

Section 7. Visit Checklists

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Appendix 7-1 Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN-020 study visits. The checklists also specify the data collection forms that must be completed at each visit. Sites are expected to conduct study procedures outlined in the visit checklist per their site SOPs.

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, when applicable. 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 or final contacts (post study exit visit)
- Document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements, if not documented on other worksheets)

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 checklists are multiple pages, enter the PTID and visit date on each page.
- For screening visits, mark the screening attempt number in step 4 of the checklist. Participants are allowed two screening attempts.
- For follow-up visits, enter the visit month in the top section of each checklist.
- The “Required at visits” column indicates when the item is required during follow-up per-protocol. Complete staff initials next to procedures completed.
- 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 nurse.”

- 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.
- For items on the checklist that contain checkboxes, one set of initials is still sufficient, even if multiple boxes are checked. Bracketing procedures which are consecutive and all done on the same date by the same staff is also acceptable.
- Entering multiple sets of initials for one procedure should be avoided as much as possible. If this is happening on a regular basis, the site should consider splitting the task into multiple items on the checklist so each procedure receives only one set of initials.
- If a procedure listed on the checklist is not performed, enter “N/D” for “not done” 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 360), it is encouraged that site staff modify the checklists included in this section to maximize the efficiency of site-specific study operations. Sites may alter the sequence of procedures, with the following exceptions:

- Informed consent for screening must be obtained before any screening procedures are performed. Screening procedures are listed in protocol Sections 7.2.
- Informed consent for enrollment must be obtained before any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in protocol Section 7.3. Follow-up procedures are listed in protocol Section 7.4.
- On the day of enrollment, random assignment must take place after final confirmation and verification of eligibility, administration of the Baseline Behavior Assessment, Baseline Vaginal Practices, and Baseline Family Planning CRF, Baseline Audio Computer Assisted Self-Interview (ACASI) Questionnaire, collection of blood for plasma archive, and self-collected vaginal swab (per LoA#2). It is recommended that for sites not doing finger stick HIV testing, blood for HIV serology and plasma archive are collected together, to limit venipuncture to a single blood draw. If a participant is subsequently found to be ineligible and is not randomized, the plasma archive sample should be destroyed.
- Pelvic exam procedures must be performed in the sequence shown on the pelvic exam checklists at visits where a pelvic exam is required. For clinically indicated pelvic exams, procedures may be documented in the chart notes rather than the Pelvic Exam checklist. For CRF completion instructions, see Sections 3, 10, and 14.
- During study follow-up, it is recommended that behavioral assessment forms and ACASI questionnaires be administered prior to the delivery of HIV and adherence counseling.

- It is recommended that procedures for determining eligibility for continued product use be conducted early in the visit to ensure that these procedures are conducted in the event that the participant needs to abruptly leave the clinic, or is short of time.
- Ideally, self-collected vaginal swabs should be collected with the vaginal ring (from the previous visit) still in place.
- VRs should be removed immediately upon identification of conditions which require a hold or discontinuation. Otherwise, timing of VR removal depends on whether a pelvic exam is being conducted:
 - At follow-up visits *without* pelvic exams, it is recommended that participants are asked not to remove current vaginal ring (VR) until immediately prior to provision of a new VR for insertion. In the event that the participant needs to leave the clinic abruptly, she will already have a VR in place or eligibility for continued product use will have been determined.
 - At follow-up visits *with* pelvic exams, it is recommended that participants are asked not to remove current VR until immediately prior to the pelvic exam. Provision of a new VR for insertion should occur after the exam.

Note that the time of each study procedure does not need to be documented in order to demonstrate the order of visit procedures if this can be accomplished through other approaches. Acceptable alternatives include using a statement in the chart note or on visit checklists which verifies correct order was executed (e.g. “*Confirmed eligibility determination, all baseline behavioral assessments completed and plasma archive and vaginal swab (LoA#2) samples collected. Participant will now be randomized.*”), or by documenting that procedures were conducted ‘per site SOPs’ which specify order. As always, *deviations* from SOPs should be explained in the chart notes. This applies to procedures listed above whose order is required (first four bullet points); the order of procedures listed above as ‘ideal’ or ‘recommended’ does not need to be demonstrated in source documentation.

**Appendix 7-1
Visit Checklists**