Section 3. Documentation Requirements

Study site staff are responsible for the collection, storage, timely submission, and quality assurance of study data collected at their site. In addition, the site is responsible for maintaining all administrative and regulatory documentation critical to the conduct of the study, known as essential documents. This section contains a listing of required essential documents that each site must maintain and keep current throughout the study, as well as procedures for establishing adequate and accurate participant research study records.

3.1 Essential Documents

The DAIDS SOP for Essential Documents in Appendix A specifies the administrative and regulatory documents that HPTN study sites must maintain for DAIDS-sponsored studies, including HPTN 046. When required documents are modified or updated, the original and modified/updated versions must be maintained. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location. However, documents must be stored in an organized manner for easy access and review.

Table 3-1 at the end of this section presents a suggested filing structure for HPTN 046 Essential Documents. The suggested structure incorporates guidance received from the DAIDS Prevention Science Branch Clinical Operations Group and the DAIDS Clinical Site Monitoring Group (PPD). Study sites are not required to adopt the suggested structure, but all sites are encouraged to consider the suggested structure when developing their filing approach for HPTN 046. All sites also are encouraged to establish a standard operating procedure (SOP) to document their filing approach. Further clarifications of the suggested filing structure are as follows.

- Essential documents may be stored in files or in binders. The files/binders listed below may be further divided, consolidated, or otherwise reorganized if desired.
- It is recommended that a contents sheet be inserted as the first page(s) of each file/binder. Within each file/binder, it is recommended that documents be filed in ascending date order.
- Open-label NVP and Study Drug related essential documents (not listed here) will be filed in the study pharmacies. A listing of essential documents to be maintained in the pharmacies is provided in Section 8.
- Certain lab related essential documents will be stored with the other essential documents listed here to facilitate routine inspection of these documents by study monitors. Other lab related essential documents (e.g., lab SOPs not listed here) may be filed in the lab.

The suggested filing structure assumes that:

- Individual HPTN 046 participant study records, including signed and dated informed consent forms, will be stored apart in the study clinic or data management area, not necessarily with the other essential documents listed here.
- The HPTN 046 Screening and Enrollment Log, Participant Identification (PTID) Number-Name Link Log, and Clinic Randomization Logs will be stored in the study clinic(s) or data management area, not necessarily with the other essential documents listed here.

- Site- and study-specific quality management documentation will be maintained separately from study-specific essential documents.

3.2 Participant Research Records

US regulations and guidelines for Good Clinical Practices (GCP) require study site staff to maintain adequate and accurate participant "case history records" containing all information pertinent to the study for each HPTN study participant. All study data should be collected in accordance with applicable specifications of this manual and the DAIDS SOP for Source Documentation included in Appendix B.

3.2.1 Participant Research Record Content

Mother and infant research records should contain all of the following elements:

- basic participant identifiers
- documentation that mothers provided written informed consent to participate in the study prior to the conduct of any study procedures
- documentation that the mother provided written informed consent to store study specimens for future testing, if applicable
- documentation that mothers and their infants met the study's enrollment eligibility criteria
- documentation that the infant met the randomization criteria
- a record of the infant's random assignment
- a record of the participant's exposure to open-label NVP and study drug
- a record of all contacts and attempted contacts with the participants, including all clinic visits, off-site contacts (e.g., at home), and all verbal and written contacts
- a record of all procedures performed by study staff during the study
- complete source documents; e.g., notes recorded by attending nurse or record of any visits to referral physicians, if available (certified copy of notes)
- a record of any AEs and SAEs including onset and resolution dates, severity grading and relationship to study product
- study-related information on the participant's condition before, during, and after the study, including:
  - subjective data obtained directly from the participant (e.g., interview responses)
  - objective data ascertained by study staff (e.g., exam and lab findings)
  - objective data obtained from non-study sources (e.g., medical records)

In addition to the above, the DAIDS SOP for Source Documentation requires that all protocol departures/deviations/violations be documented in participant's study records, along with reasons for the departures and attempts to prevent or correct the departures, if applicable.

3.2.2 Concept of Source Documentation

The ICH guidance for GCP defines source data and source documentation as follows:

The term "source data" refers to all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

The term "source documents" refers to original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiche, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the trial).

Source documents are commonly referred to as the documents —paper-based or electronic — upon which source data are first recorded. HPTN study sites must adhere to the standards of source documentation specified in the DAIDS SOP for Source Documentation in Appendix B. This SOP contains both requirements and recommendations. Study sites must comply with all requirements and are advised, but not required, to comply with all recommendations. Source documentation includes original documents and certified copies that include documentation pertaining to a subject while on study.

For each HPTN study, participant case history records typically will consist of some or all of the following:

- narrative chart notes
- visit checklists or flow sheets
- laboratory reports
- medical records or clinic charts
- DataFax case report forms
- randomization log or other documentation (when applicable)
- investigational product dispensing and accountability records (when applicable)
- other source documents and non-DataFax study forms/questionnaires

As a condition for study activation, each site must establish an SOP for source documentation that specifies the use of these documents as source documents. Study staff must follow the specifications of this SOP consistently for all study participants throughout the study. It is the responsibility of the study site to determine the most appropriate source document for each required case history element listed in Section 3.2.1. Table 3-2 at the end of this section provides example source documents for each case history element for this study. Each site must complete a site-specific version of this table. In the event that study staff are not able to record source data directly onto forms designated as source documents, the following procedures should be undertaken:

- Record the data onto an alternative source document

- enter the alternative source document into the participant's study chart
- transcribe the data from the alternative source document onto the appropriate CRF
- enter a chart note stating the reason why an alternative source document was used.

Supplemental information on the use of chart notes and DataFax and non-DataFax forms as source documents is provided below.

3.2.3 Document Organization

Study staff must make every effort to keep all research records – individual participant records as well as logs and documents pertaining to all participants – confidential and secure. All records should be securely stored in an area with access limited to authorized staff only.

All study-specific documents that are transmitted to an off-site location, including DataFax case report forms and EAE Report Forms, and all biological specimens processed in any way by non-study staff or transferred to an off-site location must be identified only by the participant's PTID number to maintain confidentiality. Inclusion of more than one identifier on other study records that are accessible only to authorized study staff is not prohibited by DAIDS; however, such records must be stored securely with limited access.

Study records must be stored in the same manner for all participants. Study records that contain participant names or other personal identifiers, such as locator forms and informed consent forms, should generally be stored separately from study records identified by PTID number. Regardless of whether the participant identifier on a particular document is the participant's name or PTID number, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated or altered on copies of original source documents. For example, if medical records obtained from a non-study medical provider bear the participant name, the original document must remain unaltered and should be stored with other study documents bearing the participant's name. A copy of the document could be added to the participant's chart, with the participant's name obliterated from the copy and his/her PTID number entered onto the document. Likewise, if supporting documentation for an Expedited Adverse Event (EAE) Report that is to be submitted to DAIDS, such as x-rays or lab reports, contains a participant's name, this should be obliterated on the copy transmitted off-site, but not on the original.

All local databases will be secured with password-protected access systems. Log books, appointment books, and any other listings that link PTID numbers to participant names or other personal identifiers should be stored securely in a location separate from records identified by either PTID number or name. These documents should never be left unattended or easily accessible to unauthorized individuals when in use.

It is strongly recommended that each site designate a single place where completed DataFax forms will be stored prior to transmission and a single place where transmitted forms will be stored prior to filing in participant charts. A similar system should be established for EAE Forms and other records (e.g., laboratory results forms) that are transmitted to off-site locations and then returned to the participant's file. As a condition for study activation, each study site must establish an SOP for data management. This SOP minimally should contain the following elements:

- Procedures for assigning PTID numbers, linking PTID numbers to participant names, and storing the name-number link log
- Procedures for establishing participant files/charts/notebooks
- During-visit participant chart and case report form review procedures
- Post-visit participant chart and case report form review procedures and timeframes
- Data transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted
- Procedures for resolving data queries sent from the SDMC
- Procedures for handling and filing field workers logs, worksheets, etc.
- Storage locations for blank case report forms
- Procedures for back-up of electronic study data
- Handling of participant study records for off-site contacts
- Confidentiality protections
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements
- QC/QA procedures related to the above (if not specified elsewhere)

3.2.4 Chart Notes

Chart notes may be used to document the following:

- Procedures performed that are not recorded on other source documents
- Pertinent data about the participant that are not recorded on other source documents
- Protocol departures/deviations/violations that are not otherwise captured on the protocol event form or other source documents

All chart notes or other tools used as source documentation must document the PTID number and/or name of the study participant to whom they pertain, the identity of the study staff member who entered information, and the date of the entry. Study sites are strongly encouraged to adopt a common format — such as the subjective-objective-assessment-plan (SOAP) format — for all chart notes, to help ensure adequacy and consistency of note content and maximize adherence to GCP standards. Further information and guidance on the SOAP format can be found in the HPTN Manual of Operations (MOP) available at: http://www.hptn.org . Alternative standardized formats are acceptable and may be adopted by study sites.

3.2.5 DataFax and Non-DataFax Forms Provided by the SDMC

Case Report Forms are designed for use with the DataFax data management system described in Section 12. The SDMC will provide these forms to each site taking part in the study. The SDMC may also provide some non-DataFax forms to each participating site. **No DataFax forms will be used as source documents in this study.**

3.3 Record Retention Requirements

All study-related regulatory and administrative documentation as well as participant research records related to each participant screened and/or enrolled in the study must be retained on-site throughout the study's period of performance and after the completion or termination of the trial.

Study records must be maintained for at least two years following the date of marketing approval of the study product for the indication in which it was studied. If no marketing application is filed, or if the application is not approved, records must be retained for two years after the US Food and Drug Administration is notified that the Investigational New Drug application for the product is discontinued.

The sponsor will provide further instructions for long-term storage of study records after the study is completed.

3.4 Product Dispensing and Accountability Records

The receipt, dispensing, and final disposition of all open-label NVP and study drug supplies used must be documented by designated study site staff in accordance with the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks*, as well as any supplemental instructions provided by DAIDS Pharmacy Affairs Branch (PAB), the study protocol, and/or Section 8 of this SSP Manual.

3.5 Protocol Deviation Reporting

The HPTN has developed a policy to cover the reporting of protocol deviations, defined as individual incidents or omissions in study conduct that result in:

- Significant added risk to the participant
- Non-adherence to significant protocol requirements
- Significant non-adherence to the International Conference on Harmonization E6: Guideline for Good Clinical Practice

Examples of protocol deviations that require formal documentation are as follows:

- Enrolling an ineligible participant
- Not obtaining informed consent prior to performing protocol-specified procedures
- Deviating from study randomization procedures
- Not completing significant protocol-specified procedures or allowing a pattern of non-compliance (*Note: Participant non-compliance with the study protocol, including study treatment specifications, is not considered a reportable protocol event.)*
- Breaching participant confidentiality
- Dispensing a larger dose of open-label NVP or study drug than specified for an infant's age
- Failing to stop open-label NVP or study drug in a infant when indicated

Protocol deviations may be identified by site staff or representatives from the CORE, SDMC, DAIDS, or the Network Lab. Site staff should consult with the Site Queries Group (046SiteQueries@hptn.org) if they are unsure whether an occurrence should be reported as a protocol deviation.

Protocol Deviation Forms must be completed with the following information:

- Occurrence date *(Note: If the deviation occurred over a period of time, the period between when the event started and ended should be specified.)*
- Awareness date on site
- Report date
- PTID of participants involved/affected *(Note: If more than one participant is involved in the deviation, the PTIDs for all participants can be included on one event form. If the deviation does not involve specific participant(s), this item will be left blank.)*
- Brief Summary of deviation (description and location of occurrence if relevant)
- Steps taken to address deviation
- Steps taken to prevent further occurrence
- Name, title and contact information of the person completing the reporting

In most cases, site staff will be asked to complete the Protocol Deviation Report Form and send a draft to the 046SiteQueries@hptn.org email distribution list before submitting to the full protocol deviation distribution list. All complete protocol deviation reports should be sent to the following distribution list and a copy kept at the site:

- 046ProtocolDeviations@HPTN.org (includes the Protocol Chair, DAIDS Medical Officer, DAIDS Clinical Operations Group Representative, DAIDS Protocol Pharmacist, CORE Protocol Specialist, SDMC Project Manager, and HPTN NL Representative)
- Investigator of Record at site
- Site Study Coordinator(s)

3.6 Ancillary Studies

Ancillary studies (or sub-studies) are defined as secondary investigations conducted in conjunction with a primary HPTN and/or International Maternal, Pediatric AIDS Clinical Trial Network (IMPAACT) study. The investigator proposing the ancillary study is responsible for ensuring that all necessary approvals are obtained and that all relevant HPTN, IMPAACT and DAIDS procedures are followed. All ancillary studies using HPTN and/or IMPAACT funding and/or data or biological specimens from a primary HPTN and/or IMPAACT study are subject to HPTN/IMPAACT administrative approval and, if applicable, to DAIDS regulatory approval. The purpose of the review and approval process is to ensure that site and central network resources are being used appropriately and that the rights and well being of human subjects are protected in accordance with the Code of Federal Regulations and ICH GCP. The administrative and regulatory requirements for the conduct of ancillary studies can be found in the HPTN Manual of Operations.

3.7 Study Publications

All manuscripts, abstracts, posters or presentations based on the results or conduct of HPTN 046 must be prepared in accordance with the IMPAACT Publication Procedures, and the Clinical Trials Agreement (CTA). The CTA specifies that Boehringer Ingelheim (BI) shall receive copies of any abstract, poster, presentation, or manuscript prior to its submission for publication with sufficient time for review and comment. Recognizing that BI staff plays an important role in the design, analysis, and interpretation of the findings of HPTN 046, reasonable consideration shall be given by the investigators and DAIDS to include appropriate individuals from BI in the authorship of publications.

Table 3-1: Suggested Filing Structure for HPTN 046 Essential Documents

File/Binder #1: HPTN 046 Protocol and Current Informed Consent Forms

- HPTN 046 Protocol (including copy of signed and dated protocol signature page): Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments issued after Version 1.0
- Currently-approved site-specific HPTN 046 informed consent forms (English version(s), translation(s), and back-translation(s))

File/Binder #2: Regulatory Authority Documentation (if applicable)

- Regulatory Authority Correspondence/Authorization/Approval/Notification of Protocol (if applicable; if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)

File/Binder #3A: IRB/EC Documentation for (IRB/EC A)

- FWA documentation for IRB/EC A
- Roster of IRB/EC A (if available)
- Relevant IRB/EC A Submission Requirements/Guidelines/SOPs
- IRB Correspondence for IRB/EC A: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere
- IRB approval documentation; include stamped consents if approval letter does not reference which version of the consents were approved

File/Binder #3B: IRB/EC Documentation for (IRB/EC B)

- FWA documentation for IRB/EC B
- Roster of IRB/EC B (if available)
- Relevant IRB/EC B Submission Requirements/Guidelines/SOPs
- IRB Correspondence for IRB/EC B: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere
- IRB approval documentation; include stamped consents if approval letter does not reference which version of the consents were approved

File/Binder #4: Product Safety Information

- Investigator's Brochure for nevirapine (Viramune) (as provided by DAIDS): current version and any subsequent updates
- Product Safety Information/Reports/Memos (as provided by DAIDS)
- Viramune Package Insert: current version and any subsequent updates

Notes:

- *Expedited adverse event reports will be stored in participant study notebooks.*
- *Documentation of IRB/EC submission of above-listed documents (if applicable) will be maintained in the relevant IRB/EC Files/Binders (i.e., File/Binder #3A and #3B).*

File/Binder #5: HPTN 046 Study-Specific Procedures (SSP) Manual

- Final version 1.0 and any subsequent updates

Notes:

- *For this reference copy of the SSP Manual, do not discard out-dated pages or sections when updates are issued; retain all versions of all pages as a complete historical record.*
- *The SSP Manual contains reference versions of all study case report forms; therefore additional (blank) copies of the case report forms need not be stored elsewhere in the essential documents files.*

File/Binder #6: HPTN 046 Study-Specific Standard Operating Procedures

- Final approved version of each SOP, and any subsequent updates to each

File/Binder #7: HPTN 046 Staffing Documentation

- FDA Form 1572 (copy of original and dated form submitted to DAIDS Protocol Registration Office, and any subsequent updates)
- HPTN 046 Investigator of Record CV (copy of CV submitted to FHI for Protocol Registration; it is recommended that CVs be updated as needed and signed and dated at least annually)
- Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
- Study Staff Roster (original submitted to FHI for study activation, and any subsequent updates)
- Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
- Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
- CVs for key study staff other than the IoR including all subinvestigators, clinicians, the study coordinator(s), and Pharmacist of Record (ensure that all CVs are current prior to initiating HPTN 046; it is recommended that CVs be updated and signed and dated at least annually)
- Study Staff Job Descriptions
- Documentation of Study Staff Training

File/Binder #8: Local Laboratory Documentation

- Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): File documentation current at time of study activation and all subsequent updates
- Local Laboratory Normal Ranges: File documentation of relevant normal ranges for all protocol-specified tests current at time of study activation and all subsequent updates
- Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7)

Note:

- *It is recommended that a cross-reference be included in this file/binder specifying the storage location(s) of other lab-related essential documents filed in the local lab(s).*

File/Binder #9: Monitoring Visit Documentation

- Monitoring Visit Log
- Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings

File/Binder #10: Documentation of Other HPTN Site Visits

- (Non-Monitoring) Site Visit Log
- HPTN CORE (FHI) Site Assessment Reports and Documentation of Response to Visit Findings
- HPTN SDMC (SCHARP) Site Visit Reports and Documentation of Response to Visit Findings
- HPTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
- Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #11: Study-Related Sponsor Communications

- Study-related communications to and from DAIDS
- Communications to and from the DAIDS RCC (includes emails acknowledging receipt or approving protocol registration from the DAIDS Protocol Registration Office)

Notes:

- *Communications related to individual study participants will be filed in participant study records.*
- *Product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.*

File/Binder #12: Other Study-Related Communications

- Key study-related communications to and from HPTN CORE (FHI)
- Key study-related communications to and from HPTN SDMC (SCHARP)
- Key study-related communications to and from HPTN Network Lab
- Other Key study-related communications

Notes:

- *Any documentation of agreements or significant discussions regarding study conduct, protocol violations, or adverse event reporting should be filed.*
- *Communications related to individual HPTN 046 study participants will be filed in individual participant study records.*
- *Product-related communications with DAIDS PAB (and its contractors) will be stored in the study pharmacy.*

File/Binder #13: Study Site Staff Meeting Documentation

- HPTN 046 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

File/Binder #14: Conference Call Documentation

- HPTN 046 Protocol Team Conference Call Summaries
- HPTN 046 Laboratory Group Conference Call Summaries
- HPTN 046 Protocol Safety Review Team Call Summaries
- Summaries of Other HPTN 046 Conference Calls, such as site-specific calls

File/Binder #15: Reference Documentation

- DAIDS SOP for Source Documentation (Version 2.0 and any subsequent updates)
- DAIDS SOP for Essential Documents (Version 2.0 and any subsequent updates)
- DAIDS Protocol Registration Policy and Procedures Manual (August 2004 and any subsequent updates)
- Manual for Expedited Reporting of Adverse Events to DAIDS (Version 1.0, May 6, 2004 and any subsequent updates)
- US Regulations Applicable to Conduct of HPTN 046 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
- HPTN Manual of Operations
- Any other relevant manuals or reference documents

File/Binder #16: Site-Specific Study Activation Documentation

- Site-Specific Study Activation Documents including Activation Notice (entire binder will be provided by FHI as a reference of all materials upon which study activation was based)

Table 3-2: Sample HPTN 046 Required Case History Element and Source Document Guide

HPTN 046 Required Case History Element	HPTN 046 Source Documents – *[EXAMPLE TEXT]*
Basic mother and infant participant identifiers (e.g., name, date of birth)	*Locator Form; Screening and Enrollment Logs; Medical Records*
Documentation that the mother provided written informed consent to participate in the study prior to initiation of study procedures.[1]	*Signed and dated Informed Consent Form; signed and dated Informed Consent Coversheet*
If she chooses, documentation that the mother provided written informed consent to storage and future use of samples[2]	*Signed and dated Specimen Storage Consent Form; signed and dated Informed Consent Coversheet*
Documentation that the mother met the Enrollment Criteria:	
Age	*Mother's Medical Record*
HIV status	*Laboratory Records*
Third trimester of pregnancy or on or before 7 days after delivery	*Mother's Medical Record*
No serious medical condition that would interfere with participation in the study as judged by the onsite clinician	*Mother's Medical Record*
Intend to Breastfeed	*Chart Note*
If not already delivered: Intend to Delivery at facility where study is based	*Chart Note or Mother's Medical Record*
Documentation that the infant met the Infant Enrollment Criteria	
Born to an HIV infected mother who is eligible and has consented to take part in the study	*Medical Birth Record*
HIV-1 DNA PCR negative from a sample obtained on or before 7 days of life.	*Laboratory Records*
Birth weight of at least 2000 gm	*Medical Birth Record*
Able to breastfeed	*Chart Note; Mothers Medical Record*
No Grade 2 or higher ALT from birth specimen	*Laboratory Records*
No Grade 3 or higher hgb, abs neutrophil count or platelet count from birth specimen	*Laboratory Records*
No Grade 2B (urticaria)	*Infant Medical Record*
No Grade 3 or 4 skin rash	*Infant Medical Record*
No confirmed or suspected clinical hepatitis	*Infant Medical Record*
No serious illness or condition that would prohibit compliance with study procedures as judged by site clinician	*Infant Medical Record*
Documentation that the infant met the Infant Randomization Criteria	
HIV-1 DNA PCR negative from a specimen obtained within 21 days of randomization on or before 8 weeks (Day 56).	*Laboratory Records*
Still breastfeeding and intending to continue breastfeeding.	*Chart Note; Mothers Medical Record*

[1] The *DAIDS SOP for Source Documentation* (Appendix B) provides detailed requirements and suggestions for documenting the informed consent process.
[2] Consent for long term storage is optional.

HPTN 046 Required Case History Element	**HPTN 046 Source Documents –** *[EXAMPLE TEXT]*
The infant did not require permanent discontinuation of open-label NVP	*Chart Note; Infant Medical Record*
The infant initiated open-label NVP	*Chart Note; Infant Medical Record*
No current Grade 2 or higher ALT	*Laboratory Records*
No current Grade 2B (urticaria)	*Infant Medical Record*
No current Grade 3 or 4 skin rash	*Infant Medical Record*
No confirmed or suspected clinical hepatitis	*Infant Medical Record*
No serious illness or condition that would prohibit compliance with study procedures as judged by site clinician	*Infant Medical Record*
No concomitant use of rifampin or oral ketoconazole	*Infant Medical Record*
Documentation of the assignment of the study drug kit and randomization	*Randomization Log*
Open-label NVP and Study Drug Dispensation	*Open-Label NVP and Study Drug Accountability Records; Study Product Receipt/Return Records*
A record of all contacts, and all attempted contacts, with the participant (e.g. home visits, telephone contacts, etc.)	*Chart Notes (signed and dated), and/or other worksheets or local documents if designated in local SOPs; Home Visitor Records*
A record of all procedures performed by study staff	*Chart Notes (signed and dated) detailing (a) procedures performed in addition to scheduled procedures and/or (b) the reason why scheduled procedures were not performed; Medical Records, Lab Records, Counseling Records, other Chart Notes (signed and dated)*
Information on the participant's condition before, during, and after the study	*Medical Records; Laboratory Records; Reports of information pertinent to the study obtained from non-study sources; Chart Notes (signed and dated)*