Section 7. Visit Checklists

This section contains examples of checklists detailing the protocol-specified procedures that must be completed at MTN-016 study visits. The checklists also specify the data collection forms that must be completed at each visit. Detailed procedural guidance for performing clinical and laboratory procedures is provided in Sections 10 and 12, respectively. Detailed forms completion instructions are provided in Section 13.

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. 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 Section 3 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 page of the checklist. If information is written on the front and back of the checklist, enter the PTID and visit date on both sides.

- Enter your initials beside only 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.

- If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "N/A" 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 FHI 360, site staff may modify the checklists included in this section to maximize the efficiency of site-specific study operations. Site staff may alter the sequence of procedures to suit local staffing and logistical requirements, with the following exceptions:

- Informed consent for screening and enrollment must be obtained before any study procedures are performed.
- Informed consent for the collection of infant HIV testing must be obtained before any samples are drawn.

NOTE: Checklists in this section are provided as guidelines for the sites. The site can choose to modify these checklists or create their own checklist. Modified checklists should be reviewed by FHI 360 prior to implementation.

Screening and Enrollment Visit: Woman

PTID:	Visit Date:	Visit Code: 1.0

Initials	Procedures
	1. Confirm participant identity. Cross-check with the MTN-016 Participant Name-PTID Link Log to determine whether a MTN-016 Participant ID number has previously been assigned to the participant. ❒ No MTN-016 PTID previously assigned ❒ MTN-PTID previously assigned ⇒ *If this is a subsequent pregnancy, STOP. Complete the Subsequent Pregnancy Visit Checklist.*
	2. Determine participant eligibility based on information available. To be eligible, participant must meet both of the following criteria: ❒ Participant has had a known confirmed pregnancy during participation in an eligible parent protocol ❒ Participant is either still pregnant, or the pregnancy outcome occurred less than one year ago ⇒ *If participant is determined to be ineligible, STOP. Do not fax any forms to SCHARP.*
	3. Administer and obtain screening and enrollment informed consent with participant according to site SOPs. [For sites using a single maternal/infant consent, both woman and infant consent are done at this time.] Complete Informed Consent Coversheet. ⇒ *If the participant does not consent to screening and enrollment, STOP. Do not fax any forms to SCHARP.*
	4. Assign an MTN-016 PTID by completing a new row in the MTN-016 Name-PTID Link Log.
	5. Obtain or update locator information
	6. If medical records will be requested from other clinical sites, obtain any necessary signed local record releases.
	7. Complete the **Woman Enrollment** form.
	8. Complete the **Woman Demographics** form.
	9. Complete the **Parent Protocol Participation** form.
	10. Complete the **Genetic Screening History** form.
	11. Obtain/update medical history. Document on **Woman Medical History Log** (non-DataFax) or approved alternative source per site SOPs.
	12. Document all medications taken during the pregnancy on the **Woman Concomitant Medications Log**.
	13. Obtain pregnancy history and complete the **Pregnancy Report and History** form. Note that MTN-016 pregnancy history form is more detailed than parent protocol.
	14. If available, review and document ultrasound exam results and complete **Ultrasound Results** form.
	15. If woman has experienced pregnancy outcome at the time of enrollment, complete all procedures identified on the **Pregnancy Outcome** form.
	16. Provide coaching or counseling on any issues as indicated by content of participant visit
	17. Provide site contact information and remind participant to contact site staff if needed prior to next scheduled visit.
	18. Schedule next visit.
	19. Provide reimbursement.

Screening and Enrollment Visit: Woman Page 2 of 2

PTID:	Visit Date:	Visit Code: 1.0

Initials	Procedures
	20. Review and fax all required DataFax forms to SCHARP DataFax: ☐ Woman Enrollment ☐ Woman Demographics ☐ Parent Protocol Participation ☐ Genetic Screening History ☐ Ultrasound Results ☐ Pregnancy Report and History ☐ Woman Concomitant Medications Log As Needed: ☐ Pregnancy Outcome
	21. Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant.

Quarterly Visit: Woman

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Complete participant registration, confirm participant's identity, verify PTID.
	2. Review/update locator information
	3. Update medical history and document on **Woman Medical History Log** (non-DataFax) or approved alternative source per site SOPs.
	4. Update the **Woman Concomitant Medications Log**. Document review with a signed and dated note on each document reviewed. Initial and date updated entries.
	5. Review genetic screening history and update the **Genetic Screening History** form accordingly.
	6. Update pregnancy history, including pregnancy-related morbidities such as hypertensive disorders of pregnancy, antenatal hemorrhage, and abnormal placentation. Update the **Pregnancy Report and History** form accordingly.
	7. Perform or schedule ultrasound if results of an ultrasound from this pregnancy are not available. Complete the **Ultrasound Results** form.
	8. If woman has experienced a pregnancy outcome at the time of visit, obtain medical records, and complete all procedures identified for the **Pregnancy Outcome** form.
	9. Inquire about social harms. If a social harm is reported, complete the **Social Harms Assessment Log form.**
	10. Complete the **Woman Follow-up Visit** form.
	11. Provide coaching or counseling on any issues as indicated by content of participant visit.
	12. Remind participant to contact site staff if needed prior to next scheduled visit.
	13. Schedule next visit and/or confirm estimated date of delivery.
	14. Provide reimbursement
	15. Fax all required DataFax forms to SCHARP DataFax: ☐ Woman Follow-up Visit ☐ Ultrasound Results ☐ Pregnancy Report and History (only refax updated pages) ☐ Genetic Screening History (only re-fax updated pages) ☐ Woman Concomitant Medications Log (only refax any new or updated pages) As Needed: ☐ Social Harms Assessment Log ☐ Pregnancy Outcome
	16. Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant.

Interim Visit: Woman

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Complete participant registration, confirm participant's identity, verify PTID.
	2. Review/update locator information.
	3. Complete the **Woman Interim Visit** form.
	4. Update medical history and document on **Woman Medical History Log** form (non-DataFax) or approved alternative source per site SOPs.
	5. Assess concomitant medications, if indicated. Review/update the **Woman Concomitant Medications Log.** Document review with a signed and dated note on each document reviewed.
	6. Inquire about social harms. If a social harm is reported, complete the **Social Harms Assessment Log** form.
	7. If reason for visit is to: ➢ Report pregnancy outcome, complete all procedures identified on the **Pregnancy Outcome** Form. ➢ Perform ultrasound assessment, complete the **Ultrasound Results** form
	8. Provide coaching or counseling on any issues as indicated by content of participant visit
	9. Remind participant to contact site staff if needed prior to next scheduled visit.
	10. Fax the required DataFax forms to SCHARP DataFax: ☐ Woman Interim Visit As Needed: ☐ Pregnancy Outcome ☐ Ultrasound Results ☐ Woman Concomitant Medications Log ☐ Woman Termination ☐ Woman End of Study Inventory ☐ Social Harms Assessment Log
	11. Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant

Subsequent Pregnancy: Woman

PTID:	Visit Date:	Visit Code: 1.0

Initials	Procedures
	1. Confirm participant identity. Cross-check with the MTN-016 Participant Name-PTID Link Log to confirm MTN-016 that Participant ID number has previously been assigned to the participant. ❒ MTN-PTID previously assigned ❒ No MTN-016 PTID previously assigned ⇒ *If this is not a subsequent pregnancy, STOP. Complete the Woman Screening & Enrollment Visit Checklist.*
	2. Determine participant eligibility based on information available. To be eligible, participant must meet both of the following criteria: ❒ Participant has had a known confirmed pregnancy during participation in an eligible parent protocol ❒ Participant is either still pregnant, or the pregnancy outcome occurred less than one year ago ⇒ *If participant is determined to be ineligible, STOP. Complete item 2 of the **Woman Enrollment** form. Do not fax any forms to SCHARP.*
	3. Administer and obtain screening and enrollment informed consent with participant according to site SOPs. [For sites using a single maternal/infant consent, both woman and infant consent are done at this time.] Complete Informed Consent Coversheet. ⇒ *If the participant does not consent to screening and enrollment, STOP. Do not fax any forms to SCHARP.*
	4. Update locator information.
	5. If medical records will be requested from other clinical sites, obtain any necessary local record releases.
	6. Complete the **Woman Subsequent Consent** form.
	7. Obtain genetic screening history and complete the **Genetic Screening History** form. ⇒ *Note that father may be different or new information may be available from previous pregnancy.*
	8. Obtain/update medical history. Document on **Woman Medical History Log** form (non-DataFax) or approved alternative source per site SOPs.
	9. Assess concomitant medications. Review/update the **Woman Concomitant Medications Log** form(s). Document review with a signed and dated note on each document reviewed. Initial and date updated entries.
	10. Obtain pregnancy history and complete the **Pregnancy Report and History** form.
	11. If available, review and document ultrasound exam results and complete the **Ultrasound Results** form.
	12. If woman has experienced the subsequent pregnancy outcome at the time of visit, obtain medical records, and complete all procedures identified for the **Pregnancy Outcome** form.
	13. Inquire about social harms. If a social harm is reported, complete the **Social Harms Assessment Log** form.
	14. Provide coaching or counseling on any issues as indicated by content of participant visit.
	15. Provide site contact information and remind participant to contact site staff if needed prior to next scheduled visit.

PTID:	Visit Date:	Visit Code: 1.0

Initials	Procedures
	16. Schedule next visit, if applicable
	17. Provide reimbursement.
	18. Review and fax all required DataFax forms to SCHARP DataFax: ☐ Woman Subsequent Consent ☐ Pregnancy Report and History ☐ Genetic Screening History ☐ Woman Concomitant Medications Log (only refax new or updated pages) ☐ Ultrasound Results As Needed: ☐ Pregnancy Outcome
	19. Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant.

Newborn Initial Visit

PTID:	Visit Date:	Visit Code: 1.0

Initials	Procedures
	1. Confirm whether or not infant consent has already been obtained. ❒ Infant consent already obtained. ❒ Infant consent not yet obtained. ☐ Explain the informed consent process to the infant's parent/guardian. ☐ Administer and obtain screening and enrollment informed consent for the infant according to site SOPs. ☐ Document process in chart notes and/or the Informed Consent Coversheet ⇒ *If the infant's parent/guardian does not consent to screening and enrollment, STOP. Do not fax any forms to SCHARP.*
	2. Confirm eligibility, assign infant PTID, and complete the **Pregnancy Outcome** form, item 9.
	3. Review/update locator information.
	4. If medical records for the infant will be requested from other clinical sites, obtain any necessary local record releases.
	5. Complete **Infant Enrollment** form.
	6. Review/update infant medical/birth history and complete the **Infant Medical History Log** form (non-DataFax).
	7. Document all medications since birth on the **Infant Concomitant Medication Log** and all vaccinations since birth on the Infant Vaccination Log
	8. Conduct and record infant physical exam as per protocol: ☐ Complete the **Infant Visit** form. ☐ Complete the **Infant Physical Exam** form. ☐ If there are any suspected or confirmed abnormalities, complete the Major Malformation Eligibility Assessment Worksheet (section 10.7.1). If directed, ☐ Complete the **Major Malformation Assessment** Form (section 10.7.2) AND ☐ Confirm that consent has been granted and collect photo images (section 10.7.3). If photographs are taken, complete the **Infant Visit** form, item 5.
	9. As necessary, perform infant HIV testing and complete **Infant HIV Test Results** and MTN-016 (Non-DataFax) LDMS Specimen Tracking Sheet
	10. Inquire about social harms. If a social harm is reported, complete the **Social Harms Assessment Log** form.
	11. Provide coaching or counseling on any issues as indicated by content of visit
	12. Remind participant to contact site staff if needed prior to next scheduled visit.
	13. Schedule next visit.
	14. Provide reimbursement.
	15. Fax the required DataFax forms to SCHARP DataFax: ☐ Infant Enrollment ☐ Infant Visit ☐ Infant Physical Exam ☐ Infant Concomitant Medications Log ☐ Updated Pregnancy Outcome Form As Needed: ☐ Infant Vaccination Log ☐ Infant HIV Test Results
	16. Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant.

Month 1, 6, and 12: Infant

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Confirm whether or not infant consent has already been obtained. ❒ Infant consent already obtained. ❒ Complete participant registration, confirm participant's identity, verify PTID. ❒ Infant consent not yet obtained. ❒ Explain the informed consent process to the infant's parent/guardian. ❒ Administer and obtain screening and enrollment informed consent for the infant according to site SOPs. ❒ Document process in chart notes and/or the Informed Consent Coversheet ❒ Confirm eligibility. ❒ Confirm and assign infant PTID, complete/update the **Pregnancy Outcome** form, item 9 and complete **Infant Enrollment.** ⇒ *If the infant's parent/guardian does not consent to screening and enrollment, STOP. Do not fax any forms to SCHARP.*
	2. Review/update locator information.
	3. Update medical history and document on **Infant Medical History Log** (non-DataFax).
	4. Review/update the **Infant Concomitant Medications Log** and the Infant Vaccination Log (if applicable). Document review with a signed and dated note on each document reviewed. Initial and date updated entries.
	5. Conduct and record infant physical exam as per protocol. ☐ Complete the **Infant Visit** form. ☐ Complete the **Infant Physical Exam** form. ☐ If there are any suspected or confirmed abnormalities, complete the Major Malformation Eligibility Assessment Worksheet (section 10.7.1). If directed, ☐ Complete the **Major Malformation Assessment** Form (section 10.7.2) AND ☐ Confirm that consent has been granted and collect photo images (section 10.7.3). If photographs are taken, complete the **Infant Visit** form, item 5.
	6. As necessary, follow-up on or perform infant HIV testing and complete **Infant HIV Test Results** and MTN-016 (Non-DataFax) LDMS Specimen Tracking Sheet
	7. Inquire about social harms. If a social harm is reported, complete the **Social Harms Assessment Log** form.
	8. Provide coaching or counseling on any issues as indicated by content of infant visit.
	9. Months 1 & 6: Remind participant to contact site staff if needed prior to next scheduled visit.
	10. Months 1 & 6: Schedule next visit
	11: Month 12: Complete the **Infant Termination** and **Infant End of Study Inventory** forms.
	12. Provide reimbursement

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	13. Fax the required DataFax forms to SCHARP DataFax: ☐ Infant Visit ☐ Infant Physical Exam As Needed: ☐ Infant Enrollment ☐ Updated Pregnancy Outcome Form ☐ Infant Concomitant Medications Log (refax any new or updated pages) ☐ Infant Vaccination Log ☐ Infant HIV Test Results ☐ Social Harms Assessment Log At Month 12 only: ☐ Infant Termination ☐ Infant End of Study Inventory
	14. Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant.

Interim Visit: Infant

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	1. Confirm whether or not infant consent has already been obtained. ❒ Infant consent already obtained. ❒ Complete participant registration, confirm participant's identity, verify PTID. ❒ Infant consent not yet obtained. ❒ Explain the informed consent process to the infant's parent/guardian. ❒ Administer and obtain screening and enrollment informed consent for the infant according to site SOPs. ❒ Document process in chart notes and/or the Informed Consent Coversheet ❒ Confirm eligibility ❒ Confirm and assign infant PTID, complete/update the **Pregnancy Outcome** form, item 9, and **Infant Enrollment**. ⇒ *If the infant's parent/guardian does not consent to screening and enrollment, STOP. Do not fax any forms to SCHARP*
	2. Review/update locator information.
	3. Complete the **Infant Interim Visit** form.
	4. Update medical history and update the **Infant Medical History Log**.
	5. Assess concomitant medications, if indicated. Review/update the **Infant Concomitant Medications Log** and the **Infant Vaccination Log**. Document review with a signed and dated note on each document reviewed.
	6. Inquire about social harms. If a social harm is reported, complete the **Social Harms Assessment Log** form.
	7. If reason for visit is to follow up on or perform infant HIV testing, complete **Infant HIV Test Results** and MTN-016 (Non-DataFax) LDMS Specimen Tracking Sheet
	8. If indicated, conduct and record infant physical exam (note: if infant is enrolling during this interim visit, full physical exam including weight, length, head circumference, and abdominal circumference (prior to 1 month of age) must be completed): ☐ Complete the **Infant Physical Exam** form. ☐ If there are any suspected or confirmed abnormalities, complete the Major Malformation Eligibility Assessment Worksheet (section 10.7.1). If directed, ☐ Complete the **Major Malformation Assessment** Form (section 10.7.2) AND ☐ Confirm that consent has been granted and collect photo images (section 10.7.3). If photographs are taken, complete the **Infant Visit** form, item 5.
	9. Provide coaching or counseling on any issues as indicated by content of visit
	10. Remind participant to contact site staff if needed prior to next scheduled visit.

PTID:	Visit Date:	Visit Code:

Initials	Procedures
	11. Fax the required DataFax forms to SCHARP DataFax: ❒ Infant Interim Visit As Needed: ❒ Infant Enrollment ❒ Updated Pregnancy Outcome Form ❒ Infant Concomitant Medications Log ❒ Infant Vaccination Log ❒ Infant HIV Test Results ❒ Infant Physical Exam ❒ Infant Visit ❒ Infant Termination ❒ Infant End of Study Inventory ❒ Social Harms Assessment Log
	12. Place all study visit checklists, chart notes, case report forms, and other study documents identified with a PTID only in an MTN-016 participant notebook assigned to the participant