

Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN 001 study visits. The checklists also specify the data collection forms that must be completed at each visit. Detailed procedural guidance for performing clinical and laboratory procedures is provided in Sections 10 and 12, respectively. Detailed forms completion instructions are provided in Section 13.

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 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 follow-up visits, mark the applicable visit 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 (FHI) CORE, 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.
- Informed consent for enrollment must be obtained before conduct of any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in the Enrollment sub-sections of protocol Section 7
- Behavioral assessments must be administered prior to HIV/STI risk reduction, male condom counseling and study product adherence counseling.
- Pelvic procedures must be performed in the sequence shown on the pelvic exam checklists.

Screening Visit: Page 1 of 3

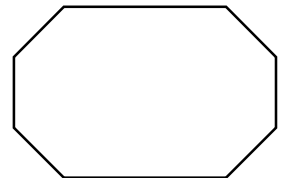
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| PTID: | Visit Date: |
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1. _____ Confirm participant identity. Cross-check with the MTN 001 Participant Name-PTID Link Log to determine whether a MTN 001 Participant ID number has previously been assigned to the participant.
2. _____ Confirm whether the participant is between the ages of 18 and 45 (inclusive) per site SOP.
3. _____ Explain the two-step (screening and enrollment) informed consent process.
4. _____ Explain the content and sequence of procedures for the remainder of the visit.
5. _____ Administer and obtain screening informed consent with participant according to site SOPs. Complete Consent Process Worksheet.

➤ *If the participant does not consent to screening, STOP. Do not fax any forms to SCHARP.*

6. _____ Complete the **Screening Consent** form.

Based on the 30-day screening and enrollment window, beginning on the day informed consent is obtained for screening; enter the participant's last possible enrollment date for this screening attempt



7. _____ Assign an MTN 001 PTID (if not done during a previous screening attempt) by completing a new row in the MTN 001 Name-PTID Link Log.
8. _____ Collect approximately ~ 20 mL urine and:
 - 8a. _____ Aliquot approximately 5-10 mL and perform qualitative pregnancy test.
 - 8b. _____ Complete testing logs and record result on the **Screening Eligibility** form (non-DataFax).

*If the participant is pregnant, STOP. Inform the participant that she is ineligible. Retain documentation completed thus far, and complete the **Screening Summary** form, but do not fax any forms to SCHARP.*

- 8c. _____ Prepare urine for SDA for Gonorrhea and Chlamydia.

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| PTID: | Visit Date: |
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- 8d. _____ Complete dipstick urinalysis using same aliquot as pregnancy test; record results for protein, nitrites and leukocytes on the **Safety Laboratory Results** form. Document results (e.g. blood, glucose), if any, in chart notes or other designated site specific document, if applicable. If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document treatment and/or additional work-up on the Concomitant Medications Log and in chart notes.
9. _____ Assess behavioral eligibility on the **Screening Eligibility and Clinical Eligibility** (non-DataFax) forms
10. _____ Provide HIV pre-test, HIV/STI risk reduction and condom counseling. Provide male condoms. *(Sites may chose to provide condoms at the end of the visit)*
11. _____ Collect blood: *(Sites to specify their site-specific volume for each tube)*
- Plain tube (no additive)
 - EDTA
12. _____ Perform HIV test
13. _____ Complete testing logs and transcribe rapid HIV test results onto the **Screening and Enrollment STI Laboratory Results** form. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results.
14. _____ Provide rapid HIV test results in the context of post-test counseling. Provide referrals if needed/requested. Explain the participant's current study eligibility status.
- *If both rapid tests are negative, the participant is considered HIV-uninfected. Continue with remainder of this checklist.*
 - *If one rapid test is positive and one is one negative, WB testing is required to clarify the participant's HIV status. Continue with remainder of this checklist OR defer further screening procedures until status is clarified.*
 - *If both rapid tests are positive, the participant is considered HIV-infected. STOP. Inform the participant that she is ineligible. Retain documentation completed thus far, and complete the **Screening Summary** form, but do not fax any forms to SCHARP.*
15. _____ Prepare remaining blood for testing at the local lab:
- Syphilis serology
 - CBC (hemoglobin, hematocrit, WBC, PLT)
 - HIV-1 Western Blot (if indicated)
 - Serum Chemistries (Phosphorous, Creatinine)
 - Liver Function Tests (AST, ALT)

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| PTID: | Visit Date: |
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- Hepatitis B Surface Antigen

16. _____ Obtain contact information and record on site specific form.
- *If the participant does not provide adequate contact information, per site-specific definition of adequate contact information, and is determined not to be a good candidate for the study (investigator decision) STOP. Inform the participant that she is ineligible. Retain documentation completed thus far, and complete the form, but do not fax any forms to SCHARP.*
17. _____ Administer the **Demographics** DataFax CRF.
18. _____ Conduct the Physical Exam and record results on the **Physical Exam** non-Data Fax form.
19. _____ Obtain medical, menstrual, and genitourinary history with documentation of current medications. Record on **Baseline Medical and Menstrual History** form (non-Data Fax) and **Concomitant Medications Log** Data Fax CRF.
20. _____ Perform and document pelvic exam using the Pelvic Exam checklist. Complete the Pelvic Exam Diagrams (non-Data Fax), **Screening and Enrollment Pelvic Exam** and **Pelvic Laboratory Results** DataFax CRFs. Treat or refer for treatment, if applicable.
21. _____ Provide contraceptive counseling. Provide and/ or refer for contraception, if applicable.
22. _____ Provide study informational material. Provide site contact information and instructions to contact the site for additional information and/or HIV/STI counseling, if needed, prior to the next visit.
23. _____ Schedule the Enrollment visit, taking into account the timing for receipt of lab results, the participant's menstrual cycle, and the 30-day screening period.
24. _____ Provide reimbursement.
25. _____ Document the visit in signed and dated chart notes. Complete the **Screening Summary** form and review all other participant chart contents for the visit, but do not fax any forms to SCHARP.

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| PTID: | Visit Date: |
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- *Note: The **Screening and Enrollment STI Laboratory Results, Pelvic Laboratory Results, Safety Laboratory Results** forms (and **HIV Test Results** form, when applicable) should be completed when all required test results are available, prior to the Enrollment Visit. Do not fax any forms to SCHARP until the participant is randomized. If the participant's lab results indicate that she is HIV-positive per protocol Appendix II or has an active RTI and/or UTI – with the exception of asymptomatic BV and asymptomatic vulvovaginal candidiasis —she is ineligible for enrollment; retain all of these DataFax forms on site but do not fax any of them to SCHARP.*

Enrollment Visit: Page 1 of 5

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| PTID: | Visit Date: |
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1. _____ Complete participant registration, confirm the participant's identity, and verify her PTID.
2. _____ Review/update locator information
3. _____ Confirm that the 30-day window has not been exceeded for the current screening attempt.
4. _____ Review chart notes and other relevant documentation from previous visit(s). Confirm the participant's current eligibility status based on all screening documentation.
5. _____ Confirm behavioral eligibility and record results on **Enrollment Eligibility** form
6. _____ Explain again the two-step informed consent process and obtain written informed consent for the study. Document the informed consent process in a chart note and on any other documents per site SOP.
*☞ If the participant does not consent to the study, complete the **Screening Summary** form and then STOP. Retain documentation completed thus far, but do not fax any forms to SCHARP.*
7. _____ Obtain written informed consent for specimen storage and possible future research testing. Document the informed consent process in a chart note and on any other documents per site SOP. Complete Consent Process Worksheet.
☞ Consent for specimen storage and possible future research testing is optional. If the participant does not consent, she may still take part in the study.
8. _____ Administer assessment of informed consent comprehension, utilizing comprehension checklist, according to local SOPs.
9. _____ Complete the **Screening Summary** form and items 1-2 of the **Enrollment** form.
10. _____ Collect ~20 mL first void urine and:
 - 10a. _____ Aliquot ~5 mL and perform pregnancy test.
 - 10b. _____ Complete testing logs and transcribe result here:

negative

positive

*☞ If the participant is pregnant, STOP. Inform the participant that she is ineligible. Retain documentation completed thus far, record results in the participant's chart notes, and complete the **Screening Summary** form. Do not fax any forms to SCHARP.*

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- 10c. ____ If clinically indicated, prepare urine for SDA for Gonorrhea and Chlamydia
11. ____ Administer the **Baseline Genital Symptoms** form.
12. ____ Review/update the **Baseline Medical and Menstrual History** and **Concomitant Medications Log**. Document review with a signed and dated note on each document reviewed. Initial and date updated entries.
13. ____ Complete the **Family Planning Methods** form by transcribing from the Baseline Medical and Menstrual History form the participants current contraceptive/family planning method (s).
14. ____ Provide contraceptive counseling. Provide or refer for contraception if applicable.
15. ____ If indicated, complete dipstick urinalysis using same aliquot as pregnancy test; record results for protein, nitrites and leukocytes on the Safety Laboratory Results form. Document results (e.g. blood, glucose), if any, in chart notes or other designated site specific document, if applicable. If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site SOP. Document treatment and/or additional work-up on the Concomitant Medications Log and in chart notes.
16. ____ Conduct physical exam as per Protocol Appendix III. Complete the **Physical Exam** (non-DataFax) form.
17. ____ Perform and document pelvic exam and CVL using the Pelvic Exam checklist. Complete the Pelvic Exam Diagrams (non-Data Fax), **Pelvic Exam and Pelvic Laboratory Results** datafax forms.
18. ____ Complete the **Clinical Eligibility** form
19. ____ If determined by site SOP, provide HIV pre-test counseling.
20. ____ Collect blood: (*Sites to include site-specific blood volume*)
 Plain tube (no additive)
 EDTA
21. ____ As determined by site SOP, perform HIV test
22. ____ If applicable, complete testing logs and transcribe rapid HIV test results onto the **Screening and Enrollment STI Laboratory Results** form. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results.

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23. _____ If applicable, provide rapid HIV test results and post-test counseling. Provide referrals if needed/requested. Explain the participant's current study eligibility status.
- *If both rapid tests are negative, the participant is considered HIV-uninfected. Continue with remainder of this checklist.*
 - *If one rapid test is positive and one is one negative, WB testing is required to clarify the participant's HIV status. Continue with remainder of this checklist OR defer further screening procedures until status is clarified.*
 - *If both rapid tests are positive, the participant is considered HIV-infected. STOP. Inform the participant that she is ineligible. Retain documentation completed thus far, and complete the **Screening Summary** form, but do not fax any forms to SCHARP.*
24. _____ Prepare blood for testing at the local lab:
- CBC (hemoglobin, hematocrit, WBC, PLT)
 - Serum Chemistries (Phosphorous, Creatinine)
 - Liver Function Tests (AST, ALT)
 - Plasma storage
 - Syphilis serology, if indicated
 - HIV-1 Western Blot, if indicated
25. _____ Complete an **LDMS Specimen Tracking Sheet** for stored samples.
26. _____ Administer the **Enrollment Behavior Assessment**
☞ *This form must be administered prior to random assignment.*
27. _____ Provide HIV/STI risk reduction and condom counseling.
28. _____ **For non-replacement participants only:** obtain the next sequential Randomization Envelope and assign it to the participant by completing the row of the MTN 001 Randomization Envelope Tracking Record that corresponds to the next sequential envelope.
29. _____ **For non-replacement participants only:** open the assigned envelope and confirm that the envelope number printed on the MTN 001 Randomization Document contained inside the envelope corresponds with the envelope number on the outside of the envelope (envelope label). Complete the Randomization Document.
30. _____ **For replacement participants only:** obtain a blank Replacement Randomization Document and the completed Randomization Document (yellow copy) of the participant being replaced. Transcribe all of the randomization information from the Randomization Document of the participant being replaced

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onto the Replacement Randomization Document. Complete the remainder of the Replacement Randomization Document.

31. _____ Complete the MTN 001 prescription(s) that correspond to the participant's first study period (vaginal, oral, or dual use) per her study randomization. Deliver the Randomization Document (or Replacement Randomization Document, for replacement participants) and prescription(s) to the pharmacy according to Option A or B below. While waiting for product supplies to be delivered, continue with the remainder of this checklist.

OPTION A:

_____ Give the completed white original Randomization Document (or Replacement Randomization Document) and prescription(s) to the participant to deliver to the pharmacy (where she will obtain product supplies herself). Retain the envelope (for non-replacement participants) and the yellow clinic copy of both the Randomization Document (or Replacement Randomization Document) and the prescription(s) in the participant's study notebook.

_____ Document the amount of product the participant received here ⇒
[or in chart notes].

OPTION B:

_____ Optional: Fax a copy of the Randomization Document (or Replacement Randomization Document) and prescription(s) to the pharmacy.

_____ Deliver the completed white original Randomization Document (or Replacement Randomization Document) and prescription(s) to the pharmacy. Retain the envelope (for non-replacement participants) and the yellow clinic copy of both the Randomization Document (or Replacement Randomization Document) and the prescription(s) in the participant's study notebook.

_____ Receive requested product supplies.

_____ Provide product supplies to the participant.

_____ Document the amount of product provided to the participant here ⇒
[or in chart notes]

32. _____ Provide counseling related to the importance of participant's study participation and product use. Provide demonstration of gel applicator, instructions for gel use, and adherence counseling for participants randomized to the study gel only or dual use regimen for the first study period. Emphasize the unknown effectiveness of the study products and the importance of condom use for protection against HIV.

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- 32a. Counsel participants to abstain from sex 24 hours prior to the End-of-the-Study Visit, if possible.
33. _____ Once product supplies arrive, complete the remainder of the **Enrollment** form.
34. _____ Reinforce the instructions to contact the site to request additional product, if needed, prior to the next visit and remind the participant that she will be asked to return unused study product that she has remaining at her next visit.
35. _____ Provide male condoms and offer panty liners.
36. _____ Provide watch device and remind participant to record (on designated site specific document) the date and time of the 3 doses of study product she takes prior to her next study visit.
37. _____ Reinforce site contact information and instructions to contact the site to report symptoms — *especially genital symptoms* — and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.
38. _____ Explain the follow-up visit schedule and schedule her Week 3 clinic visit.
39. _____ Inform the participant of tests to be performed at the next visit. Also inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.
40. _____ Treat or refer for findings as needed
41. _____ Provide reimbursement for study visit
42. _____ Complete the **Pre-Existing Conditions** form. Record all medical conditions that are ongoing at the time of participant randomization, based on source data collected throughout the screening process. Whenever possible, record a diagnosis rather than individual signs and symptoms. When this is not possible, record each individual sign or symptom. Do not record STIs or other infections that were fully treated prior to randomization. In the "comments" box for each condition, record as much information as possible on the severity and/or frequency of the condition at the time of participant randomization.
43. _____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents from both the screening and enrollment visits, including the following non-Data Fax forms:

Screening Eligibility
Enrollment Eligibility

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| PTID: | Visit Date: |
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Baseline Medical and Menstrual History
Physical Exam (x2)
Pelvic Exam Diagrams (x2)
Clinical Eligibility (x2)
Screening Summary
LDMS Specimen Tracking Sheet

44. _____ Fax all required DataFax forms to SCHARP:

Screening Consent
Demographics
Screening and Enrollment Pelvic Exam (x2)
Baseline Genital Symptoms
Screening and Enrollment STI Laboratory Results
Pelvic Laboratory Results* (x2)
Safety Laboratory Results* (x2)
Concomitant Medications Log
Family Planning Methods
Enrollment
Pre-Existing Conditions
Enrollment Behavior Assessment

☞ ***Pelvic Laboratory and Safety Laboratory Results forms are required for enrolled participants and MUST be completed, reviewed, and faxed to SCHARP once enrollment visit lab results are available. If HIV and/or other STI lab testing are conducted on samples collected at this visit, complete the **Screening and Enrollment STI Laboratory Results** form and the **HIV Test Results** form, if applicable.***

Follow-up Clinic Visits, Mid-Study Period Visit: Page 1 of 5

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| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>3-Week: _____ 10-Week: _____ 17-Week: _____</p> | |

1. _____ Complete participant registration, confirm the participant’s identity, and verify her PTID.

2. _____ Review/update locator information.

3. _____ Review chart notes and other relevant documentation from previous visit(s).

4. _____ Explain the content and sequence of procedures for today’s visit.

5. _____ Review elements of informed consent as needed.

6. _____ Collect ~20 mL urine and:
 - 6a. _____ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
 - 6b. _____ Complete testing logs and transcribe result onto the form.

If the participant is pregnant:

 - 6c. _____ Inform the participant that she must discontinue product use; arrange to collect her unused study product.
 - 6d. _____ Complete a MTN 001 Pregnancy Management Worksheet.
 - 6e. _____ Complete the Product Hold/Discontinuation Tracking Sheet (s), if applicable.
 - 6f. _____ Complete a **Study Product Hold/Resume/pK Supply/Re-Supply Slip**, marked “Permanent Discontinuation.” Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant’s study notebook.

7. _____ Collect unused study product to return to pharmacy. Document product collection in the chart notes. If participant did not bring the unused product at this visit, remind her to bring it for her next scheduled visit or make arrangements to collect the product.

8. _____ Provide and explain available exam and lab test results. Provide post-test counseling, if appropriate. Provide treatment for RTIs/STIs if needed. Document treatment on the **Concomitant Medications Log**.

9. _____ Record/transcribe the date and time of the participant’s last 3 doses of study product onto the **Study Product Adherence and Behavior Assessment** form.

10. _____ Administer the **Study Product Adherence and Behavior Assessment** form.

Follow-up Clinic Visits, Mid-Study Period Visit: Page 2 of 5

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| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>3-Week: _____ 10-Week: _____ 17-Week: _____</p> | |

11. _____ Administer the **Follow-up Genital Symptoms** form.

12. _____ Perform interval medical/menstrual history; record findings on the **Follow-up Medical History Log** form. Record interval contraceptive/family planning method use and menstrual history in a visit chart note.
 - 12a. _____ Complete a **Genital Bleeding Assessment** form for unexpected genital bleeding.

13. _____ Review and update the **Concomitant Medications Log**, if applicable.

14. _____ Complete the **Family Planning Methods** form by transcribing (from the visit chart note) the participant's current contraceptive/family planning methods.

15. _____ Provide contraceptive counseling. Provide and/or refer for contraception, if applicable.

16. _____ Collect blood as follows and complete a **Pharmacokinetics –Non-Intensive** form: : (*Sites to include site-specific blood volume*)
 - Plain tube (no additive)
 - EDTA

17. _____ Complete an **LDMS Specimen Tracking Sheet** for stored samples.

18. _____ Prepare blood for testing/storage at the local lab.
 - Serum Chemistries (Phosphorous, Creatinine)
 - Liver Function Tests (AST, ALT)
 - Tenofovir levels

19. _____ Perform physical exam per Protocol Appendix III and record on the Physical Exam (non-DataFax) form.

20. _____ Perform pelvic exam using the Pelvic Exam Checklist and complete the Pelvic Exam Diagrams, **Follow-up Pelvic Exam** and **Pelvic Laboratory Results** (if indicated) forms.
 - 20a. _____ During exam, if applicable, assess genital symptoms reported during administration of the **Follow-up Genital Symptoms** form. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

Follow-up Clinic Visits, Mid-Study Period Visit: Page 2 of 5

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| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>3-Week: _____ 10-Week: _____ 17-Week: _____</p> <p><i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i></p> | |

21. _____ If applicable, assess any non-genital symptoms reported in the participant’s interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
22. _____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests when available.
23. _____ If product use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents, and on the Product Hold/Discontinuation Tracking Sheet(s), if applicable. Inform the site’s study pharmacist of the product hold/discontinuation or resumption by completing a **Study Product Hold/Resume/pK Supply/Re-Supply Slip** and delivering the white original to him/her. Retain the yellow clinic copy in the participant’s study notebook. If the hold, discontinuation, or resumption affects product use in the CURRENT study period, complete/update the **Product Hold/Discontinuation Log** form (for holds/discontinuations, complete one form per reason). Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on holding, discontinuing or continuing with study product. Contact PSRT if there are any questions about study product or clinical management.
24. _____ For all participants (unless product is held):
- 24a. _____ Complete a **Prescription** or a **Study Product Hold/Resume/pK Supply/Re-Supply Slip**.
- 24b. _____ Follow your site-specific procedure for product re-supply.
- 24c. _____ After product supplies are received, document the number of product provided here
25. _____ Provide HIV/STI risk reduction, protocol and product use adherence, and male condom counseling. Provide condoms and panty liners.
26. _____ Schedule the next visit and inform the participant of what to expect. Remind the participant to abstain from having sex 24 hours prior to the next visit.
27. _____ Inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.

Follow-up Clinic Visits, Mid-Study Period Visit: Page 4 of 5

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| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>3-Week: _____ 10-Week: _____ 17-Week: _____</p> | |

- 28. _____ Reinforce the instructions to contact the site to request additional product, if needed, prior to the next visit and remind the participant that she will be asked to return all unused study product at her next visit.

- 29. _____ Reinforce site contact information and instructions to contact the site to report symptoms — especially genital symptoms — and/or to request for additional information, HIV/STI counseling, contraceptive counseling, and/or condoms, if needed, prior to the next visit.

- 30. _____ Provide study reimbursement

- 31. _____ Remind participant to record on her appointment card (or other designated site-specific document) the date and time of the last three doses of study product she takes prior to her next study visit.

Additionally Only If Clinically Indicated (C1-C4):

- C1. _____ Perform dipstick urinalysis on aliquot of used for pregnancy testing. Complete testing logs and transcribe protein, leukocyte, and nitrites results onto the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable.

- C2. _____ Perform culture if positive for leukocyte esterase or nitrites; may omit if culture not standard of care for UTI diagnosis. Document additional work-up in visit chart note. If applicable, provide treatment and record on the **Concomitant Medications Log** form.

- C3. _____ Prepare urine for SDA for Gonorrhea and Chlamydia. Transcribe results onto the **STI Laboratory Results** form.

- C4. _____ Collect blood for Syphilis Serology and/or HBsAg. Transcribe results onto the **STI Laboratory Results** form.

- 32. _____ Complete the **Follow-up Visit** form.

- 33. _____ Complete and review all participant chart contents for the visit, including the following non-Data Fax forms:

Physical Exam
Pelvic Exam Diagram

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| PTID: | Visit Date: |
| Please indicate to which follow-up visit this checklist applies: 3-Week: _____ 10-Week: _____ 17-Week: _____ | |

LDMS Tracking Sheet

34. _____ Complete and fax all required Data Fax forms to SCHARP:

Follow-up Visit
Follow-up Genital Symptoms
Follow-up Pelvic Exam
Family Planning Methods
Safety Laboratory Results (when all results available)
Study Product Adherence and Behavior Assessment
Pharmacokinetics – Non-Intensive

As Needed:

Follow-up Medical History Log (update/add entries as applicable)
Pelvic Laboratory Results
HIV Test Results
Genital Bleeding Assessment
Concomitant Medications Log (required for updated or new pages)
Adverse Experience Log (required if any AEs identified or updated at this visit)
Product Hold/Discontinuation Log (required if product use in current study period is held/discontinued or resumed at this visit)
Pregnancy Report and History (required if pregnancy identified at this visit)
Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)
STI Laboratory Results

Early Termination:

Termination
End of Study Inventory

Follow-up Clinic Visits, End of Study Period Visit: Page 2 of 5

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| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>6-Week: _____ 13-Week: _____ 20-Week: _____</p> | |

1. _____ Complete participant registration, confirm the participant’s identity, and verify her PTID.
2. _____ Review/update locator information.
3. _____ Review chart notes and other relevant documentation from previous visit(s).
4. _____ Review elements of informed consent as needed.
5. _____ Explain the content and sequence of procedures for today’s visit.
6. _____ Collect ~20 mL urine and:
 - 6a. _____ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
 - 6b. _____ Complete testing logs and transcribe result onto the form.

If the participant is pregnant:

 - 6c. _____ Inform the participant that she must discontinue product use; arrange to collect her unused study product.
 - 6d. _____ Complete a MTN 001 Pregnancy Management Worksheet (but do not complete a Product Hold/Discontinuation Log form at this time).
 - 6e. _____ Complete the Product Hold/Discontinuation Tracking Sheet(s), if applicable.
 - 6f. _____ Complete a **Study Product Hold/Resume/pK Supply/Re-Supply Slip**, marked “Permanent Discontinuation.” Deliver the completed white original to the pharmacy. Retain the yellow clinic copy in the participant’s study notebook.
7. _____ Collect unused study product. If participant did not bring unused product at this visit, remind her to bring it at her next scheduled visit or make arrangements to collect product.
8. _____ Provide and explain available exam and lab test results. Provide post-test counseling, if appropriate. Provide treatment for RTIs/STIs if needed. Document treatment on the **Concomitant Medications Log**.
9. _____ Observe a single AM dose of the study drug. If participant does not bring sufficient unused study product to visit for use as observed dose, study product will be dispensed to participant during study visit.

Follow-up Clinic Visits, End of Study Period Visit: Page 1 of 5

| | |
|--|-------------------|
| PTID: _____ | Visit Date: _____ |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>6-Week: _____ 13-Week: _____ 20-Week: _____</p> | |

10. _____ Administer the **Follow-up Genital Symptoms** form.
11. _____ Perform interval medical/menstrual history; record findings on the **Follow-up Medical History Log** form. Record interval contraceptive/family planning method use and menstrual history in visit chart note.
 - 11a. _____ If genital blood/bleeding is reported, complete a **Genital Bleeding Assessment** form for unexpected genital bleeding.
12. _____ Review and update the **Concomitant Medications Log**.
13. _____ Complete the **Family Planning Methods** form by transcribing (from the visit chart note) the participant's current contraceptive/family planning methods.
14. _____ Provide contraceptive counseling. Provide and/or refer for contraception, if applicable.
15. _____ Perform physical exam as per Protocol Appendix III and record on the **Physical Exam** (non-DataFax) form.
16. _____ Confirm participant abstained from sex for at least 24 hours prior to the study visit.
17. _____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
18. _____ Collect blood as follows: (*Sites to include site-specific blood volume*)
 - Plain tube(s) (no additive)
 - EDTA
19. _____ Complete an **LDMS Specimen Tracking Sheet** for stored samples.
20. _____ Prepare blood for testing/storage at the local lab.
 - Pre-dose:
 - Complete Blood Count with differential (lymphocyte) for flow cytometry calculations
 - Serum Chemistries (Phosphorous, Creatinine)
 - Liver Function Tests (AST, ALT)
 - Tenofovir
 - Plasma for storage

Follow-up Clinic Visits, End of Study Period Visit: Page 2 of 5

| | |
|---|-------------|
| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>6-Week: _____ 13-Week: _____ 20-Week: _____</p> <p><i>Note: Any protocol-specified studies or exams that were not completed on the assigned visit date must be completed at the next scheduled visit or at an interim visit.</i></p> | |

- PBMC for intracellular tenofovir (at sites with capacity)
- Plasma for flow cytometry (at sites with capacity)
- Cell lysate (at sites with capacity)

- Post-dose blood collection per randomization assignment:
 - Tenofovir
 - PBMC for intracellular tenofovir (at sites with capacity)

21. _____ Perform pelvic exam using the Pelvic Exam Checklist and complete the Pelvic Exam Diagrams, **Follow-up Pelvic Exam, Pelvic Laboratory Results and Pharmacokinetics – Non-Intensive** forms.
- 21a. _____ During exam, if applicable, assess genital symptoms reported during administration of the **Follow-up Genital Symptoms** form. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
- 21b. _____ Collect genital PK specimens at the assigned time point and record collection times on the **Pharmacokinetics – Non-Intensive** Form.
- NOTE: Pelvic exam should be timed such that the genital specimens may be collected at the randomly assigned time point. Make sure that CVL samples are collected within 15 minutes of blood collection.
22. _____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.
23. _____ If product use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents, and on the Product Hold/Discontinuation Tracking Sheet(s), if applicable. Inform the site's study pharmacist of the product hold/discontinuation or resumption by completing a **Study Product Hold/Resume/pK Supply/Re-Supply Slip** and delivering the white original to him/her. Retain the yellow copy in the participant's study notebook. Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on holding, discontinuing or continuing with study product. Contact PSRT if there are any questions about study product or clinical management.
24. _____ Record/transcribe the date and time of the participant's last 3 doses of study product onto the **Study Product Adherence and Behavior Assessment** form.

Follow-up Clinic Visits, End of Study Period Visit: Page 3 of 5

| | |
|---|-------------|
| PTID: | Visit Date: |
| Please indicate to which follow-up visit this checklist applies: 6-Week: _____ 13-Week: _____ 20-Week: _____ | |

25. _____ Administer the **Acceptability Assessment** form (Weeks 6 and 13 only), the **Final Acceptability Assessment** form (Week 20 only), and the **Product Sharing Assessment** form
26. _____ Provide HIV/STI risk education, protocol and product use adherence, and male condom and contraceptive counseling.
27. _____ Provide condoms, panty liners, and/or referrals if needed/requested.
28. _____ Schedule the next visit and inform the participant of what to expect. Also inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.
29. _____ Reinforce site contact information and instructions to contact the site to report symptoms — especially genital symptoms — and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.

Additionally Only If Clinically Indicated (C1-C4):

- C1. _____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe protein, leukocyte, and nitrites results onto the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable.
- C2. _____ Perform culture if positive for leukocyte esterase or nitrites; may omit if culture not standard of care for UTI diagnosis. Document additional work-up in visit chart note. If applicable, provide and record treatment on the **Concomitant Medications Log** form.
- C3. _____ Prepare urine for SDA for Gonorrhea and Chlamydia. Transcribe results onto the **STI Laboratory Results** form.
- C4. _____ Collect blood for Syphilis Serology and/or HBsAg. Transcribe results onto the **STI Laboratory Results** form.

30. _____ Provide study reimbursement.

Follow-up Clinic Visits, End of Study Period Visit: Page 5 of 5

| | |
|--|-------------|
| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>6-Week: _____ 13-Week: _____ 20-Week: _____</p> | |

31. _____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including Follow-up Medical History

32. _____ Complete **Follow-up Visit** form

33. _____ Complete and review all participant chart contents for the visit, including the following non-Data Fax forms:

- Physical Exam Form
- Pelvic Exam Diagram
- LDMS Specimen Tracking Sheet

34. _____ Fax all required Data Fax forms to SCHARP:

- Follow-up Visit
- Follow-up Genital Symptoms
- Family Planning Methods
- Follow-up Pelvic Exam
- Pelvic Laboratory Results
- Safety Laboratory Results (when all results available)
- Study Product Adherence and Behavior Assessment
- Product Sharing Assessment
- Acceptability Assessment (Week 6 and 13 only)
- Final Acceptability Assessment (Week 20 only)
- Acceptability Assessment
- Pharmacokinetics – Non-Intensive
- Flow Cytometry

As Needed:

- Follow-up Medical History Log (update/add entries as needed)
- Concomitant Medications Log (required for updated or new pages)
- Adverse Experience Log (required if any AEs identified or updated at this visit)
- Pregnancy Report and History (required if pregnancy identified at this visit)
- Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)
- STI Laboratory Results

Early Termination:

Follow-up Clinic Visits, End of Study Period Visit: Page 5 of 5

| | |
|--|-------------|
| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>6-Week: _____ 13-Week: _____ 20-Week: _____</p> | |

Termination
End of Study Inventory

Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 1 of 5

| | |
|---|-------------------|
| PTID: _____ | Visit Date: _____ |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>7-Week: _____ 14-Week: _____</p> | |

1. _____ Complete participant registration, confirm the participant's identity, and verify her PTID.
2. _____ Review/update locator information.
3. _____ Review chart notes and other relevant documentation from previous visit(s).
4. _____ If indicated, collect unused study product. If participant did not bring unused product at this visit, remind her to bring it at her next scheduled visit or make arrangements to collect product.
5. _____ Review elements of informed consent as needed.
6. _____ Explain the content and sequence of procedures for today's visit.
7. _____ Collect ~20 mL urine and:
 - 7a. _____ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
 - 7b. _____ Complete testing logs and transcribe result onto the form.

If the participant is pregnant:

 - 7c. _____ Inform the participant that she must discontinue product use; arrange to collect her unused study product.
 - 7d. _____ Complete a MTN 001 Pregnancy Management Worksheet
 - 7e. _____ Complete/update the Product Hold/Discontinuation Log Tracking Sheet(s), if applicable.
 - 7f. _____ Complete a **Study Product Hold/Resume/pK Supply/Re-Supply Slip**, marked "Permanent Discontinuation." Deliver the completed white original copy to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.
8. _____ Provide and explain available exam and lab test results. Provide post-test counseling, if appropriate. Provide treatment for RTIs/STIs if needed. Document treatment on the **Concomitant Medications Log**.
9. _____ Administer the **Follow-up Genital Symptoms** form
10. _____ Perform interval medical/menstrual history; record findings on the **Follow-up Medical History Log** form. Record interval contraceptive/family planning method use and menstrual history in the visit chart note
 - 10a. _____ Complete a **Genital Bleeding Assessment** form for unexpected

Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 2 of 5

| | |
|---|-------------|
| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>7-Week: _____ 14-Week: _____</p> | |

genital bleeding.

11. _____ Review and update the **Concomitant Medications Log**.

12. _____ Complete the **Family Planning Methods** form by transcribing (from the visit chart note) the participant's current contraceptive/family planning methods.

13. _____ Provide contraceptive counseling. Provide or refer for contraception, if applicable.

14. _____ Provide HIV pre-test counseling

15. _____ Collect blood as follows: (*Sites to include site-specific blood volume*)
 - Plain tube(s) (no additive)
 - EDTA

15. _____ Perform HIV test

16. _____ Complete testing logs and transcribe rapid HIV test results onto the **STI Laboratory Results** form. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results.

17. _____ Provide rapid HIV test results in the context of post-test counseling. Provide HIV/STI risk reduction and condom counseling. Provide referrals if needed/requested.
 - *If both rapid tests are negative, the participant is considered HIV-uninfected. Continue with remainder of this checklist.*
 - *If one rapid test is positive and one is one negative, WB testing is required to clarify the participant's HIV status. Continue with remainder of this checklist OR defer further procedures until status is clarified.*
 - *If both rapid tests are positive, the participant is considered HIV-infected.*

18. _____ Prepare blood for testing at the local lab.
 - CBC (hemoglobin, hematocrit, WBC, PLT)
 - Serum Chemistries (Phosphorous, Creatinine)
 - Liver Function Tests (AST, ALT)
 - HIV-1 Western Blot (if indicated)

Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 3 of 5

| | |
|---|-------------|
| PTID: | Visit Date: |
| <p>Please indicate to which follow-up visit this checklist applies:</p> <p>7-Week: _____ 14-Week: _____</p> | |

19. _____ For all participants (unless product is held):
- 19a. _____ Complete a **Prescription**.
- 19b. _____ Follow your site-specific procedures for product re-supply. The white original prescription will be taken to the pharmacy. Retain the yellow clinic copy in the participant's study notebook.
- 19c. _____ After product supplies are received, provide the supplies to the participant and document the amount of product provided here
- ↳
20. _____ Perform physical exam and record on the **Physical Exam** form. _____
21. _____ Perform pelvic exam using the Follow-Up Pelvic Exam Checklist and complete the Pelvic Exam Diagrams, **Follow-up Pelvic Exam** and **Pelvic Laboratory Results** (if indicated) forms.
- 21a. _____ During exam, if applicable, assess genital symptoms reported during administration of the **Follow-up Genital Symptoms** form. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
22. _____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.
23. _____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests.
24. _____ If product use is held/discontinued or resumed at this visit, document the rationale for the hold/discontinuation or resumption in chart notes and/or on other applicable source documents, and on the Product Hold/Discontinuation Tracking Sheet(s), if applicable. Inform the site's study pharmacist of the product hold/discontinuation by completing a **Study Product Hold/Resume/PK Supply/Re-Supply Slip** and delivering the white original to him/her. Retain the yellow clinic copy in the participant's study notebook. If the hold, discontinuation, or resumption affects product use in the CURRENT study period, complete/update the Product Hold/Discontinuation Log form (for holds/discontinuations, complete one form per reason). Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on holding, discontinuing or continuing with study product. Contact PSRT if there are any questions about study product or clinical management.

Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 4 of 5

| | |
|--|-------------|
| PTID: | Visit Date: |
| Please indicate to which follow-up visit this checklist applies: 7-Week: _____ 14-Week: _____ | |

25. _____ Provide protocol and product use adherence counseling.
26. _____ Provide condoms, panty liners, and/or referrals if needed/requested.
27. _____ Schedule the next visit and inform the participant of what to expect at that visit. Also inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.
28. _____ Reinforce site contact information and instructions to contact the site to report symptoms — especially genital symptoms — and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.
29. _____ Provide study reimbursement.
30. _____ Remind participant to record on her appointment card (or other designated site-specific document) the date and time of the last three doses of study product she takes prior to next study visit. Also, remind participant to bring in unused product at next study visit
31. _____ Complete **Follow-up Visit** form

Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 5 of 5

| | |
|--|-------------|
| PTID: | Visit Date: |
| Please indicate to which follow-up visit this checklist applies: 7-Week: _____ 14-Week: _____ | |

Additionally Only If Clinically Indicated (C1-C4):

- C1. _____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe protein, leukocyte, and nitrites onto the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable.
- C2. _____ Perform culture if positive for leukocyte esterase or nitrites; may omit if culture not standard of care for UTI diagnosis. Document additional work-up in visit chart note. If applicable, provide treatment and record treatment on the **Concomitant Medications Log**.
- C3. _____ Prepare urine for SDA for Gonorrhea and Chlamydia. Transcribe results onto the STI Laboratory Results form.
- C4. _____ Collect blood for Syphilis Serology and/or HBsAg. Transcribe results onto the **STI Laboratory Results** form.

32. _____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-Data Fax forms:

Physical Exam
Pelvic Exam Diagrams

33. _____ Fax all required Data Fax forms to SCHARP:

Follow-up Visit
Follow-up Genital Symptoms
Follow-up Pelvic Exam
Family Planning Methods
Safety Laboratory Results (when all results available)
STI Laboratory Results (when all results are available)

As Needed:

Follow-up Medical History Log (update/add entries as needed)

Follow-up Clinic Visits, Study Period 2 and 3 Start: Page 5 of 5

| | |
|--|-------------|
| PTID: | Visit Date: |
| Please indicate to which follow-up visit this checklist applies: 7-Week: _____ 14-Week: _____ | |

Pelvic Laboratory Results

Concomitant Medications Log (required for updated or new pages)

Adverse Experience Log (required if any AEs identified or updated at this visit)

Product Hold/Discontinuation Log (required if product use *in current study period* is held/discontinued or resumed at this visit)

Pregnancy Report and History (required if pregnancy identified at this visit)

Pregnancy Outcome (required if pregnancy outcome ascertained at this visit)

Early Termination:

Termination

End of Study Inventory

Follow-up Clinic Visit, Study Termination Visit: Page 1 of 4

| | |
|-------------|-------------------|
| PTID: _____ | Visit Date: _____ |
|-------------|-------------------|

1. _____ Complete participant registration, confirm the participant's identity, and verify her PTID.
2. _____ Review/update locator information.
3. _____ Review chart notes and other relevant documentation from previous visit(s).
4. _____ Review elements of informed consent as needed.
5. _____ Explain the content and sequence of procedures for today's visit.
6. _____ Collect ~20 mL urine and:
 - 6a. _____ Aliquot ~5 mL and perform pregnancy test; retain remaining urine for remainder of visit.
 - 6b. _____ Complete testing logs and transcribe result onto the form.

If the participant is pregnant:

 - 6c. _____ Complete a **Pregnancy Report and History** form.
 - 6d. _____ Explain to the participant that a post-study contact will be required to ascertain the outcome of her pregnancy.
7. _____ Collect any unused study product to return to pharmacy.
8. _____ Provide and explain available exam and lab test results from previous visit. Provide post-test counseling, if appropriate. Provide treatment for RTIs/STIs if needed. Document treatment on the **Concomitant Medications Log**.
9. _____ Administer the **Follow-up Genital Symptoms** form
10. _____ Perform interval medical/menstrual history; record findings on the **Follow-up Medical History** form. Record interval contraceptive/family planning method use and menstrual history in visit chart note
 - 10a. _____ If genital blood/bleeding is reported, conduct a pelvic exam. Complete a **Genital Bleeding Assessment** form for unexpected genital bleeding.
11. _____ Review and update the **Concomitant Medications Log**.
12. _____ Complete the **Family Planning Methods** form by transcribing (from the visit chart note) the participant's current contraceptive/family planning methods.
13. _____ Provide contraceptive counseling. Provide/refer for contraception, if applicable
14. _____ If applicable, assess any non-genital symptoms reported in the participant's interval medical/menstrual history. Provide or refer for follow-up care as needed. Document follow-up in chart notes.

Follow-up Clinic Visit, Study Termination Visit: Page 1 of 4

| | |
|-------|-------------|
| PTID: | Visit Date: |
|-------|-------------|

15. _____ Complete/update **Adverse Experience Log** form(s) if required based on interval medical/menstrual history, clinical exams/assessments, and lab tests. Contact PSRT if there are any questions about study product or clinical management.
16. _____ 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 or 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.*
17. _____ Provide HIV pre-test counseling; during pre-test counseling, reinforce that although this is the participant’s last scheduled study visit, additional visits and tests will be done if needed to confirm or clarify her HIV status.
18. _____ Collect blood as follows: (*Sites to include site-specific blood volume*)
- plain tube(s) (no additive)
 - EDTA
19. _____ Perform HIV test
20. _____ Complete testing logs and transcribe rapid HIV test results onto the **Laboratory Results** form. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results.
21. _____ Provide rapid HIV test results in the context of post-test counseling. Provide referrals if needed/requested.
- *If both rapid tests are negative, the participant is considered HIV-uninfected. Continue with remainder of this checklist.*
 - *If one rapid test is positive and one is one negative, WB testing is required to clarify the participant’s HIV status. Continue with remainder of this checklist.*
 - *If both rapid tests are positive, the participant is considered HIV-infected.*
22. _____ Complete an **LDMS Specimen Tracking Sheet** for stored samples.
23. _____ Prepare blood for testing/storage at the local lab. .
- CBC (hemoglobin, hematocrit, WBC, PLT)
 - Serum Chemistries (Phosphorous, Creatinine)
 - Liver Function Tests (AST, ALT)
 - HIV-1 Western Blot (if indicated)
 - Plasma for storage

Follow-up Clinic Visit, Study Termination Visit: Page 3 of 4

| | |
|-------|-------------|
| PTID: | Visit Date: |
|-------|-------------|

24. _____ If participant has been randomized to or selected for the In-Depth interview, is evaluable (i.e., does not meet criteria for replacement), and has given consent for participation, conduct the recorded in-depth interview.
25. _____ Provide HIV/STI risk reduction and male condom counseling. Also inform the participant of availability of HIV/STI counseling, testing, and STI treatment for partners.
26. _____ Provide condoms and/or referrals if needed/requested.
27. _____ Complete **Follow-up Visit** form.
28. _____ Completion **Termination** form.
29. _____ Complete **End of Study Inventory** form.
30. _____ Reinforce site contact information.
31. _____ Provide study reimbursement.

Additionally Only If Clinically Indicated (C1-C6):

- C1. _____ Perform dipstick urinalysis on aliquot of urine used for pregnancy testing. Complete testing logs and transcribe protein, leukocyte, and nitrites results onto the **Safety Laboratory Results** form. Document other results (e.g., blood, glucose), if any, in visit chart note, or in other designated site-specific document, if applicable.
- C2. _____ Perform if positive for leukocyte esterase or nitrites; may omit if culture not standard of care for UTI diagnosis. Document additional work-up in visit chart note. If applicable, provide treatment and record on the **Concomitant Medications Log** form.
- C3. _____ Prepare urine for SDA for Gonorrhea and Chlamydia. Transcribe results onto the **STI Laboratory Results** form.
- C4. _____ Collect blood for Syphilis Serology and/or HBsAg. Transcribe results onto the **STI Laboratory Results** form.
- C5. _____ Perform physical exam and complete non-DataFax **Physical Exam** form.
- C6. _____ Perform pelvic exam. Complete the **Follow-up Pelvic Exam** form and, if applicable, the Pelvic **Laboratory Results** form.

Follow-up Clinic Visit, Study Termination Visit: Page 3 of 4

| | |
|-------|-------------|
| PTID: | Visit Date: |
|-------|-------------|

32. _____ Schedule next visit to provide the participant with any remaining lab test results, to provide counseling if indicated, and to follow-up on any AEs, if indicated.
33. _____ If indicated, treat or refer any findings. .
34. _____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-Data Fax form:
LDMS Specimen Tracking Sheet
35. _____ Fax all required Data Fax forms to SCHARP Data Fax:

Follow-up Visit
Termination
Family Planning Methods
STI Laboratory Results
End of Study Inventory
Follow-up Genital Symptoms
Safety Laboratory Results (when all results available)

As Needed:

Follow-up Medical History Log (update/add new entries as needed)
Concomitant Medications Log (required for updated or new pages)
Adverse Experience Log (required if any AEs identified or updated at this visit)
Pregnancy Report and History (required if pregnancy identified at visit)
Pregnancy Outcome (required if pregnancy outcome ascertained at visit)

- *Note: Once the Study Termination Visit is completed, complete the MTN 001 Study Exit worksheet.*

Pelvic Exam

Screening, Enrollment, 6-week, 13-week, 20-week

Page 1 of 2

| | |
|---|-------------------|
| PTID: _____ | Visit Date: _____ |
| Please indicate to which visit this checklist applies: | |
| Screening : _____ Enrollment: _____ 6-week: _____ 13-week: _____ 20-week: _____ | |

1. _____ Explain the exam procedures to the participant and answer any participant questions.
2. _____ Using a pencil, write the PTID and specimen collection date on the frosted side of two microscope slides for vaginal wet mount. Then affix a SCHARP-provided PTID label to the other side of each slide (under the pencil markings) and write the specimen collection date in ink on each label.
3. _____ Affix a SCHARP-provided PTID label to a glass or plastic tube containing approximately six drops (100 μ L) of saline. Write the specimen collection date in ink on the label.
4. _____ Position and drape the participant comfortably.
5. _____ Palpate inguinal lymph nodes. Document abnormal findings on the **Screening and Enrollment Pelvic Exam** form or the **Follow-up Pelvic Exam** form at follow-up visits.
6. _____ Inspect external genitalia: Note all findings on the Pelvic Exam Diagrams form. Document abnormal findings in items on the **Screening and Enrollment Pelvic Exam** form or the **Follow-up Pelvic Exam** form at follow-up visits.
7. _____ Insert speculum, using warm water as lubricant if needed. Observe general state and note the position of the cervix.
8. _____ Assess for homogenous discharge. Record observation on the **Pelvic Laboratory Results** form.
9. _____ Inspect cervix and vagina: Note all findings on the Pelvic Exam Diagrams form. Document abnormal findings in items on the **Screening and Enrollment Pelvic Exam** form or the **Follow-up Pelvic Exam** form at follow-up visits.
10. _____ **Screening Visit only:** If indicated, perform Pap smear per site SOP.
11. _____ **Screening Visit only:** Record the size of speculum used and position of the participant's cervix on the **Pelvic Exam Diagrams** form.
12. _____ Collect vaginal fluids from the lateral vaginal wall via swab and swab fluids onto the pH strip. Record pH on the **Pelvic Laboratory Results** form.

Pelvic Exam
Screening, Enrollment, 6-week, 13-week, 20-week
Page 2 of 2

| | |
|--|-------------------|
| PTID: _____ | Visit Date: _____ |
| Please indicate to which visit this checklist applies: | |
| Screening : _____ Enrollment: _____ 6-week: _____ 13-week: _____ 20-week: _____ | |

13. _____ Swab vaginal fluids from the lateral vaginal wall for wet prep; proceed immediately to Step 13a or place the swab in a labeled glass or plastic tube containing approximately six drops (100 µL) of saline to allow for non-immediate slide preparation and evaluation, as follows (see also SSP Section 12):
- 13a. _____ Smear vaginal fluids from the swab onto two labeled slides.
- 13b. _____ Apply KOH to one slide, perform whiff test, then apply cover slip.
- 13c. _____ Apply saline to the second slide, emulsifies, then apply cover slip. Immediately evaluate for trichomonads, yeast buds, pseudohyphae, and clue cells.
- 13d. _____ Evaluate KOH slide for yeast buds and pseudohyphae.
- 13e. _____ If slides are read in-clinic by clinical staff, record results directly onto the **Pelvic Laboratory Results** form. If slides are read by lab staff (either in the local lab or a designated in-clinic lab area) complete testing logs and then transcribe results onto the **Pelvic Laboratory Results** form.

For screening and enrollment visits: If lab results are positive for trichomonads, yeast buds, pseudohyphae and/or clue cells, the participant is ineligible, with the exception of asymptomatic BV and asymptomatic vulvovaginal candidiasis. STOP. Inform the participant that she is ineligible. Otherwise eligible participants diagnosed with RTI and/or UTI may be enrolled after completing treatment and all symptoms have resolved. Retain documentation completed thus far, and complete the form, but do not fax any forms to SCHARP.

14. _____ Perform bimanual exam, if indicated. Document abnormal findings on the **Screening and Enrollment Pelvic Exam** form or the **Follow-up Pelvic Exam** form at follow-up visits.
15. _____ **Enrollment visit only:** Collect CVL sample. *NOTE: CVL must be performed following all other pelvic exam/lab procedures. CVL samples need to be placed on ice immediately and then frozen*
16. _____ **6- week, 13-week and 20-week visits only:** Collect CVL sample within 15 minutes of blood collection for pK procedures. *NOTE: Blood may be collected following the CVL procedure. CVL must be performed following all other pelvic exam/lab procedures. CVL samples need to be placed on ice immediately and then frozen.*

Pelvic Exam
3-week, 7-week, 10-week, 14-week, 17-week
Page 1 of 1

| | |
|--|--------------------|
| PTID: | Visit Date: |
| Please indicate to which visit this checklist applies: | |
| 3-Week : _____ 7-Week: _____ 10-week: _____ 14-week: _____ 17-week: _____ | |

1. _____ Explain the exam procedures to the participant and answer any participant questions.
2. _____ Position and drape the participant comfortably.
3. _____ Palpate inguinal lymph nodes. Document abnormal findings on the **Follow-up Pelvic Exam** form
4. _____ Inspect external genitalia: Note all findings on the **Pelvic Exam Diagrams** form. Document abnormal findings on the **Follow-up Pelvic Exam** form.
5. _____ Insert speculum, using warm water as lubricant if needed. Observe general state and note the position of the cervix.
6. _____ Assess for homogenous discharge. If indicated, perform wet mount and complete the **Pelvic Laboratory Results** form.
7. _____ Inspect cervix and vagina: Note all findings on the **Pelvic Exam Diagrams** form. Document abnormal findings in items on the **Follow-up Pelvic Exam** form.
8. _____ If indicated, perform Herpes Culture (at sites where standard of care for diagnosis)
9. _____ Perform bimanual exam, if indicated. Document abnormal findings on the **Follow-up Pelvic Exam** form.