

## Section 7. Visit Checklists

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This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN 002 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

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.
- Enter your initials beside only the procedures that you perform. Do not enter your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by lab staff.”
- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.
- If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why on the checklist (if not self-explanatory); initial and date this entry.

## 7.2 Sequence of Procedures

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

- Informed consent for screening and enrollment must be obtained before any study procedures are performed.
- Amniotic fluid and endometrial tissue must be collected during cesarean section and cord blood and placental tissue must be collected during or after the cesarean section.

*NOTE: Checklists in this section are provided as guidelines for the sites. The site can choose to modify these checklists or create their own checklist. Modified checklists should be reviewed by FHI prior to implementation.*

## Screening and Enrollment Visit: Page 1 of 3

<b>PTID:</b>	<b>Visit Date:</b>
<b>Visit Code: 01.0</b>	<b>Visit Window : Up to 4 weeks prior to C/S</b>

1. \_\_\_\_\_ Confirm participant identity. Cross-check with the MTN 002 Participant Name-PTID Link Log to determine whether a MTN 002 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. \_\_\_\_\_ Confirm the date and time when the participant's C/S is scheduled.
  - *If the participant's C/S is scheduled more than 4 weeks from this date, STOP. Reschedule the screening to occur approximately 1-4 weeks prior to C/S.*
  
4. \_\_\_\_\_ Confirm that the pregnancy term, at the time of the planned C/S, is 37 0/7 to 41 6/7 weeks (inclusive), using gestational dating criteria per site SOP.
  
5. \_\_\_\_\_ Explain the informed consent process.
  
6. \_\_\_\_\_ Explain the content and sequence of procedures for the remainder of the visit.
  
7. \_\_\_\_\_ Administer and obtain screening and enrollment informed consent with participant according to site SOPs. Complete Consent Process Worksheet.
  - *If the participant does not consent to screening and enrollment, STOP. Do not fax any forms to SCHARP.*
  
8. \_\_\_\_\_ Administer and obtain signed records release.
  
9. \_\_\_\_\_ Complete **Enrollment** form, item 1.
  
10. \_\_\_\_\_ Assign an MTN 002 PTID by completing a new row in the MTN 002 Name-PTID Link Log.
  
11. \_\_\_\_\_ Obtain contact information and record on site specific form.
  
12. \_\_\_\_\_ Review participant's prenatal record and ultrasound reports
  - *If any placental/fetal abnormalities that could affect the placental transfer, the participant is ineligible for enrollment. STOP. Do not fax any forms to SCHARP.*
  
  - *If participant has any known maternal disease with a predictable negative affect on placental function, participant is ineligible for enrollment. STOP. Do not fax any forms to SCHARP.*

## Screening and Enrollment Visit: Page 2 of 3

<b>PTID:</b>	<b>Visit Date:</b>
<b>Visit Code: 01.0</b>	<b>Visit Window : Up to 4 weeks prior to C/S</b>

➤ *If any maternal or fetal condition that necessitates urgent C/S, participant is ineligible for enrollment. STOP. Do not fax any forms to SCHARP.*

13. \_\_\_\_\_ Obtain medical history. Document all ongoing medical conditions on **Pre-existing Conditions Form**.
  
14. \_\_\_\_\_ Assess concomitant medications. Document all ongoing medications on **Concomitant Medications Log** form.
  
15. \_\_\_\_\_ Collect approximately 15-60 mL urine and:  
 15a. \_\_\_\_\_ Prepare urine for SDA for Gonorrhea and Chlamydia.
  
16. \_\_\_\_\_ Provide HIV pre-test counseling
  
17. \_\_\_\_\_ Collect blood:
  - Red Top
  - Purple Top
  
18. \_\_\_\_\_ Explain to study participant that eligibility is based on results as determined by the study HIV algorithm (Protocol Appendix II).
  
19. \_\_\_\_\_ Prepare blood for testing at the local lab:
  - Serum Creatinine
  - AST, ALT
  - Rapid HIV test
  - If required, Hepatitis B Antigen testing
  - If indicated, Syphilis serology
  
20. \_\_\_\_\_ Complete HIV testing log(s). Before disclosing results to participant, obtain independent review, verification, and sign-off of both results.
  
21. \_\_\_\_\_ Provide HIV test result and post-test counseling. Provide referrals if needed/requested. Explain the participant's current study eligibility status.
  - *If rapid test is negative, the participant is considered HIV-uninfected. Continue with remainder of this checklist.*
  
  - *If rapid test is positive, 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.*
  
22. \_\_\_\_\_ Complete **Demographics** form.

## Screening and Enrollment Visit: Page 3 of 3

<b>PTID:</b>	<b>Visit Date:</b>
<b>Visit Code: 01.0</b>	<b>Visit Window : Up to 4 weeks prior to C/S</b>

23. \_\_\_\_\_ Conduct targeted physical exam and record results on the **Targeted Physical Exam** non-Data Fax form.
24. \_\_\_\_\_ Perform and document pelvic exam per pelvic exam checklist. Complete the Pelvic Exam Diagrams non-DataFax and **Pelvic Exam** forms. Update **Pre-existing Conditions** form with any ongoing pelvic abnormalities.
25. \_\_\_\_\_ Complete the MTN 002 Eligibility Determination Checklist. If participant is determined to be eligible based on information available continue with the checklist. If participant is determined to be ineligible, STOP. Complete item 2 of the **Enrollment form**. Do not fax any forms to SCHARP.
26. \_\_\_\_\_ Provide study informational material. Provide site contact information and instructions to contact the site for additional information if needed, prior to the next visit.
27. \_\_\_\_\_ Provide reimbursement
28. \_\_\_\_\_ Document the visit in a signed and dated chart note. Complete and review all other participant chart contents for the visit.
29. \_\_\_\_\_ Once all test results are available, update **Pre-existing Conditions form** with any laboratory-based ongoing conditions. Notify participant of test results and to confirm her C/S date.
30. \_\_\_\_\_ Review and fax all required DataFax forms to SCHARP DataFax:
  - Demographics
  - Enrollment
  - Pre-existing Conditions
  - Concomitant Medications Log
  - Pelvic Exam
31. \_\_\_\_\_ Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN 002 participant notebook assigned to the participant.

## Gel Administration Visit (Day 0): Page 1 of 2

<b>PTID:</b>	<b>Visit Date:</b>
<b>Visit Code: 02.0</b>	<b>Visit Window : Within 4 weeks of Screening and Enrollment Visit</b>

1. \_\_\_\_\_ Complete participant registration, confirm the participant's identity, and verify her PTID.
  
2. \_\_\_\_\_ Review lab results from previous visit. If results preclude participant from continuing in study, inform participant and complete the **Participant Evaluability and Replacement** form and **Termination** form.
  
3. \_\_\_\_\_ Confirm this visit is no more than 28 days after the participant's Screening and Enrollment Visit.
  
4. \_\_\_\_\_ Review/update locator information
  
5. \_\_\_\_\_ Place copy of participant's informed consent form in the inpatient chart
  
6. \_\_\_\_\_ Review the inpatient chart, chart notes and other relevant documentation from previous visit(s).
  
7. \_\_\_\_\_ Update medical history. Record any new adverse events as well as any pre-existing conditions that have increased in severity or frequency on an **Adverse Experience Log** form.
  
8. \_\_\_\_\_ Assess concomitant medications. Review/update **Concomitant Medications Log** form(s). Document review with a signed and dated note on each document reviewed. Initial and date updated entries.
  
9. \_\_\_\_\_ Conduct targeted physical exam as per Protocol Appendix III. Complete the **Physical Exam** (non-DataFax) form.
  
10. \_\_\_\_\_ Perform and document pelvic exam per pelvic exam checklist. Complete the Pelvic Exam Diagrams non-DataFax and **Pelvic Exam** form.
  
11. \_\_\_\_\_ Insert saline lock, if not already in place, and collect blood:
  - Purple Top
  
11. \_\_\_\_\_ Prepare blood for testing at the local lab:
  - Maternal plasma tenofovir level
  - Flow cytometry
  
12. \_\_\_\_\_ Complete an **LDMS Specimen Tracking Sheet** for samples tested at the MTN Network Lab.
  
13. \_\_\_\_\_ Insert Tenofovir 1% gel (conducted by study physician) approximately 2 hours prior to C/S

## Gel Administration Visit (Day 0): Page 2 of 2

PTID:	Visit Date:
Visit Code: 02.0	Visit Window : Within 4 weeks of Screening and Enrollment Visit

14. \_\_\_\_\_ Schedule next study evaluation between 22-26 hours following product administration
15. \_\_\_\_\_ Collect blood for maternal plasma tenofovir level at the following time points: 1, 2, 4, 6, 8 and 12 hours. Complete **Pharmacokinetics** form at each time point as specimens are collected.
- *Note: the time points are relative to gel administration*
  - *Some time points may occur before C/S*
  - *The allowable window for each blood draw is +/- 15 minutes*
16. \_\_\_\_\_ Record Adverse Events at each PK time point listed above
17. \_\_\_\_\_ Review inpatient chart (during 1-12 hours post-gel)
18. \_\_\_\_\_ Scheduled C/S performed
19. \_\_\_\_\_ During C/S, collect:
- Amniotic fluid
  - Endometrial tissue
  - If possible, cord blood
  - If possible, placental tissue
20. \_\_\_\_\_ Following the C/S collect:
- Cord blood (if not collected during C/S)
  - Placental tissue (if not collected during C/S)
21. \_\_\_\_\_ Complete **MTN 002 Study Visit** form
22. \_\_\_\_\_ Document the visit in a signed and dated chart note. Complete and review all participant chart contents.
23. \_\_\_\_\_ Fax all required DataFax forms to SCHARP DataFax:
- MTN 002 Study Visit
  - Pharmacokinetics
  - Pelvic Exam
  - Concomitant Medications Log (any pages that have been updated)
  - Adverse Experience Log (if applicable)
  - Participant Evaluability and Replacement (if applicable)
  - Termination (if applicable)

## 24-Hour Evaluation: Page 1 of 2

<b>PTID:</b>	<b>Visit Date:</b>
<b>Visit Code: 03.0</b>	<b>Visit Window : Hour 22-26</b>

1. \_\_\_\_\_ Complete participant registration, confirm the participant's identity, and verify her PTID.
2. \_\_\_\_\_ Review/update locator information.
3. \_\_\_\_\_ Review inpatient chart of participant
4. \_\_\_\_\_ Review inpatient chart of infant
5. \_\_\_\_\_ Explain the content and sequence of procedures for this visit.
6. \_\_\_\_\_ Review elements of informed consent as needed.
7. \_\_\_\_\_ Record and update the **Concomitant Medications Log**.
8. \_\_\_\_\_ Record and update adverse events on the **Adverse Experience Log** form.
9. \_\_\_\_\_ If indicated, perform targeted physical exam and complete **Targeted Physical Exam** form.
10. \_\_\_\_\_ If indicated, perform pelvic exam and complete Pelvic Exam Diagrams non-DataFax and **Pelvic Exam** forms.
11. \_\_\_\_\_ Collect and prepare blood for maternal plasma tenofovir level. Complete item 11 of **Pharmacokinetics** form. Complete LDMS Specimen Tracking Sheet.
12. \_\_\_\_\_ Complete an **LDMS Specimen Tracking Sheet** for samples tested at the MTN Network Lab.
13. \_\_\_\_\_ Schedule the Two Week phone call
14. \_\_\_\_\_ Reinforce instructions to contact the site if the participant has any questions or concerns prior to the Two-Week phone call.
15. \_\_\_\_\_ Provide study reimbursement
16. \_\_\_\_\_ Complete the **MTN 002 Study Visit** form.
17. \_\_\_\_\_ Complete **C-section/Delivery Information** form.
18. \_\_\_\_\_ Complete and review all participant chart contents for the visit

## 24-Hour Evaluation: Page 2 of 2

<b>PTID:</b>	<b>Visit Date:</b>
<b>Visit Code: 03.0</b>	<b>Visit Window : Hour 22-26</b>

19. \_\_\_\_\_ Fax all required DataFax forms to SCHARP DataFax:

- MTN 002 Study Visit
- Pharmacokinetics
- C-section/Delivery Information

As Needed:

- Concomitant Medications Log (required for updated or new pages)
- Adverse Experience Log (required if any AEs identified or updated)

## Two-Week Phone Call: Page 1 of 1

<b>PTID:</b>	<b>Visit Date:</b>
<b>Visit Code: 04.0</b>	<b>Visit Window : Day 10-18</b>

1. \_\_\_\_\_ Complete participant registration, confirm the participant’s identity, and verify her PTID.
2. \_\_\_\_\_ Review chart notes and other relevant documentation from previous visit(s).
3. \_\_\_\_\_ If indicated, review inpatient and outpatient charts.
4. \_\_\_\_\_ Review/update locator information.
5. \_\_\_\_\_ Review elements of informed consent as needed.
6. \_\_\_\_\_ Update demographics form as needed.
7. \_\_\_\_\_ Complete/update **Adverse Experience Log** form(s) if required.
8. \_\_\_\_\_ Review/update concomitant medications and update **Concomitant Medications Log** form(s) if required.
9. \_\_\_\_\_ If indicated, schedule the next visit.
10. \_\_\_\_\_ Reinforce site contact information and instructions to contact the site with any questions.
11. \_\_\_\_\_ Send study reimbursement for phone call.
12. \_\_\_\_\_ Document the phone call in a signed and dated chart note. Complete and review all participant chart contents for the visit.
13. \_\_\_\_\_ Complete **MTN 002 Study Visit** form
14. \_\_\_\_\_ Fax the required DataFax form to SCHARP DataFax:
  - MTN 002 Study Visit
  - As Needed:
    - Concomitant Medications Log (required for updated or new pages)  
*Note: All medications must have a date stopped or be marked as “continuing at end of study” at time of study termination.*
    - Adverse Experience Log (required if any AEs identified or updated)
  - Scheduled or Early Termination:
    - Termination
    - End of Study Inventory
    - Participant Evaluability and Replacement

## Pelvic Exam: Page 1 of 1

PTID:	Visit Date:
Please indicate to which visit this checklist applies:	
Screening and Enrollment : ____ Gel Administration Day: ____ Interim: ____	

1. \_\_\_\_ Explain the exam procedures to the participant and answer any participant questions.
2. \_\_\_\_ At the screening and enrollment visit only: Affix a SCHARP-provided PTID label to a culture container for Trichomonas evaluation. Write the specimen collection date in ink on the label.
3. \_\_\_\_ Position and drape the participant comfortably.
4. \_\_\_\_ Palpate inguinal lymph nodes. Document abnormal findings on the **Pelvic Exam** form
5. \_\_\_\_ Inspect external genitalia: Note all findings on the Pelvic Exam Diagrams non-DataFax form. Document abnormal findings **Pelvic Exam** form.
6. \_\_\_\_ Insert speculum, using warm water as lubricant if needed. Observe general state and note the position of the cervix.
7. \_\_\_\_ Assess for homogenous discharge. Record observation in chart note.
8. \_\_\_\_ Inspect cervix and vagina: Note all findings on the Pelvic Exam Diagrams non-DataFax form. Document abnormal findings **Pelvic Exam** form.
9. \_\_\_\_ At the screening and enrollment visit only: Swab vaginal fluids from the lateral vaginal wall; place the swab in the Trichomonas culture container (see also SSP Section 12).
10. \_\_\_\_ If indicated, perform Wet Prep and Vaginal pH. Record observation in chart note.
11. \_\_\_\_ If indicated, perform Herpes Culture (at sites where standard of care for diagnosis)
12. \_\_\_\_ Perform bimanual exam. Note all findings on the Pelvic Exam Diagrams non-DataFax form. Document abnormal findings **Pelvic Exam** form.
13. \_\_\_\_ Record the size of speculum used and position of the participant's cervix on the Pelvic Exam Diagrams form.