

Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN-009 study visits. The checklists also specify the data collection forms that must be completed at each visit.

7.1 Visit Checklists

The sample checklists are designed to guide site staff in proper study procedures as well as to serve as source documentation of procedures performed at study visits. Refer to Section 3 of this Manual for additional information regarding source documentation. 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 the DAIDS policy on Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials for detailed information on source documentation requirements. Tips for completing visit checklists in accordance with these requirements are as follows:

- Record the participant identification number (PTID), visit date, and visit code (when applicable) in the top section of each checklist. If information is printed on the front and back of a checklist, record these details on both sides.
- Record your initials only beside the procedures that you perform. Do not record your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, record a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by lab staff”; initial and date the note.
- If all procedures listed on a checklist are performed on the date recorded in the top section of the checklist, the date need not be recorded beside each item. If procedures listed on a checklist are performed on multiple dates, record the date on which each procedure is performed, beside each item.
- If a procedure listed on the checklist is not performed, record “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, included in this section, is a suggested ordering. In consultation with the MTN CORE (FHI), site staff may modify the checklists to maximize the efficiency of site-specific study operations. If sites decide to modify the sequence of procedures to suit local staffing and logistical requirements, the following exceptions apply:

- Informed consent for screening and enrollment must be obtained before any procedures are performed.
- Assignment of PTID must be done after all eligibility criteria have been assessed.
- The behavioral questionnaire must be administered before HIV testing and risk reduction counseling.

PTID:		Visit Date:	Visit Code:
Initials	Procedures		
	1. Confirm identity per site SOPs and determine whether participant had previously enrolled in MTN-009		
	2. Verify the participant presented to site to pre-screen or screen for an HIV prevention trial: <input type="checkbox"/> Participant presented to site to pre-screen or screen for an HIV prevention trial ⇒ CONTINUE <input type="checkbox"/> Participant did NOT present to site to screen for HIV prevention trial ⇒ STOP, NOT ELIGIBLE		
	3. Offer enrollment into MTN-009 <input type="checkbox"/> Participant is willing to participate in MTN-009 ⇒ CONTINUE <input type="checkbox"/> Participant is NOT willing to participate in MTN-009 ⇒ Refer to HIV prevention trial		
	4. Verify the participant is between 18-40 years, inclusive: <input type="checkbox"/> Participant's age is between 18-40 years ⇒ CONTINUE <input type="checkbox"/> Participant's age is NOT between 18-40 years ⇒ STOP, NOT ELIGIBLE		
	5. Administer Screening and Enrollment Informed Consent per site SOP <input type="checkbox"/> Participant is willing and able to provide informed consent ⇒ CONTINUE <input type="checkbox"/> Participant is NOT willing and/or able to provide informed consent ⇒ STOP, NOT ELIGIBLE		
	6. Collect locator information and determine adequacy per site SOPs. <input type="checkbox"/> Participant is willing and able to provide adequate locator information per site SOPs ⇒ CONTINUE <input type="checkbox"/> Participant is NOT willing and/or able to provide adequate locator information per site SOPs ⇒ STOP, NOT ELIGIBLE		
	7. Assess for any condition that would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives: <input type="checkbox"/> No exclusionary condition identified ⇒ CONTINUE <input type="checkbox"/> Exclusionary condition identified ⇒ STOP, NOT ELIGIBLE		
	8. Complete items 1-6 of the Eligibility Assessment form		
	9. Assign MTN-009 PTID. The participant is now enrolled. Write the PTID at the top of this form and complete items 7-7a of the Eligibility Assessment form. Continue with enrollment procedures.		
	10. Explain procedures to be performed at today's visit		
	11. Administer Demographics form.		
	12. Administer ACASI behavioral questionnaire		
	13. Provide and document HIV counseling and testing per site SOPs: <input type="checkbox"/> Provide HIV pre-test counseling <input type="checkbox"/> Provide HIV/STI risk reduction counseling		
	14. Collect blood via fingerstick for rapid HIV tests		
	15. Perform and document two rapid HIV tests per site SOPs. Before disclosing results to participant, obtain independent review, verification, and sign-off of both results.		

PTID:		Visit Date:	Visit Code:
Initials	Procedures		
	<p>16. Provide test results and post-test counseling:</p> <ul style="list-style-type: none"> <input type="checkbox"/> If both tests negative ⇒ UNINFECTED ⇒ Refer to HIV prevention trial <input type="checkbox"/> If one test positive and one test negative ⇒ DISCORDANT ⇒ WB is required, collect blood via venipuncture as specified below. <input type="checkbox"/> If both tests positive ⇒ INFECTED ⇒ Provide referrals and collect blood via venipuncture as specified below. <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 60%;"> <ul style="list-style-type: none"> <input type="checkbox"/> 2 x 10 mL lavender top (EDTA) tube <input type="checkbox"/> 1 x 2 mL red top (EDTA) tube </div> <div style="width: 35%; background-color: #FFFF00; padding: 5px; font-size: small;"> Volumes shown are approximate. Tailor this item to reflect site-specific tube types and volumes. </div> </div> <p><input type="checkbox"/> Transcribe results onto Screening and Enrollment HIV Test Results form.</p>		
	<p>17. For participants who have at least 1 positive HIV rapid test result, prepare venipuncture blood for required testing:</p> <ul style="list-style-type: none"> • Western Blot (only if HIV rapid test results are discordant) • CD4+ T-cell count • Plasma HIV-1 RNA • Shipment of plasma for resistance testing to MTN NL 		
	<p>18. For participants confirmed HIV-uninfected per Protocol Appendix II, complete the Other Trial Participation form, when applicable.</p>		
	<p>19. Complete LDMS Specimen Tracking Sheet.</p>		
	<p>20. For participants confirmed HIV infected, participants who require WB testing, or if participants whose HIV status is unclear, schedule another visit for delivery of test results from this visit, or explain that once the site receives the results, the site will contact the participant to schedule a follow-up visit.</p>		
	<p>21. Provide referral to available resources per site SOP</p>		
	<p>22. Provide reimbursement.</p>		
	<p>23. Document the visit in a signed and dated chart note.</p>		
	<p>24. Complete and review all required visit documentation.</p>		
	<p>25. Fax all required DataFax forms to SCHARP DataFax:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Eligibility Assessment <input type="checkbox"/> Demographics <input type="checkbox"/> Screening and Enrollment HIV Test Results <input type="checkbox"/> Laboratory Test Results <input type="checkbox"/> Other Trial Participation (for participants confirmed HIV uninfected per Protocol Appendix II) 		
	<p>26. Back-up ACASI questionnaire data.</p>		
	<p>27. Upload ACASI questionnaire data to SCHARP.</p>		

PTID:		Visit Date:	Visit Code:
Initials	Procedures		
	1. Ensure all laboratory test results have been received		
	2. Review previous visit documentation		
	3. Confirm participant identity and PTID per site SOPs		
	4. Review/update locator information		
	5. Explain today's study procedures		
	6. Verify participant is ready to receive study results		
	7. Provide laboratory results in the context of post-test counseling (tick all that were provided at this visit) <ul style="list-style-type: none"> <input type="checkbox"/> Western Blot (only if screen and enroll visit rapid were discordant) <input type="checkbox"/> CD4-positive T Cell Count <input type="checkbox"/> HIV-1 RNA (viral load) <input type="checkbox"/> Resistance 		
	8. Provide referral to available resources per site SOP		
	9. Provide reimbursement		
	10. Schedule next visit (if applicable)		