

Section 6. Participant Follow-up

6.1 Study Follow-up Plan and Participant Retention Targets

Each enrolled pregnant woman will be followed through the completion of her pregnancy. Each enrolled infant will be followed until 12 months of age. To minimize bias and ensure accuracy of study results, each study site will target a minimum retention rate of 95% for all enrolled study participants. Further information on MTN-016 retention definitions and procedures is provided in Section 9.

6.2 Types of Follow-up Visits

Throughout the study follow-up period, two types of follow-up visits may be conducted:

- **Scheduled visits** are those visits required per protocol. MTN-016 specifies follow-up visits for pregnant participants quarterly. MTN-016 specifies follow-up visits for infants within 10 days of life, and at Months 1, 6, and 12. All scheduled follow-up visits are pre-assigned a visit code for purposes of data management as described in Section 13 of this SSP.
- **Interim visits** are those visits that take place between scheduled visits. Site staff may be required to assign visit codes to interim visits for purposes of data management as described in Section 13.

6.3 Follow-up Visit Scheduling

6.3.1 Target Visit Dates

Enrolled women and their infants will be scheduled to complete follow-up visits throughout their participation in the study. For each woman, all follow-up visits are targeted to take place based on her enrollment date. Target dates for infant visits are determined by the infant's date of birth.

Women enrolled while still pregnant will have follow-up visits scheduled on a quarterly basis up to and including the outcome of the pregnancy (pregnancy loss or labor and delivery).

Women enrolled after the outcome of their pregnancy will have no additional follow-up visits; if she enrolls her infant, the child will be followed up to 1 year of life.

Enrolled infants should be scheduled for follow up to conform as closely as possible to the target dates of within 10 days of birth and 1, 6, and 12 months of age. Visit windows (described in next section) may be used to gauge acceptable date ranges for using scheduled visit case report forms. Visits conducted outside of window should have data captured on Infant Interim Visit Forms.

6.3.2 Allowable Visit Windows

Acknowledging that it will not always be possible to complete follow-up visits on the targeted dates, the MTN-016 protocol allows for visits to be completed within a visit window. For each required study visit, there is an allowable visit window specifying on which study days (post-enrollment) the visit is "allowed" to be completed. For woman, the allowable visit

windows are contiguous between visits. This means there is a +/- 45 day window before and after each target follow-up visit date. In the rare instance where a woman's visit falls outside the visit window, data should be captured on the Woman Interim Visit Form.

For infants, the allowable visit windows are as follows:

- Newborn/initial visit: within 10 days of life
- Month 1 visit: +/- 2 weeks
- Month 6 visit: +/- 1 month
- Month 12 visit: +/- 1 month

Although the visit windows allow for some flexibility, the intent of the protocol-specified visit schedule is to conduct follow-up visits at specific intervals, and every effort should be made to do so. The MTN SDMC will provide the Protocol Team with routine visit adherence reports for purposes of monitoring adherence to the visit schedule (see Section 15).

6.3.3 Missed Visits

For participants who do not complete any part of a scheduled visit within the allowable window, the visit will be considered "missed" and a Missed Visit case report form will be completed to document the missed visit (see Section 13).

6.4 Follow-up Visit Procedures

Required follow-up visit procedures are listed in Protocol Sections 7.1 through 7.9. Highlighted for reference below are the primary procedural requirements.

6.4.1 Woman Follow-up Procedures

- Administrative
 - Locator information
 - Reimbursement
- Clinical
 - Update medical history
 - Update medication history
 - Update pregnancy course and/or outcome
 - Update genetic screening history
 - At least one ultrasound exam

6.4.2 Infant Follow-up Procedures

- Administrative
 - Locator information
 - Reimbursement
- Clinical
 - Update medical history
 - Update medication history
 - Weight
 - Length
 - Head circumference
 - Physical exam (see Section 10.5.3)

- Developmental screening assessment (6 and 12 months only; see Section 10.6.4)
- **If consent to photograph infant has been obtained:** photographic documentation of suspected or confirmed anomalies
- Laboratories
 - Details about labs to be obtained as part of MTN-016 can be found in Section 12 (Laboratory Considerations). There are no protocol-required laboratory specimens for healthy women or their infants. Protocol-specific labs are HIV testing (PCR) of HIV-exposed infants and resistance testing of HIV-infected infants. Note: these tests may not be obtained without formal written consent.

6.5 Participant Transfer Procedures

During the course of the study, participants may leave the area in which they enrolled in the study and re-locate to another area where the study is taking place. To maximize participant retention, participants who re-locate from one study location to another should be encouraged to continue their study participation at their new location. To accomplish this, study staff at both the original site (called the “transferring” site) and the new site (called the “receiving” site) will complete the process of a participant transfer.

Upon identifying the need for a participant transfer to another site, the transferring site will notify the receiving site as well as the MTN-016 study management team and the Network Lab. After the logistical details of the transfer have been discussed and agreed upon by the two sites, the following steps will be completed:

- The MTN SDMC will notify the transferring site of all outstanding data QC notes for the transferring participant; the transferring site will resolve these QCs.
- The transferring site will explain the transfer arrangements to the participant and obtain her written permission (Permission to Transfer form) to provide copies of her study records to the receiving site.
- The transferring site will deliver certified copies of all of the participant’s study records to the receiving site via courier or overnight mail service. The transferring site (clinic and lab, if indicated) will document all materials sent to the receiving site and inform the receiving site of the shipment date and expected arrival date. The receiving site (clinic and lab, if indicated) will confirm receipt of the shipment.
- The transferring site will complete and fax a Woman Participant Transfer/ Infant Participant Transfer, when indicated, case report form to the MTN SDMC (see Section 14 of this manual). Note that transfers must occur as woman-infant pairs, i.e., if an infant is being transferred for follow-up visits, the woman PTID materials must be certified copied and transferred along with the infant PTID materials.
- The receiving site will establish contact with the participant, obtain her written informed consent to continue in the study at the receiving site (using the receiving site’s informed consent form), and complete and fax the Woman Participant Receipt and the Infant Participant Receipt case report forms to the MTN SDMC (see Section 14 of this manual).

- Upon receipt of the both Participant Transfer and Participant Receipt (for woman and infant) forms, the MTN SDMC will re-map the participants' PTIDs to reflect the change in site follow-up responsibility. The participant's original PTID and follow-up visit schedule will remain unchanged.
- The transferring site will retain responsibility for storage, and shipment to the MTN NL, if applicable, of all specimens collected from the infant participant prior to his or her transfer, unless otherwise instructed by the MTN NL.