant to discard the bottle seals and cotton wool in the bin provided.
	39. De-brief with participant about her first study product use experience: • *Was she able to [insert gel] / [take the lighter tablet and the darker tablet]?* • *Did she have any difficulties?* • *Does she have any questions about how to use her product at home?* • *Does she have any concerns about using her product at home?* • *Would she like any additional information or instructions?* Æ If no problems or questions or concerns, proceed. Æ If yes, note and address all questions and concerns, then proceed. _____ _____ _____ _____ _____

PTID:	Visit Date:
Screening Attempt:	Visit Code: 3.0

Initials	Procedures
	40. Provide adherence counseling per Enrollment Adherence Counseling checklist; document per site SOPs.
	41. Schedule next visit and remind participant to: • Record menstrual bleeding days on appointment card • Record date and time of last product use on appointment card • Bring appointment card to next visit • Bring all unused study product to next visit • Bring any other medication she is taking to next visit
	42. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.
	43. Provide reimbursement.
	44. Ensure that chart notes, Enrollment form, Pre-Existing Conditions form, Baseline Family Planning form, and all other required visit documentation is completed.
	45. Review all visit documentation.
	46. Update participant entries in co-enrollment database.
	47. Fax all required DataFax forms to SCHARP DataFax: Æ Screening Consent Æ Demographics Æ Screening and Enrollment HIV Test Results (completed at Screening Part 1) Æ Screening and Enrollment HIV Test Results (completed at Enrollment) Æ Safety Laboratory Results Æ STI Laboratory Results Æ Screening and Enrollment Pelvic Exam Æ Vaginal Test Results Æ Pap Test Results Æ Specimen Storage/PK (completed at Screening Part 2) Æ Specimen Storage/PK (completed at Enrollment) Æ Enrollment Æ Pre-Existing Conditions Æ Concomitant Medications Log Æ Contraceptives Log Æ Baseline Family Planning Æ Baseline Behavior Assessment
	48. Back-up ACASI questionnaire data.
	49. Upload ACASI questionnaire data to SCHARP.

PTID:	Visit Date:	Visit Code: 4.0

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs.
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: Æ NOT enrolled in another study. Æ Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.
	3. Instruct participant to return unused study product to pharmacy.
	4. Review previous visit documentation.
	5. Review elements of informed consent as needed.
	6. Explain procedures to be performed at today's visit.
	7. Review/update locator information.
	8. Administer Monthly Product Adherence and Behavior Assessment form.
	9. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant. Æ Pregnant, pregnancy first identified at a previous visit: Æ Continue to HOLD study product (complete #25 accordingly). Æ If applicable, refer to MTN-016; document in chart notes. Æ Pregnant, pregnancy newly identified at today's visit: Æ HOLD study product (complete #25 accordingly). If applicable, arrange to collect product not returned today within 5 working days. Æ Initiate Pregnancy Management Worksheet Æ Complete Pregnancy Report and History form.
	10. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #15). Refrigerate remaining urine for possible additional testing (e.g., SDA).
	11. Administer Monthly Symptoms form.
	12. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.
	13. Provide contraceptive counseling; document per site SOPs.
	14. [Prescribe/provide] contraception if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.

PTID:	Visit Date:	Visit Code: 4.0

Initials	Procedures
	15. Perform dipstick urinalysis: Æ If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. Æ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.
	16. Perform physical exam including weight measurement; document per site SOPs.
	17. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.
	18. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #23-24).
	19. Provide and explain all available findings and results.
	20. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	21. If indicated, administer Hepatitis B vaccine; document per site SOPs.
	22. If required based on all available information, complete AE Log form(s).
	23. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling Æ Provide HIV/STI risk reduction counseling and condoms Æ Collect blood: Æ 1 x 5 mL lavender top (EDTA) tube Æ 1 x 5 mL red top (no additive) tube [additional blood needed for clinically indicated testing also may be collected at this time] Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes. Æ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off. Æ Provide test results and post-test counseling: Æ All tests negative. Æ At least one test positive ⇒ HOLD study product (complete #25 accordingly). If applicable, arrange to collect product not returned today within 24 hours. Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.

PTID:	Visit Date:	Visit Code: 4.0

Initials	Procedures
	24. Prepare remaining blood for required testing: • Liver and renal function tests (AST, ALT, phosphate, creatinine) If clinically indicated: • Complete blood count • Syphilis serology • Hepatitis B surface antigen • Hepatitis B surface antibody • Plasma archive (as part of sample 2 or per protocol Section 7.6.1) • HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1) • CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)
	25. Assess eligibility to continue product use: Æ ELIGIBLE: Æ Review Unused Product Returns slip completed by pharmacy staff. Æ Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs. Æ Schedule next visit. Æ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED. Æ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook. Æ NOT ELIGIBLE: Æ Schedule next visit Æ Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook *(NA if hold initiated at previous visit).* Æ Complete Product/Hold Discontinuation Log form *(NA if hold initiated at previous visit).*
	26. Reinforce scheduling of next visit and remind participant to: • Record menstrual bleeding days on appointment card • Record date and time of last product use on appointment card • Bring appointment card to next visit • Bring all unused study product to next visit • Bring any other medication she is taking to next visit
	27. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.
	28. Provide reimbursement.
	29. Ensure that chart notes and all other required visit documentation is completed.

PTID:	Visit Date:	Visit Code: 4.0

Initials	Procedures
	30. Fax all required DataFax forms to SCHARP DataFax: Æ Follow-up Visit Æ Monthly Product Adherence and Behavior Assessment Æ Monthly Symptoms Æ Follow-up HIV Rapid Test Results Æ Follow-up Family Planning Æ Product Returns and Dispensations Æ Safety Laboratory Results If Applicable: Æ Concomitant Medications Log (new and/or updated form pages) Æ Contraceptives Log (new and/or updated form pages) Æ Follow-up Pelvic Exam Æ Vaginal Test Results Æ Pap Test Results Æ STI Laboratory Results Æ HIV Western Blot Test Results Æ Specimen Storage/PK Æ Seroconverter Laboratory Test Results Æ Product Hold/Discontinuation Log (new and/or updated form pages) Æ Adverse Experience Log (new and/or updated form pages) Æ Pregnancy Report and History Æ Pregnancy Outcome

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs.
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: Æ NOT enrolled in another study. Æ Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.
	3. Instruct participant to return unused study product to pharmacy.
	4. Review previous visit documentation.
	5. Review elements of informed consent as needed.
	6. Explain procedures to be performed at today's visit.
	7. Review/update locator information.
	8. Administer Monthly Product Adherence and Behavior Assessment form.
	9. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant. Æ Pregnant, pregnancy first identified at a previous visit: Æ Continue to HOLD study product. Æ If applicable, refer to MTN-016; document in chart notes. Æ Pregnant, pregnancy newly identified at today's visit: Æ HOLD study product (complete #26 accordingly). If applicable, arrange to collect product not returned today within 5 working days. Æ Initiate Pregnancy Management Worksheet. Æ Complete Pregnancy Report and History form.
	10. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis (see #15). Refrigerate remaining urine for possible additional testing (e.g., SDA).
	11. Administer Monthly Symptoms form.
	12. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.
	13. Provide contraceptive counseling; document per site SOPs.
	14. [Prescribe/provide] contraception if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.
	15. If clinically indicated, perform dipstick urinalysis for protein, glucose, nitrites, and/or LE: ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	16. If clinically indicated, measure weight; document per site SOPs.
	17. If clinically indicated, perform physical exam; document per site SOPs.
	18. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.
	19. Determine if any other clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #24-25).
	20. Provide and explain all available findings and results.
	21. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	22. If indicated, administer Hepatitis B vaccine; document per site SOPs.
	23. If required based on all available information, complete AE Log form(s).
	24. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling Æ Provide HIV/STI risk reduction counseling and condoms Æ Collect 5 mL blood in lavender top (EDTA) tube [additional blood needed for clinically indicated testing also may be collected at this time] Æ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off. Æ Provide test results and post-test counseling: Æ All tests negative. Æ At least one test positive ⇒ HOLD study product (complete #26 accordingly). If applicable, arrange to collect product not returned today within 24 hours. Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.
	25. If clinically indicated, prepare blood for additional testing; tests that may be clinically indicated include: • Liver function tests (AST, ALT) • Renal function tests (phosphate, creatinine) • Complete blood count • Syphilis serology • Hepatitis B surface antigen • Hepatitis B surface antibody • Plasma archive (as part of sample 2 or per protocol Section 7.6.1) • HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1) • CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	26. Assess eligibility to continue product use: Æ ELIGIBLE: Æ Review Unused Product Returns slip completed by pharmacy staff. Æ Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs. Æ Schedule next visit. Æ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED. Æ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook. Æ NOT ELIGIBLE: Æ Schedule next visit Æ Complete Study Product Request Slip marked HOLD or PERMENENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook *(NA if hold initiated at previous visit).* Æ Complete Product/Hold Discontinuation Log form *(NA if hold initiated at previous visit).*
	27. Reinforce scheduling of next visit and remind participant to: • Record menstrual bleeding days on appointment card • Record date and time of last product use on appointment card • Bring appointment card to next visit • Bring all unused study product to next visit • Bring any other medication she is taking to next visit
	28. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.
	29. Provide reimbursement.
	30. Ensure that chart notes and all other required visit documentation is completed.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	31. Fax all required DataFax forms to SCHARP DataFax: Æ Follow-up Visit Æ Monthly Product Adherence and Behavior Assessment Æ Monthly Symptoms Æ Follow-up HIV Rapid Test Results Æ Follow-up Family Planning Æ Product Returns and Dispensations If Applicable: Æ Concomitant Medications Log (new and/or updated form pages) Æ Contraceptives Log (new and/or updated form pages) Æ Follow-up Pelvic Exam Æ Vaginal Test Results Æ Pap Test Results Æ STI Laboratory Results Æ Safety Laboratory Results Æ HIV Western Blot Test Results Æ Specimen Storage/PK Æ Seroconverter Laboratory Test Results Æ Product Hold/Discontinuation Log (new and/or updated form pages) Æ Adverse Experience Log (new and/or updated form pages) Æ Pregnancy Report and History Æ Pregnancy Outcome

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs.
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: Æ NOT enrolled in another study. Æ Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.
	3. Instruct participant to return unused study product to pharmacy.
	4. Review previous visit documentation.
	5. Review elements of informed consent as needed.
	6. Explain procedures to be performed at today's visit.
	7. Review/update locator information.
	8. Administer the appropriate (Oral or Vaginal) Product Adherence and Behavior Assessment form.
	9. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.
	10. Administer the appropriate follow-up ACASI Questionnaire.
	11. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant. Æ Pregnant, pregnancy first identified at a previous visit: Æ Continue to HOLD study product. Æ If applicable, refer to MTN-016; document in chart notes. Æ Pregnant, pregnancy newly identified at today's visit: Æ HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 5 working days. Æ Initiate Pregnancy Management Worksheet. Æ Complete Pregnancy Report and History form.
	12. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #17). Refrigerate remaining urine for possible additional testing (e.g., SDA).
	13. Administer Monthly Symptoms form.
	14. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs.
	15. Provide contraceptive counseling; document per site SOPs.
	16. [Prescribe/provide] contraception if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	17. Perform dipstick urinalysis: Æ If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. Æ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.
	18. Perform physical exam including weight measurement; document per site SOPs.
	19. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist.
	20. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #25-26).
	21. Provide and explain all available findings and results.
	22. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	23. If indicated, administer Hepatitis B vaccine; document per site SOPs.
	24. If required based on all available information, complete AE Log form(s).
	25. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling Æ Provide HIV/STI risk reduction counseling and condoms Æ Collect blood: Æ 1 x 10 mL lavender top (EDTA) tube Æ 1 x 5 mL lavender top (EDTA) tube Æ 1 x 5 mL red top (no additive) tube [additional blood needed for clinically indicated testing also may be collected at this time] Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes. Æ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off. Æ Provide test results and post-test counseling: Æ All tests negative. Æ At least one test positive ⇒ HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 24 hours. Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	26. Prepare remaining blood for required testing: • Liver and renal function tests (AST, ALT, phosphate, creatinine) • Plasma archive If clinically indicated: • Complete blood count • Syphilis serology • Hepatitis B surface antigen • Hepatitis B surface antibody • Plasma archive (as part of sample 2 or per protocol Section 7.6.1) • HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1) • CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)
	27. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.
	28. Assess eligibility to continue product use: Æ ELIGIBLE: Æ Review Unused Product Returns slip completed by pharmacy staff. Æ Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs. Æ Schedule next visit. Æ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED. Æ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook. Æ NOT ELIGIBLE: Æ Schedule next visit Æ Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook *(NA if hold initiated at previous visit)*. Æ Complete Product/Hold Discontinuation Log form *(NA if hold initiated at previous visit).*
	29. Reinforce scheduling of next visit and remind participant to: • Record menstrual bleeding days on appointment card • Bring appointment card to next visit • Bring all unused study product to next visit • Bring any other medication she is taking to next visit
	30. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.
	31. Provide reimbursement.
	32. Ensure that chart notes and all other required visit documentation is completed.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	33. Fax all required DataFax forms to SCHARP DataFax: Æ Follow-up Visit Æ Oral or Vaginal Product Adherence and Behavior Assessment Æ Monthly Symptoms Æ Follow-up HIV Rapid Test Results Æ Follow-up Family Planning Æ Product Returns and Dispensations Æ Safety Laboratory Results Æ Specimen Storage/PK If Applicable: Æ Concomitant Medications Log (new and/or updated form pages) Æ Contraceptives Log (new and/or updated form pages) Æ Follow-up Pelvic Exam Æ Vaginal Test Results Æ Pap Test Results Æ STI Laboratory Results Æ HIV Western Blot Test Results Æ Seroconverter Laboratory Test Results Æ Product Hold/Discontinuation Log (new and/or updated form pages) Æ Adverse Experience Log (new and/or updated form pages) Æ Pregnancy Report and History Æ Pregnancy Outcome
	34. Back-up ACASI questionnaire data.
	35. Upload ACASI questionnaire data to SCHARP.

Follow-up Pelvic Exam

Conducted semiannually, at PUEV, and when clinically indicated

PTID:	Exam Date:	Visit Code:

Initials	Procedures
	Review relevant documentation from previous and current visits.
	Prepare exam equipment and specimen collection supplies; label as needed.
	Explain exam procedures to participant and answer any questions.
	Position and drape participant comfortably.
	Palpate inguinal lymph nodes; identify all normal and abnormal findings.
	Inspect external genitalia; identify all normal and abnormal findings.
	Insert speculum, using warm water as lubricant if needed.
	Inspect cervix and vagina; identify all normal and abnormal findings.
	If clinically indicated, collect vaginal fluid for rapid BV test. Using the cotton swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.
	Annually, at PUEV, and when clinically indicated, collect vaginal fluid for rapid trichomonas test. Using the rayon swab from an OSOM kit, swab fluid from lateral vaginal wall, place swab in labeled tube (plain), and cap tube.
	Semi-Annually, Annually, and at PUEV, collect vaginal fluid (1 swab) from lateral vaginal wall for Gram stain at MTN NL. Roll swab across two labeled slides and air dry.
	If clinically indicated, collect vaginal fluid (1 swab) from lateral vaginal wall for KOH wet mount for candidiasis. Place swab in labeled tube (saline) and cap tube.
	At all exams, collect vaginal fluid (1 dacron swab) from posterior fornix for biomarker analyses at MTN NL. After tip of swab is saturated, place in labeled cryovial (PBS) and cap vial.
	At all exams, collect vaginal fluid (1 swab) from lateral vaginal wall for pH assessment. Swab fluid onto pH strip. Record pH on Vaginal Test Results form.
	At all exams, collect endocervical cells for biomarker analyses at MTN NL: • Remove cervical mucus with large cotton swab to expose cell layer (discard swab). • Insert dacron swab ~1 cm into endocervical canal and rotate two full turns. • Withdraw swab, place in labeled cryovial (PBS), and cap vial.
	At PUEV and when clinically indicated, collect ecto- and endocervical cells for Pap smear per site SOPs.
	Remove speculum and perform bimanual exam.
	Document exam per site SOPs: • Record all exam findings on Pelvic Exam Diagrams form. • Record abnormal exam findings on Follow-Up Pelvic Exam form. • Record all pelvic specimen test results on Vaginal Test Results form. • Record all Pap specimen test result on PAP Test Result form
	Record slides and swabs collected for assessment at the MTN NL on LDMS Specimen Tracking Sheet and Specimen Storage/PK form.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs.
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: Æ NOT enrolled in another study. Æ Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.
	3. Instruct participant to return unused study product to pharmacy.
	4. Review previous visit documentation.
	5. Review elements of informed consent as needed.
	6. Explain procedures to be performed at today's visit.
	7. Review/update locator information.
	8. Administer the appropriate (Oral or Vaginal) Product Adherence and Behavior Assessment form.
	9. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.
	10. Administer the appropriate follow-up ACASI Questionnaire.
	11. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant. Æ Pregnant, pregnancy first identified at a previous visit: Æ Continue to HOLD study product. Æ If applicable, refer to MTN-016; document in chart notes. Æ Pregnant, pregnancy newly identified at today's visit: Æ HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 5 working days. Æ Initiate Pregnancy Management Worksheet. Æ Complete Pregnancy Report and History form.
	12. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #17). Refrigerate remaining urine for possible additional testing (e.g., SDA).
	13. Administer Monthly Symptoms form.
	14. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable.
	15. Provide contraceptive counseling; document per site SOPs.
	16. [Prescribe/provide] contraceptives if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	17. Perform dipstick urinalysis: Æ If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. Æ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.
	18. Perform physical exam including weight and height measurements; document per site SOPs.
	19. Perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.
	20. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #25-26).
	21. Provide and explain all available findings and results.
	22. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	23. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log form, and indicate that the vaccine was given on the Follow-up Visit form.
	24. If required based on all available information, complete AE Log form(s).

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	25. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling Æ Provide HIV/STI risk reduction counseling and condoms Æ Collect blood: Æ 1 x 10 mL lavender top (EDTA) tube Æ 1 x 5 mL lavender top (EDTA) tube Æ 1 x 5 mL red top (no additive) tube [additional blood needed for clinically indicated testing also may be collected at this time] Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes. Æ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off. Æ Provide test results and post-test counseling: Æ All tests negative. Æ At least one test positive ⇒ HOLD study product (complete #28 accordingly). If applicable, arrange to collect product not returned today within 24 hours. Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.
	26. Prepare remaining blood for required testing: • Complete blood count • Liver and renal function tests (AST, ALT, phosphate, creatinine) • Plasma archive If clinically indicated: • Syphilis serology • Hepatitis B surface antigen • Hepatitis B surface antibody • Plasma archive (as part of sample 2 or per protocol Section 7.6.1) • HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1) • CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)
	27. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	28. Assess eligibility to continue product use: Æ ELIGIBLE: Æ Review Unused Product Returns Slip completed by pharmacy staff. Æ Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs. Æ Schedule next visit. Æ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED. Æ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook. Æ NOT ELIGIBLE: Æ Schedule next visit Æ Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook *(NA if hold is continuing from a previous visit)*. Æ Complete Product/Hold Discontinuation Log form *(NA if hold is continuing from a previous visit)*.
	29. Reinforce scheduling of next visit and remind participant to: • Record menstrual bleeding days on appointment card • Bring appointment card to next visit • Bring all unused study product to next visit • Bring any other medication she is taking to next visit
	30. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.
	31. Provide reimbursement.
	32. Ensure that chart notes and all other required visit documentation is completed.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	33. Fax all required DataFax forms to SCHARP DataFax: Æ Follow-up Visit Æ Oral or Vaginal Product Adherence and Behavior Assessment Æ Monthly Symptoms Æ Follow-up HIV Rapid Test Results Æ Follow-up Family Planning Æ Follow-up Pelvic Exam Æ Product Returns and Dispensations Æ Safety Laboratory Results Æ Specimen Storage/PK Æ Vaginal Test Results If Applicable: Æ Concomitant Medications Log (new and/or updated form pages) Æ Contraceptives Log (new and/or updated form pages) Æ Pap Test Result Æ STI Laboratory Results Æ HIV Western Blot Test Results Æ Seroconverter Laboratory Test Results Æ Product Hold/Discontinuation Log (new and/or updated form pages) Æ Adverse Experience Log (new and/or updated form pages) Æ Pregnancy Report and History Æ Pregnancy Outcome Æ Missed Visit
	34. Back-up ACASI questionnaire data.
	35. Upload ACASI questionnaire data to SCHARP.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs.
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: Æ NOT enrolled in another study. Æ Enrolled in another study ⇒ product hold may be required. Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT. Schedule participant to return when a response from PSRT is expected.
	3. Instruct participant to return unused study product to pharmacy.
	4. Review previous visit documentation.
	5. Review elements of informed consent as needed.
	6. Explain procedures to be performed at today's visit.
	7. Review/update locator information.
	8. Administer the Menstrual Practices and Study Disclosure Assessment form
	9. Administer the appropriate (Oral or Vaginal) Product Adherence and Behavior Assessment form.
	10. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.
	11. Administer the appropriate follow-up ACASI Questionnaire.
	12. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant. Æ Pregnant, pregnancy first identified at a previous visit: Æ Continue to HOLD study product. Æ If applicable, refer to MTN-016; document in chart notes. Æ Pregnant, pregnancy newly identified at today's visit: Æ HOLD study product (complete #30 accordingly). If applicable, arrange to collect product not returned today within 5 working days. Æ Initiate Pregnancy Management Worksheet. Æ Complete Pregnancy Report and History form.
	13. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #19).
	14. Refrigerate remaining urine for gonorrhea and Chlamydia SDA testing.
	15. Administer Monthly Symptoms form.
	16. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable.
	17. Provide contraceptive counseling; document per site SOPs.
	18. [Prescribe/provide] contraceptives if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	19. Perform dipstick urinalysis: Æ If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. Æ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If 1+ or greater for protein or glucose, product HOLD may be required; see protocol Sections 9.6 and 9.7. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.
	20. Perform physical exam including weight and height measurements; document per site SOPs.
	21. Perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.
	22. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #27-28).
	23. Provide and explain all available findings and results.
	24. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	25. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log form, and indicate that the vaccine was given on the Follow-up Visit form.
	26. If required based on all available information, complete AE Log form(s).

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	27. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling Æ Provide HIV/STI risk reduction counseling and condoms Æ Collect blood: Æ 1 x 10 mL lavender top (EDTA) tube Æ 2 x 5 mL lavender top (EDTA) tube Æ 2 x 5 mL red top (no additive) tube [additional blood needed for clinically indicated testing also may be collected at this time] Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes. Æ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off. Æ Provide test results and post-test counseling: Æ All tests negative. Æ At least one test positive ⇒ HOLD study product (complete #30 accordingly). If applicable, arrange to collect product not returned today within 24 hours. Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.
	28. Prepare remaining blood for required testing: • Complete blood count • Liver and renal function tests (AST, ALT, phosphate, creatinine) • Plasma archive • Syphilis serology If clinically indicated: • Hepatitis B surface antigen (required if susceptible but not vaccinated) • Hepatitis B surface antibody • Plasma archive (as part of sample 2 or per protocol Section 7.6.1) • HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1) • CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)
	29. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	30. Assess eligibility to continue product use: Æ ELIGIBLE: Æ Review Unused Product Returns Slip completed by pharmacy staff. Æ Provide product use instructions and adherence counseling per Follow-Up Adherence Counseling Checklist; document per site SOPs. Æ Schedule next visit. Æ Complete Study Product Request Slip marked RE-SUPPLY; product also may be RE-ISSUED. Æ Give completed white original Study Product Request Slip to participant to bring to pharmacy; retain yellow copy in participant's study notebook. Æ NOT ELIGIBLE: Æ Schedule next visit Æ Complete Study Product Request Slip marked HOLD or PERMANENTLY DISCONTINUE; deliver completed white original to pharmacy; retain yellow copy in participant's study notebook *(NA if hold is continuing from a previous visit)*. Æ Complete Product/Hold Discontinuation Log form *(NA if hold is continuing from a previous visit).*
	31. Reinforce scheduling of next visit and remind participant to: • Record menstrual bleeding days on appointment card • Bring appointment card to next visit • Bring all unused study product to next visit • Bring any other medication she is taking to next visit
	32. Provide contact information and instructions to report symptoms and/or request information, counseling, study product, or condoms before next visit.
	33. Provide reimbursement.
	34. Ensure that chart notes and all other required visit documentation is completed.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	35. Fax all required DataFax forms to SCHARP DataFax: Æ Follow-up Visit Æ Oral or Vaginal Product Adherence and Behavior Assessment Æ Menstrual Practices and Study Disclosure Assessment Æ Monthly Symptoms Æ Follow-up HIV Rapid Test Results Æ Follow-up Family Planning Æ Follow-up Pelvic Exam Æ Product Returns and Dispensations Æ Safety Laboratory Results Æ STI Laboratory Results Æ Specimen Storage/PK Æ Vaginal Test Results If Applicable: Æ Concomitant Medications Log (new and/or updated form pages) Æ Contraceptives Log (new and/or updated form pages) Æ Pap Test Result Æ HIV Western Blot Test Results Æ Seroconverter Laboratory Test Results Æ Product Hold/Discontinuation Log (new and/or updated form pages) Æ Adverse Experience Log (new and/or updated form pages) Æ Pregnancy Report and History Æ Pregnancy Outcome Æ Missed Visit
	36. Back-up ACASI questionnaire data.
	37. Upload ACASI questionnaire data to SCHARP.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs.
	2. Check for co-enrollment in other (non-approved) studies per site SOPs: Æ NOT enrolled in another study. Æ Enrolled in another study ⇒ Refer to SSP Section 10. Obtain as much information as possible about the co-enrollment — from the participant and from the other study team — for use when consulting the PSRT.
	3. Instruct participant to return unused study product to pharmacy.
	4. Review previous visit documentation.
	5. Review elements of informed consent as needed.
	6. Explain procedures to be performed at today's visit.
	7. Review/update locator information.
	8. Administer the Menstrual Practices and Study Disclosure Assessment form
	9. Administer the appropriate (Oral or Vaginal) Product Adherence and Behavior Assessment form.
	10. Determine date and time of last study product use and record on Specimen Storage/PK form. Collect and file participant source document if available.
	11. Administer Perceived Product Assessment form. • Clinician to complete item 1 or 2
	12. Administer the appropriate follow-up ACASI Questionnaire.
	13. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant. Æ Pregnant, pregnancy first identified at a previous visit: Æ If applicable, refer to MTN-016; document in chart notes. Æ Pregnant, pregnancy newly identified at today's visit: Æ Initiate Pregnancy Management Worksheet. Æ Complete Pregnancy Report and History form.
	14. Retain aliquot of urine used for pregnancy testing for dipstick urinalysis (see #20).
	15. Refrigerate remaining urine for gonorrhea and Chlamydia SDA testing.
	16. Administer Monthly Symptoms form.
	17. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable.
	18. Provide contraceptive counseling; document per site SOPs.
	19. [Prescribe/provide] contraceptives if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	20. Perform dipstick urinalysis: Æ If participant DOES NOT have urinary symptoms (per her interval medical history) test for protein and glucose only. Æ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.
	21. Perform physical exam including weight and height measurements; document per site SOPs.
	22. Perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.
	23. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #28-29).
	24. Provide and explain all available findings and results.
	25. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	26. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log, and indicate that the vaccine was given on the Follow-up Visit form.
	27. If required based on all available information, complete AE Log form(s).
	28. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling Æ Provide HIV/STI risk reduction counseling and condoms Æ Collect blood: Æ 1 x 10 mL lavender top (EDTA) tube Æ 2 x 5 mL lavender top (EDTA) tube Æ 3 x 5 mL red top (no additive) tube [additional blood needed for clinically indicated testing also may be collected at this time] Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes. Æ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off. Æ Provide test results and post-test counseling Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	29. Prepare remaining blood for required testing: • Complete blood count • Liver and renal function tests (AST, ALT, phosphate, creatinine) • Plasma archive • Syphilis serology • Hepatitis B surface antigen If clinically indicated: • Hepatitis B surface antibody • Plasma archive (as part of sample 2 or per protocol Section 7.6.1) • HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1) • CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)
	30. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.
	31. If applicable, arrange to collect product not returned today within 2 working days.
	32. Reinforce scheduling of next visit and remind participant to: • Record menstrual bleeding days on appointment card • Bring appointment card to next visit • Bring any other medication she is taking to next visit If considered an early termination visit: Æ Schedule a final study contact for disclosure of all remaining exam and lab test results. Æ If applicable, schedule contact to ascertain the participant's pregnancy outcome. Æ If applicable, schedule clinically indicated follow-up for unresolved SAEs/EAEs and previously reported AEs found to have increased severity at this visit. Æ Inform the participant of planned methods and timeframes for unblinding and dissemination of study results. Æ Determine and document whether participant is willing to be contacted about future studies for which she may be eligible. Æ Reinforce site contact information, update participant locator information, and determine participant preference for post-study contact.
	33. Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit.
	34. Provide reimbursement.
	35. Ensure that chart notes and all other required visit documentation is completed.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	36. Fax all required DataFax forms to SCHARP DataFax: Æ Follow-up Visit Æ Oral or Vaginal Product Adherence and Behavior Assessment Æ Menstrual Practices and Study Disclosure Assessment Æ Monthly Symptoms Æ Pap Test Result Æ Follow-up HIV Rapid Test Results Æ Follow-up Family Planning Æ Follow-up Pelvic Exam Æ Perceived Product Assessment Æ Product Returns and Dispensations Æ Product Use End Visit Æ Safety Laboratory Results Æ STI Laboratory Results Æ Specimen Storage/PK Æ Vaginal Test Results If Applicable: Æ Concomitant Medications Log (new and/or updated form pages) Æ Contraceptives Log (new and/or updated form pages) Æ HIV Western Blot Test Results Æ Seroconverter Laboratory Test Results Æ Adverse Experience Log (new and/or updated form pages) Æ Pregnancy Report and History Æ Pregnancy Outcome
	37. Back-up ACASI questionnaire data.
	38. Upload ACASI questionnaire data to SCHARP.

If the PUEV is not completed, only the PPA and PEV forms are to be completed. Do not complete a Missed Visit form or any other VOICE CRF for this visit.

Note: *Use this checklist only for participants who are completing a scheduled Study Exit Visit approximately 8 weeks after their PUEV. If a participant is completing an early termination visit, use the PUEV checklist instead.*

PTID:	Visit Date:	Visit Code: 89.0

Initials	Procedures
	1. Confirm participant identity and PTID per site SOPs.
	2. Review previous visit documentation.
	3. Review elements of informed consent as needed.
	4. Explain procedures to be performed at today's visit.
	5. Review update locator information.
	6. Administer the Menstrual Practices and Study Disclosure Assessment form.
	7. Administer the Study Exit Behavior Assessment form.
	8. Administer the Product hold/Discontinuers/SEV ACASI Questionnaire.
	9. Collect urine (15-60 mL), aliquot ~5 mL, and perform pregnancy test: Æ NOT pregnant. Æ Pregnant, pregnancy first identified at a previous visit: Æ If applicable, refer to MTN-016; document in chart notes. Æ Pregnant, pregnancy newly identified at today's visit: Æ Initiate Pregnancy Management Worksheet. Æ Complete Pregnancy Report and History form. Æ Explain to the participant that she will continue to be followed until the outcome of her pregnancy can be ascertained.
	10. Retain aliquot of urine used for pregnancy testing for possible dipstick urinalysis (see #15). Refrigerate remaining urine for possible additional testing (e.g., SDA).
	11. Administer Monthly Symptoms form.
	12. Collect interval medical and menstrual history with documentation of current medications and herbal/traditional preparations; document per site SOPs. Update Concomitant Medications Log and/or Contraceptives Log if applicable. For medications/contraceptives that the participant continues to use at this visit, mark the "Continuing at end of study" box in the "Date Stopped" field.
	13. Provide contraceptive counseling; document per site SOPs.
	14. [Prescribe/provide] contraceptives if indicated; update reproductive history documentation and Contraceptives Log form if applicable. Complete Follow-Up Family Planning form.
	15. If clinically indicated, perform dipstick urinalysis: Æ If participant has urinary symptoms, test for protein, glucose, nitrites, and LE. ⇒ If 1+ or greater for protein, nitrites and LE also should be tested. ⇒ If positive for nitrites and LE, and participant is symptomatic, treat for UTI per site SOPs; document per site SOPs and record on Concomitant Medications Log form. Complete testing logs and transcribe results onto Safety Laboratory Results form.

PTID:	Visit Date:	Visit Code: 89.0

Initials	Procedures
	16. If clinically indicated, measure weight and/or perform physical exam. Document per site SOPs.
	17. If clinically indicated, perform and document pelvic exam per Follow-Up Pelvic Exam Checklist and site SOPs.
	18. Determine if any clinically indicated urine or blood testing is required. ⇒ If yes, document per site SOPs; blood required for testing should be collected when blood is drawn for HIV testing (see #24-25).
	19. Provide and explain all available findings and results.
	20. If RTI/STI is diagnosed, provide treatment; document per site SOPs and record on Concomitant Medications Log form. If indicated, offer STI testing and/or treatment for partners; document per site SOPs.
	21. If indicated, administer Hepatitis B vaccine; document per site SOPs. Record the vaccination as a separate entry on the Concomitant Medications Log, and indicate that the vaccine was given on the Follow-up Visit form.
	22. If required based on all available information, complete AE Log form(s).
	23. Review all Adverse Experience Log forms completed for the participant and update the forms as needed. For AEs that are "continuing" at this visit, update the status/outcome of the AE to "continuing at end of study participation." Any SAEs/EAEs identified as continuing at this visit must be re-evaluated within 30 days. Any previously reported AEs found to have increased in severity at this visit also must be re-evaluated in 30 days. Consult with the IoR/designee to establish a clinically appropriate follow-up plan for the participant and document the plan on the participant's file.
	24. Provide and document HIV counseling and testing per site SOPs: Æ Provide HIV pre-test counseling. Æ Provide HIV/STI risk reduction counseling and condoms. Æ Collect blood: Æ 1 x 10 mL lavender top (EDTA) tube Æ 1 x 5 mL lavender top (EDTA) tube [additional blood needed for clinically indicated testing also may be collected at this time] Æ Perform and document rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off. Æ Provide test results and post-test counseling: Æ At least one test positive ⇒ Advise the participant that additional visits and tests may be needed to confirm or clarify her HIV status. Æ Provide referrals if needed/requested. Æ Offer HIV counseling and testing for partner(s). Æ Transcribe rapid test results onto Follow-up HIV Rapid Test Results form.

PTID:	Visit Date:	Visit Code: 89.0

Initials	Procedures
	25. Prepare remaining blood for required testing: • Plasma archive If clinically indicated: • Complete blood count • Liver and renal function tests (AST, ALT, phosphate, creatinine) • Syphilis serology • Hepatitis B surface antigen • Hepatitis B surface antibody • HIV-1 RNA PCR (as part of sample 2 or per protocol Section 7.6.1) • CD4+ T cell count (as part of sample 2 or per protocol Section 7.6.1)
	26. Complete Specimen Storage/PK form and LDMS Specimen Tracking Sheet.
	27. If the Termination and PUEV visits are conducted during the same visit, arrange to collect product not returned today within 2 working days. If Termination visit only, all study product should have already been collected prior to termination, so no product collection necessary.
	28. Reinforce site contact information and: Æ If applicable, schedule a final study contact for disclosure of all remaining exam and lab test results. Æ If applicable, schedule contact to ascertain the participant's pregnancy outcome. Æ If applicable, schedule clinically indicated follow-up for unresolved SAEs/EAEs and previously reported AEs found to have increased in severity at this visit. Æ Inform the participant of planned methods and timeframes for unblinding and dissemination of study results. Æ Determine and document whether participant is willing to be contacted about future studies for which she may be eligible. Æ Determine participant preference for post-study contact.
	29. Provide reimbursement.
	30. Ensure that chart notes and all other required visit documentation is completed.

PTID:	Visit Date:	Visit Code: 89.0

Initials	Procedures
	31. Fax all required DataFax forms to SCHARP DataFax: Æ Menstrual Practices and Study Disclosure Assessment Æ Study Exit Behavior Assessment Æ Monthly Symptoms Æ Follow-up HIV Rapid Test Results Æ Follow-up Family Planning Æ Specimen Storage/PK Æ End of Study Inventory Æ Study Exit Visit Æ Termination If the Study Exit/Termination Visit is not completed, only the SEV, TM and ESI forms are to be completed. Do not complete a Missed Visit form or any other VOICE CRF for this visit. If Applicable: Æ Follow-up Pelvic Exam Æ Vaginal Test Results Æ Pap Test Results Æ Safety Laboratory Results Æ STI Laboratory Results Æ HIV Western Blot Test Results Æ Seroconverter Laboratory Test Results Æ Adverse Experience Log (new and/or updated form pages) Æ Pregnancy Report and History Æ Pregnancy Outcome Æ Product Returns and Dispensations
	32. Back-up ACASI questionnaire data.
	33. Upload ACASI questionnaire data to SCHARP.