

Section 6. Visit Checklists

The visit checklists located on the MTN-015 Study Implementation Materials webpage (<http://www.mtnstopshiv.org/node/468>) detail the protocol-specified procedures that must be completed at MTN-015 study visits. The checklists also specify the data collection forms that must be completed at each visit. In addition to the guidance provided on the checklists, detailed procedural guidance for performing clinical and laboratory procedures is provided in Sections 8-10 of this manual. Detailed form completion instructions are provided in Section 12 of this manual.

The sample visit 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. 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 recorded 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, 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 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 upon 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.

The sequence of procedures presented on the visit checklists is a suggested ordering. In consultation with FHI 360, site staff may modify the checklists 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 two exceptions:

- Informed consent for must be obtained before any procedures are performed.
- Gynecologic exam procedures must be performed in the sequence shown on the gynecologic exam checklist.