

Section 6. Visit Checklists

This section contains visit-specific checklists 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 this SSP Manual to reflect their local procedures.

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 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.
- The visit codes are included in the top section of the checklist. See Section 12 for visit coding instructions.
- 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 upon which 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, with the following exceptions:

- At screening, infant feeding options counseling must precede consent for study enrollment and final eligibility determination.
- Informed consent for study enrollment must be obtained before any screening procedures are performed.
- Assessment of infant feeding practices should occur prior to infant feeding counseling.
- Assessment of adherence to open-label NVP or study drug dosing should occur prior to adherence counseling.

Maternal Screening Evaluations
(3rd Trimester of Pregnancy on or Before Day 7 after Delivery)
Visit Code: 1.0

Participant ID:	Visit Date
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Notes:

- Only HIV-infected women who, after thorough infant feeding options counseling by a designated counselor clearly wish to breastfeed should be referred to the study counselors for screening.
- Standard Clinical Procedures for the intrapartum/infant ARV regimen for prevention of maternal to child HIV transmission should be followed.
- HIV-infected women may be enrolled at any time during the 3rd trimester of pregnancy or on or before day 7 after delivery.
- The screening visit procedures can be completed over multiple visits. However, the study consent process must be completed before any study procedures.
- The specimen storage consent is for storage and testing of samples that are NOT required by the study protocol and is therefore optional. Women who choose to participate in the study do not have to provide consent for specimen storage to be enrolled.
- If documented confirmation of the mother's HIV status (as evidenced by 2 positive EIAs; or 1 positive EIA or rapid test and 1 WB, or 2 separate positive rapid tests) is not available in the medical records; then a confirmatory test should be given after study consent has been obtained and prior to enrollment.
- Mothers will not be considered enrolled until eligibility of the infant has been determined (within 7 days after birth) and the infant is enrolled.
- If a volunteer is found ineligible, withdraws consent or refuses further screening at any time prior to enrollment, further assessments should be immediately discontinued. The reasons for discontinuing screening must be documented in source documents.
- At each visit during screening and after enrollment, brief notes on provision of HIV and infant feeding counseling should be recorded, volunteer's reactions, issues and concerns discussed, etc. Record in study source documents.
- The evaluations for Maternal Screening and Labor and Delivery visits can be combined into one visit for women who have not completed the screening evaluations prior to delivery; duplicate blood work does not need to be done (see Labor and Delivery Evaluations Checklist).

_____ Introduce the study, explain the informed consent process, provide a brief overview of the benefits, risks, procedures, and requirements

_____ Ensure infant feeding options counseling has been provided and re-assess mother's intent to breastfeed; document in study source documents.






_____ Administer Study Enrollment Informed Consent; obtain all signatures and dates and offer the volunteer a copy of the consent form to keep; document in informed consent coversheet.

_____ Administer Specimen Storage Consent (optional); document in study source records.

Note: The Specimen Storage Consent can be administered at any time during screening or follow-up.

Maternal Screening Evaluations
(3rd Trimester of Pregnancy on or Before Day 7 after Delivery)
Visit Code: 1.0

Participant ID:	Visit Date
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- _____ Assign next sequential HPTN Participant ID number; enter into Screening/Enrollment Log.
- _____ Obtain documentation of HIV test results from medical records (at least one positive EIA and one positive Western blot or at least 1 rapid test and 1 positive Western blots).
- _____ If documented confirmation of the mothers HIV status is not available, provide pre-HIV test counseling; collect blood for HIV testing and inform volunteer when HIV results will be available; document in study source documents.
- _____ 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 and/or clinical chart.
- _____ Complete medical history and record on study source documents.
- _____ Complete physical exam. If mother is undergoing screening prior to labor and delivery, conduct obstetric exam and estimation of gestational age and complete study source documents.
- _____ Ascertain if mother is taking any antiretroviral medications and record on study source documents; complete  **Mother's Antiretroviral Medication Log** if needed.
- _____ Collect and process blood for the following purposes and complete  **Mother's Laboratory Results Form** and  **Specimen Tracking Sheet** (report results on  **Mothers Laboratory Results Form** when available).
 - ▶ CBC with differential, CD4+ cell count
 - ▶ Confirmatory HIV test (if required)
 - ▶ 4 X 1.0 mL aliquot plasma frozen and stored on site for shipment to NL
 - ▶ Dried Blood Spot Storage
- _____ Document any other procedures performed in study source documents.
- _____ Complete and review required data collection forms. **Submit DataFax Forms to SCHARP only after infant enrollment**
 - Screening/Enrollment Log (non-DataFax)
 - Mother's Laboratory Results Form (DataFax)
 - Specimen Tracking Sheet (non-DataFax)
 - Locator Form (non-DataFax)
 - Mother's Antiretroviral Medication Log (if needed, DataFax)

Labor and Delivery Evaluations (on or before day 7 after delivery) Visit Code: 2.0

Participant ID:	Visit Date
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Notes:

- The evaluations for Maternal Screening and Labor and Delivery visits can be combined into one visit for women who have not completed the screening evaluations prior to delivery; duplicate blood work is not required (see Maternal Screening Evaluations Checklist).
- Information on labor and delivery should be ascertained regardless of whether the woman delivered at the study clinic, noting the source of information.

- _____ Confirm participant identity and PTID number.
- _____ Confirm volunteer's continued willingness to participate.
- _____ Provide infant feeding options counseling and re-assess mother's intent to breastfeed; document in study source documents.
- _____ Update contact information for the volunteer.
- _____ Ascertain obstetric/medical history and delivery information; obtain copy of hospital record if possible or record in study source documents.
- _____ Determine if mother received standard of care ARV regimen for prevention of mother to infant HIV transmission for this or for a previous pregnancy or ARV regimen for treatment; record on study source documents.
- _____ Conduct post-delivery physical exam; record on study source documents.
- _____ Collect and process blood for the following purposes and complete  **Mother's Laboratory Results Form** and  **Specimen Tracking Sheet** (report results on  **Mother's Laboratory Results Form** when available).
 - ▶ CBC with differential
 - ▶ CD4+ cell count
 - ▶ 4 X 1.0 mL aliquot plasma frozen and stored on site for shipment to NL
 - ▶ Dried Blood Spot Storage
- _____ Document any other procedures performed in study source documents.
- _____ Complete and review required data collection forms. **Submit DataFax Forms to SCHARP after infant enrollment**
 - Mother's Laboratory Result Form (DataFax)
 - Specimen Tracking Sheet (non-DataFax)

Infant Birth Visit – Day 0
(on or before day 7 post birth)
Visit Code: 2.0


Participant ID:	Visit Date
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
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
- Infants must be born to a mother who has consented to take part in this study.
- Sites should follow standard procedures for dispensing the ARV regimen for PMTCT to infants born to HIV-infected women.
- The Infant Birth Form should be completed using available information regardless of whether the infant was delivered at the study clinic, noting the source of information.
- DNA PCR, Hemoglobin, and ALT results are required to assess the infant’s eligibility for enrollment (within 7 days of life).



_____ Assign infant PTID number; enter into Screening/Enrollment Log.




_____ Assess mother’s intent/ability to breastfeed; record in clinical chart.

_____ Assess birth history; obtain copy of hospital record if possible or record on study source documents; record on  **Infant Birth Form**.

_____ Complete physical exam including evaluation of pre-existing conditions; complete study source documents; record on  **Infant Birth Form**.

_____ Document doses of infant ARVs received for prevention of mother-to child transmission on study source documents; record on  **Infant Birth Form**.

_____ Document all concomitant medications in study source documents. Complete  **Infant’s Concomitant Medications Form** (for antibiotics, antifungals, and antimicrobials) and  **Infant’s Antiretroviral Medication Log** (for antiretrovirals other than single-dose nevirapine for PMTCT) if required.

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

- ▶ CBC with differential
- ▶ ALT
- ▶ HIV-1 DNA or Quantitative RNA PCR
- ▶ Plasma Storage for shipment to the NL
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage

_____ Document any other procedures performed in study source documents.




_____ Complete and review required data collection forms. **Submit DataFax Forms to SCHARP after enrollment**


- Infant Birth Form (DataFax)
- Infant’s Concomitant Medications Log (if required, DataFax)
- Infant’s Antiretroviral Medication Log (if required, DataFax)
- Infant’s Laboratory Results Form (DataFax)
- Specimen Tracking Sheet (non-DataFax)

Enrollment Procedures
(on or before day 7 after delivery)
Visit Code: 2.0

Participant ID:	Visit Date
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Note:

- Prior to enrollment, all eligibility criteria for both the mother and infant assessed during screening should be carefully reviewed, confirmed, and documented in source documents. Infant DNA PCR, hemoglobin and ALT results must be available prior to enrollment.
 - ▶ If not eligible, enter the reason not eligible onto the  **Screening/Enrollment Log**; no further assessments will be done on the mother or her infant. Complete  **Mother's Screening Outcome Form** and submit to SCHARP. No other DataFax forms are submitted to SCHARP.
 - ▶ If eligible, enter in  **Screening/Enrollment Log**, continue visit procedures and prepare for enrollment and dispensing of open-label NVP.

_____ Complete  **Mother's Enrollment Form** with information collected at screening, labor and delivery, and birth visits.

_____ Complete  **Mother's Demographics Form** with information collected at screening.

Dispensing of Open-Label NVP

Note: Procedures for pharmacist dispensing open-label NVP to clinic staff or directly to the participant are included in the SSP in Sections 8.5 – 8.5.3. Please modify the steps below according to your site's procedures.

_____ Investigator of Record or designee reviews eligibility information and documents review in study source documents.

_____ Authorized clinician completes and signs the  **Open-Label Nevirapine Prescription**.

_____ Dispenser obtains 30 mL bottle(s) of open-label NVP, oral syringes, and Dispensing Slip.

_____ Dispenser verifies that the dose to be administered is accurate, that the syringes are marked correctly, and that the information on the labels has been completed.

_____ Dispenser provides instructions to the mother and demonstrates how to dispense open-label NVP suspension. If the infant was not dosed with open-label NVP in the clinic, the dispenser instructs the mother to record the date the first dose was given to the infant. The initial supply of open-label NVP suspension and oral syringes will be provided to the mother in a re-sealable plastic bag prior to discharge.

_____ The Dispensing Slip should be returned on the day of dispensation, but it can be returned for up to five days after dispensation to the mother. The Dispensing Slip and original Prescription are kept in the pharmacy. A copy of the Prescription is filed in the participant's clinical chart.

Enrollment Procedures
(on or before day 7 after delivery)
Visit Code: 2.0

Participant ID:	Visit Date
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_____ Complete and/or review required data collection forms.

- Screening/Enrollment Log (non-DataFax)
- Mother's Screening Outcome Form (DataFax)
- Prescription (non-DataFax)
- Dispensing Slip (non-DataFax)
- Infant Birth Form (DataFax)
- Infant's Concomitant Medications Log (if required, DataFax)
- Infant's Antiretroviral Medication Log (if required, DataFax)
- Infant's Laboratory Results Form (DataFax)
- Mother's Laboratory Results Form (DataFax)
- Mother's Enrollment Form (DataFax)
- Mother's Demographics Form (DataFax)
- Mother's Antiretroviral Medications Form (if required, DataFax)

Submit Maternal DataFax forms from Screening and Labor and Delivery and Infant Birth and Enrollment forms, and all accompanying DataFax forms to SCHARP after enrollment.

Complete Mother's Screening Outcome form and submit to SCHARP for all mothers screened and assigned a Participant ID, regardless of whether or not they were enrolled.

Infant's Follow-up Visit

2 and 5 weeks


Visit Code: 3.0 and 55.0


Participant ID:	Visit Date
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Notes:


- Non-randomized infants who are determined to be HIV-infected will be taken off of open-label NVP and will undergo all study procedures except adherence assessment and HIV testing for 3 months only. Referrals for any available care and treatment should be provided.
- Non-randomized infants who stop breastfeeding will be taken off of open-label NVP and will undergo all study procedures except adherence assessment for 3 months only.


_____ Confirm identity and verify Participant ID number.



_____ Record information on breastfeeding and open-label NVP initiation on the  **Infant's Breastfeeding and Open-Label NVP Dosing Initiation Form** (2-week visit only or when open-label NVP dosing is initiated).



_____ Assess medical history and complete study source documents; record on  **Infant's Follow-up Visit Form**.




_____ Perform physical exam and complete study source documents; record on  **Infant'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  **Infant's Adverse Experience Log**.

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form and fax to RCC within 3 business days of site awareness**.

_____ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

_____ Document all concomitant medications in study source documents. Complete  **Infant's Concomitant Medications Form** (for antibiotics, antifungals, and antimicrobials) and  **Infant's Antiretroviral Medication Log** (for infected infants on antiretroviral therapy) if required.

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




- ▶ CBC with differential
- ▶ ALT
- ▶ HIV-1 DNA PCR or Quantitative RNA PCR testing; if positive, repeat test on a second sample drawn on a different day on or before the participant's next scheduled visit for confirmation
- ▶ CD4+ cell count (*for infants with confirmed HIV infection only at 2 weeks only*)
- ▶ Plasma storage for NVP resistance, HIV-1 RNA PCR and NVP concentrations
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage

Infant's Follow-up Visit
2 and 5 weeks
Visit Code: 3.0 and 55.0

Participant ID:	Visit Date
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Dispense open-label NVP if indicated.

Note: Procedures for pharmacist dispensing to clinic staff or directly to the participant at follow-up visits are included in the SSP in Section 8.5-8.5.3. Please modify the steps below according to your sites procedures.

- ___ Determine if infant is eligible for continued open-label NVP dosing (See Protocol section 6.2.2).
- ___ If open-label NVP is permanently discontinued, complete the  **Infant's Open-Label NVP Permanent Study Drug Discontinuation Form.**
- ___ Collect the open-label NVP bottles previously dispensed and give to the pharmacist. Do not measure or record the amount of open-label NVP returned.
- ___ If infant is still on open-label NVP, collect open-label NVP dosing and adherence information; record on  **Infant's Study Drug Dosing Form** (if the Infant's Open-Label NVP Permanent Study Drug Discontinuation form has been previously submitted, this form is not completed).
- ___ Dispenser obtains 30 mL bottle(s) of open-label NVP, oral syringes, and Dispensing Slip.
- ___ Dispenser verifies that the dose to be administered is accurate, that the syringes are marked correctly, and that the information on the labels has been completed.
- ___ Dispenser reviews instructions for dispensing open-label NVP, counsels the mother regarding adherence, and provides her with the supply of open-label NVP and oral syringes in a re-sealable plastic bag.
- ___ The  **Dispensing Slip** should be returned on the day of dispensation, but it can be returned for up to five days after dispensation to the mother. It will be kept in the pharmacy.
- ___ Document any other procedures performed in study source documents.
- ___ Complete and/or review required data collection forms.
 - Infant's Breastfeeding and Open-Label NVP Dosing Initiation Form (2 week visit only or when open-label NVP is initiated)
 - Infant's Study Drug Dosing Form (DataFax)
 - Infant's Open-label NVP Permanent Study Drug Discontinuation Form (if study drug is permanently discontinued, DataFax)
 - Dispensing Slip (if required, non-DataFax)
 - Infant's Breastfeeding Log (if required, DataFax)
 - Infant's Laboratory Results Form (DataFax)
 - Specimen Tracking Sheet (non-DataFax)
 - Infant's Concomitant Medications Form (if required, DataFax)

- Infant's Antiretroviral Medication Log (if required, DataFax)
- Infant's Adverse Experience Log (if required, DataFax)
- DAIDS EAE Form (if required, non DataFax)

Infant's Follow-up Visit
6 weeks
Visit Code: 5.0


Participant ID:	Visit Date
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Notes:

- Infants who are determined to be HIV-infected will not be eligible to be randomized or to receive any study drug, but will still undergo all study procedures through 3 months only, except adherence assessment and HIV testing. Referrals for any available care and treatment should be provided.
- Infants who have stopped breastfeeding by this visit will not be eligible for randomization, but will still undergo all study procedures through 3 months, except adherence assessment.
- Open-label NVP will be dispensed through 42 days of age. The target day for randomization is Day 42 (6 weeks) however; eligible infants can be randomized from 6 weeks (42 days) through 8 weeks (56 days) of life. For steps for randomization please see Randomization Checklist.


___ Confirm identity and verify Participant ID number.


___ Confirm Mother's intent/ability to breastfeed; record on study source documents.



___ Assess medical history and complete study source documents; record on  **Infant's Follow-up Visit Form.**



___ Perform physical exam and complete study source documents; record on  **Infant's Follow-up Visit Form.**

___ Complete the  **Infant's Permanent Open-label Nevirapine Discontinuation Form**, if not completed at a previous visit.

___ 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, complete  **DAIDS EAE Form and fax to RCC within 3 business days of site awareness.**

___ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

___ Document all concomitant medications in study source documents. Complete  **Infant's Concomitant Medications Form** (for antibiotics, antifungals, and antimicrobials) and  **Infant's Antiretroviral Medication Log** (for infected infants on antiretroviral therapy) if required.

Infant's Follow-up Visit
6 weeks
Visit Code: 5.0

Participant ID:	Visit Date
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_____ Collect and process blood for the following purposes and complete  **Infant's Laboratory Results Form** and  **Specimen Tracking Sheet** (report results on  **Infant's Laboratory Results Form** when available).

- ▶ CBC with differential
- ▶ ALT
- ▶ CD4+ cell count (for infants with confirmed HIV infection only)
- ▶ Plasma storage for NVP resistance, HIV-1 RNA PCR and NVP concentrations
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage

_____ Complete and review required data collection forms.

- Infant's Follow-up Visit Form (DataFax)
- Infant's Study Drug Dosing Form (DataFax)
- Infant's Open-label NVP Permanent Study Drug Discontinuation Form (if open-label NVP is permanently discontinued, DataFax)
- Dispensing Slip (if required, non-DataFax)
- Infant's Breastfeeding Log (if required, DataFax)
- Infant's Laboratory Results Form (DataFax)
- Specimen Tracking Sheet (non-DataFax)
- Infant's Concomitant Medications Form (if required, DataFax)
- Infant's Antiretroviral Medication Log (if required, DataFax)
- Infant's Adverse Experience Log (if required, DataFax)
- DAIDS EAE Form (if required, non DataFax)

Randomization Procedures

6 weeks (Day 42)

(42 to 56 days (6 to 8 weeks))

Participant ID:	Visit Date
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Note:

- Enrolled infants who have initiated the open-label NVP regimen are eligible for randomization
- Prior to randomization, the infant randomization criteria, specified in Section 4.3 of the protocol should be reviewed, confirmed, and documented in source documents.
 - ▶ If not eligible, record the reason not eligible onto the study source documents; no further assessments will be done on the mother and the infant will be followed for 3 months only.
 - ▶ If eligible, record details in study source documents; continue visit procedures and prepare for randomization.
- In the case of multiple birth, infants will be randomized only if both/all are eligible for randomization and will be randomized to the same study arm.

Randomizing and Dispensing of Randomization Packets

Note: Procedures for pharmacist dispensing to clinic staff or directly to the participant are included in the SSP in Sections 8.6 – 8.6.3. Please modify the steps below according to your site's procedures.

_____ Investigator of Record or designee reviews infant randomization criteria eligibility information and documents review in study source documents.

_____ Authorized clinician completes and signs the  **Study Drug Prescription**.


_____ Investigator or designee (kit assigner) assigns infant(s) a kit number by strata by recording infant participant ID number on the  **Protocol Randomization Log**.

_____ The corresponding randomization packet is obtained from the clinic incubator or pharmacy.

_____ Kit assigner or pharmacist adds the Participant ID number to the randomization packet labels and study drug bottle.

_____ Dispenser removes the first pre-labeled 30 mL bottle of study drug and oral syringes from the randomization packet and verifies that the dose to be administered is accurate and that the syringes are marked correctly.

_____ Dispenser confirms that the information on the randomization packet label and study drug bottle label has been completed correctly before tearing off the removable portions of the study drug bottle label and placing one label on the source document (one label will also be added to the CRF).

_____ Dispenser adds the date of dispensation to the randomization packet label and attaches the right portion onto the  **Dispensing Slip**. The dispenser will complete the Dispensing Slip by adding the infant participant ID number, date of dispensation, and his/her initials.

Randomization Procedures
6 weeks (Day 42)
(42 to 56 days (6 to 8 weeks))

Participant ID:	Visit Date
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_____ Dispenser reviews with mother how to dispense study syrup. If the infant was not dosed with the study drug in the clinic, the dispenser instructs the mother to record the date the first dose was given to the infant. The initial supply of study drug and oral syringes will be provided to the mother in a re-sealable plastic bag prior to discharge.

_____ The Dispensing Slip should be returned on the day of dispensation, but it can be returned for up to five days after dispensation to the mother. The Dispensing Slip and original Prescription are kept in the pharmacy. A copy of the Prescription is filed in the participant's clinical chart.

_____ Complete  **Infant Study Drug Dosing Form**

_____ Complete  **Protocol Randomization Log**

_____ Complete  **Infant Randomization Form**

_____ Complete and/or review required data collection forms.

- Study Drug Prescription (non-DataFax)
- Protocol Randomization Log (non-DataFax)
- Dispensing Slip (non-DataFax)
- Infant's Study Drug Dosing Form (DataFax)
- Infant Randomization Form (DataFax)

Infant's Follow-up Visit

8 weeks


Visit Code: 6.0


Participant ID:	Visit Date
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Notes:


- Randomized infants who are determined to be HIV-infected will be taken off of study drug and will undergo all study procedures for 18 months except adherence assessment and HIV testing. Referrals for any available care and treatment should be provided.
- Randomized infants who stop breastfeeding earlier than 6 months will be taken off of study drug and will undergo all study procedures for 18 months except adherence assessment.
- Mothers of randomized infants who withdraw from the study prior to the 18-month evaluation will be asked if they are willing to have procedures performed before they withdraw as outlined in Section 5.5.7.2 of the SSP prior to study withdrawal.


_____ Confirm identity and verify Participant ID number.



_____ Record information on study drug initiation on the  **Infant's Randomization Form** (*when study drug dosing is initiated*).



_____ Assess medical history and complete study source documents; record on  **Infant's Follow-up Visit Form**.




_____ Perform physical exam and complete study source documents; record on  **Infant'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  **Infant's Adverse Experience Log**.

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form** and fax to **RCC within 3 business days of site awareness**.

_____ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

_____ Document all concomitant medications in study source documents. Complete  **Infant's Concomitant Medications Form** (for antibiotics, antifungals, and antimicrobials) and  **Infant's Antiretroviral Medication Log** (for infected infants on antiretroviral therapy) if required.

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

- ▶ ALT

Infant's Follow-up Visit

8 weeks

Visit Code: 6.0

Participant ID:	Visit Date
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- ▶ Plasma storage for NVP resistance, HIV-1 RNA PCR and NVP concentrations
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage

Dispense study drug if indicated.

Note: Procedures for pharmacist dispensing to clinic staff or directly to the participant at follow-up visits are included in the SSP in Section 8.6-8.6.3. Please modify the steps below according to your sites procedures.

- _____ Determine if infant is eligible for continued study dosing (See Protocol section 6.2.3).
- _____ Collect the Study Product bottles previously dispensed and give to the pharmacist. Do not measure or record the amount of study product returned.
- _____ If infant has not been randomized and it is Day 56 or earlier, refer to the randomization procedures at week six. Complete the ✍ **Permanent Open-label Nevirapine Discontinuation Form**, if this has not already been done.
- _____ If infant is still receiving study drug, collect infant study drug dosing and adherence information; record on ✍ **Infant's Study Drug Dosing Form** (if the Permanent Study Drug Discontinuation Form has been previously submitted, this form is not completed).
- _____ Dispenser obtains infant packet for the infant kit number with the pre-labeled 30 mL bottle(s) of study drug, oral syringes, and Dispensing Slip. The pharmacist will complete all information on each part of the infant packet label and the study drug bottle label, with the exception of the date of dispensation.
- _____ Dispenser verifies that the dose to be administered is accurate, that the syringes are marked correctly, and that the information on the labels has been completed.
- _____ The removable portions of the study drug bottle labels will be torn off, and one label for each bottle will be placed on the source document (one label for each will also be added to the CRF).
- _____ Dispenser adds the date of dispensation to the infant packet label and attaches the right portion to the ✍ **Dispensing Slip**. The dispenser will complete the Dispensing Slip by adding the infant participant ID number, date of dispensation, and his/her initials.
- _____ Dispenser reviews instructions for dispensing study syrup, counsels the mother regarding adherence, and provides her with the supply of study drug and oral syringes in a re-sealable plastic bag.
- _____ The ✍ **Dispensing Slip** should be returned on the day of dispensation, but it can be returned for up to five days after dispensation to the mother. It will be kept in the pharmacy.

Infant's Follow-up Visit
8 weeks
Visit Code: 6.0

Participant ID:	Visit Date
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_____ Document any other procedures performed in study source documents.

_____ Complete and review required data collection forms.

- Infant's Follow-up Visit Form (DataFax)
- Infant Randomization Form (DataFax)(*when study drug is initiated*)
- Infant's Study Drug Dosing Form (DataFax)
- Dispensing Slip (if required, non-DataFax)
- Infant's Breastfeeding Log (if required, DataFax)
- Infant's Laboratory Results Form (DataFax)
- Specimen Tracking Sheet (non-DataFax)
- Infant's Concomitant Medications Form (if required, DataFax)
- Infant's Antiretroviral Medication Log (if required, DataFax)
- Infant's Adverse Experience Log (if required, DataFax)
- DAIDS EAE Form (if required, non DataFax)

Infant's Follow-up Visit

3 Month Visit


Visit Code: 7.0


Participant ID:	Visit Date
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Notes:

- Randomized infants who are determined to be HIV-infected will be taken off of study drug and will undergo all study procedures except adherence assessment and HIV testing. Referrals for any available care and treatment should be provided.
- Randomized infants who stop breastfeeding earlier than 6 months will be taken off of study drug and will undergo all study procedures except adherence assessment.
- Mothers of randomized infants who withdraw from the study prior to the 18-month evaluation will be asked if they are willing to have procedures performed before they withdraw as outlined in Section 5.5.7.2 of the SSP prior to study withdrawal



_____ Confirm identity and verify Participant ID number.



_____ Assess medical history and complete study source documents forms; record on  **Infant's Follow-up Visit Form.**




_____ Perform physical exam and complete study source documents forms; record on  **Infant'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  **Infant's Adverse Experience Log.**

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form and fax within 3 business days of site awareness to RCC.**

_____ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

_____ Document all concomitant medications in study source documents. Complete  **Infant's Concomitant Medications Form** (for antibiotics, antifungals, and antimicrobials) and  **Infant's Antiretroviral Medication Log** (for infected infants on antiretroviral therapy) if required.

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

- ▶ CBC with differential
- ▶ ALT
- ▶ HIV-1 DNA PCR or Quantitative RNA PCR testing ; if positive, repeat test on a second sample drawn on a different day on or before the participant's next scheduled visit for confirmation
- ▶ Plasma storage for NVP resistance, HIV-1 RNA PCR and NVP concentrations
- ▶ CD4+ cell count (for infants with confirmed HIV infection only)
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage





Infant's Follow-up Visit 3 Month Visit

Visit Code: 7.0

Participant ID:	Visit Date
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Dispensing of Infant Packets if infant is receiving study drug or received study drug at the last visit:

Note: Procedures for pharmacist dispensing to clinic staff or directly to the participant are included in the SSP in Section 8.6-8.6.3. Please modify the steps below according to your sites procedures.

- _____ Determine if infant is eligible for continued dosing (See Protocol section 6.2.3).
- _____ If the study drug is permanently discontinued, complete the  **Infant's Permanent Study Drug Discontinuation Form**.
- _____ Collect study drug bottles previously dispensed and give to the pharmacist. Do not measure or record the amount of study drug returned.
- _____ If infant is still on study drug, collect infant study drug dosing and adherence information; record on  **Infant's Study Drug Dosing Form** (if the Permanent Study Drug Discontinuation form has been previously submitted, this form is not completed).
- _____ Dispenser obtains infant packet for the infant kit number with the pre-labeled 30 mL bottle(s) of study drug, oral syringes, and Dispensing Slip. The pharmacist will complete all information on each part of the infant packet label and the study drug bottle label, with the exception of the date of dispensation.
- _____ Dispenser verifies that the dose to be administered is accurate, that the syringes are marked correctly, and that the information on the labels has been completed.
- _____ The removable portions of the study drug bottle labels will be torn off, and one label for each bottle will be placed on the source document (one label for each will also be added to the CRF).
- _____ Dispenser adds the date of dispensation to the infant packet label and attaches the right portion to the  **Dispensing Slip**. The dispenser will complete the Dispensing Slip by adding the infant participant ID number, date of dispensation, and his/her initials.
- _____ Dispenser reviews instructions for dispensing study syrup, counsels the mother regarding adherence, and provides her with the supply of study drug and oral syringes in a re-sealable plastic bag.
- _____ The  **Dispensing Slip** should be returned on the day of dispensation, but it can be returned for up to five days after dispensation to the mother. It will be kept in the pharmacy.
- _____ Document any other procedures performed in study source documents.

- _____ Complete and review required data collection forms.
 - Infant's Follow-up Visit Form (DataFax)
 - Infant's Study Drug Dosing Form (DataFax)
 - Infant's Permanent Study Drug Discontinuation Form (if not completed previously, DataFax)
 - Infant's Breastfeeding Log (if required, DataFax)

- Infant's Laboratory Results Form (DataFax)
- Specimen Tracking Sheet (non-DataFax)
- Infant's Concomitant Medications Form (if required, DataFax)
- Infant's Adverse Experience Log (if required, DataFax)
- Infant's Antiretroviral Medication Log (if required, DataFax)
- DAIDS EAE Form (if required, non DataFax)

Infant's Follow-up Visit

4 and 5 months


Visit Code: 8.0 and 9.0


Participant ID:	Visit Date
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Notes:


- Infants who are determined to be HIV-infected will be taken off of study drug and will undergo all study procedures except adherence assessment and HIV testing. Referrals for any available care and treatment should be provided.
- Infants who stop breastfeeding earlier than 6 months will be taken off of study drug and will undergo all study procedures except adherence assessment.
- Mothers of infants who withdraw from the study prior to the 18-month evaluation will be asked if they are willing to have procedures performed before they withdraw as outlined in Section 5.5.7.2 of the SSP prior to study withdrawal



_____ Confirm identity and verify Participant ID number.



_____ Assess medical history and complete study source documents; record on  **Infant's Follow-up Visit Form.**

_____ Perform physical exam and complete study source documents; record on  **Infant'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  **Infant's Adverse Experience Log.**

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form and fax to RCC within 3 business days of site awareness.**


_____ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

_____ Document all concomitant medications in study source documents. Complete  **Infant's Concomitant Medications Form** (for antibiotics, antifungals, and antimicrobials) and  **Infant's Antiretroviral Medication Log** (for infected infants on antiretroviral therapy) if required.

Dispensing of Infant Packets if infant is receiving study drug or received study drug at the last visit:




Note: Procedures for pharmacist dispensing to clinic staff or directly to the participant are included in the SSP in Section 8.6-8.6.3. Please modify the steps below according to your sites procedures.

_____ Determine if infant is eligible for continued dosing (See Protocol section 6.2.3).

_____ If the study drug is permanently discontinued, complete the  **Infant's Permanent Study Drug Discontinuation Form.**

Infant's Follow-up Visit
4 and 5 months
Visit Code: 8.0 and 9.0

Participant ID:	Visit Date
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- _____ Collect study drug bottles previously dispensed and give to the pharmacist. Do not measure or record the amount of study drug returned.
- _____ If infant is still on study drug, collect infant study drug dosing and adherence information; record on  **Infant's Study Drug Dosing Form** (if the Permanent Study Drug Discontinuation form has been previously submitted, this form is not completed).
- _____ Dispenser obtains infant packet for the infant kit number with the pre-labeled 30 mL bottle(s) of study drug, oral syringes, and Dispensing Slip. The pharmacist will complete all information on each part of the infant packet label and the study drug bottle label, with the exception of the date of dispensation.
- _____ Dispenser verifies that the dose to be administered is accurate, that the syringes are marked correctly, and that the information on the labels has been completed.
- _____ The removable portions of the study drug bottle labels will be torn off, and one label for each bottle will be placed on the source document (one label for each will also be added to the CRF).
- _____ Dispenser adds the date of dispensation to the infant packet label and attaches the right portion to the  **Dispensing Slip**. The dispenser will complete the Dispensing Slip by adding the infant participant ID number, date of dispensation, and his/her initials.
- _____ Dispenser reviews instructions for dispensing study syrup, counsels the mother regarding adherence, and provides her with the supply of study drug and oral syringes in a re-sealable plastic bag.
- _____ The  **Dispensing Slip** should be returned on the day of dispensation, but it can be returned for up to five days after dispensation to the mother. It will be kept in the pharmacy.
- _____ Document any other procedures performed in study source documents.
- _____ Complete and review required data collection forms.
 - Infant's Follow-up Visit Form (DataFax)
 - Infant's Study Drug Dosing Form (DataFax)
 - Infant's Permanent Study Drug Discontinuation Form (if study drug is permanently discontinued, DataFax)
 - Dispensing Slip (if required, non-DataFax)
 - Infant's Breastfeeding Log (if required, DataFax)
 - Infant's Concomitant Medications Form (if required, DataFax)
 - Infant's Antiretroviral Medication Log (if required, DataFax)
 - Infant's Adverse Experience Log (if required, DataFax)
 - DAIDS EAE Form (if required, non DataFax)

Infant's Follow-up Visit

6 Month Visit


Visit Code: 10.0


Participant ID:	Visit Date
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Notes:

- Infants who are determined to be HIV-infected will be taken off of study drug and will undergo all study procedures except adherence assessment and HIV testing. Referrals for any available care and treatment should be provided.
- Infants who stop breastfeeding earlier than 6 months will be taken off of study drug and will undergo all study procedures except adherence assessment.
- Mothers of infants who withdraw from the study prior to the 18-month evaluation will be asked if they are willing to have procedures performed before they withdraw as outlined in Section 5.5.7.2 of the SSP prior to study withdrawal



_____ Confirm identity and verify Participant ID number.



_____ Assess medical history and complete study source documents forms; record on  **Infant's Follow-up Visit Form.**




_____ Perform physical exam and complete study source documents forms; record on  **Infant'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  **Infant's Adverse Experience Log.**

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form and fax within 3 business days of site awareness to RCC.**

_____ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

_____ Document all concomitant medications in study source documents. Complete  **Infant's Concomitant Medications Form** (for antibiotics, antifungals, and antimicrobials) and  **Infant's Antiretroviral Medication Log** (for infected infants on antiretroviral therapy) if required.



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

- ▶ CBC with differential
- ▶ ALT
- ▶ HIV-1 DNA PCR or Quantitative RNA PCR testing ; if positive, repeat test on a second sample drawn on a different day on or before the participant's next scheduled visit for confirmation
- ▶ Plasma storage for NVP resistance, HIV-1 RNA PCR and NVP concentrations
- ▶ CD4+ cell count (for infants with confirmed HIV infection only)
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage

Infant's Follow-up Visit
6 Month Visit
Visit Code: 10.0

Participant ID:	Visit Date
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If infant received study drug at the last visit:

- _____ Complete the  **Infant's Permanent Study Drug Discontinuation Form.**
- _____ Collect study drug bottles previously dispensed and give to the pharmacist. Do not measure or record the amount of study drug returned.
- _____ If infant is still on study drug, collect infant study drug dosing and adherence information; record on  **Infant's Study Drug Dosing Form** (if the Permanent Study Drug Discontinuation form has been previously submitted, this form is not completed).
- _____ Document any other procedures performed in study source documents
- _____ Complete and review required data collection forms.
 - Infant's Follow-up Visit Form (DataFax)
 - Infant's Study Drug Dosing Form (DataFax)
 - Infant's Permanent Study Drug Discontinuation Form (if not completed previously, DataFax)
 - Infant's Breastfeeding Log (if required, DataFax)
 - Infant's Laboratory Results Form (DataFax)
 - Specimen Tracking Sheet (non-DataFax)
 - Infant's Concomitant Medications Form (if required, DataFax)
 - Infant's Adverse Experience Log (if required, DataFax)
 - Infant's Antiretroviral Medication Log (if required, DataFax)
 - DAIDS EAE Form (if required, non DataFax)


**Infant's Follow-up Visit
9 Month Visit
Visit Code: 11.0**


Participant ID:	Visit Date
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Notes:

- Infants who are determined to be HIV-infected will undergo all study procedures except HIV testing. Referrals for any available care and treatment should be provided.
- Mothers of infants who withdraw from the study prior to the 18-month evaluation will be asked if they are willing to have procedures performed before they withdraw as outlined in Section 5.5.7.2 of the SSP prior to study withdrawal



_____ Confirm identity and verify Participant ID number.



_____ Assess medical history, perform physical exam and complete study source documents forms; record on  **Infant's Follow-up Visit Form.**




_____ If a non-serious adverse event that occurred before 8 months of age is reported retrospectively, record detailed information in study source documents and complete the  **Infant's Adverse Experience Log.** For non-serious events that occur after 8 months of age, including lab abnormalities, only record information in study source documents.

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

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form and fax within 3 business days of site awareness to RCC.**

_____ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

_____ Document all concomitant medications in study source documents. Complete  **Infant's Concomitant Medications Form** (for antibiotics, antifungals, and antimicrobials taken through 8 months of life) and fax form to the SDMC. Complete  **Infant's Antiretroviral Medication Log** if required (for infected infants on antiretroviral therapy).

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

- ▶ HIV-1 DNA PCR or Quantitative RNA PCR testing ; if positive, repeat test on a second sample drawn on a different day on or before the participant's next scheduled visit for confirmation
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage

_____ Document any other procedures performed in study source records.

**Infant's Follow-up Visit
9 Month Visit
Visit Code: 11.0**

Participant ID:	Visit Date
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_____ Complete and review required data collection forms.

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


Infant's Follow-up Visit 12 Month Visit Visit Code: 12.0


Participant ID:	Visit Date
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Notes:



- Infants who are determined to be HIV-infected will undergo all study procedures except HIV testing. Referrals for any available care and treatment should be provided.
- Mothers of infants who withdraw from the study prior to the 18-month evaluation will be asked if they are willing to have procedures performed before they withdraw as outlined in Section 5.5.7.2 of the SSP prior to study withdrawal


_____ Confirm identity and verify Participant ID number.




_____ Assess medical history, perform physical exam, and complete study source documents; record on  **Infant'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  **Infant's Adverse Experience Log** for SAEs and EAEs only.

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form and fax within 3 business days of site awareness to RCC.**

_____ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

_____ Document all concomitant medications in study source documents. Complete  **Infant's Antiretroviral Medication Log** (for infected infants on antiretroviral therapy) if required.

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

- ▶ CBC with differential
- ▶ HIV-1 DNA PCR or Quantitative RNA PCR testing; if positive, repeat test on a second sample drawn on a different day on or before the participant's next scheduled visit for confirmation
- ▶ Plasma storage for NVP resistance, HIV-1 RNA PCR and NVP concentrations
- ▶ CD4+ cell count (*for infants with confirmed HIV infection only*)
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage

_____ Document any other procedures performed in study source documents.

_____ Complete and review required data collection forms.

- Infant's Follow-up Visit Form (DataFax)
- Infant's Breastfeeding Log (if required, DataFax)
- Infant's Laboratory Results Form (DataFax)
- Specimen Tracking Sheet (non-DataFax)
- Infant's Adverse Experience Log (if required, DataFax)
- Infant's Antiretroviral Medication Log (if required, DataFax)
- DAIDS EAE Form (if required, non DataFax)


Infant's Follow-up Visit 18 Month Visit Visit Code: 13.0


Participant ID:	Visit Date
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Note:

- Randomized infants who are determined to be HIV-infected will undergo all study procedures except HIV testing. Referrals for any available care and treatment should be provided.



_____ Confirm identity and verify Participant ID number.




_____ Assess medical history, perform physical exam, and complete study source documents; record on  **Infant's Follow-up Visit Form.**

_____ Document all concomitant medications in study source documents. Complete  **Infant's Antiretroviral Medication Log** if required (for infected infants on antiretroviral therapy).

_____ 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 SAEs and EAEs only.

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form and fax within 3 business days of site awareness to RCC**

_____ Collect infant feeding practices information; record on  **Infant's Follow-up Visit Form** and  **Infant's Breastfeeding Log**, if needed.

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

- ▶ HIV EIA or rapid test; if positive, confirm results on a second sample drawn on a different day for confirmation
- ▶ Plasma storage for NVP resistance, HIV-1 RNA PCR and NVP concentrations
- ▶ CBC with differential (*for infants with confirmed HIV infection only*)
- ▶ CD4+ cell count (*for infants with confirmed HIV infection only*)
- ▶ Cell Pellet Storage
- ▶ Dried Blood Spot Storage

_____ Document any other procedures performed in study source documents and complete and review required data collection forms.

- Infant's Follow-up Visit Form (DataFax)
- Infant's Breastfeeding Log (if required, DataFax)
- Infant's Laboratory Results Form (DataFax)
- Specimen Tracking Sheet (non-DataFax)
- Infant's Antiretroviral Medication Log (if required DataFax)
- Infant's Adverse Experience Log (if required, DataFax)
- DAIDS EAE Form (if required, non DataFax)
- Infant's End of Study Inventory (DataFax)
- Infant's Termination Form (DataFax)

Mother's Follow-up Visit
2 and 6 weeks, 3, 6, and 12 months
Visit Code: 3.0, 5.0, 7.0, 10.0, 12.0

Participant ID:	Visit Date
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Note:


- Mothers of enrolled infants who are not eligible for randomization will have no further assessments done and will be done terminated.
- Mothers of randomized infants who withdraw from the study prior to the 18-month evaluation will be asked if they are willing to have procedures performed before they withdraw as outlined in Section 5.5.7.2 of the SSP prior to study withdrawal.


_____ Confirm identity and verify Participant ID number.


_____ Review/update participant contact and locator information.




_____ Provide infant feeding counseling; record on study source documents. *Note: Counseling should occur after the infant feeding practices assessment has been completed as part of the infant's follow-up visit.*

_____ Assess medical history and complete study source documents; record relevant information on  **Mother's Follow-up Visit Form.**

_____ Document any antiretroviral medication being taken in source documents; update  **Mother's Antiretroviral Medication Log** (if required).

_____ Perform physical exam and complete study source documents; record relevant information on  **Mother's Follow-up Visit Form.**

_____ Complete  **Mother's WHO Clinical Stage Assessment Form** at the 6 week and 6 and 12 month visits using information obtained from the medical history, physical exam, and laboratory test results from the current and past visits.

_____ Collect and process samples for the following purposes and complete  **Mother's Laboratory Results Form** and  **Specimen Tracking Sheet** (report results on  **Mother's Laboratory Results Form** when available).

- ▶ CBC with differential
- ▶ CD4+ cell count
- ▶ Plasma storage for HIV-1 RNA PCR
- ▶ Plasma storage for NVP resistance testing
- ▶ Breast milk storage (as long as the infant is breastfeeding)
- ▶ Dried Blood Spot Storage






_____ Document any other procedures performed in study source documents.

_____ Complete and review required data collection forms.

- Mother's Follow-up Visit Form (DataFax)
- Mother's Laboratory Results Form (DataFax)
- Specimen Tracking Sheet (non-DataFax)
- Mother's Antiretroviral Medication Log (if required, DataFax)
- Mother's WHO Clinical Stage Assessment Form (6 weeks, 6 and 12 months only, DataFax)

Mother's Follow-up Visit
18 month Visit
Visit Code: 13.0

Participant ID:	Visit Date
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- ___ Confirm identity and verify Participant ID number.
- ___ Provide infant feeding counseling; record on study source documents. *Note: Counseling should occur after the infant feeding practices assessment has been completed as part of the infant's follow-up visit.*
- ___ Assess medical history and complete study source documents; record relevant information on  **Mother's Follow-up Visit Form.**
- ___ Document any antiretroviral medication being taken in study source documents; update  **Mother's Antiretroviral Medication Log** (if required).
- ___ Perform physical exam and complete study source documents; record relevant information on  **Mother's Follow-up Visit Form.**
- ___ Collect and process samples for the following purposes and complete  **Mother's Laboratory Results Form** and  **Specimen Tracking Sheet.**
 - ▶ Plasma storage for NVP resistance testing
 - ▶ Dried Blood Spot Storage
- ___ Document any other procedures performed in study source documents
- ___ Complete and review required data collection forms.
 - Mother's Follow-up Visit Form (DataFax)
 - Mother's Laboratory Results Form (DataFax)
 - Specimen Tracking Sheet (non-DataFax)
 - Mother's Antiretroviral Medication Log (if required, DataFax)
 - Mother's End of Study Inventory (DataFax)
 - Mother's Termination Form (DataFax)

Infant's Interim Visit


Visit Code: 3.X – 13.X

Participant ID:	Visit Date
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
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
- Interim visits may occur at any time during the study in addition to the regularly scheduled visits.

_____ Confirm identity and verify Participant ID number.

_____ Complete  **Infant's Interim Visit Form** only if another DataFax form is also completed for this visit.

_____ Collect medical history, perform physical exam, and complete study source documents, if needed.

_____ For all serious events or events that meet the criteria for expedited reporting, record detailed information in study source documents and complete the  **Infant's Adverse Experience Log**. For all non-serious events, record detailed information in study source documents, but only complete the  **Infant's Adverse Experience Log** through 8 months of age.

_____ For all events that meet the criteria for expedited reporting, complete  **DAIDS EAE Form and fax within 3 days of site awareness to RCC**.

_____ If clinical laboratory tests are done, record results in clinical chart.

_____ If confirmatory HIV testing is done, complete  **Infant's Laboratory Results Form**.

_____ Update  **Infant's Concomitant Medications Form** (if required).

_____ Update  **Infant's Antiretroviral Medication Log** (if required).

_____ If open-label NVP (prior to 6 weeks of age) or study drug is needed, dispense open-label NVP or study drug according to procedures on Infant Follow-up Checklist.

_____ Document any other procedures performed in study source documents.

_____ Complete and review required data collection forms, if applicable.

- Infant's Interim Visit Form (if required, DataFax)
- Infant's Adverse Experience Log (if required, DataFax)
- Infant's Concomitant Medications Form (if required, DataFax)
- Infant's Antiretroviral Medication Log (if required, DataFax)
- DAIDS EAE Form (non-DataFax)
- Infant's Open-Label NVP Permanent Study Drug Discontinuation Form (whenever open-label NVP is ever permanently discontinued, DataFax)
- Infant's Permanent Study Drug Discontinuation Form (*whenever study drug is permanently discontinued*, DataFax)
- Dispensing Slip (if required, non-DataFax)

Mother's Interim Visit

Visit Code: 3.X – 13.X

Participant ID:	Visit Date
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Notes:

- Interim visits may occur at any time during the study in addition to the regularly scheduled visits.
- No DataFax forms are required for mother's interim visits, however all interim visits, and the results of all interim laboratory tests, must be documented in study source documents.

____ Confirm identity and verify Participant ID number.

____ Collect medical history and complete study source documents forms, if needed.

____ Complete physical exam and complete study source documents forms, if needed.

____ Document any other procedures performed in study source documents.

____ Complete and review required data collection forms, if applicable.

Signed and dated study source document* (non-DataFax)

*Study source document is at a minimum is required for interim visits