

Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN-007 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 and product use 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.
- 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 “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.
- 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 and protocol and product adherence counseling.
- Rectal specimens must be collected the order outlined in the rectal examination visit checklists. Rectal samples should be collected in the following order:
 1. Rectal swab for GC/CT
 2. Rectal swab for microflora
 3. Rectal sponge for cytokines
 4. Digital rectal examination
 5. Rectal lavage/effluent for epithelial sloughing
 6. Stool sample for fecal calprotectin
 7. *Flexible sigmoidoscopy and biopsies at 15 cm for Histology, Cytokine RT PCR, Mucosal T cell phenotyping, and mucosal gene expression array
 8. *Anoscopic biopsies at 9 cm for Histology, Cytokine RT PCR, Mucosal T cell phenotyping, and mucosal gene expression array

*Note: If at anytime the collection of biopsies is limited, rectal biopsies should be collected in the following order of importance:

1. Histology
2. Mucosal Gene Expression Array
3. Cytokine RT PCR
4. Mucosal T Cell Phenotyping.

Screening Visit

PTID:	Visit Date:	Visit Code: 1.0
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1. _____ Confirm whether the participant is ≥ 18 years of age. Explain the two-step (screening and enrollment) informed consent process.
2. _____ Confirm participant identity. Cross-check with the MTN-007 Participant Name-PTID Link Log to determine whether a MTN-007 Participant ID number has previously been assigned to the participant.
3. _____ Explain the content and sequence of procedures for the remainder of the visit.
4. _____ Obtain locator information and record on site specific form.

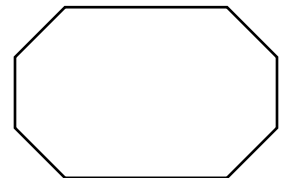
If the participant does not provide adequate contact information, and is determined not to be a good candidate for the study (investigator decision) STOP. Inform the participant that he/she is ineligible. Retain documentation completed thus far, and complete the form, but do not fax any forms to SCHARP.

5. _____ Review consent with participant according to local SOPs.
6. _____ Administer and obtain screening informed consent with participant. Complete Consent Process Coversheet.

If the participant does not consent to screening, STOP. Inform the participant that he/she is ineligible.

7. _____ Assign an MTN-007 PTID (if not done during a previous screening attempt) by completing a new row in the MTN-007 Name-PTID Link Log.
8. _____ Complete the **Screening Consent** CRF.

Based on the 36-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.



9. _____ Administer the **Demographics** CRF.

Screening Visit

PTID:	Visit Date:	Visit Code: 1.0
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10. _____ Collect approximately 15-60 mL urine and:
- 10a. _____ Aliquot approximately 5-10 mL for qualitative pregnancy (*for females of childbearing potential only*) and dipstick urinalysis tests.
- 10b. _____ Complete testing logs and record result on the **Screening Visit Eligibility** (non-DataFax) CRF.
- 10c. _____ Complete dipstick urinalysis and record results for protein, glucose, nitrites, and leukocytes according to local SOP and on **Laboratory Results** CRF. 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 in chart notes.
- 10d. _____ Prepare remaining urine for gonorrhea and chlamydia NAAT. Record results on **STI Laboratory** CRF when available.

If the participant is pregnant, STOP. Inform the participant that she is ineligible. Retain documentation completed thus far. Do not fax any forms to SCHARP.

11. _____ Assess behavioral eligibility by administering the **Screening Visit Eligibility** (non-DataFax) CRF.
12. _____ Provide HIV pre-test, HIV/STI risk reduction and condom counseling. Provide study-specific male condoms. (*Sites may choose to provide condoms at the end of the visit*).
13. _____ Collect blood:
- Plain tube (no additive)
 - EDTA
14. _____ Prepare blood for testing at the local lab:
- HIV-1 serology
 - Syphilis RPR
 - HSV-1 and HSV-2 serology
 - CBC with differential and platelets
 - BUN, creatinine, Calculated creatinine clearance, ALT, AST
 - Hepatitis B Surface Antigen
- Tailor this item to reflect site-specific tube types and volumes.
15. _____ Obtain medical history with documentation of current medications. Record on **Participant Reported Baseline Medical and Menstrual History** form (non-Data Fax, pages 7-8 completed only for females), and **Concomitant Medications Log** CRF.

Screening Visit

PTID:	Visit Date:	Visit Code: 1.0
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- 16. _____ Provide contraceptive counseling and [prescribe/provide/refer for] contraception, if applicable and document in chart notes.
- 17. _____ Perform Physical Exam per protocol section 7.11 and record findings on the **Physical Exam** (non-DataFax) CRF.
- 18. _____ Perform and document rectal exam using the *Screening Rectal Exam Checklist*. Record findings on the **Rectal Exam** CRF.
- 19. _____ Evaluate findings identified during rectal and physical examinations and medical and menstrual history review. Refer for or provide any clinically indicated treatment; document in chart notes and update **Concomitant Medications Log** CRF, if applicable. Assess clinically eligibility by completing the **Medical Eligibility** (non-DataFax) CRF.

NOTE: Medical Eligibility (non-DataFax) CRF will be completed at screening but finished at enrollment, when all labs and medical/clinical information are available.

- 20. _____ 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.
- 21. _____ Schedule the Enrollment Visit, taking into account the timing for receipt of test results and the 36-day screening period.
- 22. _____ Provide reimbursement.
- 23. _____ Complete the **Pre-Existing Conditions** CRF. Record all medical conditions that are ongoing at the time of screening, based on source data collected throughout the screening process.

Note: Whenever possible, record a diagnosis rather than individual signs and symptoms. When this is not possible, record each individual sign or symptom. 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 screening.

- 24. _____ Document the visit in a signed and dated chart note.
- 25. _____ Complete and review all other participant chart contents for the visit, but do not fax any forms to SCHARP DataFax.

Screening Visit

PTID:	Visit Date:	Visit Code: 1.0
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*NOTE: The **STI Laboratory Results** and **Laboratory Results** CRFs (and **HIV Test Results** CRF) 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 is deemed ineligible, retain all DataFax forms on site but do not fax any of them to SCHARP.*

Screening Rectal Exam

PTID:	Visit Date:	Visit Code: 1.0
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1. _____ Review chart notes and other relevant documentation.
2. _____ Affix a SCHARP-provided PTID label to the required primary tube at the time of collection. Record PTID and write the specimen collection date in ink on the label.
3. _____ Explain the exam procedures to the participant and answer any participant questions.
4. _____ Position the participant in a lateral position on the left side. Drape the participant comfortably.
5. _____ Inspect the anus and surrounding region visually. Document abnormal findings on items # 1-1a of the **Rectal Exam** CRF and in chart notes.
6. _____ Use study specified lubricant to lubricate the anoscope. Gently insert anoscope into the rectum (until the lateral ‘wings’ touch the anal margin). Remove the obturator.
7. _____ Collect the rectal swab for GC/CT testing by removing it from the plastic tube and inserting through the anoscope placing in contact with the rectal wall. Gently turn the swab 360 degrees and remove. Place the rectal swab in the transport tube, break off shaft of swab and cap.
8. _____ Slowly and gently remove anoscope.
9. _____ Perform a digital rectal examination by inserting a gloved finger, lubricated with study specified lubricant, into the anal canal and sweep around the internal anal circumference. Document abnormal findings on items #2-2a of the **Rectal Exam** CRF. Any unexpected discomfort should also be documented in chart notes and/or in the comments field of the Rectal Exam CRF.
10. _____ Evaluate any abnormalities for eligibility.

Enrollment Visit

PTID:	Visit Date:	Visit Code: 2.0
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1. _____ Complete participant registration, confirm the participant’s identity, and verify PTID per site SOPs.

2. _____ Review and/or update locator information.

3. _____ Confirm that the 36-day window has not been exceeded for the current screening attempt.

4. _____ Review chart notes and other relevant documentation from previous visit(s). Provide test results from previous visit(s), if applicable.

5. _____ Confirm the participant’s behavioral and clinical eligibility status based on all screening documentation. Complete the **Enrollment Visit Eligibility** (non-DataFax) CRF.

6. _____ Provide HIV test results in the context of post-test counseling. [Before disclosing result(s) to participant, obtain independent review, verification, and sign-off of results(s)]. Provide referrals if needed/requested. Explain the participant’s current study eligibility status.

If the participant is HIV-positive per protocol Appendix II, STOP. Provide appropriate post-test counseling, and inform the participant that he/she is ineligible. Refer to local care providers for follow-up and treatment of HIV. Retain documentation completed thus far but do not fax any forms to SCHARP.

7. _____ Explain again the two-step informed consent process and obtain written informed consent for enrollment into the study. Document the informed consent process in a chart note and on any other documents per site SOP. Complete Consent Process Coversheet.

If the participant does not consent to the study, STOP. Retain documentation completed thus far, but do not fax any forms to SCHARP.

8. _____ Administer assessment of informed consent comprehension, utilizing comprehension checklist, per site SOP

9. _____ 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 Coversheet.

Consent for specimen storage and possible future research testing is optional. If the participant does not consent, he/she may still take part in the study.

Enrollment Visit

PTID:	Visit Date:	Visit Code: 2.0
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10. _____ Complete items 1-3 of the **Enrollment** CRF.
11. _____ Collect 15-60 mL urine:
- 11a. _____ Aliquot approximately 5-10 mL and perform qualitative pregnancy test (*For females of childbearing potential only*)
- 11b. _____ Complete testing logs and record result on the **Medical Eligibility** (non-DataFax) CRF.

If the participant is pregnant, STOP. Inform the participant that she is ineligible. Retain documentation completed thus far. Do not fax any forms to SCHARP.

- 11c. _____ If clinically indicated, prepare remaining urine for gonorrhea and chlamydia NAAT. Record results on **STI Laboratory Results** CRF when available.
12. _____ Review/update the **Participant-reported Baseline Medical and Menstrual History** (non-DataFax) CRF (pages 7-8 are for females only) and **Concomitant Medications Log**, including family planning methods as necessary. Document review with a signed and dated note on each document reviewed. Initial and date updated entries.
13. _____ Provide contraceptive counseling and [prescribe/ provide/refer] for contraception, if applicable.
14. _____ Perform the physical exam as per Protocol Section 7.11 and record findings on the **Physical Exam** (non-DataFax) form.
15. _____ Provide HIV pre-test counseling if clinically indicated. Collect blood. (Specimen collection must occur prior to randomization)
- Plain tube (no additive)
- EDTA
16. _____ Prepare blood for testing at the local lab:
- Plasma archive**
- Syphilis RPR (if clinically indicated)
- HIV Serology (if clinically indicated)
17. _____ Perform and document rectal exam using the *Enrollment Visit Rectal Exam Checklist*. Record findings on the **Rectal Exam** CRF.

Tailor this item to reflect site-specific tube types and volumes.

Enrollment Visit

PTID:	Visit Date:	Visit Code: 2.0
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18. _____ Evaluate findings identified during rectal and physical examinations and medical and menstrual history review. Refer for or provide any clinically indicated treatment; document in chart notes and update **Concomitant Medications Log** CRF, if applicable.

19. _____ Administer the **CASI Baseline Behavioral Questionnaire (BBQ)**. Complete item 7 of the **Enrollment** CRF.

This must be administered prior to HIV/STI risk reduction counseling as well as random assignment

20. _____ **Randomization procedures:**
For Non-Replacement Participants Only: obtain the next sequential MTN-007 Clinic Randomization Envelope and assign it to the participant per site SOPs.

Replacement Participants Only: obtain the study notebook and prescriptions for the participant being replaced. Based on the randomization assignment of the participant being replaced (completed yellow copy of prescription), obtain the appropriate blank MTN-007 replacement prescription. Transcribe all of the randomization information from the pre-printed MTN-007 Prescription of the participant being replaced onto the blank MTN-007 replacement prescription.

21. _____ Inform the participant of his/her assignment [“gel” or “no treatment (no gel)”].
 21a. _____ ***Participants assigned to “no treatment (no gel)”:*** Complete the prescription and deliver the top (white) copy of the completed prescription to the pharmacy and store the bottom (yellow) copy and opened envelope in the participant’s study notebook.

21b. _____ ***Participants assigned to “gel”:*** Store both prescriptions and the opened envelope in the participant’s study notebook. The single dose gel prescription will be completed and delivered to the pharmacy at the Treatment 1 Visit. The seven-day gel prescription will be completed and delivered to the pharmacy at the Treatment 2 Visit.

22. _____ Provide HIV/STI risk reduction and male condom counseling. Provide counseling related to the importance of participant’s study participation and product use. Provide protocol adherence counseling. Provide study condoms and lubricant. Emphasize the unknown effectiveness of the study products and the importance of condom use for protection against HIV.

Enrollment Visit

PTID:	Visit Date:	Visit Code: 2.0
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23. _____ Complete the remainder of the **Enrollment** CRF.
24. _____ Reinforce site contact information and instructions to contact the site to report symptoms and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.
25. _____ Explain the follow-up visit schedule to the participant and schedule Treatment 1 Visit. Inform the participant of tests to be performed at the next visit.
26. _____ Provide reimbursement for study visit.
27. _____ Review/update **Pre-existing Conditions** CRF. Record all medical conditions that are ongoing at the time of participant randomization, based on source data collected throughout the screening and enrollment process.
28. _____ Document the visit in a signed and dated chart note.
29. _____ Complete and review all participant chart contents from both the screening and enrollment visits, including the following non-DataFax forms:
- Screening Visit Eligibility
 - Enrollment Visit Eligibility
 - Medical Eligibility
 - Participant-reported Baseline Medical and Menstrual History
 - Physical Exam (completed at the Screening Visit)
 - Physical Exam (completed at the Enrollment Visit)
 - LDMS Specimen Tracking Sheet
30. _____ Fax all required DataFax CRFs to SCHARP:
- Demographics
 - Screening Consent
 - Rectal Exam (completed at the Screening Visit)
 - STI Laboratory Results
 - Laboratory Results
 - Concomitant Medications Log
 - Pre-existing Conditions
 - Rectal Exam (completed at the Enrollment Visit)
 - Enrollment
 - Anoscopy and Sigmoidoscopy Results
 - Specimen Storage

Enrollment Rectal Exam

PTID:	Visit Date:	Visit Code: 2.0
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1. _____ Review chart notes and other relevant documentation.
2. _____ Explain the exam procedures to the participant and answer any participant questions.
3. _____ Affix a SCHARP-provided PTID label to the specimen collection tubes at the time of collection. Record the PTID and write the specimen collection date in ink on the label.
4. _____ Position the participant in a lateral position on the left side. Drape the participant comfortably.
5. _____ Inspect the anus and surrounding region visually. Document abnormal findings on items # 1-1a of the **Rectal Exam** CRF and in chart notes.
6. _____ Use study provided lubricant to lubricate the anoscope. Gently insert the anoscope into the rectum (until the lateral ‘wings’ touch the anal margin). Remove the obturator.
7. _____ If clinically indicated, collect the rectal swab for GC/CT testing by removing it from the plastic tube and inserting it through the anoscope placing in contact with the rectal wall. Gently turn the swab 360 degrees and remove. Place the rectal swab in the transport tube, break off shaft of swab and cap.
8. _____ Collect the rectal swab for Microflora by inserting the swab through the anoscope and place in contact with the rectal wall. Gently turn the swab 360 degrees gently and remove from rectum. Slowly remove the swab and place into a transport tube (labeled with a SCHARP-provided label), submerging the swab into the gel. Break off the shaft of the swab and cap
9. _____ Collect the rectal sponge for Cytokines by inserting the sponge through the anoscope and place in contact with the rectum (approximately 9 cm in the rectum). *The sponge should remain in place for five minutes.*
10. _____ Remove rectal sponge and place in a specimen collection tube (labeled with a SCHARP-provided label). Slowly remove anoscope.
11. _____ Perform a digital rectal examination by inserting a gloved finger, lubricated with study specified lubricant, into the anal canal and sweep around the internal anal circumference. Document abnormal findings on items #2-2a of the **Rectal Exam** CRF. Any unexpected discomfort should also be documented in chart notes and/or in the comments field of the **Rectal Exam** CRF.

Enrollment Rectal Exam

PTID:	Visit Date:	Visit Code: 2.0
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12. _____ Position specimen pan provided in the Genova Diagnostic Calprotectin Kit onto available toilet.
13. _____ Prepare appropriate pre-packaged enema bottle for **rectal lavage** and apply a small amount of study specified lubricant to the tip of the enema bottle. Gently insert enema bottle into the rectum and slowly dispell the fluid into the rectum.

Instruct participant to hold the fluid in the rectum for approximately 3-5 minutes then expel it, including stool, into the specimen pan placed over the toilet.

14. _____ Transfer stool sample for **fecal calprotectin** with the flat wooden stick provided in the Genova Diagnostics-provided kit into the white top vial and prepare for transport.
15. _____ Transfer effluent for assessment of **epithelial sloughing** to a conical tube for initial processing and prepare per Section 12 of the SSP for shipment to the MTN Network Lab.
16. _____ Re-position the participant in a lateral position on the left side. Drape the participant comfortably.
17. _____ Use study provided lubricant to lubricate the tip of the sigmoidoscope. Insert the sigmoidoscope into the anal canal.
18. _____ Using the jumbo endoscopic foreceps, collect seven rectal biopsies at approximately 15 cm from the anal verge via flexible sigmoidoscopic biopsy. Remove sigmoidoscope following specimen collection.
19. _____ Use study provided lubricant to lubricate the anoscope. Insert the anoscope into the anal canal until the anoscope ‘wings’ touch the anal verge. Remove the obturator.
20. _____ Using the jumbo endoscopic foreceps, collect seven rectal biopsies at approximately 9 cm from the anal verge via **anoscopic** biopsy. Remove anoscope following specimen collection.

Enrollment Rectal Exam

PTID:	Visit Date:	Visit Code: 2.0
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Note: Required biopsies are to be collected as follows:

- 1 biopsy at each location for Histology (15 cm and 9 cm)
 - 2 biopsies at each location for Cytokine RT PCR (15 cm and 9 cm)
 - 3 biopsies at each location for Mucosal T Cell Phenotyping (15 cm and 9 cm)
 - 1 biopsy at each location for Mucosal Gene Expression Array. (15 cm and 9 cm)
21. Obtain vital signs and document in chart notes. Evaluate any abnormal findings
22. Document exam findings on the **Anoscopy and Sigmoidoscopy Results** CRF. Document specimen collection and storage on the **Specimen Storage** CRF and the **LDMS Specimen Tracking Sheet** (non-Datafax) CRF.

Treatment 1 Visit

PTID:	Visit Date:	Visit Code: 3.0
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1. _____ Confirm the participant's identity, and verify PTID per site SOPs.
2. _____ Review and/or update locator information.
3. _____ Review chart notes and other relevant documentation from previous visit(s).
Provide test results from previous visit(s), if applicable.
4. _____ Explain the content and sequence of procedures for today's visit. Review elements of informed consent as needed.
5. _____ Collect 15-60 mL urine and:
 - 5a. _____ Aliquot approximately 5-10 mL and perform qualitative pregnancy test (**For females of childbearing potential only**)
 - 5b. _____ Complete testing logs and record result on the **Follow-Up Visit/Phone Call CRF**.
 - 5c. _____ If clinically indicated, prepare remaining urine for gonorrhea and chlamydia NAAT. Record results on **STI Laboratory Results CRF**, when available.

If the participant is pregnant, modify remaining study visit procedures per protocol section 7.8.2. If the participant is pregnant and is randomized to gel arm:

- 5d. _____ Inform the participant that she will be discontinued from the study product use and will not be provided with any study gel.
- 5e. _____ Complete a **Pregnancy Report and History CRF** and a **Product Hold/Discontinuation Log CRF**.
6. _____ Perform interval medical/menstrual history; record findings on the **Participant Reported Follow-up Medical and Menstrual History** form. Review and update the **Concomitant Medications Log** (including family planning methods) as necessary.
7. _____ Provide contraceptive counseling and [provide and/or refer] for contraception, if applicable.
8. _____ Perform physical exam per Protocol Section 7.11 and record findings on the **Physical Exam** (non-DataFax) form.
9. _____ Perform and document rectal exam using the *Treatment 1 Visit Rectal Exam Checklist*. Record findings on the Rectal Exam CRF.

Treatment 1 Visit

PTID:	Visit Date:	Visit Code: 3.0
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10. _____ Evaluate findings identified during rectal and physical examinations and medical and menstrual history review. Refer for or provide any clinically indicated treatment; document in chart notes and update **Concomitant Medications Log** CRF, if applicable.

11. _____ **ASSESS ELIGIBILITY TO CONTINUE PRODUCT USE BASED ON INTERVAL MEDICAL/MENSTRUAL HISTORY AND RECTAL EXAM FINDINGS**

NOT ELIGIBLE (Gel Participants Only): Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on holding or discontinuing study product. Contact PSRT if there are any questions.

11a. _____ If product use is discontinued at this visit, document the rationale in chart notes and/or on other applicable source documents. Complete the **Product Hold/Discontinuation Log** and a **Study Gel Request Slip** to inform the site’s pharmacist of the product discontinuation.

11b. _____ Deliver the white copy of the completed Study Gel Request Slip to the pharmacy; retain the yellow copy in the participant’s study notebook.

ELIGIBLE (Gel Participants Only): Request single dose of study product from pharmacy.

11a. _____ Follow site-specific procedure for product supply. Complete the MTN 007 Prescription – Single Dose Gel (“replacement prescription – gel” for gel replacement participants). Record the participant ID and mark if written informed consent was provided.

11b. _____ Deliver completed white copy to the pharmacy. The original prescription must be delivered to the pharmacist in order for the study product to be dispensed. The yellow copy of the prescription will be retained in the participant’s study notebook.

11c. _____ After product supply is received, document the number of applicators provided here

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12. _____ Provide HIV/STI risk reduction, protocol adherence, product use adherence, and condom counseling. Provide study-provided male condoms and lubricant.

13. _____ Explain the follow up schedule to the participant and schedule the Treatment 2 Visit and inform the participant of what to expect.

Treatment 1 Visit

PTID:	Visit Date:	Visit Code: 3.0
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14. _____ Remind the participant about the Follow-up Phone Assessment that must occur within 24 hours of this visit.
15. _____ 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.
16. _____ Provide study reimbursement
17. _____ Complete **AE Log** form(s), if required, based on interval medical/menstrual history, clinical exams/assessments, and lab tests when available.
18. _____ Complete the **Follow-up Visit/Phone Call CRF**.
19. _____ Document the visit in a signed and dated chart note. Complete and review all participant chart contents for the visit, including the following non-DataFax forms:
- Physical Exam
 - Participant-reported Follow-up Medical and Menstrual History
 - LDMS Specimen Tracking Sheet
20. _____ Fax all required DataFax CRFs to SCHARP:
- Rectal Exam
 - Anoscopy and Sigmoidoscopy results
 - Follow-up Visit/Phone Call
 - Specimen Storage
- If applicable:*
- Adverse Experience Log
 - HIV Test Results
 - Missed Visit
 - Pregnancy Outcome
 - Pregnancy Report and History
 - STI Laboratory Results
 - Concomitant Medications Log
 - Product Hold/Discontinuation Log

Treatment 1 Visit Rectal Exam

PTID:	Visit Date:	Visit Code: 3.0
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1. _____ Review chart notes and other relevant documentation.
2. _____ Explain the exam procedures to the participant and answer any participant questions.
3. _____ Affix a SCHARP-provided PTID labels to the specimen collection tubes at the time of collection. Record the PTID and write the specimen collection date in ink on the label.
4. _____ Position the participant in a lateral position on the left side. Drape the participant comfortably.
5. _____ Inspect the anus and surrounding area visually. Document abnormal findings on items # 1-1a of the **Rectal Exam** CRF and in chart notes.
6. _____ If clinically indicated, lubricate the anoscope with the study specified lubricant and insert the anoscope into the anal canal until the anoscope ‘wings’ touch the anal verge. Remove the obturator.
7. _____ If clinically indicated, collect the rectal swab for GC/CT testing by removing it from the plastic tube and inserting it through the anoscope placing in contact with the rectal wall. Gently turn the swab 360 degrees and remove. Place the rectal swab in the transport tube, break off shaft of swab and cap. Slowly remove anoscope.
8. _____ **ELIGIBLE (Gel Participants Only):** Under the observation of the study clinician, instruct participant to self-administer the single dose of study gel.
9. _____ Lubricant the anoscope with the study specified lubricant and insert the anoscope into the anal canal until the anoscope ‘wings’ touch the anal verge. Remove the obturator.
10. _____ Collect the rectal swab for **Microflora** by inserting the swab through the anoscope and place in contact with the rectal wall. Gently turn the swab 360 degrees gently and remove from rectum. Slowly remove the swab and place into a transport tube (labeled with a SCHARP-provided label), submerging the swab into the gel. Break off the shaft of the swab and cap.
11. _____ Collect the rectal sponge for **Cytokines** by inserting the sponge through the anoscope and place in contact with the rectum (approximately 9 cm in the rectum). *Note: The sponge should remain in place for five minutes.*

Treatment 1 Visit Rectal Exam

PTID:	Visit Date:	Visit Code: 3.0
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12. _____ Remove rectal sponge and place in a specimen collection tube (labeled with a SCHARP-provided label). Slowly remove anoscope.

13. _____ Perform a digital rectal examination by inserting a gloved finger, lubricated with study specified lubricant, into the anal canal and sweep around the internal anal circumference. Document abnormal findings on items #2-2a of the **Rectal Exam** CRF. Any unexpected discomfort should also be documented in chart notes and/or in the comments field of the **Rectal Exam** CRF.

14. _____ Position specimen pan provided in the Genova Diagnostic Calprotectin Kit onto available toilet.

15. _____ Prepare appropriate pre-packaged enema bottle for **Rectal Lavage** by applying a small amount of study specified lubricant to the tip of the enema bottle. Gently insert enema bottle into the rectum and slowly dispell the fluid into the rectum.

Note: Instruct participant to hold the fluid in the rectum for approximately 3-5 minutes then expel it, including stool, into the specimen pan placed over the toilet.

16. _____ Transfer stool sample for **fecal calprotectin** with the flat wooden stick provided in the Genova Diagnostics-provided kit into the white top vial and prepare for transport.

17. _____ Transfer effluent for assessment of **epithelial sloughing** to a conical tube for initial processing and prepare per Section 12 of the SSP for shipment to the MTN Network Lab.

18. _____ Re-position the participant in a lateral position on the left side. Drape the participant comfortably.

19. _____ Use study provided lubricant to lubricate the tip of the sigmoidoscope. Insert the sigmoidoscope into the anal canal.

20. _____ Using the jumbo endoscopic forceps, collect seven rectal biopsies at approximately 15 cm from the anal verge via flexible sigmoidoscopic biopsy. Remove sigmoidoscope following specimen collection.

21. _____ Use study provided lubricant to lubricate the anoscope. Insert the anoscope into the anal canal until the anoscope ‘wings’ touch the anal verge.
Remove the obturator.

Treatment 1 Visit Rectal Exam

PTID:	Visit Date:	Visit Code: 3.0
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22. _____ Using the jumbo endoscopic forceps, collect seven rectal biopsies at approximately 9 cm from the anal verge via **anoscopic** biopsy. Remove anoscope following specimen collection.

Note: Required biopsies are to be collected as follows within 30 minutes of gel application:

- _____1 biopsy at each location for Histology (15 cm and 9 cm)
 - _____2 biopsies at each location for Cytokine RT PCR (15 cm and 9 cm)
 - _____3 biopsies at each location for Mucosal T Cell Phenotyping (15 cm and 9 cm)
 - _____1 biopsy at each location for Mucosal Gene Expression Array (15 cm and 9 cm)
23. _____ Obtain vital signs and document in chart notes. Evaluate any abnormal findings.
24. _____ Document exam findings on the **Anoscopy and Sigmoidoscopy Results** CRF. Document specimen collection and storage on the **Specimen Storage** CRF and the **LDMS Specimen Tracking Sheet** (non-DataFax) CRF.

Follow-Up Phone Assessment (24 hours After Treatment 1 Visit)

PTID:	Visit Date:	Visit Code: 4.0
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1. ___ Confirm the participant’s identity and verify PTID per site SOPs.
2. ___ Review chart notes and other relevant documentation from previous visit(s).
3. ___ Review elements of informed consent as needed.
4. ___ Explain the content and sequence of procedures for today’s phone assessment.
5. ___ Inquire about any AEs the participant may have experienced as a result of study product or procedures performed during the Treatment 1 Visit.
6. ___ Refer for follow-up care as needed. Document follow-up in chart notes. If required based on all available information, complete **AE Log** CRF and/or **Product Hold/Discontinuation Log** CRF.
7. ___ 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.
8. ___ Complete **Follow-up Visit/Phone Call** CRF.
9. ___ Document the visit in a signed and dated chart note. Complete and review case report forms for the visit.
10. ___ Fax all required DataFax forms to SCHARP:
 - Follow-up Visit/Phone Call

If applicable:

 - Adverse Experience Log
 - Missed Visit
 - Product Hold/Discontinuation Log

Additional Comments:

Treatment 2 Visit

PTID:	Visit Date:	Visit Code: 5.0
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1. _____ Confirm the participant's identity and verify PTID per site SOPs.
2. _____ Review/update locator information.
3. _____ Review chart notes and other relevant documentation from previous visit(s).
Provide test results from previous visit(s), if applicable.
4. _____ Review elements of informed consent as needed. Explain the content and sequence of procedures for today's visit.
5. _____ Collect 15-60 mL urine and:
 - 5a. _____ Aliquot approximately 5-10 mL and perform qualitative pregnancy test (*For females of childbearing potential only*)
 - 5b. _____ Complete testing logs and record result on the **Follow-Up Visit/Phone Call CRF**.
 - 5c. _____ If clinically indicated, prepare remaining urine for gonorrhea and chlamydia NAAT. Record results on **STI Laboratory Results CRF**, when available.

If the participant is pregnant, modify remaining study visit procedures per protocol section 7.8.2. If the participant is pregnant and is randomized to gel arm:

- 5d. _____ Inform the participant that she will be discontinued from the study product use and will not be provided with any study gel.
- 5e. _____ Complete a **Pregnancy Report and History CRF** and a **Product Hold/Discontinuation Log CRF**.
6. _____ Perform interval medical/menstrual history; record findings on the **Participant Reported Follow-up Medical and Menstrual History** (non-DataFax) CRF. Review and update the **Concomitant Medications Log** (including family planning methods) as necessary.
7. _____ Provide contraceptive counseling and [provide and/or refer for] contraception, if applicable.
8. _____ If clinically indicated, perform physical exam as per Protocol Section 7.11. Record findings on the Physical Exam (non-DataFax) CRF.
9. _____ If clinically indicated, perform and document rectal exam using the *Treatment 2 Visit Rectal Exam Checklist*. Record findings on the **Rectal Exam CRF**.

Treatment 2 Visit

PTID:	Visit Date:	Visit Code: 5.0
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10. _____ Evaluate findings identified during rectal and physical examinations and medical and menstrual history review. Refer for or provide any clinically indicated treatment; document in chart notes and update **Concomitant Medications Log** CRF, if applicable.

11. _____ **ASSESS ELIGIBILITY TO CONTINUE PRODUCT USE BASED ON INTERVAL MEDICAL/MENSTRUAL HISTORY AND RECTAL EXAM FINDINGS, IF APPLICABLE**

NOT ELIGIBLE (Gel Participants Only): Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on discontinuing study product. Contact the PSRT if there are any questions.

11a. _____ If product use is discontinued at this visit, document the rationale in chart notes and/or on other applicable source documents. Complete the **Product Hold/Discontinuation Log** and a **Study Gel Request Slip** to inform the site's pharmacist of the product discontinuation.

11b. _____ Deliver the white copy of the completed Study Gel Request Slip to the pharmacy; retain the yellow clinic copy in the participant's study notebook.

ELIGIBLE (Gel Participants Only): Request a seven day supply of study product from pharmacy:

11a. _____ Follow site-specific procedures for product supply. Complete the MTN 007 Prescription - Seven Day Gel ("replacement prescription – gel" for replacement participants). Record the participant's ID (PTID) on the prescription.

11b. _____ Deliver completed white copy to the pharmacy. The original prescription must be delivered to the pharmacist in order for the study product to be dispensed. The yellow copy of the prescription will be retained in the participant's study notebook.

11c. _____ After product supply is received, document the number of applicators provided here

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12. _____ **Gel Participants Only:** Provide instructions on the use of the Phone Reporting System (PRS). Provide product use counseling.

Treatment 2 Visit

PTID:	Visit Date:	Visit Code: 5.0
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13. _____ Provide counseling related to the importance of study participation. Provide HIV/STI risk education, protocol adherence, and male condom counseling. Provide male condoms and lubricant. Provide referrals if needed/requested. Emphasize the unknown effectiveness of the study product and the importance of condom use for protection against HIV.
14. _____ Explain the follow-up visit schedule to the participant and schedule Final Clinic Visit and inform the participant of what to expect.
15. _____ Reinforce site contact information and instructions to contact the site to report symptoms – especially rectal symptoms – and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.
16. _____ Provide study reimbursement.
17. _____ Complete **AE Log** CRF, if required, based on interval medical/menstrual history, clinical exams/assessments, and lab tests when available.
18. _____ Complete **Follow-up Visit/Phone Call** CRF.
19. _____ 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:
- Participant-reported Follow-up Medical and Menstrual History
 - LDMS Tracking Sheet, *if applicable*
 - Physical Exam, *if applicable*
20. _____ Fax all required Data Fax forms to SCHARP:
- Follow-up Visit/Phone Call
- If applicable:*
- Adverse Experience Log
 - Anoscopy and Sigmoidoscopy Results
 - Concomitant Medications Log
 - HIV Test Results
 - Missed Visit
 - Pregnancy Outcome
 - Pregnancy Report and History
 - Product Hold/Discontinuation Log
 - Rectal Exam
 - Specimen Storage
 - STI Laboratory Results

Treatment 2 Visit Rectal Exam

PTID:	Visit Date:	Visit Code: 5.0
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Mark "Not applicable or N/A" next to all procedures that are not clinically indicated for the visit.

1. _____ Review chart notes and other relevant documentation.
2. _____ Explain the exam procedures to the participant and answer any participant questions.
3. _____ Affix a SCHARP-provided PTID labels to the specimen collection tubes at the time of collection. Record the PTID and write the specimen collection date in ink on the label.
4. _____ Position the participant in a lateral position on the left side. Drape the participant comfortably.
5. _____ Inspect the anus and surrounding area visually. Document abnormal findings on items # 1-1a of the **Rectal Exam** CRF and in chart notes.
6. _____ If clinically indicated, lubricate the anoscope with the study specified lubricant and insert the anoscope into the anal canal until the anoscope 'wings' touch the anal verge. Remove the obturator.
7. _____ If clinically indicated, collect the rectal swab for GC/CT testing by removing it from the plastic tube and inserting it through the anoscope placing in contact with the rectal wall. Gently turn the swab 360 degrees and remove. Place the rectal swab in the transport tube, break off shaft of swab and cap.
8. _____ Perform a digital rectal examination by inserting a gloved finger, lubricated with study specified lubricant, into the anal canal and sweep around the internal anal circumference. Document abnormal findings on items #2-2a of the **Rectal Exam** CRF. Any unexpected discomfort should also be documented in chart notes and/or in the comments field of the **Rectal Exam** CRF.
9. _____ If clinically indicated, use study specified lubricant to lubricate the anoscope. Insert the anoscope into the anal canal until the anoscope 'wings' touch the anal verge. Remove the obturator.
10. _____ Using the jumbo endoscopic forceps, collect seven rectal biopsies at approximately 9 cm from the anal verge via **anoscopic** biopsy. Remove anoscope following specimen collection.

Treatment 2 Visit Rectal Exam

PTID:	Visit Date:	Visit Code: 5.0
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Mark "Not applicable or N/A" next to all procedures that are not clinically indicated for the visit.

Note: Required biopsies are to be collected as follows:

- _____ 1 biopsy (9 cm) for Histology
- _____ 2 biopsies (9 cm) for Cytokine RT PCR
- _____ 3 biopsies (9 cm) for Mucosal T Cell Phenotyping
- _____ 1 biopsy (9 cm) for Mucosal Gene Expression Array.

11. _____ Obtain vital signs and document in chart notes. Evaluate any abnormal findings.
12. _____ Document exam findings on the **Anoscopy and Sigmoidoscopy Results** CRF. Document specimen collection and storage on the **Specimen Storage** CRF and the **LDMS Specimen Tracking Sheet** (non-DataFax) CRF.

Final Clinic Visit

PTID:	Visit Date:	Visit Code: 6.0
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1. _____ Confirm the participant’s identity and verify PTID per site SOPs.
2. _____ Review/update locator information.
3. _____ Review chart notes and other relevant documentation from previous visit(s). Provide test results from previous visit(s), if applicable.
4. _____ Review elements of informed consent as needed. Explain the content and sequence of procedures for today’s visit.
5. _____ Collect 15-60 mL urine and:
 - 5a. _____ Aliquot approximately 5-10 mL for qualitative pregnancy (*for females of childbearing potential only*) and dipstick urinalysis tests.
 - 5b. _____ Complete testing logs and record result on the **Follow Up Visit/Phone Call CRF**.
 - 5c. _____ Complete dipstick urinalysis and record results for protein, glucose, nitrites, and leukocytes according to local SOP and on **Laboratory Results CRF**. If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site. Document treatment and/or additional work-up in chart notes. Update Concomitant Medications Log if necessary
 - 5d. _____ If clinically indicated, prepare remaining urine for gonorrhea and chlamydia NAAT. Record results on **STI Laboratory Results CRF**, when available.

If the participant is pregnant, modify remaining study visit procedures per protocol section 7.8.2. If the participant is pregnant and is randomized to gel arm:

 - 5e. _____ Complete a **Pregnancy Report and History CRF**.
6. _____ **Gel Participants Only:** Collect used and unused study product. Document product collection in the chart notes. If participant did not bring the unused product at this visit, make arrangements to collect the product. Complete **Study Product Returns CRF**.
7. _____ Perform interval medical/menstrual history; record findings on the **Participant Reported Follow-up Medical and Menstrual History** (non-DataFax) CRF. Review and update the **Concomitant Medications Log CRF** (including family planning methods) as necessary

Final Clinic Visit

PTID:	Visit Date:	Visit Code: 6.0
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8. _____ Perform the physical exam as per protocol section 7.11 and record findings on the **Physical Exam** (non-DataFax) CRF.

9. _____ ***Gel Participants Only:*** Administer **Product Acceptability Questionnaire**.

10. _____ Provide HIV pre-test, HIV/STI risk reduction and condom counseling. Provide study-specific male condoms. Provide referrals if needed/requested.

11. _____ Collect blood:
 - Plain tube (no additive)
 - EDTA

12. _____ Prepare blood for testing at the local lab:
 - CBC with differential and platelets
 - BUN, Creatinine, ALT, AST
 - Syphilis RPR
 - HIV-1 serology

Tailor this item to reflect site-specific tube types and volumes.

13. _____ Perform and document rectal exam using the *Final Clinic Visit Rectal Exam Checklist*. Record findings on the **Rectal Exam** CRF.

14. _____ Evaluate findings identified during rectal examination and medical and menstrual history review. Refer for or provide any clinically indicated treatment; document in chart notes and update **Concomitant Medications Log** CRF, if applicable.

15. _____ Schedule/remind the participant of the Follow-up Phone Assessment/Termination Visit and inform the participant of what to expect.

16. _____ 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.

17. _____ Provide HIV test results in the context of post-test counseling, when available. [Before disclosing result(s) to participant, obtain independent review, verification, and sign-off of results(s)]. Provide referrals if needed/requested. Provide referrals if needed/requested. Provide treatment for RTIs/STIs if needed.

18. _____ Provide study reimbursement.

Final Clinic Visit

PTID:	Visit Date:	Visit Code: 6.0
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19. _____ Complete **AE Log** form(s), if required, based on interval medical/menstrual history, clinical exams/assessments, and lab tests when available.
20. _____ Complete the **Follow-up Visit/Phone Call** CRF.
21. _____ 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:
- LDMS Tracking Sheet
 - Participant Reported Follow Up Medical and Menstrual History
 - Physical Exam
22. _____ Fax all required DataFax forms to SCHARP:
- Anoscopy and Sigmoidoscopy Results
 - Follow-up Visit/Phone Call
 - Laboratory Results
 - Rectal Exam
 - Specimen Storage
 - STI Laboratory Results
 - Study Product Returns (for participants in the treatment arms only)

If applicable:

- Adverse Experience Log
- Concomitant Medication Log
- HIV Test Results
- Missed Visit
- Pregnancy Outcome
- Pregnancy Report and History

Final Clinic Visit Rectal Exam

PTID:	Visit Date:	Visit Code: 6.0
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1. _____ Review chart notes and other relevant documentation.
2. _____ Explain the exam procedures to the participant and answer any participant questions.
3. _____ Affix a SCHARP-provided PTID labels to the specimen collection tubes at the time of collection. Record the PTID and write the specimen collection date in ink on the label.
4. _____ Position the participant in a lateral position on the left side. Drape the participant comfortably.
5. _____ Inspect the anus and surrounding area visually. Document abnormal findings on items # 1-1a of the **Rectal Exam** CRF and in chart notes.
6. _____ If clinically indicated, lubricant the anoscope with the study specified lubricant and insert the anoscope into the anal canal until the anoscope 'wings' touch the anal verge. Remove the obturator.
7. _____ If clinically indicated, collect the rectal swab for GC/CT testing by removing it from the plastic tube and inserting it through the anoscope placing in contact with the rectal wall. Gently turn the swab 360 degrees and remove. Place the rectal swab in the transport tube, break off shaft of swab and cap.
8. _____ Collect the rectal swab for **Microflora** by inserting the swab through the anoscope and place in contact with the rectal wall. Gently turn the swab 360 degrees gently and remove from rectum.
9. _____ Slowly remove the swab and place into a transport tube (labeled with a SCHARP-provided label), submerging the swab into the gel. Break off the shaft of the swab and cap.
10. _____ Collect the rectal sponge for **Cytokines** by inserting the sponge through the anoscope and place in contact with the rectum (approximately 9 cm in the rectum). *Note: The sponge should remain in place for five minutes.*
11. _____ Remove rectal sponge and place in a specimen collection tube (labeled with a SCHARP-provided label). Slowly remove anoscope.

Final Clinic Visit Rectal Exam

PTID:	Visit Date:	Visit Code: 6.0
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12. _____ Perform a digital rectal examination by inserting a gloved finger, lubricated with study specified lubricant, into the anal canal and sweep around the internal anal circumference. Document abnormal findings on items #2-2a of the **Rectal Exam** CRF. Any unexpected discomfort should also be documented in chart notes and/or in the comments field of the **Rectal Exam** CRF.
13. _____ Position specimen pan provided in the Genova Diagnostic Calprotectin Kit onto available toilet.
14. _____ Prepare appropriate pre-packaged enema bottle for **Rectal Lavage** by applying a small amount of study specified lubricant to the tip of the enema bottle. Gently insert enema bottle into the rectum and slowly dispell the fluid into the rectum.

Note: Instruct participant to hold the fluid in the rectum for approximately 3-5 minutes then expel it, including stool, into the specimen pan placed over the toilet.

15. _____ Transfer stool sample for **fecal calprotectin** with the flat wooden stick provided in the Genova Diagnostics-provided kit into the white top vial and prepare for transport.
16. _____ Transfer effluent for assessment of **epithelial sloughing** to a conical tube for initial processing and prepare per Section 12 of the SSP for shipment to the MTN Network Lab.
17. _____ Re-position the participant in a lateral position on the left side. Drape the participant comfortably.
18. _____ Use study provided lubricant to lubricate the tip of the sigmoidoscope. Insert the sigmoidoscope into the anal canal.
19. _____ Using the jumbo endoscopic foreceps, collect seven rectal biopsies at approximately 15 cm from the anal verge via flexible sigmoidoscopic biopsy. Remove sigmoidoscope following specimen collection.
20. _____ Use study provided lubricant to lubricate the anoscope. Insert the anoscope into the anal canal until the anoscope ‘wings’ touch the anal verge. Remove the obturator.
21. _____ Using the jumbo endoscopic foreceps, collect seven rectal biopsies at approximately 9 cm from the anal verge via **anoscopic** biopsy. Remove anoscope following specimen collection.

Final Clinic Visit Rectal Exam

PTID:	Visit Date:	Visit Code: 6.0
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Note: Required biopsies are to be collected as follows:

_____ 1 biopsy at each location for Histology (15 cm and 9 cm)

_____ 2 biopsies at each location for Cytokine RT PCR (15 cm and 9 cm)

_____ 3 biopsies at each location for Mucosal T Cell Phenotyping (15 cm and 9 cm)

_____ 1 biopsy at each location for Mucosal Gene Expression Array (15 cm and 9 cm)

22. _____ Obtain vital signs and document in chart notes. Evaluate any abnormal findings.
23. _____ Document exam findings on the **Anoscopy and Sigmoidoscopy Results** CRF. Document specimen collection and storage on the **Specimen Storage** CRF and the **LDMS Specimen Tracking Sheet** (non-DataFax) CRF.

Follow-Up Phone Assessment/Termination Visit

PTID:	Visit Date:	Visit Code: 7.0
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1. _____ Confirm the participant’s identity and verify PTID per site SOPs.
2. _____ Review chart notes and other relevant documentation from previous visit(s).
3. _____ Review elements of informed consent as needed. Explain the content and purpose for the follow up phone assessment.
4. _____ Inquire about any AEs the participant may have experienced as a result of study product or procedures performed during the Final Clinic Visit.
5. _____ Refer for follow-up care as needed. Document follow-up in chart notes. If required based on all available information, complete **AE Log** CRF.
6. _____ 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.
7. _____ Complete **Follow-up Visit/Phone Call** CRF and **Termination** CRF
8. _____ Document the visit in a signed and dated chart note.
9. _____ Complete and review case report forms and participant chart contents for the visit.
10. _____ Fax all required DataFax forms to SCHARP:
 - Follow-up Visit/Phone Call
 - End of Study Inventory
 - Termination

If applicable:

 - AE Log Form
 - Missed Visit

Additional Comments:

Interim Visit

PTID:	Visit Date:	Visit Code:
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1. _____ Confirm the participant’s identity and verify PTID per site SOPs.
2. _____ Review/update locator information.
3. _____ Review chart notes and other relevant documentation from previous visit(s).
Provide test results from previous visit(s), if applicable.
4. _____ Review elements of informed consent as needed. Explain the content and sequence of procedures for today’s visit
5. _____ Collect 15-60 mL urine and:
 - 5a. _____ Aliquot approximately 5-10 mL for qualitative pregnancy (*for females of childbearing potential only*).
 - 5b. _____ Complete testing logs and record result on the **Interim Visit** CRF.
 - 5c. _____ If clinically indicated, complete dipstick urinalysis and record results for protein, glucose, nitrites, and leukocytes according to local SOP and on **Laboratory Results** CRF. If dipstick urinalysis is positive for leukocytes or nitrites, provide treatment and/or additional UTI work-up per site. Document treatment and/or additional work-up in chart notes. Update Concomitant Medications Log if necessary.
 - 5d. _____ If clinically indicated, prepare remaining urine for gonorrhea and chlamydia NAAT. Record results on **STI Laboratory Results** CRF, when available.

If the participant is pregnant, modify remaining study visit procedures per protocol section 7.8.2. If the participant is pregnant and is randomized to gel arm:

- 5e. _____ Complete a **Pregnancy Report and History** CRF and a **Product Hold/Discontinuation Log** CRF
6. _____ Perform interval medical/menstrual history, record findings on the **Participant Reported Follow-up Medical and Menstrual History** (non-DataFax) CRF. Review and update the **Concomitant Medications Log** (including family planning methods) as necessary.
7. _____ If clinically indicated, perform physical exam as per protocol section 7.11 and record findings on the **Physical Exam** (non-DataFax) CRF.
8. _____ If clinically indicated, perform and document rectal exam using the *Interim Visit Rectal Exam Checklist*. Record findings on the **Rectal Exam** CRF.

Interim Visit

PTID:	Visit Date:	Visit Code:
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9. _____ Evaluate findings identified during rectal and physical examinations and medical and menstrual history review. Refer for or provide any clinically indicated treatment; document in chart notes and update **Concomitant Medications Log** CRF, if applicable.

10. _____ If HIV testing is clinically indicated, provide HIV pre-test counseling.

11. _____ If clinically indicated, collect blood:

- Plain tube (no additive)
- EDTA

12. _____ Prepare blood for testing at the local lab:

- HIV-1 serology (if indicated)
- Syphilis RPR (if indicated)
- CBC with differential and platelets (if indicated)
- BUN, Creatinine, ALT, AST (if indicated)

Tailor this item to reflect site-specific tube types and volumes.

13. _____ **ASSESS ELIGIBILITY TO CONTINUE PRODUCT USE BASED ON INTERVAL MEDICAL/MENSTRUAL HISTORY AND RECTAL EXAM FINDINGS, IF APPLICABLE**

NOT ELIGIBLE (Gel Participants Only): Refer to Protocol Section 9.4 and the SSP Manual, Section 10, for guidelines on discontinuing study product. Contact PSRT if there are any questions.

13a. _____ If product use is discontinued at this visit, document the rationale in chart notes and/or on other applicable source documents. Complete the **Product Hold/Discontinuation Log** and a **Study Gel Request Slip** to inform the site's pharmacist of the product discontinuation.

13b. _____ Deliver the white copy of the completed Study Gel Request Slip to the pharmacy; retain the yellow copy in the participant's study notebook.

14. _____ **Gel Participants Only:** If study product is resupplied at this visit, complete a **Study Gel Request Slip**. Document the rationale in chart notes and/or on other applicable source documents. Contact the PSRT if there are any questions about study product or clinical management. If product use is discontinued, collect used and unused study product. Document product collection in the chart notes and on the **Interim Visit** CRF. If participant did not bring the unused product at this visit, make arrangements to collect the product.

Interim Visit

PTID:	Visit Date:	Visit Code:
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15. _____ Provide and explain available exam and lab test results. Provide post-test counseling and appropriate referrals, if applicable. Provide HIV/STI risk reduction and condom counseling. Provide study-specific male condoms and lubricants. Provide referrals if needed/requested.
16. _____ Complete/update **Adverse Experience Log** CRF, if required, based on interval medical/menstrual history, clinical exams/assessments, and lab tests when available.
17. _____ Reinforce site contact information and instructions to contact the site to report symptoms — especially rectal symptoms — and/or to request for additional information, HIV/STI counseling, and/or condoms, if needed, prior to the next visit.
18. _____ Remind/schedule the participant of their next scheduled visit, if applicable.
19. _____ Complete **Interim Visit** CRF.
20. _____ Document the interim visit in a signed and dated chart note. Complete and review all participant chart contents and case report forms for the visit, including the following non-DataFax forms:
- Participant-reported Follow-up Medical and Menstrual History
 - LDMS Specimen Tracking Sheet, *if applicable*
 - Physical Exam, *if applicable*
21. _____ Fax all required Data Fax forms to SCHARP:
- Interim Visit
- If applicable:*
- Adverse Experience Log
 - Concomitant Medication Log
 - HIV Test Results
 - Laboratory Results
 - Pregnancy Outcome
 - Pregnancy Report and History
 - Product Hold/Discontinuation Log
 - Rectal Exam
 - STI Laboratory Results

Interim Visit Rectal Exam

PTID:	Visit Date:	Visit Code:
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Mark "Not applicable or N/A" next to all procedures that are not clinically indicated for the visit.

1. Review chart notes and other relevant documentation.
2. Explain the exam procedures to the participant and answer any participant questions.
3. Affix a SCHARP-provided PTID labels to the specimen collection tubes at the time of collection. Record the PTID and write the specimen collection date in ink on the label.
4. Position the participant in a lateral position on the left side. Drape the participant comfortably.
5. Inspect the anus and surrounding area visually. Document abnormal findings on items # 1-1a of the **Rectal Exam** CRF and in chart notes.
6. Lubricate the anoscope with the study specified lubricant and insert the anoscope into the anal canal until the anoscope 'wings' touch the anal verge. Remove the obturator.
7. Collect the rectal swab for GC/CT testing by removing it from the plastic tube and inserting it through the anoscope placing in contact with the rectal wall. Gently turn the swab 360 degrees and remove. Place the rectal swab in the transport tube, break off shaft of swab and cap. Slowly remove anoscope.
8. Perform a digital rectal examination by inserting a gloved finger, lubricated with study specified lubricant, into the anal canal and sweep around the internal anal circumference. Document abnormal findings on items #2-2a of the **Rectal Exam** CRF. Any unexpected discomfort should also be documented in chart notes and/or in the comments field of the **Rectal Exam** CRF.
9. Use study provided lubricant to lubricate the tip of the sigmoidoscope. Insert the sigmoidoscope into the anal canal.
10. Using the jumbo endoscopic forceps, collect seven rectal biopsies at approximately 15 cm from the anal verge via flexible sigmoidoscopic biopsy. Remove sigmoidoscope following specimen collection.
11. Use study provided lubricant to lubricate the anoscope. Insert the anoscope into the anal canal until the anoscope 'wings' touch the anal verge. Remove the obturator.

Interim Visit Rectal Exam

PTID:	Visit Date:	Visit Code:
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Mark "Not applicable or N/A" next to all procedures that are not clinically indicated for the visit.

12. _____ Using the jumbo endoscopic forceps, collect seven rectal biopsies at approximately 9 cm from the anal verge via **anoscopic** biopsy. Remove anoscope following specimen collection.

Note: Required biopsies are to be collected as follows:

- _____ 1 biopsy at each location for Histology (15 cm and 9 cm)
 - _____ 2 biopsies at each location for Cytokine RT PCR (15 cm and 9 cm)
 - _____ 3 biopsies at each location for Mucosal T Cell Phenotyping (15 cm and 9 cm)
 - _____ 1 biopsy at each location for Mucosal Gene Expression Array (15 cm and 9 cm)
13. _____ Obtain vital signs and document in chart notes. Evaluate any abnormal findings.
14. _____ Document exam findings on the **Anoscopy and Sigmoidoscopy Results** CRF. Document specimen collection and storage on the **Specimen Storage** CRF and the **LDMS Specimen Tracking Sheet** (non-DataFax) CRF.

Early Termination Visit

PTID:	Visit Date:	Visit Code:
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1. _____ Confirm the participant’s identity and verify PTID per site SOPs.

2. _____ Review/update locator information.

3. _____ Review chart notes and other relevant documentation from previous visit(s). Provide test results from previous visit(s), if applicable.

4. _____ Review elements of informed consent as needed. Explain the content and sequence of procedures for today’s visit. Determine visit code for this visit (regular or interim) based on participant’s completed visits and visit window calendar.

5. _____ Collect 15-60 mL urine and:
 - 5a. _____ Aliquot approximately 5-10 mL for qualitative pregnancy (*for females of childbearing potential only*) and dipstick urinalysis tests.
 - 5b. _____ Complete testing logs and record result on the **Follow Up Visit/Phone Call CRF** or **Interim Visit CRF** (depending on visit code assigned to the visit).
 - 5c. _____ Complete dipstick urinalysis and record results for protein, glucose, nitrites, and leukocytes according to local SOP and on **Laboratory Results CRF**. Document treatment and/or additional work-up in chart notes. Update **Concomitant Medications Log** if necessary.
 - 5c. _____ If clinically indicated, prepare remaining urine for gonorrhea and chlamydia NAAT. Record results on **STI Laboratory Results CRF**, when available.

If the participant is pregnant, modify remaining study visit procedures per protocol section 7.8.2. If the participant is pregnant and is randomized to gel arm:

- 5e. _____ Complete a **Pregnancy Report and History CRF**.

6. _____ ***Gel participants Only:*** If applicable, collect used and unused study product. Document product collection in the chart notes. If participant did not bring the unused product at this visit, make arrangements to collect the product. Complete **Study Product Returns CRF**. If participant is terminating prior to the Treatment 1 or Treatment 2 Visit, complete a MTN-007 Study Product Request Slip for the pharmacy to document permanent discontinuation of study product.

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7. _____ Perform interval medical/menstrual history, recording information on the **Participant Reported Follow-up Medical and Menstrual History** form. Review and update the **Concomitant Medications Log** (including family planning methods) as necessary.

8. _____ Conduct physical exam as per protocol section 7.11 and record findings on the **Physical Exam** (non-DataFax) CRF.

9. _____ ***Gel Participants Only:*** Administer Product Acceptability Questionnaire.

10. _____ Provide HIV pre-test, HIV/STI risk reduction and condom counseling. Provide study-specific male condoms. Provide referrals if needed/requested.

11. _____ Collect blood:
 - Plain tube (no additive)
 - EDTA

12. _____ Prepare blood for testing at the local lab:
 - CBC with differential and platelets
 - BUN, Creatinine, ALT, AST
 - Syphilis RPR
 - HIV-1 serology

Tailor this item to reflect site-specific tube types and volumes.

13. _____ Perform and document rectal exam using the *Early Termination Visit Rectal Exam Checklist*. Record findings on the **Rectal Exam** CRF.

14. _____ Evaluate findings identified during rectal and physical examinations and medical and menstrual history review. Refer for or provide any clinically indicated treatment; document in chart notes and update **Concomitant Medications Log** CRF, if applicable.

15. _____ If applicable, schedule Follow-up Phone Assessment and inform the participant of what to expect.

16. _____ Provide HIV test results in the context of post-test counseling when available. [Before disclosing result(s) to participant, obtain independent review, verification, and sign-off of results(s)]. Provide referrals if needed/requested. Provide referrals if needed/requested. Provide treatment for RTIs/STIs if needed.

17. _____ Provide study reimbursement.

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18. _____ Complete **AE Log** form(s), if required, based on interval medical/menstrual history, clinical exams/assessments, and lab tests when available.
19. _____ Complete the remainder **Follow-up Visit/Phone Call** or **Interim Visit** CRF, as applicable.
20. _____ Complete the **Termination** CRF and **End of Study Inventory** CRF.
21. _____ 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:
- LDMS Tracking Sheet (if rectal specimens for storage were collected)
 - Participant Reported Follow Up Medical and Menstrual History
 - Physical Exam
22. _____ Fax all required DataFax forms to SCHARP:
- Follow-up Visit/Phone Call or Interim Visit
 - Anoscopy and Sigmoidoscopy Results, if applicable
 - Specimen Storage, if applicable
 - Laboratory Results
 - Rectal Exam
 - STI Laboratory Results
 - Study Product Returns (for participants in the treatment arms only and if applicable)
 - End of Study Inventory
 - Termination
- If applicable:*
- Adverse Experience Log
 - Concomitant Medication Log
 - HIV Test Results
 - Missed Visit
 - Pregnancy Outcome
 - Pregnancy Report and History

Early Termination Visit Rectal Exam

PTID:	Visit Date:	Visit Code:
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Mark "Not applicable or N/A" next to all procedures that are not clinically indicated for the visit.

1. ____ Review chart notes and other relevant documentation.
2. ____ Explain the exam procedures to the participant and answer any participant questions.
3. ____ Affix a SCHARP-provided PTID labels to the specimen collection tubes at the time of collection. Record the PTID and write the specimen collection date in ink on the label.
4. ____ Position the participant in a lateral position on the left side. Drape the participant comfortably.
5. ____ Inspect the anus and surrounding area visually. Document abnormal findings on items # 1-1a of the **Rectal Exam** CRF and in chart notes.
6. ____ If clinically indicated, lubricate the anoscope with the study specified lubricant and insert the anoscope into the anal canal until the anoscope 'wings' touch the anal verge. Remove the obturator.
7. ____ If clinically indicated, collect the rectal swab for GC/CT testing by removing it from the plastic tube and inserting it through the anoscope placing in contact with the rectal wall. Gently turn the swab 360 degrees and remove. Place the rectal swab in the transport tube, break off shaft of swab and cap. Remove anoscope following specimen collection.
8. ____ Perform a digital rectal examination by inserting a gloved finger, lubricated with study specified lubricant, into the anal canal and sweep around the internal anal circumference. Document abnormal findings on items #2-2a of the **Rectal Exam** CRF. Any unexpected discomfort should also be documented in chart notes and/or in the comments field of the **Rectal Exam** CRF.
9. ____ If clinically indicated, use study provided lubricant to lubricate the tip of the sigmoidoscope. Insert the sigmoidoscope into the anal canal.
10. ____ Using the jumbo endoscopic forceps, collect seven rectal biopsies at approximately 15 cm from the anal verge via flexible sigmoidoscopic biopsy. Remove sigmoidoscope following specimen collection.

Early Termination Visit Rectal Exam

PTID:	Visit Date:	Visit Code:
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Mark "Not applicable or N/A" next to all procedures that are not clinically indicated for the visit.

11. ___ If clinically indicated, use study specified lubricant to lubricate the anoscope.
Insert the anoscope into the anal canal until the anoscope 'wings' touch the anal verge.
Remove the obturator.

12. ___ Using the jumbo endoscopic forceps, collect seven rectal biopsies at approximately 9 cm from the anal verge via **anoscopic** biopsy. Remove anoscope following specimen collection.

Note: Required biopsies are to be collected as follows:

___ 1 biopsy at each location for Histology (15 cm and 9 cm)

___ 2 biopsies at each location for Cytokine RT PCR (15 cm and 9 cm)

___ 3 biopsies at each location for Mucosal T Cell Phenotyping (15 cm and 9 cm)

___ 1 biopsy at each location for Mucosal Gene Expression Array (15 cm and 9 cm)

13. ___ Obtain vital signs and document in chart notes. Evaluate any abnormal findings.

14. ___ Document exam findings on the **Anoscopy and Sigmoidoscopy Results** CRF.
Document specimen collection and storage on the **Specimen Storage** CRF and the **LDMS Specimen Tracking Sheet** (non-DataFax) CRF.