

Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN-005 study visits. The checklists also specify the data collection forms that must be completed at each visit.

7.1 Use of Visit Checklists

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

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

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

- Enter the participant identification number (PTID) and visit date in the top section of each checklist. If information is written on the front and back of the checklist, enter the PTID and visit date on both sides.
- For screening visits, enter the screening attempt number in the top section of the checklist.
- For follow-up visits, enter the visit code in the top section of each checklist.
- Enter your initials only beside the procedures that you perform. Do not enter your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by lab staff.”
- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.
- Procedures should not be left blank. If a procedure listed on the checklist is not performed, enter “ND” for “not done” or “NA” for “not applicable” beside the item and record the reason why on the checklist (if not self-explanatory); initial and date this entry.

7.2 Sequence of Procedures

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

- Informed consent for screening must be obtained before any screening procedures are performed. Screening procedures are listed in protocol Section 7.1.
- Informed consent for enrollment must be obtained before any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in protocol Section 7.2. Follow-up procedures are listed in protocol Section 7.3.
- On the day of enrollment, random assignment must take place after confirmation of eligibility, completion of the ACASI Baseline Questionnaire and collection of blood for plasma archive.
- Pelvic exam procedures must be performed in the sequence shown on the pelvic exam checklists.
- At follow-up visits, ACASI questionnaires must be administered prior to the delivery of HIV/STI and adherence counseling.