

## Section 6. Visit Checklists

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This section contains visit-specific checklists for Cohort 4 that detail the protocol-specified procedures that must be completed at various 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 are contained in Sections 9 and 10 of this manual, respectively. Detailed forms completion instructions are contained in Section 12. Sites may adapt the sample checklists included in these study-specific procedures (SSP) Manual to reflect their local procedures. Checklists in the section are for Protocol Version 2.0 and include Cohort 4 only. Checklists for Cohorts 1, 2 and 3 are included in previous versions of this manual.

### 6.1 Use of Checklists

Visit checklists are designed to guide site staff in proper study procedures performed at visits. Note, however, that checklists do not serve as primary source documentation. Source documentation should exist for all procedures performed. Section 3 and Appendix B of this manual provide detailed information on source documentation requirements. For example, chart notes may be required to document procedures performed at unscheduled study visits and/or to explain why procedures in addition to those specified on a checklist may have been performed and/or why procedures specified on a checklist were not performed. Chart notes also may be required to document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements).

Some specific tips for completing the visit checklists include:

- Enter the Participant ID (PTID) number and visit date in the top section of each checklist. If information is written onto both sides of the checklist, enter the Participant ID number and visit date on both sides.
- If all procedures listed on the checklist are performed on the visit date entered in the top section of the form, the date need not be entered beside each item.
- If procedures are performed on dates other than the visit date entered in the top section of the form, enter the date the procedures are actually completed, along with your initials.
- 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 on the checklist; initial and date this entry.

### 6.2 Sequence of Procedures

The sequence of procedures presented on the visit checklists is a suggested ordering. Individual study sites may modify the checklists contained in this section to maximize the efficiency of study operations at the site. Sites may alter the sequence of procedures to suit local staffing and logistical requirements, except when specified.

## **Mother's Eligibility Criteria – Protocol Version 2.0 Cohort 4**

### **Inclusion Criteria**

- Is the mother at least 18 years of age?
- Does she have a documented HIV-1 infection?
- Is she willing and able to provide written informed consent for screening and study participation?
- Does she intend to deliver at the study site?
- Is she willing to be contacted or visited at home?
  
- Is she willing to be admitted to and remain in the delivery facility through Day 7 postpartum

### **Exclusion Criteria**

- Has the mother had prior treatment with Tenofovir?
- Does she have an active opportunistic infection and/or serious bacterial infection?
- Does she have any of the following laboratory values as follows on the most recent test prior to study entry:
  - ♦ hemoglobin < 8 gm/dL?
  - ♦ alanine aminotransferase (ALT [SGPT]) > 3 x upper limit of normal (ULN)?
  - ♦ serum creatinine > 1.5 mg/dL?
- According to WHO definitions, has the mother had chronic malabsorption or diarrhea during this pregnancy (defined as chronic diarrhea for at least 1 month)?
- Does she have evidence of clinically significant disease or a condition that would compromise the ability of the participant to complete the study or the study requirements as determined by the study clinician?
- Is her pregnancy known to be a multiple gestation (prior to enrollment)?
- Is she participating in any other therapeutic or vaccine trial during this pregnancy?
- Did she use of any of the following disallowed medications within two weeks of her anticipated delivery date:
  - ♦ investigational agents?
  - ♦ heparin?
  - ♦ highly nephrotoxic drugs (for example, amphotericin B, cidovofir, ganciclovir, or valganciclovir), dideoxyinosine?
- Does she have any other condition or situation that, in the opinion of the investigator, would interfere with study participation or interpretation?

**COHORT 4**  
**Maternal Screening Evaluations**  
**(Anytime During Pregnancy)**

<b>Participant ID:</b>	<b>Visit Date:</b>
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**Note:**

- Standard Clinical Procedures for HIV counseling and testing and administration of the intrapartum/infant ARV regimen for prevention of maternal to child HIV transmission should be followed.
- Only HIV-infected women should be referred to the study counselors for screening.
- The screening visit procedures can be completed over multiple visits. However, the screening consent form must be completed before any screening procedures are done.
- If documented confirmation of the mother's HIV status is not available in the medical records; then a confirmatory test should be given.
- If a volunteer is found ineligible, withdraws consent or refuses further screening at any time prior to labor and delivery, discontinue further assessments. The reasons for discontinuing screening must be documented in site source documents.

\_\_\_\_\_ Introduce the study, explain the two-step informed consent process (screening and enrollment) and obtain informed consent for screening. Offer the volunteer a copy of the consent form to keep; document process on the **Informed Consent Coversheet**.

\_\_\_\_\_ Assign next sequential HPTN PTID number; enter into **Screening/Enrollment Log**.

\_\_\_\_\_ Obtain documentation of HIV test results from medical records.

\_\_\_\_\_ If documented confirmation of the mothers HIV status by Western Blot is not available, provide pre-HIV test counseling; collect blood for a confirmatory Western Blot HIV test and inform volunteer when HIV results will be available; document in study source documents. Complete **LDMS Specimen Tracking Sheet**.

\_\_\_\_\_ Obtain contact/identifying information for the volunteer; determine the best way to contact the volunteer; record on Locator Form.

\_\_\_\_\_ Obtain demographic information; record in study source documents. Complete **Mother's Demographic Form**. *Note: Demographic information can be collected anytime prior to enrollment. The Mother's Demographics CRF will only be submitted to SCHARP after mother/infant pair is enrolled.*

\_\_\_\_\_ Document any other procedures performed in study source documents.

\_\_\_\_\_ Complete and review required data collection forms. Submit DataFax forms to SCHARP AFTER mother is enrolled.

- Screening/Enrollment Log (non-DataFax)
- LDMS Specimen Tracking Sheet (non-DataFax)
- Locator Form (non-DataFax)

**COHORT 4**  
**Maternal Screening Evaluations**  
**( ≥ 34 Weeks Gestation)**

<b>Participant ID:</b>	<b>Visit Date:</b>
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**Note:**

- The screening visit procedures can be completed at one visit or over multiple visits. However, the study screening consent process must be completed before any screening procedures are done and the study consent process must be completed before any study procedures are done.
- Mothers will not be considered enrolled until labor and delivery.
- If a volunteer is found ineligible, withdraws consent or refuses further screening at any time prior to labor and delivery. The reasons for discontinuing screening must be documented in site source documents.
- Documentation that the mother met the inclusion/exclusion criteria (protocol sections 3.1 and 3.2) must be present in study source documents. A blanket statement regarding all such inclusion criteria, such as, “The participant meets all inclusion criteria outlined in the protocol,” is NOT adequate. Appropriate documentation includes, but is not limited to clinical records, signed and dated chart notes, and laboratory result reports. (Other than the laboratory results for the mother for screening this information will not be transcribed onto CRFs.)

- \_\_\_ Confirm participant identity and PTID number.
- \_\_\_ Complete medical/obstetric history which includes eligibility assessments; record on study source documents.
- \_\_\_ Complete physical exam which includes eligibility assessments; record on study source documents.
- \_\_\_ Review medical/obstetric history and physical exam findings. Complete **Mother’s Pre-existing Conditions Form**
- \_\_\_ Ascertain if mother has taken any antiretroviral medications or other medications during this pregnancy and record on study source documents. Complete **Mother’s Antiretroviral Medication Log** and/or **Mother’s Concomitant Medications Log**.
- \_\_\_ Collect and process blood for the following purposes; complete **LDMS Specimen Tracking Sheet** (report results on **Mother’s Screening and Enrollment Laboratory Results Form** when available).
  - ▶ CBC with differential
  - ▶ Chemistries (bilirubin, aspartate aminotransferase (AST), ALT [SGPT], creatinine, calcium, phosphorus, alkaline phosphatase)
  - ▶ HIV RNA PCR
  - ▶ TDF Resistance (plasma storage)
- \_\_\_ Administer Informed Consent for Enrollment; obtain all signatures and dates and offer the volunteer a copy of the consent form to keep; document on the **informed consent coversheet**.
- \_\_\_ Document any other procedures performed in study source documents.
- \_\_\_ Complete and review required data collection forms. Submit DataFax form to SCHARP only after the mother/infant pair has been enrolled.

**COHORT 4**  
**Maternal Enrollment Evaluations: Labor and Delivery**

<b>Participant ID:</b>	<b>Visit Date:</b>
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**Note:**

- Documentation that the mother met the inclusion/exclusion criteria (protocol sections 3.1 and 3.2) must be present in study source documents. A blanket statement regarding all such inclusion criteria, such as, “The participant meets all inclusion criteria outlined in the protocol,” is NOT adequate. Appropriate documentation includes, but is not limited to clinical records, signed and dated chart notes, and laboratory result reports. (Other than the laboratory results for the mother for screening this information will not be transcribed onto CRFs.)
- Mother’s enrolled in Cohort 1, 3 and 4 will be given their TDF dose during labor defined as > 3 cm or regular uterine contractions or 4 hours prior to a scheduled c-section. See Section 8 of the Study Specific Procedures Manual for additional dosing instructions.
- See Section 10.6 of the Study Specific Procedures manual for instructions on pk sampling.

\_\_\_ Confirm participant identity and PTID number.

\_\_\_ Update contact information for the volunteer.

\_\_\_ Obtain demographic information; record in study source documents; and/or on **Mother’s Demographic Form** (if not done at screening visits).

\_\_\_ Ascertain interim obstetric/medical history including any ARVs or other medications taken during this pregnancy and record on study source documents.

Review all clinical, laboratory and other study source documents. Determine if the mother meets the inclusion and exclusion criteria and make certain that all of the eligibility criteria have been documented in the study source documents. Complete the **Mother’s Eligibility Checklist**.

- If participant is not eligible for enrollment then record reason in study source documents and on screening/enrollment log. No further assessments should be done.
- If participant is eligible, determine which cohort the mother/infant pair will be enrolled record in study source documents and on screening/enrollment log. Complete **Mother’s Delivery and Enrollment Form**.

\_\_\_ Review source documents and complete **Mother’s Delivery and Enrollment Form** (all cohorts) and **Pre-existing Conditions Form**

\_\_\_ Review source documents and complete **Mother’s Antiretroviral Medication Log** and/or **Concomitant Medications Log**, if needed

\_\_\_ Obtain the next sequential enrollment packet for the specified cohort. Check expiry date.

\_\_\_ Remove the **Cohort 4 Prescription Form - Mother** from the packet, add the PTID to the form. Verify informed consent has been obtained and then initial the prescription form.

- \_\_\_\_\_ The IoR or authorized prescriber reviews, signs and dates the **Cohort 4 Prescription Form - Mother** (within 24 hours). Return the original prescription form (top copy) to the pharmacy and file the copy in the participant's chart.
- \_\_\_\_\_ Add the PTID number to the **Study Product Label**, which is affixed to the study drug
- \_\_\_\_\_ Document the date the packet has been assigned on the cohort specific **Clinic Packet Log**.
- \_\_\_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on Mother's Laboratory Results Form when available). All Specimens must be collected **PRIOR to TDF dosing**
  - ▶ TDF resistance testing (plasma storage) (collected during active labor)
  - ▶ CBC with differential
  - ▶ CD4+ cell count
  - ▶ Chemistries (bilirubin, AST, ALT [SGPT], creatinine, calcium, albumin, phosphorus, alkaline phosphatase)
  - ▶ HIV RNA PCR (collected during active labor)
- \_\_\_\_\_ Administer dose during labor defined as > 3 cm or regular uterine contractions or 4 hrs prior to a scheduled c-section. See Section 8.6.1 of the Study Specific Procedures Manual for additional dosing instructions.
- \_\_\_\_\_ Record date and time of TDF dose on **PK and Dosing Non-Data Fax Form**. Complete **Mother's Delivery and Enrollment Form**
- \_\_\_\_\_ Collect PK Specimens as follows:
  - ▶ Delivery PK sample
  - ▶ Amniotic Fluid Storage for TDF concentration
  - ▶ Cord Blood
  - ▶ Record date and time of collection of cord blood and delivery PK specimen on **LDMS Specimen Tracking Sheet** , **PK and Dosing Non-Data Fax Form** and on **Mothers PK Form (delivery) and Cohort 4 Infant PK Form** (cord blood).
- \_\_\_\_\_ Ascertain clinical delivery information and document in study source documents and on **Mother's Delivery and Enrollment Form**. Complete **Mother's Antiretroviral Medication Log** and/or **Concomitant Medications Log**, if needed.
- \_\_\_\_\_ For all serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Mother's Adverse Experience Log**.
- \_\_\_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
- \_\_\_\_\_ Document any other procedures performed in study source documents.
- \_\_\_\_\_ Complete and review required data collection forms. **Submit DataFax forms to SCHARP after enrollment.**
  - Mother's Demographic Form

- Mother's Screening and Enrollment Laboratory Result Form with results from screening visits
- Mother's Screening and Enrollment Laboratory Result Form with results from Labor and Enrollment
- Mother's Pharmacokinetics Form
- LDMS Specimen Tracking Sheet (non-DataFax)
- Mother's Eligibility Checklist (non-DataFax)
- Mother's PK and Dosing Form (non-DataFax)
- Mother's Prescription Form and Clinic Packet Log
- Mother's Delivery and Enrollment Form
- Pre-existing conditions Form
- Mother's Antiretroviral Medication Log
- Concomitant Medications Log, if needed.
- Mother's Adverse Experience Log, if needed
- DAIDS EAE Form, if needed

## **Cohort 4 Infant Eligibility Criteria**

### **Inclusion Criteria**

- Was the infant born to an HIV-infected mother enrolled in the study?

### **Exclusion Criteria for Dosing**

- Did the infant weigh less than 2000 grams at birth?
- Does the infant have a severe congenital malformation or other medical condition not compatible with life or that would interfere with study participation or interpretation, as judged by the examining clinician?
- Does the infant have a known Grade 2 or higher serum creatinine level?
- Does the infant have any Grade 3 or higher laboratory toxicity?

*(Note: test results not required prior to dosing initiation)*

**COHORT 4  
Infant Birth Visit  
1<sup>st</sup> Dose**

<b>Participant ID:</b>	<b>Visit Date:</b>
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**Note:**

- Infants must be born to a mother who has consented to take part in this study.
- Sites should follow standard procedures for dispensing ARV regimen for PMTCT to infants born to HIV-infected women.
- Documentation that the infant met the inclusion criteria for initial dosing (protocol section 3.4) must be present in study source documents before dosing. A blanket statement regarding all such inclusion criteria such as, “The participant meets all inclusion criteria for dosing outlined in the protocol,” is NOT adequate. Appropriate documentation includes, but is not limited to clinical records, signed and dated chart notes, and laboratory result reports.
- Infant’s enrolled will be given their 1<sup>st</sup> TDF dose as soon as possible, within 12 hours of birth. See Section 8.6.2 of the Study Specific Procedures Manual for additional dosing instructions.
- Infant’s will have their first pk sample drawn within 1 hour before TDF dose. See Section 10.6 of the Study Specific Procedures manual for instructions on pk sampling. *Note: If cord blood is collected and the infant receives the first dose of TDF  $\leq$  2 hours after birth this specimen can be omitted.*

\_\_\_\_\_ Assign HPTN Infant Participant ID number; enter into **Screening/Enrollment Log**.

\_\_\_\_\_ Review birth and neonatal history and complete physical exam record on study source documents and on **Infant Birth Form** and **Infant’s Antiretroviral Medications Log**.

\_\_\_\_\_ Review all clinical, laboratory and other study source documents. Determine if the infant meets the inclusion criteria for initial dosing and make certain that all of the eligibility criteria have been documented in the study source documents. If the infant is not eligible for further dosing record reason on study source documents and complete **Infant Early Discontinuation of Study Drug Form**. Mothers and infant’s remain in follow-up.

Return unused suspension and unused oral syringes that was part of the mother’s enrollment packet to the pharmacy. Document return on Clinic Packet Log.

\_\_\_\_\_ Obtain the enrollment packet that was used for the mother (Check expiry date.)

\_\_\_\_\_ Remove the **Prescription Form for Cohort 4 – Infant** from the packet, add the PTID to the form. Verify informed consent has been obtained and then initial the prescription form.

\_\_\_\_\_ The IoR or authorized prescriber reviews and signs and dates the **Prescription Form for Cohort 4 - Infant**. Return the original prescription form (top copy) to the pharmacy within 24 hours and file the copy in the participant’s chart.

- \_\_\_\_\_ Add the PTID number to the **Study Product Label**, which is affixed to the study drug
- \_\_\_\_\_ Document the date the packet was assigned on the cohort specific **Clinic Packet Log**.
- \_\_\_\_\_ Collect blood for pre-dose PK specimen within 1 hour before dose; record on **LDMS Specimen Tracking Sheet** and **Cohort 4 Infant Pharmacokinetics Form**. See PK specimen Collection Tables in the SSP Section for additional instructions) Note: If cord blood is collected and the infant receives the first dose of TDF  $\leq$  2 hours after birth this specimen can be omitted.
- \_\_\_\_\_ Administer infant dose as soon as possible after birth within 12 hours. See Section 8.6.2 of the Study Specific Procedures Manual for additional dosing instructions.
- \_\_\_\_\_ Record date and time of TDF dose in **PK and Dosing Form** and **Cohort 4 Infant Pharmacokinetics Form**.
- \_\_\_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on Infant's Laboratory Results Form when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ CBC with differential
  - ▶ Chemistries (bilirubin, AST, ALT [SGPT], creatinine, calcium, albumin, phosphorus, alkaline phosphatase)
  - ▶ HIV DNA or RNA PCR
  - ▶ Dried Blood Spot (storage)
- \_\_\_\_\_ Collect pk specimens. See PK specimen Collection tables and procedures in Section 10.6 of the SSP manual; record on **LDMS Specimen Tracking Sheet**, **PK and Dosing Form** and **Cohort 4 Infant Pharmacokinetics Form**.
- \_\_\_\_\_ Document any other procedures performed in study source documents.
- \_\_\_\_\_ Review birth and neonatal history and physical exam findings complete **Infant's Antiretroviral Medications Log** and **Infant's Concomitant Medications Log**, if needed.
- \_\_\_\_\_ For all serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Infant's Adverse Experience Log**.
- \_\_\_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
- \_\_\_\_\_ Assess infant's eligibility for continued dosing and document on study source documents. If the infant is not eligible for further dosing record on study source documents and **Infant Early Discontinuation of Study Drug Form**.
  - Infant Birth Form
  - Infant's Eligibility Checklist (non-DataFax)
  - Infant's Concomitant Medications Log (if required)
  - Infant's Antiretroviral Medication Log
  - Infant's Laboratory Results Form
  - LDMS Specimen Tracking Sheet (non-DataFax)

- Cohort 4 Infants Pharmacokinetics Form
- PK and Dosing Form (non-DataFax)
- Prescription Form for Cohort 4 – Infant and Clinic Packet Log
- Infant’s AE Log (if required)
- DAIDS EAE Form (if required)

**COHORT 4**  
**Maternal 28 – 48 hrs pp**

<b>Participant ID:</b>	<b>Visit Date:</b>
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**Note:**

- See Section 10.6 of the Study Specific Procedures manual for instructions on pk sampling.

\_\_\_\_\_ Confirm participant identity and PTID number.

\_\_\_\_\_ Update contact information for the volunteer.

\_\_\_\_\_ Ascertain interim obstetric/medical history and record on study source documents. Complete the **Mother’s Follow-up Visit Form**.

\_\_\_\_\_ Complete symptom-directed physical exam and record on study source documents. Complete **Mother’s Follow-up Visit Form**.

\_\_\_\_\_ Ascertain if mother has taken any antiretroviral medications or other medications and record on study source documents; complete **Mother’s Antiretroviral Medication Log** and **Concomitant Medications Log**, if needed.

\_\_\_\_\_ For ALL serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Mother’s Adverse Experience Log**.

\_\_\_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.

\_\_\_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on Mother’s Laboratory Results Form when available).

- ▶ CBC with differential
- ▶ Chemistries (bilirubin, AST, ALT [SGPT], creatinine, calcium, albumin, phosphorus, alkaline phosphatase)

\_\_\_\_\_ If breastfeeding, collect breast milk and complete **Specimen Tracking Sheet** (report storage on **Mother’s Laboratory Results** Form after stored).

\_\_\_\_\_ Document any other procedures performed in study source documents.

\_\_\_\_\_ Complete and review required data collection forms.

- Mother’s Follow-up Visit Form
- Mother’s Laboratory Result Form
- LDMS Specimen Tracking Sheet (non-DataFax)
- Mother’s Pharmacokinetics Form
- Mother’s PK and Dosing Form (non-DataFax)
- Mother’s Antiretroviral Medication Log, if needed

- Concomitant Medications Log, if needed, if needed
- Mother's Adverse Experience Log, if needed
- DAIDS EAE Form, if needed

**COHORT 4  
Infant - Dose 2, 3, 4, 5, 6 and 7  
and pk Sampling Procedures**

<b>Participant ID:</b>	<b>Visit Date:</b>
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**Note:**

- Infant's must have clinical records and laboratory reports reviewed for toxicities (see protocol section 4.6.1) prior to receiving each dose of TDF
- Infant's will be given 6 mg/kg of the TDF suspension for 7 days initiated at birth (within 12 hours of birth). The second dose must be administered within 16 to 32 hours after the birth dose and five subsequent doses must be administered daily every 24 hours (+/- 2 hours). See Section 8.6.2 of the Study Specific Procedures Manual for additional dosing instructions.
- Infant's will have pk samples drawn before and after administering the birth, 4<sup>th</sup> and 7<sup>th</sup> dose of TDF. (Note a pk sample must be drawn **just prior to administering the 2<sup>nd</sup> and 5<sup>th</sup> dose of TDF**). See Section 10.6 of the Study Specific Procedures manual for instructions on pk sampling.

\_\_\_ Confirm participant identity and Infant Participant ID number.

\_\_\_ Assess infant's eligibility for continued dosing and document on study source documents. If the infant is not eligible for further dosing record reason on study source documents and complete **Infant Early Discontinuation of Study Drug Form**. Mothers and infant's remain in follow-up.

Return any remaining TDF suspension and unused oral syringes to the pharmacy Document return on **Clinic Packet Log**. See Section 8.6 for additional instructions.

\_\_\_ If eligible for continued dosing obtain the TDF suspension from the assigned enrollment packet in the refrigerator. Check expiry date.

\_\_\_ Collect blood for pre-dose PK specimen prior to 2<sup>nd</sup>, 4<sup>th</sup>, 5<sup>th</sup> and 7<sup>th</sup> within 1 hour before dosing; record on **LDMS Specimen Tracking Sheet, Dosing and PK Form**, and **Cohort 4 Infant Pharmacokinetics Form**. See PK Specimen Collection Tables in the SSP Section 10.6 for additional instructions)

\_\_\_ Administer infant dose after collecting pre-dose pk sample. See Section 8.6.2 of the Study Specific Procedures Manual for additional dosing instructions.

\_\_\_ Record date and time of TDF dose on PK and Dosing Form and on **Cohort 4 Infant Pharmacokinetics Form**.

\_\_\_ Collect pk specimens post dosing (4<sup>th</sup> and 7<sup>th</sup> dose). See Section Section 10.6 of the Study Specific Procedures Manual for instructions on pk sampling. Record on **LDMS Specimen Tracking Sheet, PK and Dosing Form** and **Cohorts 4 Infant Pharmacokinetics Form**.

\_\_\_ Document any other procedures performed in study source documents.

- Cohort 4 Infants Pharmacokinetics Form
- PK and Dosing Form (non-DataFax)

- LDMS Specimen Tracking Sheet (non-DataFax)
- Infant's AE Log (if required) (Data-Fax)
- DAIDS EAE Form (if required)

**COHORT 4  
Infant Day 3**

<b>Participant ID:</b>	<b>Visit Date:</b>
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**Note:**

- See Visit Checklist for Dose 2, 3, 4, 5, 6 and 7 and pk Sampling Procedures

\_\_\_\_\_ Confirm participant identity and Infant Participant ID number.

\_\_\_\_\_ Complete physical exam and review medical history record on study source documents and on **Infant Follow-up Visit Form**.

\_\_\_\_\_ Review history and physical exam findings complete **Infant's Antiretroviral Medications Log** and **Infant's Concomitant Medications Log**, if needed.

\_\_\_\_\_ For all serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Infant's Adverse Experience Log**.

\_\_\_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.

- Infant Follow-up Form
- Infant's Local Radiologic Assessment
- Infants Pharmacokinetics Form
- PK and Dosing Form (non-DataFax)
- Infant's Concomitant Medications Log (if required)
- Infant's Antiretroviral Medication Log (if required)
- LDMS Specimen Tracking Sheet (non-DataFax)
- Infant's AE Log (if required) (Data-Fax)
- DAIDS EAE Form (if required)

**COHORT 4**  
**Infant Day 5 - 7**

<b>Participant ID:</b>	<b>Visit Date:</b>
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**Note:**

- See Visit Checklist Dose 2, 3, 4, 5, 6 and 7 and pk Sampling Procedures

\_\_\_\_\_ Confirm participant identity and Infant Participant ID number.

\_\_\_\_\_ Complete physical exam and review medical history record on study source documents and on **Infant Follow-up Visit Form**.

\_\_\_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on **Infant's Laboratory Results Form** when available).

- ▶ TDF resistance testing (plasma storage)
- ▶ CBC with differential
- ▶ Chemistries (bilirubin, AST, ALT [SGPT], creatinine, calcium, albumin, phosphorus, alkaline phosphatase)
- ▶ HIV DNA or RNA PCR
- ▶ Dried Blood Spot (storage)

\_\_\_\_\_ Document any other procedures performed in study source documents.

\_\_\_\_\_ Review history and physical exam findings complete **Infant's Antiretroviral Medications Log** and **Infant's Concomitant Medications Log**, if needed.

\_\_\_\_\_ For all serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Infant's Adverse Experience Log**.

\_\_\_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.

- Infant Follow-up Form
- Infant's Laboratory Results Form
- Infant's Concomitant Medications Log (if required)
- Infant's Antiretroviral Medication Log (if required)
- Specimen Tracking Sheet (non-DataFax)
- Infant's AE Log (if required)
- DAIDS EAE Form (if required)

**COHORT 4**  
**Maternal 5 to 7 days pp**

<b>Participant ID:</b>	<b>Visit Date:</b>
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- \_\_\_ Confirm participant identity and PTID number.
- \_\_\_ Update contact information for the volunteer.
- \_\_\_ Ascertain interim obstetric/medical history and record on study source documents. Complete the **Mother's Follow-up Visit Form**.
- \_\_\_ Ascertain if mother has taken any antiretroviral medications or other medications and record on study source documents; complete **Mother's Antiretroviral Medication Log** and/or **Concomitant Medications Log**, if needed.
- \_\_\_ Complete symptom-directed physical exam and record on study source documents. Complete **Mother's Follow-up Visit Form**.
- \_\_\_ For ALL serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Mother's Adverse Experience Log**.
- \_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
- \_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on Mother's Laboratory Results Form when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ CBC with differential
  - ▶ Chemistries (bilirubin, AST, ALT [SGPT], creatinine, calcium, albumin, phosphorus, alkaline phosphatase)
  - ▶ HIV RNA PCR
- \_\_\_ If breastfeeding, collect breast milk and complete **Specimen Tracking Sheet** (report storage on **Mother's Laboratory Results Form** after stored).
- \_\_\_ Document any other procedures performed in study source documents.
- \_\_\_ Complete and review required data collection forms.
  - Mother's Follow-up Visit Form
  - Mother's Laboratory Result Form
  - LDMS Specimen Tracking Sheet (non-DataFax)
  - Mother's Antiretroviral Medication Log, if needed
  - Concomitant Medications Log, if needed
  - Mother's Adverse Experience Log, if needed
  - DAIDS EAE Form, if needed

**COHORT 4**  
**Maternal 6 weeks pp**

<b>Participant ID:</b>	<b>Visit Date:</b>
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- \_\_\_ Confirm participant identity and PTID number.
- \_\_\_ Update contact information for the volunteer.
- \_\_\_ Ascertain interim obstetric/medical history and record on study source documents. Complete the **Mother's Follow-up Visit Form**.
- \_\_\_ Complete symptom-directed physical exam and record on study source documents. Complete **Mother's Follow-up Visit Form**.
- \_\_\_ Ascertain if mother has taken any antiretroviral medications or other medications and record on study source documents; complete **Mother's Antiretroviral Medication Log** and/or **Concomitant Medications Log**, if needed.
- \_\_\_ For ALL serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Mother's Adverse Experience Log**.
- \_\_\_ For all events that meet the criteria for expedited reporting, complete **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
- \_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on Mother's Laboratory Results Form when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ CBC with differential
  - ▶ Chemistries (bilirubin, AST, ALT [SGPT], creatinine, calcium, albumin, phosphorus, alkaline phosphatase)
  - ▶ HIV RNA PCR
- \_\_\_ If breastfeeding, collect breast milk and complete **LDMS Specimen Tracking Sheet** report storage on **Mother's Laboratory Results** Form after sample is processed and stored.
- \_\_\_ Document any other procedures performed in study source documents.
- \_\_\_ Complete and review required data collection forms.
  - Mother's Follow-up Visit Form
  - Mother's Laboratory Result Form
  - Specimen Tracking Sheet (non-DataFax)
  - Mother's Antiretroviral Medication Log, if needed
  - Concomitant Medications Log, if needed.
  - Mother's Adverse Experience Log, if needed
  - DAIDS EAE Form, if needed

**COHORT 4**  
**Maternal 12 weeks pp**

<b>Participant ID:</b>	<b>Visit Date:</b>
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- \_\_\_ Confirm participant identity and PTID number.
- \_\_\_ Update contact information for the volunteer.
- \_\_\_ Ascertain interim obstetric/medical history and record on study source documents. Complete the **Mother's Follow-up Visit Form**.
- \_\_\_ Complete symptom-directed physical exam and record on study source documents. Complete **Mother's Follow-up Visit Form**.
- \_\_\_ Ascertain if mother has taken any antiretroviral medications or other medications and record on study source documents; complete **Mother's Antiretroviral Medication Log** and/or **Concomitant Medications Log**, if needed.
- \_\_\_ For ALL serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Mother's Adverse Experience Log**.
- \_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
- \_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on Mother's Laboratory Results Form when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ HIV RNA PCR (plasma storage, to be assayed later, if needed)
- \_\_\_ If breastfeeding, collect breast milk and complete **LDMS Specimen Tracking Sheet** report storage on **Mother's Laboratory Results** Form after sample is processed and stored.
- \_\_\_ Document any other procedures performed in study source documents.
- \_\_\_ Complete and review required data collection forms.
  - Mother's Follow-up Visit Form
  - Mother's Laboratory Result Form
  - Specimen Tracking Sheet (non-DataFax)
  - Mother's Antiretroviral Medication Log, if needed
  - Concomitant Medications Log, if needed.
  - Mother's Adverse Experience Log, if needed
  - DAIDS EAE Form, if needed

**COHORT 4**  
**Infant Week 12**

<b>Participant ID:</b>	<b>Visit Date:</b>
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- \_\_\_\_\_ Confirm participant identity and Infant Participant ID number.
- \_\_\_\_\_ Complete physical exam and review medical history record on study source documents and on Infant Follow-up Visit Form.
- \_\_\_\_\_ Obtain x-rays of the thoracic spine and left wrist record in study source documents and on **Infant Local Radiologic Assessment Form**.
- \_\_\_\_\_ Collect and process blood for the following purposes and complete **Specimen Tracking Sheet** (report results on **Infant's Laboratory Results Form** when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ HIV DNA or RNA PCR (breastfeeding infants ONLY)
  - ▶ Dried Blood Spot (storage)
- \_\_\_\_\_ Document any other procedures performed in study source documents.
- \_\_\_\_\_ Review birth and neonatal history and physical exam findings complete **Infant's Antiretroviral Medications Log** and **Infant's Concomitant Medications Log, if needed**.
- \_\_\_\_\_ For all serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Infant's Adverse Experience Log**.
- \_\_\_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
- \_\_\_\_\_ Complete and review required data collection forms.
  - Infant Follow-up Form (DataFax)
  - Infant's Laboratory Results From (DataFax)
  - Infant's Concomitant Medications Log (if required) (DataFax)
  - Infant's Antiretroviral Medication Log (if required) (DataFax)
  - Specimen Tracking Sheet (non-DataFax)
  - Infant's AE Log (if required) (Data-Fax)
  - DAIDS EAE Form (if required)

**COHORT 4**  
**Maternal 6 months pp**

<b>Participant ID:</b>	<b>Visit Date:</b>
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- \_\_\_ Confirm participant identity and PTID number.
- \_\_\_ Update contact information for the volunteer.
- \_\_\_ Ascertain interim obstetric/medical history and record on study source documents. Complete the **Mother's Follow-up Visit Form**.
- \_\_\_ Complete symptom-directed physical exam and record on study source documents. Complete **Mother's Follow-up Visit Form**.
- \_\_\_ Ascertain if mother has taken any antiretroviral medications or other medications and record on study source documents; complete **Mother's Antiretroviral Medication Log** and/or **Concomitant Medications Log**, if needed.
- \_\_\_ For ALL serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Mother's Adverse Experience Log**.
- \_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
- \_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on Mother's Laboratory Results Form when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ HIV RNA PCR (plasma storage, to be assayed later if needed)
- \_\_\_ Document any other procedures performed in study source documents.
- \_\_\_ Complete and review required data collection forms.
  - Mother's Follow-up Visit Form
  - Mother's Laboratory Result Form
  - LDMS Specimen Tracking Sheet (non-DataFax)
  - Mother's Antiretroviral Medication Log, if needed
  - Concomitant Medications Log, if needed.
  - Mother's Adverse Experience Log, if needed
  - DAIDS EAE Form, if needed

## COHORT 4 Infant Month 6

<b>Participant ID:</b>	<b>Visit Date:</b>
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- \_\_\_\_\_ Confirm participant identity and Infant Participant ID number.
- \_\_\_\_\_ Complete physical exam and review medical history record on study source documents and on Infant Follow-up Visit Form.
- \_\_\_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on **Infant's Laboratory Results Form** when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ HIV DNA or RNA PCR (breastfeeding infants ONLY)
  - ▶ Dried Blood Spot (storage)
- \_\_\_\_\_ Document any other procedures performed in study source documents.
- \_\_\_\_\_ Review birth and neonatal history and physical exam findings complete **Infant's Antiretroviral Medications Log** and **Infant's Concomitant Medications Log, if needed.**
- \_\_\_\_\_ For all serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Infant's Adverse Experience Log.**
- \_\_\_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
  - Infant Follow-up Form
  - Infant's Laboratory Results Form
  - Infant's Concomitant Medications Log (if required)
  - Infant's Antiretroviral Medication Log (if required)
  - LDMS Specimen Tracking Sheet (non-DataFax)
  - Infant's AE Log (if required)
  - DAIDS EAE Form (if required)

**COHORT 4**  
**Maternal 12 months pp**

<b>Participant ID:</b>	<b>Visit Date:</b>
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- \_\_\_ Confirm participant identity and PTID number.
- \_\_\_ Update contact information for the volunteer.
- \_\_\_ Ascertain interim obstetric/medical history and record on study source documents. Complete the **Mother's Follow-up Visit Form**.
- \_\_\_ Complete symptom-directed physical exam and record on study source documents. Complete **Mother's Follow-up Visit Form**.
- \_\_\_ Ascertain if mother has taken any antiretroviral medications or other medications and record on study source documents; complete **Mother's Antiretroviral Medication Log** and **Concomitant Medications Log**, if needed.
- \_\_\_ For ALL serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Mother's Adverse Experience Log**.
- \_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
- \_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on Mother's Laboratory Results Form when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ HIV RNA PCR (plasma storage, to be assayed later if needed)
- \_\_\_ Document any other procedures performed in study source documents.
- \_\_\_ Complete and review required data collection forms.
  - Mother's Follow-up Visit Form
  - Mother's Laboratory Result Form
  - Specimen Tracking Sheet (non-DataFax)
  - Mother's Antiretroviral Medication Log, if needed
  - Concomitant Medications Log, if needed.
  - Mother's Adverse Experience Log, if needed
  - DAIDS EAE Form, if needed

**COHORT 4**  
**Infant Month 12**

<b>Participant ID:</b>	<b>Visit Date:</b>
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- \_\_\_\_\_ Confirm participant identity and Infant Participant ID number.
- \_\_\_\_\_ Complete physical exam and review medical history record on study source documents and on Infant Follow-up Visit Form.
- \_\_\_\_\_ Collect and process blood for the following purposes and complete **LDMS Specimen Tracking Sheet** (report results on **Infant's Laboratory Results Form** when available).
  - ▶ TDF resistance testing (plasma storage)
  - ▶ HIV DNA or RNA PCR (breastfeeding infants ONLY)
  - ▶ Dried Blood Spot (storage)
- \_\_\_\_\_ Document any other procedures performed in study source documents.
- \_\_\_\_\_ Review birth and neonatal history and physical exam findings complete **Infant's Antiretroviral Medications Log** and **Infant's Concomitant Medications Log, if needed.**
- \_\_\_\_\_ For all serious and non-serious adverse events or events that meet the criteria for expedited reporting to DAIDS, including lab abnormalities, record detailed information in study source documents. Complete the **Infant's Adverse Experience Log.**
- \_\_\_\_\_ For all events that meet the criteria for expedited reporting, report through DAERS or on the **DAIDS EAE Form** and fax to RCC within 3 days of site awareness.
  - Infant Follow-up Form
  - Infant's Laboratory Results Form
  - Infant's Concomitant Medications Log (if required)
  - Infant's Antiretroviral Medication Log (if required)
  - LDMS Specimen Tracking Sheet (non-DataFax)
  - Infant's AE Log (if required)
  - DAIDS EAE Form (if required)

End of Study CRFs

- Infant End of Study Inventory
- Infant Termination