

HIVNET 024

PHASE III TRIAL OF ANTIBIOTICS TO REDUCE CHORIOAMNIONITIS-RELATED PERINATAL HIV TRANSMISSION

STUDY-SPECIFIC PROCEDURES MANUAL OF OPERATIONS

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HIVNET 024 MOP: updated December 16, 2003
Supersedes MOP dated August 12, 2002

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1. Introduction

This section specifies the sources of procedural information available to study site staff, the general requirements of study sites, and the process by which study sites are approved to initiate study implementation.

1.1 Sources of Protocol Information

All study procedures must be conducted in accordance with the study protocol and this manual. In the event that these documents are not consistent in their instructions, the specifications of the protocol always take precedence. A copy of the protocol is included as Section 2 of this manual.

Study site staff are encouraged to contact the HPTN CORE Protocol Specialist/Clinical Research Manager with all questions related to interpretation and proper implementation of the protocol. The HPTN SDMC Protocol Operations Coordinator should be contacted regarding all questions related to data collection and/or data management.

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This manual contains study specific procedural instructions only. In addition to the sources described above, required policies and procedures for the management of the investigational product for this study can be found in the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks* manual.

1.2 Study Site Responsibilities

In addition to the provisions set forth in the study protocol, study sites conducting this trial must:

- Designate and train staff in the goals and purpose of the study and the proper conduct of study procedures.
- Ensure that all study staff are trained/certified for their respective study roles in accordance with locally accepted standards of practice.

- Establish local standard operating procedures (SOP) to ensure that all study staff members are kept appropriately informed of study progress and any modification to the study protocol, manuals, checklists, etc.
- Establish local SOPs to ensure that study documentation is kept up-to-date and that only current versions of study protocols, operations manuals, and data collections forms are utilized.
- Establish a local log linking study participant names and ID numbers, and store this log in accordance with the record keeping requirements specified in the study protocol and this manual (see Section 3).
- Obtain copies of applicable US Federal, national and local public health regulations and guidelines pertinent to study procedures; establish local SOPs and train appropriate staff members to ensure that these regulations and guidelines are followed.

1.3 Study Activation Process

Prior to undertaking any study procedures, each study site must obtain approval from its local and US IRB, the HPTN CORE, the HPTN Central Lab and NIAID's Pharmaceutical Affairs Branch (PAB) and Regulatory Affairs Branch (RAB). Approval from the HPTN CORE, Central Lab, PAB and RAB comes in the form of "site activation." This section outlines the steps taken to obtain these approvals. Conduct of any study procedures prior to completing these steps is incompatible with human subjects regulations and the individual subcontract with the HPTN CORE.

1.3.1 Protocol Distribution

The HPTN CORE Protocol Specialist/CRM will distribute the final implementation version of the protocol and associated materials to each study site. Additional protocol-associated materials will be distributed by the HPTN SDMC POC.

1.3.2 Development and HPTN CORE Review of Site-Specific Informed Consent Form

The study site staff, in conjunction with the protocol chairs, will adapt the template informed consent form as required to reflect local procedures and regulations. Staff will coordinate translation of the consents into local language and back-translation into English. On the last page of the translated and back-translated consents, the name of the primary person responsible for translation should be documented.

The Protocol Specialist will assess whether the back-translation (1) includes all the required elements of informed consent and (2) adequately and accurately represents the study in language understandable to study participants. The Protocol Specialist will communicate findings to the protocol chairs and study site coordinator (or other designee) by e-mail.

After informed consents have been reviewed by the Protocol Specialist and all concerns have been addressed, the consents may be submitted to IRBs.

1.3.3 Local and US IRB Approval

Protocol Chairs and/or study site staff will submit the following materials for review by the local and US IRB:

- The study protocol and site-specific informed consent form;
- Any participant information sheets, promotional materials, advertisements, flyers, etc; and

- Key data collection instruments and any other study-related materials, as required by the IRB.

1.3.4 Site Registration and Activation

Upon obtaining local and US IRB approval of the protocol, site specific consent form and other associated materials, study site staff will submit to the Protocol Specialist a site registration packet containing the following documents:

- A completed Form 1572;
- Current Curriculum Vitae of the Investigator of Record;
- A copy of the letter documenting US and in-country IRB approval of the study and associated materials; and
- A copy of the IRB-approved site-specific informed consent form and translations.

The Protocol Specialist will review these documents and submit them to the Regulatory Compliance Center (RCC). The Protocol Specialist will notify the Protocol Chairs and study site of any deficiencies identified in the site registration documents by HPTN CORE or RCC staff. Site staff will respond to any such deficiencies and resubmit documents as required.

After the informed consents have been reviewed and approved by RCC, RCC will notify the HPTN CORE Protocol Specialist and the Regulatory Affairs Branch (RAB) nurse specialist. The RAB nurse specialist will provide written approval and will notify OHRP so that OHRP can add this study to the site's Cooperative Project Assurance (CPA). RCC/RAB approval will be transmitted via e-mail; a hardcopy confirmation will follow via fax.

Note: Approval to begin study operations is also dependent upon 1) the Pharmaceutical Affairs Branch (PAB) approval of a written pharmacy plan that adequately describes the study site's procedures for management and dispensing of product during the course of the study and 2) approval from the Central Laboratory.

Following receipt of PAB and RCC/RAB approval and all other site registration documentation, the Protocol Specialist will complete a Site Activation Checklist and will forward to the HPTN CORE PI. The HPTN CORE PI will sign the Protocol Activation Memo, which will be sent to the Protocol Chair for the site. Protocol activities involving human subjects may commence upon receipt of the Protocol Activation Memo.

1.3.5 Site Registration and Activation Following Full Protocol Amendment

Once the amended version has been submitted to and approved by the regulatory arm of the Division of AIDS, the new version of the protocol is submitted to the FDA. Upon notification that the new version has been submitted to the FDA, the HPTN CORE specialist will send that approved version to the Protocol PIs and to the team. The sites have 90 days from the receipt of that new version to be approved by Protocol Registration Office and activated to proceed under the new version. To achieve this, the sites must:

- Make any revisions to the informed consents as are indicated
- Submit the revised site-specific informed consent in the English, local language(s) and back translation to the Protocol Specialist for review

- Once the Protocol Specialist has approved the informed consents, the amended protocol and revised informed consents (all translations), should be submitted to the US IRB and local EC for approval. The cover letter to the IRB/EC should request that the following elements be included with the letter of approval:
 - Full number, title and version number of the protocol
 - Specific approval of the protocol and of any and all informed consents submitted (rather than a broad and non specific letter of approval)
 - Permission to continue to use the version of the protocol currently in use pending approvals from the other IRB/EC and DAIDS

The local EC and US IRB letters of approval should be forwarded to the Protocol Specialist along with copies of the approved informed consents. The Protocol Specialist will forward these materials to the PRO. Review by the PRO is usually completed within 10 to 14 working days. The site will be informed if further materials are necessary. Once the PRO approves the site under the new version of the protocol, the Protocol Specialist will notify the site of activation of that version of the protocol. At that time, the site must use only the new, approved informed consents.

2. Study Protocol

This section contains a complete reference copy of the study protocol. In the event that the protocol is modified during the course of the study, site staff should update this copy so that it always reflects current study requirements.

Protocol Version Number and Date

Date Approved for Implementation

3. Documentation Requirements

This section contains a listing of required administrative documentation that each study site must maintain and keep throughout the study, as well as procedures for establishing adequate and accurate study participant case histories and investigational product inventories. These procedures are based on applicable United States Federal regulations (21 CFR Parts 50 and 312), and standards of Good Clinical Practice.

3.1 Administrative Documentation

Each study site must maintain the following administrative study documents throughout the course of the study. When documents are modified or updated, the original and the modified/updated versions must be maintained.

- Site activation packet and documentation of PAB, RAB and HPTN CORE approvals to begin study operations
- Study protocol with completed signature page
- Applicable US Federal, national and local public health reporting requirements pertinent to study procedures (e.g. for HIV and STDs); documentation of any exemptions from such requirements
- All local study-specific standard operating procedures (SOPs)
- Minutes of study-related conference calls and meetings
- Other written communications related to study implementation
- The local performance site's CPA number
- All IRB correspondence (local and US)
- Listing of all local laboratories and documentation of their accreditation to perform the testing for which they have been contracted
- Local lab reference ranges for protocol required tests
- Study staff roster and signature sheet and CVs for all staff members
- Study monitoring visit log

3.2 Source Documentation Guidelines

The DAIDS Source Documentation Standard Operating Procedure (SOP) should govern source documentation requirements at each HPTN site. If any of the instructions in this Manual of Operations conflicts with the DAIDS Source Documentation SOP, those of the SOP should be followed.

3.2.1 Definition and Concept of Source Document

A source document is defined as the first document on which study-related information is recorded. Study sites must adhere to the following standards of source documentation:

- Although information may be copied from source documents onto other forms, or entered into a computer database, all original source documents must be maintained in the participant chart.
- The study participant whose information is contained in a source document must be identified by name or Participant ID number, but not both, on the document.

- All individuals who enter information onto source documents must be identified on the document, and must date all entries. If entries from multiple dates are included on a single document, the date of each entry must be noted.
- Changes to entries on source documents must be initialed and dated by the individual making the revision. If the reason for a revision is not readily apparent from the data, an explanation also must be entered
- Source documents prepared by study laboratories must be reviewed, signed and dated by designated study site staff.

3.2.2 Case History Guidelines

United States Federal regulations (21 CFR 312.62[b]) require that case histories for participants enrolled in clinical trials include “all observations pertinent to the investigational drug or employed as a control in the investigation.” Case histories should contain:

- basic participant identification information;
- information demonstrating that each participant meets the study’s selection criteria;
- information on each participant’s exposure to the study medication/placebo, including date, time and quantity dispensed;
- documentation that the participant provided written informed consent to participate in the study;
- records of all contacts with the participant;
- information obtained from tests and exams, including physical exams, lab test results, x-rays, progress notes, consultations, diagnostic test results;
- study related information on the participant’s condition before, during, and after the study, including (a) data obtained directly from the participant, (b) data ascertained by study site staff, and (c) data obtained from non-study providers;
- narrative progress notes and source documentation of clinical laboratory or physical examination findings; and
- DataFax forms.

3.2.2.1. Progress notes

Sites must maintain signed, dated progress notes documenting each participant contact, the nature of the contact and the condition of the participant. Any procedure that is not otherwise documented in a primary source should be included in the progress note. At a minimum, progress notes should include the following:

- date, type, location (if off-site) and, if interim contact, reason for the visit/contact/interaction;
- description of the general status of the participant; and
- the signature or identifying code of the staff member who entered the note.

3.2.2.2. DataFax forms as Source Documents

DataFax forms have been designed, in many cases, to serve as source documents, that is, the first place to which data pertinent to the condition of a study participant are entered. In general, if information is entered directly and initially on the DataFax form, it is a source

document. If data are abstracted from information recorded elsewhere (e.g., hospital record or narrative participant chart), it is not a source document.

- All DataFax forms must be initialed and dated by the individual responsible for data collection for forms used as source documents and for data transcription/entry for forms that do not serve as source documents.
- All corrections to entries on DataFax forms, even those made during initial entry of information, must be initialed and dated by the individual who made the change.

3.3 Document Organization

The study site principal investigator will maintain all source documents, including case histories, handwritten notes, and original laboratory results reports. All data collection forms and source documents must be kept in locked files in a secure area, with access limited to study site staff. Source documents should be kept together with the data collection forms in locked participant files unless standard clinic procedures prevent this. If source documents are stored separately from participant files, their location must be known and they must be readily accessible to any authorized study monitor. All locator information must be kept in locked files in a secure area apart from all other study documents. In order to protect participant confidentiality, under no circumstances may documents bearing participant names or other personal identifiers be stored together with documents bearing the Participant ID number. All records must be available at all times for inspection by NIAID, HPTN CORE, and HPTN SDMC staff.

Each site must maintain a log or database containing the link between participant names and ID numbers. Written logs (and/or database printouts) must be stored in a secure location separate from participant files, with access limited to site staff. Electronic files containing the link must be password protected and maintained in a directory separate from any study data; file encryption is encouraged.

3.4 Study Drug Inventory

The receipt, dispensing and return of all study supplies will be documented by study site staff on appropriate log forms.

Separate accountability records must be maintained for each shipment of product received by the study site. A separate record also must be maintained for all product supplies returned to the study site unused by the participant.

As with case history documentation, all product inventory records must be stored in a locked file cabinet in a secure area at the site pharmacy, with access limited to study site staff.

3.5 Record Retention Requirements

All records must be retained on-site throughout the study's period of performance. The HPTN CORE will provide each site with written instructions for long-term record storage at the completion of the period of performance.

The investigator will retain study records for at least 5 years after the end of the study or until advised by HPTN CORE that record retention is no longer necessary.

4. Informed Consent Procedures

4.1 IRB Review and Reports

Prior to implementation the protocol and informed consent forms must be approved by the institutional review board (IRB) of each participating institution and by host country scientific/ethical committees. The study site principal investigator is responsible for preparation of all submission documents and periodic reports required by the IRB.

This protocol and the informed consent documents and any subsequent modifications will be reviewed and approved by the IRB and Ethics Committees responsible for the oversight of the study.

A Cooperative Project Assurance (CPA) application (as required by the Department of Health and Human Services) must be on file with OHRP for each performance site prior to study implementation.

Each site principal investigator will make safety and progress reports to the HPTN CORE CRM at FHI. In addition, the principal investigator will report to the HPTN CORE any changes in the research activity or any unanticipated problems involving risks to human subjects or others.

Each principal investigator will make safety and progress reports to the IRB at least annually and within 3 months of study termination or completion. These reports will include the same information provided to FHI: the total number of subjects enrolled, the number of subjects completing the study, any changes in the research activity and any unanticipated problems involving risks to human subjects or others.

4.2 Informed Consent

Participants in research trials have a basic right to know and understand that they are participating in research. This study requires compliance with the Declaration of Helsinki regarding the rights of human subjects, and further compliance with FDA regulations and the ICH Guide to GCP. A consent form and any other trial-related material provided to study candidates for information must be reviewed and approved by the site's IRB. No changes in the consent form may be made without review and approval by the IRB.

Before participants are consented to continue with follow up in the study, the purpose and nature of the study will be explained. The participant must agree that she understands the investigational nature of the study, its inherent risks and benefits, other treatment alternatives, her rights to terminate participation in the study without affecting her health care at the clinic, whom to contact with questions regarding the study, and desire to continue with the study.

Any counseling about the study must be done in such a way so that the candidate does not feel pressured to sign the form or participate in the trial. The consent process must not be rushed—she should have adequate time to read the consent form or have it read to her. She

must have access to other study personnel, e.g., an investigator, to ask questions and have her questions answered. Study staff should make every effort possible to ensure that the candidate understands what has been proposed.

The candidate's right to confidentiality must be protected. The environment in which consent counseling or other counseling takes place must be private, both out of sight and earshot of other people. The environment must also be comfortable and uncompromising to the candidate, e.g., she must be fully clothed.

The candidate must have signed or marked the consent form before any procedures for the study are undertaken. In the event that a participant is unable to read or write, GCP guidelines dictate that a second witness must be present during the consent process and sign the informed consent attesting that the person who has been consented is the same person who has made the mark. If this method is felt to be in any way detrimental to the participant (i.e., threatens confidentiality, is coercive, undermines the participant's opportunity to understand the consent process), the site is obligated to raise this issue with the local EC.

This process of informed consent is ongoing. Study participants must be informed promptly about any new information that might have an impact on their decision to remain in the study. Study participants must also have access to key study personnel including the investigator to answer questions that may come up during the course of the study.

The signed informed consent documents will become a permanent part of the participant's clinic records. While the informed consents will be audited in the same manner as other records, copies will not be transferred to any agency outside of the clinic.

4.3 Confidentiality

The confidentiality of all participants enrolled in this study will be protected to the fullest extent possible. Participants' study site records may be audited by FHI staff, and/or other sponsoring organizations, or other individuals authorized to audit the study. Study participants should not be identified by name on any case report form or on any other documentation sent from the study site to the HIVNET Statistical Center, FHI, or other sponsoring organization. All study records will be kept in a locked file cabinet. All computer entry and networking programs will identify participants with coded identification numbers only. The list linking participant ID numbers to other identifying information will be stored separately from coded study forms and source records, in a locked file in a room with access limited to site staff. Participants will not be reported by name in any report or publication resulting from data collected in this study.

4.4 Informed consent documents

This section contains a complete reference copy of the study informed consents and translations. In the event that the informed consents are modified during the course of the study, site staff should update this copy so that it always reflects current study consents.

<u>Consent Version Number and Date</u>	<u>Date Approved for Implementation</u>
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

5. Participant Accrual

HIVNET 024 was closed to accrual on February 21, 2003 based on recommendations of the DSMB.

5.1 Cohort Description

5.1.1 Inclusion Criteria

- 20-24 weeks gestation;
- Willing to give informed consent for screening and HIV testing through the study OR documented HIV infection
- Willing to give informed consent for enrollment into the study;
- Willing to take antibiotic treatment as scheduled;
- Legally of age to give informed consent (18 years of age in Tanzania and Malawi and 16 years of age in Zambia);
- Willing to come back for follow-up visits for one year post-partum.

5.1.2 Exclusion Criteria

- Have taken antibiotics, other than treatment for syphilis or gonorrhea, within the last two weeks;
- Are allergic to penicillin, ampicillin, erythromycin, or metronidazole;
- Have known major illnesses likely to influence pregnancy outcome including diabetes, severe renal or heart disease, or active tuberculosis, prior to randomization;
- Have known major obstetric problems such as placenta previa, ruptured membranes or multiple pregnancy prior to randomization;
- Have known central nervous system diseases, including seizures;
- Are taking anticoagulant drugs.

5.2 Randomization

Randomization was halted at the same time that accrual was halted.

Participants were randomized at 20-24 weeks gestation in a double-blinded fashion to receive either the active agent (metronidazole, erythromycin, ampicillin) or matched placebo. The randomization designed by the HIVNET Statistical Center used permuted block algorithms with varying block size, blocked within study site to ensure balance between assignments is maintained within each study site. Study antibiotics were packaged according to the randomization and sent to the study site. Randomization was performed by assigning study participant identification numbers, and thus study antibiotics, to participants in sequential order.

HIV-infected and HIV-uninfected participants have been randomized in separate strata. There were 2 separate lists with identification numbers, one for HIV-infected and one for HIV-uninfected women. However, the identification numbers of HIV-infected and HIV-uninfected women were interspersed to keep their HIV-status blinded. For each 5 HIV-infected women who had been enrolled and randomized by assigning the 5 consecutive identification numbers from the list for HIV-infected women, one HIV-uninfected women could have been enrolled and assigned the next available number from the list for HIV-uninfected women. At sites enrolling only HIV-infected participants, there was only one randomization list.

5.3 Transfer of Participants

Note: The procedure for the transfer of patients is pending details about the management of study drugs once a patient has transferred. Consequently, the guidelines below are incomplete. Sites should contact the Pharmacy Affairs Branch in the event that a participant expresses a desire to transfer from one site to another. Once approval and instructions from the PAB have been obtained, the following steps should be taken.

If a participant needs to transfer to another HPTU, the Clinic Coordinator at the original HPTU is responsible for notifying the Protocol Specialist and the Clinic Coordinator at the receiving HPTU. After details of the transfer have been agreed upon, the following should occur:

- identify (SDMC) and resolve (original HPTU) all outstanding QCs involving the transferring participant;
- obtain approval for release of information from the participant (original HPTU) authorizing transfer of files to receiving HPTU;
- send copies of study files (original HPTU) to receiving HPTU as soon as possible;
- complete and fax Participant Transfer form to SDMC (original HPTU);
- forward a copy of Participant Transfer form to CL (original HPTU);
- complete and fax Participant Receipt form to the SDMC (receiving HPTU); and participant signs a new informed consent at the receiving HPTU.

Note: The participant retains the original assigned Participant ID.

6. Visit Schedule

Version 5.0 of the protocol includes 4 Schedules of Evaluations. However, given that all active participants in HIVNET 024 have delivered and all infants are beyond the 4-6 week follow-up visit, only 2 Schedules of Evaluations apply:

- Evaluations for women/infant pairs who return for final follow up at 3, 6 or 9 months post delivery
- Evaluations for women/infant pairs who return for final follow up at 12 months post delivery

Please note that – with the adoption of 024 Version 5.0 and this MOP -- there are to be NO further laboratory samples collected on the following 3 groups:

- Mothers, whether HIV infected or not
- Infants with a confirmed HIV diagnosis (2 consecutive positive HIV-RNA tests drawn on different days)
- Infants born to women enrolled as HIV uninfected

6.1 Schedule of Evaluations

Evaluations for women/infant pairs who return for final follow up at 3, 6 or 9 months post delivery

Evaluations	Visit N (Visit 6, 7, or 8)	Post-Test Counseling Visit N + 4 to 6 weeks (HIV-indeterminate infants only)	Post-Test Counseling Visit N + 8 to 12 weeks (HIV-indeterminate infants only)
Maternal:			
Discontinuation	X		
All Infants:			
Weight	X	X	X
General Health	X	X	X
Concomitant meds	X	X	X
HIV-Indeterminate Infants ONLY			
Post-test counseling		X	X
DBS	<p>If already confirmed HIV-infected (i.e., 2 positive tests), do not draw DBS; terminate.</p> <p>If confirmation of previous single positive result needed, collect DBS and schedule for Visit post-test counseling.</p> <p>If all previous DBS studies have been negative, collect DBS and schedule for post-test counseling.</p>	<p>If result of Visit N confirms HIV status, do not draw DBS; terminate.</p> <p>If result of Visit N is negative, no blood draw; terminate.</p> <p>If result of Visit N is positive and confirmation is necessary, obtain DBS and schedule for post-test counseling</p>	<p>If result of last visit confirms HIV status, no blood draw; terminate.</p>

Evaluations for women/infant pairs who return for final follow up at 12 months post delivery

Evaluations	Visit 9 12 months	Post-Test Counseling 12 months + 1-2 weeks (HIV-indeterminate infants only)	Post-Test Counseling 12 months + 9-10 weeks (HIV-indeterminate infants only)	Post-Test Counseling 12 months + 13 to16 weeks (HIV-indeterminate infants only)
Maternal:				
Termination	X			
All Infants:				
Weight	X	X		X
General Health	X	X		X
Concomitant meds	X	X		X
HIV-exposed infants ONLY				
Post-test counseling	X	X		X
ELISA, DBS	<p>If already confirmed HIV-infected (i.e., 2 positive tests), do not draw DBS or ELISA; terminate.</p> <p>If of unknown HIV status with no previous positive HIV results, obtain ELISA and DBS. Schedule for post-test counseling. Note:</p> <ul style="list-style-type: none"> • If ELISA negative, do not send DBS to UNC • If ELISA positive, send DBS to UNC 	<p>If ELISA negative, do not draw blood; terminate.</p> <p>If ELISA positive, draw DBS and schedule for post-test counseling.</p>	<p>If both RNA PCRs are positive, HIV infection is confirmed. No blood draw; terminate.</p> <p>If both RNA PCRs are negative, status at final visit is uninfected. No blood draw; terminate.</p> <p>If results of the RNA assays are equivocal, obtain DBS and schedule for post-test counseling.</p>	<p>If result of last visit confirms HIV status, no blood draw; terminate.</p>

6.2 Visit Checklists

Given that all active participants in HIVNET 024 have delivered and all infants are beyond the 4-6 week follow-up visit, the visit checklist for 3 months post-delivery and beyond is below.

6.2.1 Visit Checklist for final follow-up visit(s) at 3, 6, 9 or 12 months

Non-Laboratory Data	Labs
Final Visit (3, 6 or 9 months) <ul style="list-style-type: none"> • Infant Viability and Health • Schedule for post-test counseling 	For HIV-exposed infants of indeterminate status (1 or no positive HIV RNA): <ul style="list-style-type: none"> • DBS for HIV RNA PCR
Post-test Counseling Visit (Final visit + 4 to 6 weeks) <ul style="list-style-type: none"> • Post-test counseling • <i>Discontinue follow up</i> 	For infants with negative HIV RNA PCR result or infants confirmed as HIV-infected: <ul style="list-style-type: none"> • No blood draw
<ul style="list-style-type: none"> • Post-test counseling • Schedule for post-test counseling 	For HIV-exposed infants with positive HIV RNA PCR result: <ul style="list-style-type: none"> • DBS for HIV RNA PCR
Post-test Counseling Visit (Final visit + 10 to 12 weeks) <ul style="list-style-type: none"> • Post-test counseling • <i>Discontinue follow up</i> 	For infants confirmed as HIV-infected: No blood draw
Final Visit (12 months) <ul style="list-style-type: none"> • Infant Viability and Health • Infant feeding modality • Schedule for post-test-counseling 	For HIV-exposed infants of indeterminate status (1 or no positive HIV RNA): <ul style="list-style-type: none"> • ELISA • DBS for HIV RNA PCR
Post-test Counseling Visit (12 months + 1 to 2 weeks) <ul style="list-style-type: none"> • Post-test counseling • <i>Discontinue follow up</i> 	For infants with negative ELISA result: <ul style="list-style-type: none"> • No blood draw
<ul style="list-style-type: none"> • Post-test counseling • Schedule for post-test counseling 	For HIV-exposed infants with positive ELISA: <ul style="list-style-type: none"> • DBS for HIV RNA PCR
Post-test Counseling Visit (12 months + 9 to 10 weeks) <ul style="list-style-type: none"> • Post-test counseling • <i>Discontinue follow up if HIV infection status of the infant has been determined</i> • Schedule for post-test counseling if test results are equivocal 	For infants with 2 negative or 2 positive RNA PCRs: <ul style="list-style-type: none"> • No blood draw For infants with equivocal final RNA results: <ul style="list-style-type: none"> • DBS for HIV RNA PCR

7. Instructions for Product Use/Administration and Accountability

As a sponsor of clinical investigations, the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases of the National Institutes of Health must comply with the U.S. Food and Drug Administration (FDA) regulations governing the receipt, use, and disposition of study products being investigated in clinical trials. DAIDS has the responsibility of assuring that all investigators establish and maintain adequate records of study product disposition to comply with FDA regulations and the standards of research involving the use of study products.

This section includes general information and guidelines for study product management and is written to provide information for the Pharmacist of Record. The pharmacist at each clinical site/center who is designated the "Pharmacist of Record" will manage and control the study products used in clinical trials programs/networks sponsored by DAIDS. Pharmacists are expected to follow these guidelines. For any questions or clarifications contact the Protocol Pharmacist, Scharla Estep, RPh at (01)-301-435-3746 or sr72v@nih.gov. Sites should follow their pharmacy plans and their site specific SOPs for product management and accountability as approved by the DAIDS Pharmacy Affairs Branch (PAB).

The pharmacist at each clinical site/center participating in DAIDS-sponsored trials, who is designated as the Pharmacist of Record, is the primary individual who is expected to develop and maintain a study product management system, which includes the technical procedures for study product ordering, control, dispensing, and accountability. The Investigator of Record is responsible for the control and accountability of the study antibiotics, nevirapine and matching placebo, and multivitamins. The investigator is expected to delegate all responsibilities for control and accountability of the study antibiotics and nevirapine product to an appropriate pharmacist who is under the supervision of the investigator or the institution.

Control of study drugs requires that the proper storage conditions for protocol-provided study products, including segregation, security, temperature, and temperature monitoring, light, moisture, ventilation, and sanitation are provided. To provide adequate security, the study products should be stored in a limited-access area, an area that is locked when not in use. Systems must be in place for identifying and alerting staff that proper storage conditions are not being maintained so that procedures for timely interventions and resolutions can occur. The study products should be accessible only to authorized personnel, such as the Pharmacist of Record or his/her pharmacist-designee.

Accountability of study drugs requires that appropriate records of the receipt and disposition of the protocol-specific study products be maintained. Accurate records for the inventory of the participant kits and their individual contents (i.e. study antibiotics and multivitamins), bulk antibiotics (replacement doses), and nevirapine tablets (active and placebo) and nevirapine suspension must be maintained to document:

- Receipt by the site from the DAIDS Clinical Research Products Management Center (CRPMC);
- Dispensing of study products to study participants;
- Return of unused study antibiotics and nevirapine products;

- Final disposition demonstrating that dispensing, receipt, and return records reconciled or, if not reconciled, documentation to explain any discrepancies in these records.

Periodic physical inventories must be conducted to reconcile the physical amounts with the inventory balances on the accountability record. It is strongly recommended that, at a minimum, these inventories be performed once per month. These periodic physical inventories should be documented with a date and signature on the accountability record itself by entering this information on the first available line of the record.

The DAIDS Participant Kit Accountability Record, Investigational Accountability Record, and Log of Returned Doses, or equivalent records approved by PAB must be used to document the receipt and disposition of all study products received from the CRPMC. Sample forms are provided as attachments at the end of this section.

All entries on the Accountability Records must be made in ink. As with other original study records and data forms, no erasable ink or “white-out” correctional fluid may be used on dispensing/inventory records. Corrections may be made only by drawing a single line through the incorrect entry, then writing the correct entry and initialing and dating the correction. Explanations of corrections or other relevant comments may be written in the comment space for that line.

The following conditions must be fulfilled:

- The investigator has determined each maternal study participant and infant study participant meets protocol eligibility criteria and has signed an informed consent to participate in the protocol.
- The investigator ensures that the study antibiotics and nevirapine product is dispensed and used according to the approved protocol.
- The investigator ensures that study participants understand how to use the study antibiotics and nevirapine product and checks for correct use during the course of the study.
- The study antibiotics and nevirapine products are stored as specified by the manufacturer and according with applicable regulatory requirements, including locked storage with access only by authorized study staff members.

7.1 Ordering and Receipt of Study Drugs

Ordering:

Initial supplies of study products will be shipped by the DAIDS Clinical Research Product Management Center. **It will be the responsibility of the site Pharmacist to notify the CRPMC when any study supplies have reached a six week supply so that additional kits/study drugs may be shipped.** A procedure should be developed to ensure that sufficient supplies of the study product are always available in the institution for the duration of the study. The order should be placed electronically by the Pharmacist of Record and must include the site number, the site name, the name of the Investigator of Record, and name and amount of study product requested. The order may be emailed to the

CRPMC at the following address: CRPMC.Ph@mckessonbio.com. The DAIDS CRPMC will respond once they have received the email. It is the site pharmacist's responsibility that if a response is not received within 1 business day – a follow up email or fax will be sent.

Receipt:

The protocol-provided study products will be packaged in containers designed to maintain the proper storage conditions for the study products during shipment. Upon receipt, the pharmacist must verify that the quantity of participant kits, bulk antibiotics, nevirapine tablets, matching placebo tablets, and nevirapine suspension matches the amount listed on the invoice included with the shipment from the CRPMC and the conditions of the participant kits, bulk antibiotics, nevirapine suspension, tablets, and matching placebo must, also, be inspected. .

If there are discrepancies or if the supply appears to be damaged, the Pharmacist of Record should contact the NIAID Clinical Research Products Management Center immediately by fax [(01) 301-294-2905] or e-mail [CRPMC.Ph@mckessonbio.com]. This notification must be documented on the invoice and dated. The Pharmacist of Record should maintain a hardcopy document of any emails or faxes from the NIAID Clinical Research Products Management Center.

All shipping documents such as packing slips, commercial invoices and any import permits that may have been received with the shipment. must then be kept in the pharmacy files with the rest of the accountability records.

The kits will include the study antibiotics and multivitamins as well as bottles that may be used to dispense the NVP tablets (active or placebo) and NVP oral suspension and an oral syringe. Each individual kit is sealed. Therefore, all of the study drugs in a participant kit must be inspected immediately prior to initial dispensation to a participant.

Inventory:

Periodic physical inventories must be conducted to reconcile the physical amounts with the inventory balances on the accountability record. It is strongly recommended that, at a minimum, these inventories be performed once per month. These periodic physical inventories should be documented with a date and signature on the accountability record itself by entering this information on the first available line of the record.

- A physical count of the sealed participant kits, the replacement doses, the nevirapine products, and the contents of the opened participant kits should be compared to the investigational agent accountability records and participant kit accountability records, which should match the inventory balance. If any problems are found they must be further investigated. Any discrepancies in the inventory or dispensing records must be documented, dated and signed to indicate what the discrepancy entails and what steps were taken to resolve it, if it could not be resolved. If the discrepancy could not be resolved a detailed report must be sent (mail, fax, or email) to the Protocol Pharmacist stating the discrepancy. After documentation of the discrepancy, the inventory balance may be adjusted to match the actual inventory.

7.2 Dispensing Study Drug

Each participant must be determined eligible for the study and have signed a consent form, prior to dispensing any study antibiotics, multivitamins, nevirapine or matching placebo. Refer to Sections 4 and 5 for study eligibility criteria and informed consent.

Prepare and dispense the study antibiotics and nevirapine in accordance with the protocol and Section 7.4 of this manual.

7.2.1 Redispensing Lost or Misplaced Medications

In the event that a participant loses or misplaces her antenatal study antibiotics/placebo (dispensed at 20-24 weeks):

- The pharmacist must receive a prescription requesting the additional antibiotics/placebo
- The envelope in the participant's kit may be opened and drug dispensed from the appropriate emergency bulk supply
- There must be clear documentation in the participant's chart regarding the lost doses
- The appropriate inventory form(s) must be completed

In the event that a participant loses or misplaces her intrapartum study antibiotics/placebo (dispensed at 26-30 weeks) prior to labor:

- The pharmacist must receive a prescription requesting the additional antibiotics/placebo
- The replacement blister pack(s) from the participant's kit may be dispensed
- The envelope in the participant's kit does NOT need to be opened
- There must be clear documentation in the participant's chart regarding the lost doses
- The appropriate inventory form must be completed

In the event that a participant loses or misplaces any of her intrapartum study replacement antibiotics/placebos prior to the onset of labor:

- The pharmacist must receive a prescription requesting the additional antibiotics/placebo
- The envelope in the participant's kit may be opened and more drug dispensed from the appropriate emergency bulk supply
- There must be clear documentation in the participant's chart regarding the lost doses
- The appropriate inventory form(s) must be completed

7.2.2 Unused Study Drugs Returned by Participants

Any study drugs drug returned by participants should be stored separately from the main inventory and not dispensed to another participant. These doses should be identifiable by participant ID number. (See sample Return of Dispensed Unused Doses forms at the end of this section.).

7.2.3 Return/Disposal of Clinical Supplies

Return or disposal of clinical supplies may be requested by PAB for any of the following reasons:

- The protocol is completed or terminated, and undispensed investigational agents remain that may not be transferred to another DAIDS protocol.
- The study product has been dispensed to the patient and was returned
- The study product has expired.
- The study product has been stored improperly.
- The investigational agents return has been requested by the Pharmaceutical Affairs Branch (PAB) Pharmacist.

7.3 Study Drug Formulation and Acquisition

Study Antibiotics and Placebo

This study will employ ampicillin, metronidazole, and erythromycin, and identical appearing placebos.

Nevirapine

HIV-infected women and their neonates will be offered nevirapine. NVP (nevirapine, Viramune®) will be supplied as two 100 mg tablets for mothers and as a 10 mg/ml oral suspension for infants. Both products should be stored between 15 and 30°C (between 59 and 86°F).

7.4 Dosage Regimens

Study Antibiotics

At 20 – 24 weeks, participants randomized to the active agent will receive metronidazole 250 mg TID and erythromycin 250 mg TID for 7 days. Participants randomized to the control group will receive identically appearing placebos. All women in both treatment and control arms will receive a standard vitamin/mineral preparation daily from enrollment in the study until delivery.

With the onset of labor and/or rupture of membranes, metronidazole 250 mg, in addition to ampicillin 500 mg will be administered orally every 4 hours. Each woman will be asked to continue using the medications after delivery, three times per day, until the 21-pill course is completed.

Nevirapine

HIV-infected participants: With the onset of labor and/or rupture of membranes, a dose of nevirapine 200 mg (2 100 mg tablets or 1 200 mg tablet) will be administered orally to all HIV-infected participants who accept nevirapine.

HIV-exposed infants: Infants born to HIV-infected participants who received intrapartum nevirapine greater than 1 hour prior to delivery will received a single oral dose of 2 mg/kg nevirapine suspension at 72 hours post-delivery or at discharge from the

nursery, whichever comes first. Infants born to HIV-infected participants who r did not receive intrapartum nevirapine greater than 1 hour prior to delivery will received a single oral dose of 2 mg/kg nevirapine suspension as soon as possible after delivery.

7.5 Product Administration

7.5.1 Study Antibiotics

At enrollment, participants will receive a 7-day course of erythromycin and metronidazole, or placebo, in a blister pack. Participants will be instructed to take one metronidazole pill and one erythromycin pill three times a day for seven days, until the pills are gone. Participants will be informed of possible side effects of taking the pills and will be instructed what to do if they experience any of the side effects (see informed consent). Participants will be asked to bring their blister packs to their next study visit. At visit 2.0 (26-30 weeks), the remaining pills in the blister packs will be counted for adherence and recorded on a case report form. If the participant does not bring the blister packs, the participant will be asked about number of pills taken and the information will be recorded. If, for any reason other than medical, a participant does not take the antibiotics on schedule, she should be encouraged to resume dosing regardless of the timing in terms of the stated protocol schedule.

Also at visit 2.0, the participant will be given 9 pills each of metronidazole or ampicillin (or placebo), and will be instructed to take one of each at onset of labor and subsequently every four hours, until arriving at the hospital or clinic for delivery. These instructions will be reiterated at visit 3.0 (36 weeks). In addition, at visit 2.0, (26-30 week visit), the participant will receive an additional bottle of multivitamin tablets.

The pharmacist may go ahead (after visit 2.0) and dispense the remaining 12 capsules each of metronidazole or ampicillin (or matching placebos) to the clinic, for use when the participant arrives in labor. When arriving at the hospital for delivery, participants will be asked how many pills they have taken, and the antibiotic course will continue through delivery, administered by study staff. Any pills remaining after delivery will be given to the patient to take 3 times per day until the pills are gone.

7.5.2 Nevirapine

All HIV-infected participants will be offered nevirapine. HIV-infected participants who accept the nevirapine will be given two 100 mg tablets or 1 200 mg tablet at visit 2.0 and will be instructed to take the dose at the onset of labor. These instructions will be reiterated at visit 3.0. When arriving at the hospital, HIV-infected participants who accepted nevirapine will be asked if they took the nevirapine, and this will be recorded. If the nevirapine was not taken, the participant will be given a 200 mg dose.

If a participant is dosed in false labor, she will receive an additional dose at onset of active labor if more than 48 hours have passed since initial dosing. Participants who vomit within 30 minutes of dosing will be redosed; participants who vomit more than 30 minutes after dosing with nevirapine will not be redosed. Infants born to mothers who had intended to receive nevirapine prenatally but who either did not take the prenatal

nevirapine or who took the nevirapine within one hour of delivery should receive the infant nevirapine dose as soon after birth as the infant can tolerate liquids by mouth.

Those HIV-infected participants who do not accept nevirapine and all HIV-uninfected participants will be offered nevirapine placebo at visit 2.0 to maintain participant confidentiality. HIV-infected participants at sites where HIV-uninfected participants are not enrolled will not be given nevirapine placebo if they refuse nevirapine.

Maternal dosing:

- For spontaneous labor, the mother should be assessed as soon as possible after arriving in labor and delivery. If she has not yet taken 200 mg NVP at onset of labor, dosing should proceed when in the clinician's best judgment the woman is expected to deliver within 24 hours of presentation. A second dose of 200 mg NVP will be given 48 hours after the first if the woman remains in labor.
- If a woman has taken NVP and is subsequently assessed to be in false labor, she should re-initiate study dosing procedures as outlined above if she returns in labor and more than 48 hours have passed since she received NVP.
- If labor is induced and a cervical ripening agent is used, NVP should be given after the cervical ripening agent has been removed or discontinued and in the clinician's best judgment the woman is expected to deliver within 24 hours. A second dose of 200 mg NVP will be given 48 hours after the first if the woman remains in labor.
- If oxytocin is used after the cervical ripening agent, or as the sole agent for induction, NVP should be given when in the clinician's best judgment the woman is expected to deliver within 24 hours. A second dose of 200 mg NVP will be given 48 hours after the first if the woman remains in labor.
- For an emergency or non-elective Cesarean section, the woman should receive NVP as soon as the decision is made to do the Cesarean section.
- For an elective Cesarean section, the NVP will be given 4-12 hours before the scheduled procedure. Women who vomit within 30 minutes of dosing will receive a second 200 mg dose of NVP. Women who vomit 31 minutes or more after dosing will not receive an additional dose.

Infant dosing:

- The neonate will be given the oral NVP no later than 48-72 hours post birth if the mother was dosed during labor more than 1 hour and less than 48 hours before giving birth.

Note: if the mother did not deliver at the clinic, the infant can be dosed up to 7 days after delivery.

- The neonate will be given the oral NVP dose as soon as possible post delivery in the event that the mother was not dosed during labor, that she gave birth less than 1 hour after taking nevirapine, or that more than 48 hours elapsed between her taking NVP and giving birth.
- Should the infant vomit within 30 minutes of NVP administration, the dose will be readministered once.
- See the Infant Dosing Chart below.
- The infant dose should be calculated to two decimal points

INFANT WEIGHT/DOSE CALCULATION CHARTS: NVP delivered at 10 mg/ml oral suspension

Weight (kg)	Dose 2mg/kg
2.5 kg	0.5 ml
2.6 kg	0.5 ml
2.7 kg	0.5 ml
2.8 kg	0.6 ml
2.9 kg	0.6 ml
3.0 kg	0.6 ml
3.1 kg	0.6 ml
3.2 kg	0.6 ml
3.3 kg	0.7 ml
3.4 kg	0.7 ml
3.5 kg	0.7 ml
3.6 kg	0.7 ml
3.7 kg	0.7 ml
3.8 kg	0.8 ml
3.9 kg	0.8 ml
4.0 kg	0.8 ml
4.1 kg	0.8 ml
4.2 kg	0.8 ml
4.3 kg	0.9 ml
4.4 kg	0.9 ml
4.5 kg	0.9 ml

7.6 Documenting Product Use/Administration and Symptoms

Product use will be documented on the 26-30 Week Visit form, the Labor Dosing form, the Infant Dosing Form and the Postpartum Pill Count form. Symptoms related to study product use will be documented in the participant chart, and on the 26-30 week Antenatal Visit form, the Postpartum Pill Count form, the 4-6 week visit Follow-up Form and the Illness/AE form.

7.7 Study Product Destruction

As required in Title 21 CFR 312.59, HIVNET 024 protocol study products provided by the CRPMC are to be destroyed, with a DAIDS Clinical Site Monitoring Group (CSMG) monitor present, only for the following reasons:

- The protocol is completed, terminated, or the protocol has been deregistered at this site, and undispensed study products remain.
- The study product has been dispensed to the participant and was returned to the site/center or affiliated site.
- The study product has expired. Expired product must be removed from active stock and placed in quarantine until a letter is received from the CRPMC or DAIDS PAB authorizing destruction.
- The study product has been stored improperly and can no longer be safely used.
- The study product's destruction has been requested by a PAB pharmacist.
- The study product's destruction has been requested by a CRPMC recall letter:
 1. when the study is terminated, or
 2. when the investigational label does not contain an expiration date and the manufacturer has notified the CRPMC that the product has expired.

The pharmacist must respond immediately to recall notices as indicated on the recall notice. NOTE: A recall notice is not issued for research medications (commercial or investigational) that are labeled with an expiration date.

For sites Participating in HIVNET 024, the Pharmacist of Record should contact the Protocol Pharmacist or CRPMC prior to destroying any study products.

Instructions For Destroying Expired/Recalled Study Product in the Presence of a DAIDS CSMG Monitor

Any product that has been quarantined at the site for which the site has received a Drug Expiration Notice or Recall letter may be destroyed in the Presence of a DAIDS CSMG Monitor (unless otherwise stated in the notice/letter). The amounts to be destroyed must be verified by the DAIDS CSMG monitor. For "Amount to be Destroyed", please be specific. Enter the total number of dosage units to be destroyed. For example, if destroying 1 bottle of 100 tablets, document this as 1 X 100. If you are destroying a partial bottle, indicate the number of tablets or capsules in the bottle. Once the product(s) is destroyed, the Site Pharmacist and DAIDS CSMG monitor should sign the document and complete the required information. This form should then be refaxed to the CRPMC and the original kept on file by the Pharmacist of Record.

Instructions For Destroying Participant Specific Study Product in the Presence of a DAIDS CSMG Monitor

1. The Pharmacist of Record should complete the Study Product Inventory of Kits for Return/Destruction.
2. Contact the HIVNET 024 Protocol Pharmacist (sr72v@nih.gov) by email requesting the destruction of study kits. The email should include the specific kit

numbers that the site wishes to destroy. The list of PIDs should be broken down in the same order as they are listed on the Study Product Inventory of Kits with no more than 10 kits/page.

3. Once the HIVNET 024 Protocol Pharmacist issues a tentative approval of the destruction of specific kits, the Pharmacist of Record should complete the DAIDS HIVNET 024 Study Product Destruction Form. A copy of the DAIDS Study Product Destruction Form appears at the end of this document. This is a standard form that should be photocopied and used for destruction of HIVNET 024 Participant Specific Study Products (e.g. multivitamins packaged in kits by the CRPMC, antibiotics/placebos packaged in blister cards). This Pharmacist Signature and DAIDS CSMG Monitor Signatures will not be completed until the study products are destroyed. Destruction must be in the presence of a DAIDS CSMG monitor after the monitor has verified the quantities stated on this form against the actual physical counts. (These counts must also match the information provided on the Study Product Inventory of Kits for Return/Destruction).
4. Use a separate form for each investigator and site.
5. Complete the top, middle section of the form by entering the investigator's name and identification number and the site number.
6. Print or type the pharmacy address on the form.
7. For multivitamins, nevirapine tablets or placebo, or nevirapine suspension that have been returned from the participant the line item should list a specific lot number for the product. Include the study product name, strength and dosage form, quantity (see below), manufacturer, and lot number. If unable to determine the lot number of a product because, for example, a participant combined the contents of several vials, then list this item separately and enter "various lots" in the lot number column.
 - a. Quantity: For undispensed study products, please be specific. Enter the total number of dosage units destroyed. For example, if destroying 1 bottle of 500 capsules, document this as 1 X 500. If you are destroying a partial bottle, indicate the number of tablets or capsules in the bottle.
8. For participant antibiotic/placebo returns, list each line item by product name and disregard the lot number. For kit inventories, it is not necessary to list each participant's study products separately. Simply list the total number of erythromycin/placebo, the total number of ampicillin/placebo, and the total number of metronidazole/placebo being destroyed and attach the "Study Product Inventory of Kits for Return/Destruction" records for those items being destroyed.
9. After destruction, the Pharmacist of Record and DAIDS CSMG Monitor should sign and date the form and include the pharmacy phone number. A copy of the completed destruction notice should be faxed to the CRPMC.

10. Keep a copy of this record in the pharmacy files.

11. Mail the original to the following address:

NIAID Clinical Research Products Management Center
c/o McKesson BioServices
1055 First Street, Suite 125
Rockville, Maryland 20850

ATTN: HIVNET 024

National Institute of Allergy and Infectious Diseases Division of AIDS HIVNET 024 STUDY PRODUCT DESTRUCTION FORM	The products listed below were ordered by: Dr. _____ Investigator No. _____ Site: _____				FOR NIAID/CRPMC USE ONLY R.D. Number: _____ Date processed: _____ Signature of Reviewing Official: _____			
HIVNET 024	Product Name	Strength/Dose	Quantity (specify tablet, btl, vial)		Mfg	Lot Number (NVP or MVIs)	Comments	
			Full	Partial Amount				
Instructions: 1. Sign and date the form 2. One lot number per line. 3. Attach a copy of the authorization from the Protocol Pharmacist or PAB for each of the study products destroyed. 4. Attach a copy of the Study Product Inventory of Kits for Return/Destruction 4. Keep a copy of the completed forms and mail original to: NIAID CLINICAL RESEARCH PRODUCTS MANAGEMENT CENTER c/o McKesson BioServices 1055 First Street, Suite 125 Rockville, MD 20850 ATTN: HIVNET 024					Pharmacist Signature: _____ Preparer (if other than pharmacist): _____ Title: _____ Telephone: _____		DAIDS CSMG Monitor Signature: _____ Title: _____ Address: _____ Telephone: _____ Photocopying is authorized. Revised 8/01	

HIVNET 024 MOP: updated December 16, 2003
 Supersedes MOP dated August 12, 2002

Example of Drug Accountability documentation record for nevirapine (NVP) tablets, NVP placebo tablets, NVP oral suspension, and replacement antibiotic capsules.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASE/DIVISION OF AIDS, Division of AIDS

Investigational Agent Drug Accountability Record

Name of Institution		Investigator of Record		
Protocol Number: HIVNET 024	Drug Name/Strength/Dosage Form:			
Package Size	Quantity:	Storage Temp:	Lot Number*:	Expiration Date:*

Note: Only ONE lot number per page (A separate log must be used for NVP, NVP placebo tablets and NVP oral suspension). Expiration dates may not be available for all agents.

Participant ID NO.	Script Number	Date Dispensed (dd/mm/yy)	QUANTITY dispensed or received*	BALANCE Balance Forward []	Dispensed by (initials)	Comments (Additional comments may be made on the back of this form if necessary)
			No. tablets or capsules OR Amount of oral susp(ml)			

8. Adverse Experience Reporting Guidelines

These guidelines were compiled using the Code of Federal Regulations, the International Conference on Harmonization Guidelines, and from experience gained through previous reporting of adverse experiences and dialogue with the Regulatory Affairs Branch of the Division of AIDS. Serious Adverse Events should be reported according to the guidelines outlined in the “Division of AIDS Serious Adverse Event Reporting Manual for HIV Prevention Trial Network” (June 1, 2001). Because this is a protocol involving neonates/infants, DAIDS requires that all Grade 2, 3, and 4 SAEs be reported on all infants enrolled.

As specified in the DAIDS SAE Reporting Manual, reporting of SAEs to DAIDS are required only for events related to *investigational* study drug exposure. In the context of 024, nevirapine is the only investigational drug administered.

8.1 Adverse Experience Definitions

The following definitions are derived from the DAIDS HPTN SAE Manual.

Adverse Experience (AE): Any untoward medical occurrence, in a study participant who has received an investigational product that may or may not have had a causal relationship with this treatment. The adverse experience can therefore be any unfavorable or unintended sign (including an abnormal laboratory finding), symptom, or disease.

Serious Adverse Experience (SAE): A serious adverse event is an adverse experience occurring at any dose of an investigational product that results in the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. (21 CFR 312.32)

Patient/Subject Identification: If an infant of an enrolled mother is not born alive, the mother is considered to be the study participant and the adverse experience (e.g., Grade 4 stillbirth) is reported as an event for the mother. If the infant is born alive and lives very briefly before demise, the infant is considered to be the study participant and the adverse experience (e.g., Grade 5 death) is reported as an event for the infant.

8.2 Adverse Experience Grading

Toxicity grades are assigned by the site to indicate the severity of Adverse Experiences. The DAIDS “Table for Grading Severity of Adverse Experiences” (Toxicity Table) can be found in Appendix III. The Toxicity Table should be used by site clinicians to assign toxicity grades to all Adverse Experiences, including abnormal laboratory values. For clinical and laboratory events NOT identified in the Toxicity Table, refer to the specific “Guide for Estimating Severity Grade” within the Toxicity Table. In determining infant

< 3 months of age) ALT toxicity, for which there is no defined DAIDS toxicity table, use the toxicity table ranges established for infants > 3 months of age.

There are five toxicity grades that can be assigned to an SAE, which are defined as follows:

- 1 = Mild
- 2 = Moderate
- 3 = Severe
- 4 = Life -threatening
- 5 = Death

8.3 Non-Serious Adverse Experiences

Abnormalities at Baseline/Enrollment

For participants who enter a study with documented pre-existing abnormalities, an AE should be reported if the:

- severity increases a full grade level or more over baseline;
- severity increases to a reportable level using the Guide for Estimating Severity from the DAIDS Toxicity Table;
- participant's condition becomes serious, in the opinion of the clinician, due to the increasing severity of the abnormality.

All pre-existing abnormalities should be recorded in the patient's medical chart.

Abnormalities Within 8 Weeks of Exposure to the Investigational Product (NVP)

Non-serious Adverse Experiences in the mother that occur within 8 weeks of exposure to the investigational product, regardless of relatedness or expectedness to the investigational product, must be documented on the Illness/Adverse Experience case report form. The exposure to investigational product dictates whether such a non-serious adverse experience must be reported. Therefore, it is critical that clinicians obtain accurate medication histories from the participants.

Non-serious Adverse Experiences in infants, regardless of relatedness or expectedness to the investigational product, that occur within 8 weeks of exposure to the investigational product must be documented on the Illness/Adverse Experience case report form.

Abnormalities Within 2 Weeks of Exposure to Study Antibiotics/Placebo

Non-serious Adverse Experiences in the mother that occur within 2 weeks of exposure to study antibiotics/placebo, regardless of relatedness or expectedness to the antibiotics/placebo, must be documented on the Illness/Adverse Experience case report form. The exposure to study antibiotics/placebo dictates whether such a non-serious adverse experience must be reported. Therefore, it is critical that clinicians obtain accurate medication histories from the participants.

Non-serious Adverse Experiences in infants, regardless of relatedness or expectedness to the study antibiotics/placebo, that occur within 2 weeks of exposure to study antibiotics/placebo must be documented on the Illness/Adverse Experience case report form.

Follow-up Information

A new Illness/Adverse Experience case report form is not required when submitting follow-up information for a previously reported AE, except in cases where the severity of the AE increases by at least one grade. In general, the existing case report form should be updated and resubmitted. If the severity increases by a grade or more (this includes Grade 5 - Death) a second Illness/Adverse Experience form must be submitted. Abnormal lab results for tests done to verify or further diagnose an AE that was previously reported should not be reported as a new AE. This information should be added to the comments section of the original case report form.

8.4 Serious Adverse Experiences

8.4.1 Reporting and Relationship to Study Product

Relationship between a Serious Adverse Experience and an Investigational Product (Nevirapine) is determined by the site investigator or subinvestigator. In general, relationship is one of the main criteria used to determine the reportability of a Serious Adverse Experience to **RCC**. There are four relationship assessment categories:

- Definitely related
- Probably related
- Possibly related
- Not related

In some cases, events assessed by the site investigator as *Not related* to the Investigational Product (nevirapine) are not reported on an SAE Form. However, such events must have an alternative, definitive etiology documented in the volunteer's medical record.

Reportable Regardless of Relationship to Investigational Product (Nevirapine)

The following must be reported to the **RCC** SAE office regardless of the whether or not the event took place within 8 weeks of exposure to the Investigational Product.

- Death
- Congenital Anomaly/Birth Defect or Spontaneous Abortion, includes:
 - Congenital anomaly/birth defect occurring in a neonate/infant born to a mother who has received Investigational Product or
 - Spontaneous abortion occurring in a mother who has received Investigational Product

Note: All congenital anomalies/birth defects and spontaneous abortions are assigned a Grade 4 toxicity.

- Permanent Disability/Incapacity. A substantial disruption of a person’s ability to conduct normal life functions resulting from an adverse experience in a person participating in a clinical trial.

Note: All permanent disabilities/incapacities are assigned a Grade 4 toxicity.

For the SAEs listed above, submit SAE Form to the Regulatory **Compliance** Center (**RCC**) within 3 working days of site awareness.

Reportable if relationship to Investigational Product (Nevirapine) is assessed as: definitely, probably or possibly related

The following events must be reported to the **RCC** SAE office if the event occurs anytime within 8 weeks of exposure to investigational product and are deemed to be *Definitively, Probably or Possibly Related* to administration of the IP:

- Grade 3 and 4 adverse experiences for intensive reporting (maternal adverse experiences)
- Grade 2 through 4 adverse experiences for neonate/infant reporting (infant adverse experiences)
- Any adverse event of any toxicity grade (1 – 4) considered serious by the site investigator

For the SAEs listed above, submit SAE Form to the Regulatory **Compliance** Center (**RCC**) within 3 working days of site awareness.

TABLE 8-1. REPORTABLE SAEs

EVENT	REPORT IF EVENT OCCURS	REPORT IF RELATIONSHIP TO INVESTIGATIONAL PRODUCT	REPORTING TIME FRAME
<ul style="list-style-type: none"> • Death (includes neonatal deaths) • Congenital anomaly/Birth defect • Spontaneous abortion • Permanent disability/Incapacity 	Within 8 weeks of exposure to investigational product.	Definitely Probably Possibly Not related	Submit completed SAE Form to RCC Office within 3 working days of site awareness
	ANYTIME after receiving Investigational Product during study follow-up	Definitely Probably Possibly	Submit completed SAE Form to RCC within 3 working days of site awareness
<ul style="list-style-type: none"> • Recurrent event with new etiology or higher toxicity grade • Maternal Grade 3 and 4 events • Neonate/infant Grade 2 through 4 event • Grade 1 or 2 event considered unusual 	Within 8 weeks of exposure to investigational product.	Definitely Probably Possibly	Submit completed SAE Form to RCC within 3 working days of site awareness

8.4.2 Follow-Up Information

In most cases, resolution or follow-up information pertaining to previously reported SAEs does not need to be reported to **RCC** as an Updated SAE Report. However, for some events, more information may be required to determine if an IND Safety Report is necessary.

Any follow-up information should be clearly marked as “Update Information” and include the Protocol Number and Participant Identification Number. For the circumstances listed below, or as requested, the site is required to submit follow-up information as soon as it becomes available.

- **SAEs that become IND Safety Reports:** DAIDS must comply with the Code of Federal Regulations and submit Safety Reports to the FDA within fifteen (15) calendar days of receiving the SAE form.
- **Changes to Relationship Assessment:** The clinical site obtains new information that *changes* the site investigator’s assessment of the relationship between the event and Investigational Product.
- **Updated Information on a Death:** The clinical site submitted an initial SAE Form and obtains new information that changes the Cause of Death and/or the relationship assessment to the Investigational Product.

8.4.3 Recurrent Events

Serious Adverse Experiences (SAEs) that have been reported and occur again with a new etiology or occur at a higher toxicity grade should be reported on a new SAE Form

8.4.4 Means of Reporting Serious Adverse Experiences (SAEs)

SAEs that meet reporting requirements must be reported on a Division of AIDS SERIOUS ADVERSE EXPERIENCE FORM. See section 8.6 for instructions.

8.5 Documentation

- Illness/Adverse Experience Form: This form is described in Section 9.
- SAE Form: See section 8.6 for instructions.
- Safety Report: A Safety Report is used to report to the FDA and product manufacturers serious adverse experiences that are unexpected and possibly, probably or definitely related to an investigational drug.
- Serious Adverse Experience Database: Family Health International will keep a database documenting all SAEs received by **RCC** (AE number, date of occurrence, date identified, date notification was received by the Protocol Chair, and date the SAE was reported to FHI, DAIDS, RAB, the manufacturer and FDA). The data will be reconciled with the HPTN SDMC database and study CRFs at the study monitoring visits.

8.6 Instructions for Completing the DAIDS SAE FORM

HEADER INFORMATION

Shaded Box: Do Not Write in this Box. This is for **RCC** SAE Office use only.

Site Report Date: Enter the date the SAE Form was completed by the site.

Site Awareness Date: Enter the date the site first became aware OR was first notified of the SAE.

Clinical Site: Print the name of the clinical site.

Clinical Site Number: Provide the clinical site number assigned by the statistical center.

Telephone Number and E-mail Address: Provide the most appropriate telephone number and E-mail address for the **RCC** SAE Office to contact for additional information.

Completed by: Print the name and title of the person filling out the SAE Form.

Protocol Number: Enter the protocol number that this participant is currently enrolled in.

Participant ID Number: Enter the 9-digit Participant ID (PID) in the spaces provided. Use the appropriate PID format.

Age: Enter the age of the participant and circle the appropriate units.

Gender: Check the appropriate gender of the participant.

ITEM 1

Check the ONE main reason this SAE is being reported.

ITEM 2

Serious Adverse Experience: List ONE key word, diagnosis or cause of death for the SAE being reported.

Toxicity Grade of SAE: Circle the toxicity grade to indicate the severity of the SAE. The toxicity grade assigned to the SAE should be made using the DAIDS Toxicity Table.

Study Week: Enter the week of study during which the SAE occurred.

SAE Onset Date: Enter the date when the SAE first occurred at the assigned toxicity grade level. (For SAEs that are lab abnormalities, use the specimen collection date).

ITEM 3

Complete the Investigational Product (IP) information table

Investigational Product: Enter the Investigational Product that the participant is receiving in the clinical trial. List one Investigational Product per line. For the purposes of 024, nevirapine is the only Investigational Product dispensed.

Dose, Route, Schedule of Investigational Product at SAE Onset: Enter the dose, route, and schedule of the Investigational Product that was administered at the time of the SAE.

Date Investigational Product First Started: Enter the Initial Date that the participant began taking the IP.

Date Investigational Product Last Taken: Enter the Last Date that the participant took the IP. If the participant is being Continued on the IP in response to the SAE, this field should be left blank.

Investigational Product Management at SAE Onset: Using the key provided below the table, enter the IP Management code that represents how the IP was managed as a result of the SAE.

Date of Investigational Product Management: Enter the date when the IP management became effective. This field should be left blank when “0” is entered as the IP management code.

Relationship Assessment: Mark the appropriate relationship assessment for the IP listed.

Regarding intrauterine exposure to IP: Be sure to note on the form if an infant’s exposure to the IP was intrauterine and be sure to mark the appropriate relationship assessment.

ITEM 4

If the SAE being reported is a **Lab Abnormality**, complete the Table provided or attach copies of laboratory reports. If attaching copies of laboratory reports, remember to remove participant identifiers from source documents and attach a PID label or write the PID on the lab reports.

ITEM 5

Complete the Concomitant Medications table. For the purposes of 024, concomitant medications are defined as drugs other than the Nevirapine and may include the other study antibiotics and vitamins. List the concomitant medications taken during the months prior to/as SAE onset or attach a copy of the participant’s Concomitant Medications forms. If attaching a copy of the Concomitant Medications form, remember to remove participant identifiers and attach a PID label or write the PID on the copy.

ITEM 6

Serious Adverse Experience Summary: In this narrative section, provide in English a brief summary of the SAE. Include any pertinent past medical history and all relevant information and details surrounding the event. If applicable, attach copies of source documentation (i.e., progress notes, discharge summaries, hospital records, diagnostic tests). If attaching copies of source documentation, remember to remove participant identifiers (i.e., name, birth date, etc.) and attach a participant identification label or write the participant identification number on the copy. Please make sure that the writing is legible.

ITEM 7

Site Physician Signature: Signature of the Investigator of Record (IoR) listed on the FDA Form 1572, who has reviewed and verified the data on the SAE Form for accuracy and completeness and who assessed the relationship of the SAE to the Investigational Product(s). If the physician is not available to sign the SAE Form, please submit it within the time frame described in the HPTN SAE Manual without the signature (i.e., within 3 working days of site awareness of SAE). The signature page can be resubmitted independently to the **RCC** when the investigator or subinvestigator has signed the SAE Form.

**DIVISION OF AIDS
REGULATORY OPERATION CENTER
SERIOUS ADVERSE EXPERIENCE (SAE) FORM
HIV PREVENTION TRIALS NETWORK (HPTN)**

SAE Office Phone: 1-800-537-9979 or 301-897-1709

RCC OFFICE FAX: 1-800-275-7619 or 301-897-1710

SAE Email: SAE@tech-res.com

SAE Office Use Only	SAE Tracking Number _____	Protocol Number _____
Date Received In RCC	Type of Report: <input type="checkbox"/> Initial <input type="checkbox"/> Update	

Site Report Date: ___/___/___
 D D M M Y Y Y Y

Site Awareness Date: ___/___/___
 D D M M Y Y Y Y

Clinical Site: _____

Clinical Site Number: _____

Telephone Number: (___) _____

E-mail Address: _____

Completed by: _____
(Print Name/Title)

Signature: _____

Protocol Number

Participant ID Number (Use appropriate format)
(Use label or write in)

H024

____ - ____ - ____ OR ____ - ____ - ____
Site/Protocol Participant ID Chk Site/Protocol Part. ID Chk Cohort

Age: __ __ Years/Months/Days (Circle)

Gender: __ Male __ Female

1. Main reason SAE is being reported (Check One Category)

- Death
- Congenital anomaly/Birth Defect
- Permanent disability/Incapacity
- SAE meets reporting requirements, but is NOT any category above
- SAE is considered serious for this participant by the site physician, but is NOT at a reportable level

2. Serious Adverse Experience Data

Serious Adverse Experience (key word, diagnosis, or cause of death)	Toxicity Grade* (circle one)	Study Week	Onset Date Day Month Year
_____	1 2 3 4 5	_____	___/___/___

*1= Mild, 2= Moderate, 3= Severe, 4= Life-threatening, 5=Death

HIVNET 024 MOP: updated December 16, 2003
Supersedes MOP dated August 12, 2002

Participant ID Number:
(Use appropriate format)

Site Report Date: ____ / ____ / ____
D D M M Y Y Y Y

____ - ____ - ____ OR ____ - ____ - ____
Site/Protocol Participant ID Chk Site/Protocol Part. ID Chk Cohort

3. Investigational Product Information

Investigational Product (IP) (List 1 per line)	Dose, Route, Schedule of IP at SAE Onset	Date IP First Started (DD/MM/YYYY)	Date IP Last Taken (DD/MM/YYYY)	IP Mgmt At SAE Onset*	Date of IP Mgmt (DD/MM/YYYY)	Relationship Assessment (Mark 1 Assessment per line)
1. Nevirapine						<input type="checkbox"/> Definitively related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related
2.						<input type="checkbox"/> Definitively related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related
3.						<input type="checkbox"/> Definitively related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related
4.						<input type="checkbox"/> Definitively related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related
5.						<input type="checkbox"/> Definitively related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related
6.						<input type="checkbox"/> Definitively related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related

* IP Management: C=IP Continued without Change in Dose or Schedule
 T= IP Temporarily Held due to SAE
 D=IP Permanently Discontinued due to SAE

R=IP Dose or Schedule Reduced
 O=IP Course Completed or Patient Off IP at SAE onset

4. Relevant Laboratory Test Results

Complete the table below, or send copies of the data forms or other lab results

Lab Test	Lab Result	Site Normal	Collection Date (DD/MM/YYYY)	Previous Lab Result	Collection Date (DD/MM/YYYY)

HIVNET 024 MOP: updated December 16, 2003
 Supersedes MOP dated August 12, 2002

Participant ID Number:
(Use appropriate format)

Site Report Date: ____ / ____ / ____
D D M M Y Y Y Y

____ - ____ - ____ OR ____ - ____ - ____
Site/Protocol Participant ID hk Site/Protocol Part. ID Chk Cohort

5. Concomitant Medications

List ALL non-study concomitant medications being taken during the month prior to/at SAE onset below, or attach a copy of the Concomitant Medications form.

- a. _____ c. _____ e. _____
- b. _____ d. _____ f. _____

6. Serious Adverse Experience Summary

In English, briefly describe the sequence of the signs and/or symptoms (including dates), relevant past medical history, diagnoses, interventions and/or treatment of the SAE, the participant's response to treatment, and the outcome. Copies of progress reports, discharge summaries, hospital records, diagnostic tests, etc., may be attached.

7. Physician Signature

Site Physician (Signature): _____
Signature indicates verification of data accuracy and completeness

Date: ____ / ____ / ____
D D M M Y Y Y Y

Site Physician (Name Printed): _____

9. Data Collection

This section contains information on the data collection procedures for this study. Included are form completion instructions as well as information on Participant ID numbers and the study visit schedule and forms requirements.

9.1 Participant ID Numbers

The HPTN SDMC will provide each study site with a list of Participant ID numbers to be assigned to study participants at the Enrollment Visit. A participant is randomized with the assignment of a sequential Participant ID number. These numbers will take the form:

sss-xxxx-k-c where:

sss is the three-digit code assigned to the site

xxxx is a unique four-digit identifier assigned to the participant,

k is a check digit, and

c is a one-digit identifier assigned to the cohort in which the participant will be enrolled. For this study, cohort refers to whether the participant is a mother or an infant. All mother Participant ID numbers will have "0" as a cohort identifier; Infants ID numbers will have 1 (or 2 for a twin, or 3 for the third triplet). Mothers and their infants will have linked Participant ID numbers, with the first 8 digits identical for each mother-infant pair. For example, the infant of mother 522-0050-1-0 would be assigned ID number 522-0050-1-1. If mother 521-0075-4-0 has twins, the first born is assigned 521-0075-4-1, and the second 521-0075-4-2

Note: The cohort identifier (c) for infants will not appear on the list of Participant ID numbers provided by the HPTN SDMC; study site staff will assign this portion of the ID number according to birth order.

9.2 Visit Scheduling and Coding

9.2.1 Scheduled Visits

Visit Codes

This study has 10 scheduled study visits, with data submitted to the HPTN SDMC for Enrollment and all visits after enrollment and randomization. Two-digit visit codes are used to identify the study visit at which data collection forms are completed.

Whenever possible, the visit codes will be included in the barcode on the form or pre-printed in the visit code boxes at the top of the form. In some cases, especially for forms used at multiple visits, site staff will be responsible for entering the visit code in the visit code boxes.

Table 9-2: Visit codes for Enrollment and Follow-up Visit Forms

Visit	Visit Code	Window
Enrollment	01.0	20-24 weeks gestation
First Antenatal Visit (26-30 weeks)	02.0	25-35 weeks gestation (<i>However, if the participant comes in late for her first antenatal visit, this visit should be done whenever she comes in, even if after 35 weeks</i>)
Second Antenatal Visit (36 weeks)	03.0	36 weeks - end of gestation
Labor/Delivery/ Birth	04.0	If mother does not deliver at study site, complete forms to the extent possible when participant returns for first post-natal visit. Perform heel stick for infant PCR as soon as the mother brings the baby to the clinic, even if it is more than 7 days after birth.
4-6 weeks	05.0	4-11 weeks
3 months	06.0	12-23 weeks
6 months	07.0	24-36 weeks
9 months	08.0	37-51 weeks
12 months	09.0	52 weeks-18 months

Visit Scheduling

Screening may take place anytime between 16 and 23 weeks gestation. Enrollment may take place anytime after the Screening Visit between 20 and 24 weeks gestation. If a woman is screened and found eligible before 20 weeks, she must return at 20-24 weeks gestation for the enrollment visit.

The study has two Antenatal visits between Enrollment and Labor/Delivery. In general the First Antenatal Visit occurs between 25 and 35 weeks of gestation, however, the procedures for the First Antenatal Visit should always be performed at the participant's first study visit back to the clinic, even if this is later than 35 weeks of gestation. Because important information about adherence to the study antibiotics regimen and specimens are collected at the First Antenatal Visit this visit should not be missed if at all possible. ***If this visit does not take place, due to premature delivery or failure of the mother to return for antenatal appointments before delivery, the First Antenatal Study Visit form must still be completed to document adherence to the study drugs.***

Similarly, if the mother does not delivery at a study site clinic, the Mother's Labor Dosing, Mother's Intrapartum, and Infant Birth forms must be completed with all available information once the mother returns for postnatal care, including the heelstick for specimen collection and nevirapine dosing, if applicable.

See Table 9-1 for requirements for completing other scheduled visits.

Missed Visits

A Missed Visit form should be completed when the staff are confident that a scheduled study visit will not take place. In general, a late visit is considered to be "missed" if it makes more sense to conduct the procedures of the next scheduled visit. For this study (see Table 9-1), after the Labor/Birth visit, a visit is considered to be missed if it would fall within a week of the next scheduled visit. Submission of the Missed Visit form will "turn off" expectations of data collection forms for this visit in the DataFax system.

In the event that a participant presents to complete a missed visit after a Missed Visit form has been submitted but within the correct visit window, place a line through the previously submitted Missed Visit form and re-fax it to the HPTN SDMC. Complete all of the scheduled visit procedures, code all visit forms with the scheduled visit code, and fax the forms to the HPTN SDMC.

A Missed Visit form should never be completed for the First Antenatal Study Visit or the Labor/Delivery/Birth visit.

9.2.2 Interim Visits

Participant-initiated interim visits may occur at any time after Enrollment. Off-schedule visits to assess illnesses/AEs are considered interim visits. The forms that may be used to document interim visits include *Mother's* and *Infant's Illness/AE*, *Lab Results*, *Specimen Collection*, *Mother's Pelvic Exam*, and *Mother's or Infant's Follow-up*.

Note: Additional visits required to complete procedures that are not performed at a scheduled visit (e.g., because a participant must leave the site before all procedures can be performed) are not considered interim visits. Code forms completed at such visits with the scheduled visit code.

Study site staff will assign visit codes to interim visits as follows:

When a unscheduled, non-protocol required visit occurs, the following guidelines should be used for assigning the visit code.

- Record the two digit Visit Code for the most recent scheduled visit.

Note: Use this code even when that scheduled visit was not completed.

- Use the guide below to complete the third box (first after the decimal point).

— Type

1 — First Interim Visit after the most recent scheduled visit.

2 — Second Interim Visit after the most recent scheduled visit.

Example #1:

If a mother returns to the clinic two days after her labor/delivery visit (Visit Code 04.0) record the visit code:

Visit Code for this Interim Visit:

0 4 . 1

Visit Code

Example #2:

If the mother returns again 6 days after her labor/delivery visit (Visit Code 04.0) record the visit code:

Visit Code for this Interim Visit:

0 4 . 2

Visit Code

9.3 Schedule of Forms

9.3.1 Required and Optional Forms by Visit

Tables 9-2 and 9-3 list maternal scheduled study visits and forms to be submitted at those visits. The tables indicate the visit codes for each visit, and both required and optional forms to be completed and faxed after each visit.

**Table 9-2: Schedule of Forms for DataFax 051
HIV024 Chorioamnionitis Mother Study**

The data collection forms required for each scheduled study visit are listed on the Visit Checklists and are summarized in the table below.

ENROLLMENT 20-24 Weeks		Visit Code: 01.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)		Sequence # (ps)	
MC-1	Mother's Eligibility	002	BC 0101		BC 0101	
ME-1 ME-2	Mother's Enrollment	003, 004	BC 0101		BC 0101	
DM-1	Mother's Demographics	005	BC 0101		BC 0101	
PRE-1	Mother's Pre-existing Conditions	050			□□□	
PE-1	Mother's Pelvic Exam	009	0 1 . 0	1	□□ . □	1
MLR-1 MLR-2	Mother's Laboratory Results	007, 008	0 1 . 0	1	□□ . □	1
MSC-1	Mother's Specimen Collection	006	0 1 . 0	1	□□ . □	1
FIRST ANTENATAL VISIT 26-30 Weeks		Visit Code: 02.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)		Sequence # (ps)	
PE-1	Mother's Pelvic Exam	009	0 2 . 0	1	□□ . □	1
MLR-1 MLR-2	Mother's Laboratory Results	007, 008	0 2 . 0	1	□□ . □	1
MSC-1	Mother's Specimen Collection	006	0 2 . 0	1	□□ . □	1
AVA-1 AVA-2	Mother's First Antenatal Study Visit	010, 011, 014	BC 0201		BC 0201	
AE-1	Mother's Illness/AE (Optional)	420	□□		□□□□ □□	
SECOND ANTENATAL VISIT 36 Weeks		Visit Code: 03.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)		Sequence # (ps)	
MLR-1 MLR-2	Mother's Laboratory Results	007, 008	0 3 . 0	1	□□ . □	1
AVB-1 AVB-2	Mother's Second Antenatal Study Visit	012, 013	BC 0301		BC 0301	
AE-1	Mother's Illness/AE (Optional)	420	□□		□□□□ □□	

**Table 9-2: (Continued) Schedule of Forms for DataFax 051
HIV024 Chorioamnionitis Mother Study**

The data collection forms required for each scheduled study visit are listed on the Visit Checklists and are summarized in the table below.

LABOR & DELIVERY		Visit Code: 04.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)		Sequence # (ps)	
MIP-1 MIP-2 MIP-3 MIP-4 MIP-5	Mother's Intrapartum	031 032 033 034 035	BC 0401		BC 0401	
LD-1 LD-2	Labor Dosing	028, 029	BC 0401		BC 0401	
MD-1	Mother's Discharge	019	BC 0401		BC 0401	
AE-1	Mother's Illness/AE (Optional)	420	□□		□□□□ □□	
POSTPARTUM 4-6 Weeks		Visit Code: 05.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)		Sequence # (ps)	
PPC-1	Postpartum Pill Count	020	BC 005		BC 005	
MFU-1	Mother's Follow-up	021	05.0 1		□□.□ 1	
AE-1	Mother's Illness/AE (Optional)	420	□□		□□□□ □□	
FOLLOW-UP 3 Months		Visit Code: 06.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)		Sequence # (PS)	
MFU-1	Mother's Follow-up	021	06.0 1		□□.□ 1	
AE-1	Mother's Illness/AE (Optional)	420	□□		□□□□ □□	
FOLLOW-UP 6 Months		Visit Code: 07.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)		Sequence # (ps)	
MFU-1	Mother's Follow-up	021	07.0 1		□□.□ 1	
AE-1	Mother's Illness/AE (Optional)	420	□□		□□□□ □□	
FOLLOW-UP 9 Months		Visit Code: 08.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)		Sequence # (ps)	
MFU-1	Mother's Follow-up	021	08.0 1		□□.□ 1	
AE-1	Mother's Illness/AE (Optional)	420	□□		□□□□ □□	

Table 9-2: (Continued) Schedule of Forms for DataFax 051 HIV024 Chorioamnionitis Mother Study

The data collection forms required for each scheduled study visit are listed on the Visit Checklists and are summarized in the table below.

FOLLOW-UP 12 Months		Visit Code: 09.0	FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)	
MFU-1	Mother's Follow-up	021	09.0 1	. . 1	
AE-1	Mother's Illness/AE (Optional)	420	
CM-1	Mother's Concomitant Medications	423	
TM-1	Mother's Termination	490		
ADMINISTRATIVE		Visit Code:	FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)	
COM-1	Mother's Comments	461	. . . 1	. . . 1	
MV-1	Mother's Missed Visit	463	. . . 1	. . . 1	

**Table 9-3: Schedule of Forms for DataFax 052
HIV024 Chorioamnionitis Infant Study**

The data collection forms required for each scheduled study visit are listed on the Visit Checklists and are summarized in the table below.

BIRTH/RANDOMIZATION		Visit Code: 04.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)		
IB-1	Infant Birth	001	BC 0401	BC 0401		
IND-1	Infant Nevaripine Dosing	009	BC 0401	BC 0401		
ILR-1	Infant's Laboratory Results	004	0 4 . 0 1	0 4 . 0 1		
AE-1	Infant's Illness/AE (Optional)	420				
FOLLOW-UP 4-6 Weeks		Visit Code: 05.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)		
IFU-1 IFU-2	Infant's Follow-up Visit	002 003	0 5 . 0 1	. . . 1		
ILR-1	Infant's Laboratory Results	004	0 5 . 0 1	. . . 1		
AE-1	Infant's Illness/AE (Optional)	420				
FOLLOW-UP 3 Months		Visit Code: 06.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)		
IFU-1 IFU-2	Infant's Follow-up Visit	002 003	0 6 . 0 1	. . . 1		
ILR-1	Infant's Laboratory Results	004	0 6 . 0 1	. . . 1		
AE-1	Infant's Illness/AE (Optional)	420				
FOLLOW-UP 6 Months		Visit Code: 07.0		FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)		
IFU-1 IFU-2	Infant's Follow-up Visit	002 003	0 7 . 0 1	. . . 1		
ILR-1	Infant's Laboratory Results (Optional)	004	0 7 . 0 1	. . . 1		
AE-1	Infant's Illness/AE (Optional)	420				

**Table 9-3: (Continued) Schedule of Forms for DataFax 052
HIV024 Chorioamnionitis Infant Study**

The data collection forms required for each scheduled study visit are listed on the Visit Checklists and are summarized in the table below.

FOLLOW-UP		Visit Code: 08.0	FOR SC USE ONLY		
9 Months					
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)	
IFU-1 IFU-2	Infant's Follow-up Visit	002 003	0 8 . 0 1	□ □ . □ 1	
ILR-1	Infant's Laboratory Results (Optional)	004	0 8 . 0 1	□ □ . □ 1	
AE-1	Infant's Illness/AE (Optional)	420	□ □	□ □ □ □ □ □	
FOLLOW-UP		Visit Code: 09.0	FOR SC USE ONLY		
12 Months					
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)	
IFU-1 IFU-2	Infant's Follow-up Visit	002 003	0 9 . 0 1	□ □ . □ 1	
ILR-1	Infant's Laboratory Results	004	0 9 . 0 1	□ □ . □ 1	
AE-1	Infant's Illness/AE (Optional)	420	□ □	□ □ □ □ □ □	
CM-1	Infant's Concomitant Medications	423	□ □	□ □ □ □ □ □	
TM-1	Infant's Termination	490		□ □ □ □ □ □	
ADMINISTRATIVE		Visit Code:	FOR SC USE ONLY		
Acronym	Form Name	Plate #	Sequence # (site)	Sequence # (ps)	
COM-1	Infant's Comments	461	□ □ . □ 1	□ □ . □ 1	
MV-1	Infant's Missed Visit	463	□ □ . □ 1	□ □ . □ 1	

9.4 Forms Instructions

9.4.1 Data Collection Forms

Updating Forms

When a form is updated by the SC, the version number and date on that particular form will be updated and a new set of forms sent to the sites. As soon as a site receives the revised form, all unused copies of the previous version should be collected and destroyed.

Form Completion Tips

- Always use a black or blue medium ballpoint pen to complete forms. Do not use any other type of writing implement.
- Legibly print written responses or comments.
- Press firmly when recording data or writing comments.
- Keep all responses within the margins of the individual data boxes.
- Do not type data onto forms. Handwrite all data on all DataFax forms.
- Record data on the front of forms only. DataFax cannot read the back of forms.
- Do not use the 0.5-inch margins at the top, bottom, or sides of the forms for recording data, it will not be seen by the data entry staff at the SC.
- Record “specify” responses in the space provided. If the line provided is not long enough, continue in another blank area of the form (within the margins).
- Never mark over or punch holes through the bar or barcode at the top of each form. DataFax requires the barcode each time the form is faxed in.
- **Never** use “white-out” on DataFax forms, or any data collection forms.
- Do not attach Post-It notes to DataFax forms.

Copying Completed Forms

No completed DataFax form should ever be copied. Only the original of any completed DataFax form should be maintained at the study site.

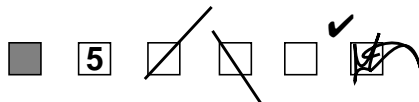
Marking Item Boxes

Many items have a box or series of boxes for recording a response. Mark the box clearly with an **X** or a clearly defined **✓**. Do not shade in the box or mark it with a slash or other character.

Correct:



Incorrect:



- Do not mark more than one box in response to an item *unless instructed to do so*. Many items provide boxes marked with a *yes*, a *no* or other distinct answer, and should only have one box marked.

Entering Numeric Data

The data management staff viewing your faxes are able to interpret many different handwriting styles for numerical data as long as they are clearly written and not ambiguous or confusing.

- Right justify all numerical data and fill in any blank leading boxes with zeroes. Any blank boxes will result in a QC note. For example, to record a 7 into a three-digit box, enter a 0 in the first two boxes, and a 7 in the third box:

Correct: Incorrect:

0	0	7
---	---	---

		7
--	--	---

This example is incorrect, and would result in a QC note.

- Write the number completely within the margins of the box as shown in the example below; try not to touch the edges or stray outside the margins.

In the following example, the 4 on the right could be misinterpreted as a 7 or a 1.

Correct: Incorrect:

4

4

Correcting Mistakes

If a numeric box is completed incorrectly, draw a single line through the incorrect entry, place the correct answer near the box, and initial and date the correction as shown below. Remember that your responses are being read by the data management staff at the SC. As long as your corrections are clear, they will be interpreted correctly.

Make all corrections to the original form. Never transfer information on a completed DataFax form to a new form.

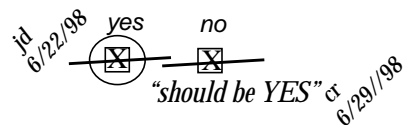
5	4
--------------	---

jd 6/22/98

If an X is marked in the wrong box, draw a single line through the incorrectly marked box, initial and date it, then mark the correct box as shown below.

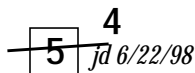
jd 6/22/98	yes	no
	X	X

If the correct answer has previously been crossed out, circle the correct item, write an explanation in a blank area near the item, and initial and date all corrections.



When changing an entry, draw a single line through the incorrect entry so that it still can be read. Do not obliterate by excessive cross-outs.

Correct: Incorrect:

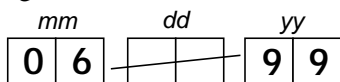


Always initial and date any changes you make to the data.

Handling Missing and Unknown Data

Blank items on data forms are considered missing data and will therefore result in a QC note *unless* they are blank due to skip pattern requirements. To avoid a QC note on items where the answer to an item is not known or is unavailable, or where the participant refuses to answer an item, draw a line through the blank boxes corresponding to the item.


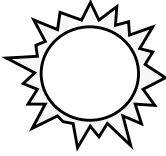
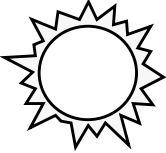

For example, when complete information for a date is unavailable, draw a single line through the boxes:



9.4.2 Use of 24-hour Clock

Times are to be entered using a 24-hour clock. See “24 hour clock Conversion Table” below for assistance in converting to the 24-hour clock.

24 hour clock Conversion Table:

	24:00 Midnight → 24 00	12:00 Noon → 12 00	
	1:00 a.m. → 01 00	1:00 p.m. → 13 00	
	2:00 a.m. → 02 00	2:00 p.m. → 14 00	
	3:00 a.m. → 03 00	3:00 p.m. → 15 00	
	4:00 a.m. → 04 00	4:00 p.m. → 16 00	
	5:00 a.m. → 05 00	5:00 p.m. → 17 00	
	6:00 a.m. → 06 00	6:00 p.m. → 18 00	
	7:00 a.m. → 07 00	7:00 p.m. → 19 00	
	8:00 a.m. → 08 00	8:00 p.m. → 20 00	
	9:00 a.m. → 09 00	9:00 p.m. → 21 00	
	10:00 a.m. → 10 00	10:00 p.m. → 22 00	
	11:00 a.m. → 11 00	11:00 p.m. → 23 00	

9.4.3 Study Site Review of Data Collection Forms

It is recommended that sites review each completed form for completeness and legibility before faxing to DataFax. The following list can be used as a review checklist.

- Never record any information on a DataFax form that identifies the participant, other than the Participant ID Number. This includes the participant's name, address, or any other personal identifiers.
- Make sure all items are answered, unless skipped according to the instructions on the form.
- Make sure only one response box per item is marked, unless instructed otherwise.
- Make sure all written entries are clear enough to be legible after faxing.
- Make sure the date/Staff ID or initial lines are completed on every page.
- Take extra care to ensure that nothing is written on or above the DataFax barcode as this can result in misread forms.
- Check for common errors. The largest percentage of avoidable QC notes are associated with:
 - missing dates
 - missing, transposed or incorrectly transcribed Participant ID numbers
 - missing entry for the lead item that begins a skip pattern
 - missing visit codes

9.4.4 Faxing DataFax Forms

Whenever possible, forms should be faxed to DataFax within 48 hours following the participant's visit. Keep in mind that the sooner a form is transmitted the sooner the data will enter the study database. Additional/updated data can be provided by refaxing the updated form.

Mother's Forms

9.4.5 Mother's Eligibility (MC-1)

Description and Purpose

The *Mother's Eligibility* form documents that the participant signed informed consent and met eligibility criteria.

Form-Specific Instructions

- Do not enroll the participant if the answer to any of items 1 through 7 is “no”, or the answer to any of items 8 through 13 is “yes.”
- The date to be entered at the top right-hand corner is the date the participant was enrolled and assigned a participant ID number.
- Item 14 documents whether the study antibiotics were dispensed to the participant. If not, please indicate the reason.
- If a participant is later found to be ineligible after enrollment and randomization, change the appropriate item on this form and refax it. In such cases, **Do not take the participant off study**. Once a mother is enrolled and randomized she and her infant must continue to be followed on study, and their data will be included in later analyses.

Figure 9-1
Mother's Eligibility (MC-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)					Mother's Eligibility (MC-1)			
HIV 024 Chorio (051)		MC-1 (002)		Visit (101)		Page 1 of 1		
Participant ID <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;">0</div> <div style="border: 1px solid black; padding: 2px;">0</div> <div style="border: 1px solid black; padding: 2px;">0</div> - <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> - <div style="border: 1px solid black; padding: 2px;"> </div> - <div style="border: 1px solid black; padding: 2px;">0</div> </div> <div style="display: flex; justify-content: space-between; font-size: small; margin-top: 2px;"> Site Number Participant Number Chk. Cohort </div>					Mother's Eligibility <div style="display: flex; justify-content: space-around; align-items: center; margin-top: 5px;"> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> </div> <div style="display: flex; justify-content: space-around; font-size: x-small; margin-top: 2px;"> dd mm yy </div>			
ELIGIBILITY CHECKLIST								
1. Did the participant provide informed consent for HIV testing?							yes	no
							<input type="checkbox"/>	<input type="checkbox"/>
2. Has the participant been tested for HIV?							<input type="checkbox"/>	<input type="checkbox"/>
3. Did the participant provide informed consent for this study?							<input type="checkbox"/>	<input type="checkbox"/>
4. Is the participant within 20-24 weeks gestation?							<input type="checkbox"/>	<input type="checkbox"/>
5. Does the participant intend to deliver at a study site hospital or clinic?							<input type="checkbox"/>	<input type="checkbox"/>
6. Is the participant willing to take treatment as scheduled?							<input type="checkbox"/>	<input type="checkbox"/>
7. Is the participant willing to come back for follow-up visits throughout this pregnancy and for one year following birth?							<input type="checkbox"/>	<input type="checkbox"/>
If no to any of the above, participant is ineligible.								
8. Has the participant taken antibiotics, other than treatment for syphilis or gonorrhea, within the last 2 weeks?							yes	no
							<input type="checkbox"/>	<input type="checkbox"/>
9. Does the participant have a known allergy to penicillin, ampicillin, erythromycin, or metronidazole?							<input type="checkbox"/>	<input type="checkbox"/>
10. Does the participant have a known major illness likely to influence pregnancy outcome, including diabetes, severe renal or heart disease, or active tuberculosis?							<input type="checkbox"/>	<input type="checkbox"/>
11. Does the participant have known major obstetric complications of the current pregnancy, such as placenta previa, ruptured membranes, or multiple pregnancy?							<input type="checkbox"/>	<input type="checkbox"/>
12. Does the participant have any known central nervous system diseases, including seizures?							<input type="checkbox"/>	<input type="checkbox"/>
13. Is the participant taking anticoagulant drugs (e.g., Coumadin, Heparin)?							<input type="checkbox"/>	<input type="checkbox"/>
14. Was antenatal study drug dispensed?							yes	no
							<input type="checkbox"/>	<input type="checkbox"/>
If no, indicate reason: _____							If yes to any of the above, participant is ineligible.	
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001					SAMPLE			<div style="border: 1px solid black; padding: 2px; display: inline-block;">0 1</div>
hivnet0msHIV024_chorio0mseligibility_mother.fm							Language Staff Initials / Date	

9.4.6 Mother's Demographics (DM-1)

Description and Purpose

The *Demographics* form collects demographic and socioeconomic information from participants.

Form-Specific Instructions

- For Item 1 enter the participant's birthdate if known, otherwise enter her age or estimated age.
- Item 3 is total number of years of education. Do not include any years of pre-school or kindergarten, or any years of school that the participant repeated.
- Item 5 asks about marital status of the participant, mark the one best answer.
 - **Never married and not living with a partner**
Neither legally married nor living with a partner like a married couple.
 - **Married**
Legally married.
 - **Living with partner**
Living with a partner like a married couple.
 - **Separated**
Married but living apart.
 - **Divorced**
Married then legally divorced and not living with a subsequent partner.
 - **Widowed**
Married and husband has died and participant is not living with a subsequent partner.
- If item 5 is answered as "never married", "divorced" or "widowed", then items 6 and 7 are skipped.
- Item 6, record years of education for the husband or partner in the same way as item 4 above.

Figure 9-2
Mother's Demographics (DM-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)				Mother's Demographics (DM-1)												
HIV 024 Chorio (051)		DM-1 (005)		Visit (101)		Page 1 of 1										
Participant ID <div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 2px;">000</div> <div style="border: 1px solid black; padding: 2px;">- [] [] [] [] - [] [] - [] []</div> <div style="border: 1px solid black; padding: 2px;">0</div> </div> <p style="font-size: small; margin-top: 2px;">Site Number Participant Number Chk Cohort</p>				Mother's Demographics				Form Completion Date <div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; padding: 2px;">[] []</div> <div style="border: 1px solid black; padding: 2px;">[] []</div> <div style="border: 1px solid black; padding: 2px;">[] []</div> </div> <p style="font-size: small; margin-top: 2px; text-align: center;">da mm yy</p>								
<p>1. What is your date of birth? [] [] [] [] [] [] [] [] OR Age: [] [] years (estimate OK)</p> <p style="text-align: center; font-size: small;">dd mm yy</p>																
<p>2. Are you able to read? <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i></p>																
<p>3. How many years of education have you had (excluding kindergarten, pre-school, and repeated years)? [] [] years</p>																
<p>4. What is your occupation? <i>Mark only one.</i></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> <i>homemaker</i> <input type="checkbox"/> <i>self-employee</i> </div> <div style="width: 45%;"> <input type="checkbox"/> <i>formal employment</i> <input type="checkbox"/> <i>other, specify</i> _____ </div> </div>																
<p>5. What is your current marital status? <i>Mark only one.</i></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> <i>never married and not living with partner</i> → Go to Item 8. <input type="checkbox"/> <i>married</i> <input type="checkbox"/> <i>living with partner</i> </div> <div style="width: 45%;"> <input type="checkbox"/> <i>separated</i> <input type="checkbox"/> <i>divorced</i> → Go to Item 8. <input type="checkbox"/> <i>widowed</i> → Go to Item 8. </div> </div>																
<p>6. How many years of education has your spouse/partner had (excluding kindergarten, pre-school, and repeated years)? [] [] years</p>																
<p>7. What is your spouse/partner's occupation? <i>Mark only one.</i></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> <i>none</i> <input type="checkbox"/> <i>self-employee</i> </div> <div style="width: 45%;"> <input type="checkbox"/> <i>formal employment</i> <input type="checkbox"/> <i>other, specify</i> _____ </div> </div>																
<p>8. What kind of housing do you live in? <i>Mark only one.</i></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> <i>rent house</i> <input type="checkbox"/> <i>rent room</i> <input type="checkbox"/> <i>own house</i> </div> <div style="width: 45%;"> <input type="checkbox"/> <i>staff quarters</i> <input type="checkbox"/> <i>stay with relatives</i> <input type="checkbox"/> <i>other, specify</i> _____ </div> </div>																
<p>9. What utilities do you have on your premises? <i>Read categories.</i></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 10%; text-align: center; font-size: small;">yes</th> <th style="width: 10%; text-align: center; font-size: small;">no</th> </tr> </thead> <tbody> <tr> <td><i>electricity</i></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td><i>running water</i></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table>									yes	no	<i>electricity</i>	<input type="checkbox"/>	<input type="checkbox"/>	<i>running water</i>	<input type="checkbox"/>	<input type="checkbox"/>
	yes	no														
<i>electricity</i>	<input type="checkbox"/>	<input type="checkbox"/>														
<i>running water</i>	<input type="checkbox"/>	<input type="checkbox"/>														
<p>10. What do you use for cooking each day? <i>Mark all that apply.</i></p> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <input type="checkbox"/> <i>electric stove</i> <input type="checkbox"/> <i>gas stove</i> </div> <div style="width: 30%;"> <input type="checkbox"/> <i>paraffin stove</i> <input type="checkbox"/> <i>charcoal stove</i> </div> <div style="width: 30%;"> <input type="checkbox"/> <i>fire wood</i> </div> </div>																
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001				SAMPLE				<div style="display: flex; justify-content: space-between;"> <div style="border: 1px solid black; padding: 2px;">01</div> <div style="border-bottom: 1px solid black; width: 50px;"></div> </div> <p style="font-size: x-small; margin-top: 2px;">Language Staff initials /Date</p>								
hivnetforms/HIV024_chorioforms/demographics_mother_fm																

9.4.7 Mother's Enrollment (ME-1, ME-2)

Description and Purpose

The purpose of *Mother's Enrollment* form is to record information about the participant's medical, obstetric and sexual history, and documents the physical exam and gestational age at enrollment.

Form-Specific Instructions

- Item 1 is the total number of pregnancies for the mother, including the current pregnancy. The answer for item 1, if she has had no twin births, is item 2 + item 3 + item 5 + item 6 + item 7 + 1 (for the current pregnancy). If she has had twins, subtract 1 for each set of twins from the total.
- For item 8 record any problems during the current pregnancy, ongoing or resolved. If the problem is ongoing at the time of enrollment document on the *Mother's Pre-existing Conditions* form.
- If the answer to item 10 is "yes", record the medications on the *Mother's Concomitant Medications Log* form.
- Items 11 and 12 are questions about the number of sexual partners a participant has had during her lifetime and during this pregnancy, respectively. The number of partners should include all men with which she has had sexual intercourse during the time period specified, **including** her husband (but only if she has actually had sexual intercourse with him during that time period).
- Items 15 through 21 record details of the physical exam done at the Enrollment Visit.
- If item 19 is "yes", abnormal inguinal nodes, be sure to indicate whether or not the nodes were painful or suppurative using the yes/no boxes to the right of the question.
- For item 20, date of last menstrual period, mark the "unknown" box only if a good estimate of this date is not available.

Figure 9-3
Mother's Enrollment (ME-1, ME-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's Enrollment (ME-1)																																							
HIV 024 Chorio (051)		ME-1 (003)		Visit (101)		Page 1 of 2																																					
Participant ID <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;">0</div> <div style="border: 1px solid black; padding: 2px;">0</div> <div style="border: 1px solid black; padding: 2px;">0</div> <div style="border: 1px solid black; padding: 2px;">-</div> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;">-</div> <div style="border: 1px solid black; padding: 2px;">0</div> </div> <div style="display: flex; justify-content: space-between; font-size: small; margin-top: 2px;"> Site Number Participant Number Chk Cohort </div>				Enrollment Date <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> <div style="border: 1px solid black; padding: 2px;"> </div> </div> <div style="display: flex; justify-content: space-around; font-size: small; margin-top: 2px;"> dd mm yy </div>																																							
OBSTETRIC / MEDICAL HISTORY																																											
1. Total number of pregnancies, including this pregnancy: (Interviewer: If no twins, Q2 + Q3 + Q5 + Q6 + Q7 + 1 = Q1) <input style="width: 40px;" type="text"/>																																											
2. Number of abortions or miscarriages (< 20 weeks): <input style="width: 40px;" type="text"/>				5. Number of children born alive, but died within 7 days: <input style="width: 40px;" type="text"/>																																							
3. Number of stillbirths (> 20 weeks): <input style="width: 40px;" type="text"/>				6. Number of children born alive, but died after 7 days: <input style="width: 40px;" type="text"/>																																							
4. Number of children born > 3 weeks early (i.e., < 37 weeks): <input style="width: 40px;" type="text"/>				7. Total number of children alive today: <input style="width: 40px;" type="text"/>																																							
8. During this pregnancy have you... <table style="width: 100%; border: none;"> <tr> <td style="width: 80%;"></td> <td style="text-align: center; font-size: small;">yes</td> <td style="text-align: center; font-size: small;">no</td> </tr> <tr> <td>had any vaginal bleeding?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>been diagnosed with hypertension?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>been treated for malaria?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: right;"><i>If yes, how many times:</i> <input style="width: 40px;" type="text"/></td> <td colspan="2"></td> </tr> <tr> <td>had any other medical problem? Specify: _____</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>									yes	no	had any vaginal bleeding?	<input type="checkbox"/>	<input type="checkbox"/>	been diagnosed with hypertension?	<input type="checkbox"/>	<input type="checkbox"/>	been treated for malaria?	<input type="checkbox"/>	<input type="checkbox"/>	<i>If yes, how many times:</i> <input style="width: 40px;" type="text"/>			had any other medical problem? Specify: _____	<input type="checkbox"/>	<input type="checkbox"/>																		
	yes	no																																									
had any vaginal bleeding?	<input type="checkbox"/>	<input type="checkbox"/>																																									
been diagnosed with hypertension?	<input type="checkbox"/>	<input type="checkbox"/>																																									
been treated for malaria?	<input type="checkbox"/>	<input type="checkbox"/>																																									
<i>If yes, how many times:</i> <input style="width: 40px;" type="text"/>																																											
had any other medical problem? Specify: _____	<input type="checkbox"/>	<input type="checkbox"/>																																									
9. Have you... <table style="width: 100%; border: none;"> <tr> <td style="width: 80%;"></td> <td style="text-align: center; font-size: small;">yes</td> <td style="text-align: center; font-size: small;">no</td> </tr> <tr> <td>had three or more loose, watery stools per day over the last 2 weeks?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>had fever (hot to the touch) for more than 2 weeks in the last 3 months?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>had a cough (coughing all day) for more than 2 weeks in the last 3 months?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>had recurrent itchy vaginal discharge in the last 3 months?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>had <i>Herpes zoster</i> or shingles in the last 3 months?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>received treatment for tuberculosis in the last 3 months?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>had oral thrush in the last month?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>had unintentional weight loss in the last month?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>had swollen glands for more than 1 month in the last 3 months?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>been admitted to hospital for a reason other than labor and delivery in the last 12 months?</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td colspan="3" style="text-align: right;"><i>If yes, indicate reason:</i> _____</td> </tr> </table>									yes	no	had three or more loose, watery stools per day over the last 2 weeks?	<input type="checkbox"/>	<input type="checkbox"/>	had fever (hot to the touch) for more than 2 weeks in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	had a cough (coughing all day) for more than 2 weeks in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	had recurrent itchy vaginal discharge in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	had <i>Herpes zoster</i> or shingles in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	received treatment for tuberculosis in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	had oral thrush in the last month?	<input type="checkbox"/>	<input type="checkbox"/>	had unintentional weight loss in the last month?	<input type="checkbox"/>	<input type="checkbox"/>	had swollen glands for more than 1 month in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>	been admitted to hospital for a reason other than labor and delivery in the last 12 months?	<input type="checkbox"/>	<input type="checkbox"/>	<i>If yes, indicate reason:</i> _____		
	yes	no																																									
had three or more loose, watery stools per day over the last 2 weeks?	<input type="checkbox"/>	<input type="checkbox"/>																																									
had fever (hot to the touch) for more than 2 weeks in the last 3 months?	<input type="checkbox"/>	<input type="checkbox"/>																																									
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been admitted to hospital for a reason other than labor and delivery in the last 12 months?	<input type="checkbox"/>	<input type="checkbox"/>																																									
<i>If yes, indicate reason:</i> _____																																											
10. Are you currently taking any medications? <table style="width: 100%; border: none;"> <tr> <td style="width: 40%;"></td> <td style="text-align: center; font-size: small;">yes</td> <td style="text-align: center; font-size: small;">no</td> </tr> <tr> <td></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table> <div style="text-align: right; margin-top: 2px;"> <i>If yes, enter on Concomitant Medications Log.</i> </div>									yes	no		<input type="checkbox"/>	<input type="checkbox"/>																														
	yes	no																																									
	<input type="checkbox"/>	<input type="checkbox"/>																																									
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001				SAMPLE		<input style="width: 40px;" type="text" value="01"/>																																					
hivnetfomsHIV024_choriofoms/enrollment_mother.fm				Language		Staff Initials / Date																																					

Figure 9-4
Mother's Enrollment (ME-1, ME-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Mother's Enrollment (ME-2)	
HIV 024 Chorio (051)	ME-2 (004)	Visit (101)	Page 2 of 2
Participant ID			
0 0 0	- [] [] [] []	- [] - []	Mother's Enrollment
<small>Site Number</small>	<small>Participant Number</small>	<small>Chk</small>	<small>Cohort</small>
SEXUAL HISTORY			
11. How many sexual partners, including your spouse, have you had during your lifetime?	[] [] []	<i>number of partners</i>	
12. How many sexual partners, including your spouse, have you had during this pregnancy?	[] [] []	→ If 0 partners, go to item 14.	
13. During this pregnancy, how often did your spouse and other sexual partners use condoms? <i>Mark only one.</i>	[]	[]	[]
	<small>never</small>	<small>sometimes</small>	<small>always</small>
14. In the last year, have you been treated for:	[]	[]	
syphilis?			
genital ulcers?	[]	[]	
abnormal vaginal discharge?	[]	[]	
PHYSICAL EXAM			
15. Weight: [] [] [] kilograms	16. Height: [] [] [] centimeters		
17. Blood Pressure: [] [] [] / [] [] [] mmHg			
18. Physical Exam: [] []	→ If abnormal, record below. Mark all that apply.		
	<small>normal</small>	<small>abnormal</small>	
<input type="checkbox"/> generalized wasting	<input type="checkbox"/> genital ulcers		
<input type="checkbox"/> generalized lymphadenopathy	<input type="checkbox"/> Herpes zoster		
<input type="checkbox"/> Kaposi's sarcoma			
<input type="checkbox"/> dermatitis			
<input type="checkbox"/> other, specify: _____			
19. Abnormal inguinal nodes: [] []	<small>yes</small>	<small>no</small>	
	[]	[]	
	→		
Are nodes painful?	[]	[]	
Are nodes suppurative?	[]	[]	
20. Date of last menstrual period (estimate if unsure): [] [] [] [] [] []	<small>dd</small>	<small>mm</small>	<small>yy</small>
	[] []	[] []	[] []
	OR [] <i>Unknown</i>		
21. Fundal height: [] [] cm above pubic symphysis, using flexible tape			
<input type="checkbox"/> [] [] [] [] April 19, 2001	SAMPLE	[] []	_____
<small>hivnet/forms/HIV024_chorio/forms/enrollment_mother.fm</small>		<small>Language</small>	<small>Staff Initials / Date</small>

9.4.8 Mother's Pre-existing Conditions (PRE-1)

Description and Purpose

The purpose of the Mother's Pre-existing Conditions form is to document any ongoing medical conditions that a participant has at the time of enrollment onto the trial.

Form-Specific Instructions

- Enter only ongoing conditions at the time of enrollment, this should include recurring conditions (such as migraine headaches, herpes infections, or psoriasis) and conditions that are diagnosed at the Enrollment Visit, including conditions, such as sexually transmitted infections, that are diagnosed by lab tests performed on specimens collected at the Enrollment Visit.
- If the participant has no ongoing medical conditions or allergies at the time of enrollment, mark the "No pre-existing conditions" box and fax to SCHARP DataFax.
- For each condition, indicate whether the condition is an illness or an allergy.
- Grade each condition according to the DAIDS Toxicity Table in the Protocol. If the condition become worse by at least one grade while the participant is on the trial, and it becomes worse within the AE reporting time periods (See Section 8 of the SSP for AE reporting guidelines) it may need to be reported as an adverse experience on an *Illness/AE Log* form.

Figure 9-5
Mother's Pre-existing Conditions (PRE-1)

Statistical Center for HIV/AIDS Research and Prevention (SCHARP)				Mother's Pre-existing Conditions (PRE-1)		
				Page <input style="width: 20px; height: 15px;" type="text"/>		
HIV024 Chorio (051)		PRE-1(050)				
Participant ID <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> - <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> - <input style="width: 20px; height: 15px;" type="text"/> - <input style="width: 20px; height: 15px;" type="text"/>				Site Number Participant Number Chk. Cohort		
Mother's Pre-existing Conditions				Contact Date <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/>		
<input type="checkbox"/> No pre-existing conditions reported. ➔ End of form. Fax to SCHARP DataFax.				<i>Note: Number pages sequentially (01, 02, 03) for each participant.</i>		
1. Condition Type	Severity	Description: _____				
<input type="checkbox"/> Illness	<input type="checkbox"/> Grade 1 - Mild	_____				
<input type="checkbox"/> Allergy	<input type="checkbox"/> Grade 2 - Moderate	Date Diagnosis: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/>				
	<input type="checkbox"/> Grade 3 - Severe	<i>mm yy</i>				
	<input type="checkbox"/> Grade 4 - Life-threatening	Comments: _____				

2. Condition Type	Severity	Description: _____				
<input type="checkbox"/> Illness	<input type="checkbox"/> Grade 1 - Mild	_____				
<input type="checkbox"/> Allergy	<input type="checkbox"/> Grade 2 - Moderate	Date Diagnosis: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/>				
	<input type="checkbox"/> Grade 3 - Severe	<i>mm yy</i>				
	<input type="checkbox"/> Grade 4 - Life-threatening	Comments: _____				

3. Condition Type	Severity	Description: _____				
<input type="checkbox"/> Illness	<input type="checkbox"/> Grade 1 - Mild	_____				
<input type="checkbox"/> Allergy	<input type="checkbox"/> Grade 2 - Moderate	Date Diagnosis: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/>				
	<input type="checkbox"/> Grade 3 - Severe	<i>mm yy</i>				
	<input type="checkbox"/> Grade 4 - Life-threatening	Comments: _____				

4. Condition Type	Severity	Description: _____				
<input type="checkbox"/> Illness	<input type="checkbox"/> Grade 1 - Mild	_____				
<input type="checkbox"/> Allergy	<input type="checkbox"/> Grade 2 - Moderate	Date Diagnosis: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/>				
	<input type="checkbox"/> Grade 3 - Severe	<i>mm yy</i>				
	<input type="checkbox"/> Grade 4 - Life-threatening	Comments: _____				

5. Condition Type	Severity	Description: _____				
<input type="checkbox"/> Illness	<input type="checkbox"/> Grade 1 - Mild	_____				
<input type="checkbox"/> Allergy	<input type="checkbox"/> Grade 2 - Moderate	Date Diagnosis: <input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/>				
	<input type="checkbox"/> Grade 3 - Severe	<i>mm yy</i>				
	<input type="checkbox"/> Grade 4 - Life-threatening	Comments: _____				

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001		SAMPLE		<input style="width: 20px; height: 15px;" type="text"/> <input style="width: 20px; height: 15px;" type="text"/>		
hivnetforms/HIV024_chorio/forms/preexisting_conditions.fm				Language Staff Initials / Date		

9.4.9 Pelvic Exam (PE-1)

Description and Purpose

The *Pelvic Exam* form documents the pelvic exams done at the Enrollment and First Antenatal visits. It may also be used to document any pelvic exams done at interim or unscheduled visits during the antenatal period (see section 9.2.2 - *Interim Visits*).

Form-Specific Instructions

- The date recorded in the top right-hand corner of the form is the date of the exam, not the date that the form was completed.
- Item 1 is completed based on the exam of the external genitalia.
- Item 2 documents the vaginal exam. If a vaginal discharge is present also mark the severity of discharge (mild, moderate, severe) using the boxes to the right and mark all the conditions that the discharge may be associated with (pus, trich, monilia, BV) or the presence of blood. The completion of this last item is based on the examiner's judgement before test results are available.
- Item 3 is the vaginal pH level taken during the pelvic exam.
- Item 4 is the result of the whiff test performed during the pelvic exam.
- Item 5 records the exam of the cervix, including cervical ectopy. If cervical discharge, friability or condyloma is present indicate the severity (mild, moderate, severe) using the boxes to the right.
- Item 6 documents the bimanual exam. If any adnexal or uterine tenderness is present, record the severity using the boxes to the right.

Figure 9-6
Pelvic Exam (PE-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)						Pelvic Exam (PE-1)					
						Visit Code		1			
HIV 024 Chorio (051)			PE-1(009)			Page 1 of 1					
Participant ID 000 - - - - 0 Pelvic Exam						Exam Date dd mm yy					
Site Number	Participant Number	Chk	Cohort								
1. External Genitalia:						yes	no				
warts						<input type="checkbox"/>	<input type="checkbox"/>				
ulcers						<input type="checkbox"/>	<input type="checkbox"/>				
other, specify: _____						<input type="checkbox"/>	<input type="checkbox"/>				
2. Vagina:						yes	no				
epithelial bleeding						<input type="checkbox"/>	<input type="checkbox"/>				
sub-epithelial hemorrhage						<input type="checkbox"/>	<input type="checkbox"/>				
oedema						<input type="checkbox"/>	<input type="checkbox"/>				
condyloma						<input type="checkbox"/>	<input type="checkbox"/>				
vesicles						<input type="checkbox"/>	<input type="checkbox"/>				
bullae						<input type="checkbox"/>	<input type="checkbox"/>				
vaginal epithelial disruption						<input type="checkbox"/>	<input type="checkbox"/>				
other, specify: _____						<input type="checkbox"/>	<input type="checkbox"/>				
abnormal vaginal discharge						<input type="checkbox"/>	<input type="checkbox"/>				
If discharge present, is it consistent with: Mark all that apply.						dys	trichomoniasis	monilia	BV	blood	
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>											
3. Vaginal pH level:						<input type="checkbox"/>	<input type="checkbox"/>				
						<i>positive</i>		<i>negative</i>			
4. Whiff test:						<input type="checkbox"/>	<input type="checkbox"/>				
						If yes, mark severity.					
						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
						<i>mild</i>		<i>moderate</i>		<i>severe</i>	
5. Cervix:						yes	no				
cervical discharge						<input type="checkbox"/>	<input type="checkbox"/>				
epithelial disruption or friability						<input type="checkbox"/>	<input type="checkbox"/>				
condyloma						<input type="checkbox"/>	<input type="checkbox"/>				
vesicles						<input type="checkbox"/>	<input type="checkbox"/>				
ulcerations						<input type="checkbox"/>	<input type="checkbox"/>				
other, specify: _____						<input type="checkbox"/>	<input type="checkbox"/>				
cervical ectopy (percentage of cervical surface area)						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
								0%	1-25%	26-50%	≥ 51%
6. Bimanual Exam:						yes	no				
adnexal tenderness						<input type="checkbox"/>	<input type="checkbox"/>				
uterine tenderness						<input type="checkbox"/>	<input type="checkbox"/>				
adnexal masses						<input type="checkbox"/>	<input type="checkbox"/>				
uterine masses						<input type="checkbox"/>	<input type="checkbox"/>				
						If yes, mark severity.					
						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
						<i>mild</i>		<i>moderate</i>		<i>severe</i>	
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>		April 19, 2001				SAMPLE		01		Language	
hivnet/forms/HIV024_chorio/forms/pelvic_exam_mother.fm								Staff Initials / Date			

9.4.10 Mother's Laboratory Results (MLR-1, MLR-2)

Description and Purpose

The *Mother's Laboratory Results* form is used to document local laboratory results from specimens collected at the mother's antenatal visits (Enrollment, First Antenatal Study Visit, Second Antenatal Study Visit). It may also be used to record relevant local lab results from interim visits or follow-up visits.

Form-Specific Instructions

- The date in the top right hand corner is the date the specimens were collected. The only exception to this is at enrollment when the HIV and syphilis specimens would have been collected during the screening process. At the enrollment visit, the date should be the date all other specimens required for enrollment (wet mount, gonorrhea, chlamydia) were collected.
- Mark the Not Done/Not Collected boxes only if a specimen was not obtained at all. For example, mark the Not Done/Not Collected box if a specimen is not required at this particular visit, or if specimen collection was overlooked. If a specimen was collected, but the results are not available, then leave this box blank, but cross out the results boxes, initial and date, and mark as "NA". Document the reason results are not available in the "Comments" section. Never leave both the Not Done/Not Collected box and the results boxes blank.
- Use item 1 to document the mother's final HIV diagnosis at enrollment on the trial based on specimens collected at screening. In most cases, it will only be completed at the Enrollment Visit. However, this item may also be used to document seroconversion of a HIV negative mother if seroconversion is suspected and she is counseled and tested for HIV infection.
- Item 2 is the syphilis diagnosis from specimens collected at screening. In most cases, this diagnosis will only be completed at the Enrollment Visit, but may be used to document a syphilis diagnosis at anytime during the trial.
- Item 3 is a record of wet mount results, including *Trichomonas*, *Candida*, and clue cells. Item 3b, *Candida* results may have both "hyphae" and "buds" marked, but not one of those choices in addition to "negative".
- Items 6 through 16 document the results of the CBC, differential and other hematologic tests. If Hemoglobin (item 7), Platelets (9), or White Blood Cells (10) meet the criteria for grade 3 or 4 according to the DAIDS toxicity table mark an "x" (not a number) in the "Grade 3 or 4" box to the right of the results. **Grade 3 or 4 lab results may need to be reported on an *Illness/AE Log* form if not associated with an already reported diagnosis (see Section 8).** For example, a grade 3 hemoglobin value would not be reported as a separate AE if associated with an already reported AE of malaria, but a grade 3 platelet count not known to be associated with another diagnosis would be reported on an AE form.
- Use the "Comments" sections to document any problems or reasons why expected results are not available, for example, if the sample was insufficient for testing. If documentation is necessary, use the "Comments" section on the same page as the item in question.

Figure 9-7
Mother's Laboratory Results (MLR-1, MLR-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's Laboratory Results (MLR-1)			
				Visit Code		<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
HIV 024 Chorio (051)		MLR-1 (007)		Page 1 of 2			
Participant ID <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> - <input style="width: 20px; height: 20px;" type="text"/>				Specimen Collection Date <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <i>dd mm yy</i>			
Mother's Laboratory Results <small>Site Number Participant Number Chk Cohort</small>							
Not Done/Not Collected							
				<i>positive</i>		<i>negative</i>	
<input type="checkbox"/>	1.	HIV diagnosis	<input type="checkbox"/>	<input type="checkbox"/>		If Enrollment visit, record from screening results.	
<input type="checkbox"/>	2.	Syphilis diagnosis	<input type="checkbox"/>	<input type="checkbox"/>			
3. Wet mount:				<i>positive</i>		<i>negative</i>	
<input type="checkbox"/>	3a.	<i>Trichomonas vaginalis</i>	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="checkbox"/>	3b.	<i>Candida albicans</i>	<input type="checkbox"/>	<i>hyphae</i>	<i>buds</i>	<i>negative</i>	
		<i>Mark all that apply.</i>					
<input type="checkbox"/>	3c.	Clue cells	<input type="checkbox"/>	<i>≥ 20%</i>	<i>< 20%</i>	<i>negative</i>	
<input type="checkbox"/>	4.	<i>N. gonorrhoeae</i> culture	<input type="checkbox"/>	<i>positive</i>		<i>negative</i>	
<input type="checkbox"/>	5.	<i>Chlamydia</i> EIA	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	
Comments: <i>For each comment, please specify item number.</i> _____ _____ _____ _____							
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001				SAMPLE		<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
<small>hivnet/forms/HIV024_chorio/forms/lab_results_mother.fm</small>				<small>Lang usage</small>		<small>Staff Initials / Date</small>	

Figure 9-8
Mother's Laboratory Results (MLR-1, MLR-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)				Mother's Laboratory Results (MLR-2)		
				Visit Code	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
HIV 024 Chorio (051)		MLR-2 (008)		Page 2 of 2		
Participant ID						
<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	Mother's Laboratory Results		
Site Number		Participant Number		Chk	Cohort	
HEMATOLOGY						
<input type="checkbox"/>	6.	RBC	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	$10^6/\mu\text{L}$	Grade 3 or 4?	
<input type="checkbox"/>	7.	Hemoglobin	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	g/dl	<input type="checkbox"/>	
<input type="checkbox"/>	8.	Hematocrit.....	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	%	<input type="checkbox"/>	
<input type="checkbox"/>	9.	Platelets.....	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	$10^3/\mu\text{L}$	<input type="checkbox"/>	
<input type="checkbox"/>	10.	WBC.....	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	$10^3/\mu\text{L}$	<input type="checkbox"/>	
<input type="checkbox"/>	11.	Lymphocytes	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	%	<input type="checkbox"/>	
<input type="checkbox"/>	12.	Monocytes.....	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	%	<input type="checkbox"/>	
<input type="checkbox"/>	13.	Granulocytes	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	%	<input type="checkbox"/>	
<input type="checkbox"/>	14.	CD4	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	cells/ μL	<input type="checkbox"/>	
<input type="checkbox"/>	15.	CD8	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	cells/ μL	<input type="checkbox"/>	
<input type="checkbox"/>	16.	Additional Flow Cytometry				<input type="checkbox"/>
<input type="checkbox"/>	16a.	% CD4	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	%	<input type="checkbox"/>	
<input type="checkbox"/>	16b.	% CD8	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	%	<input type="checkbox"/>	
<input type="checkbox"/>	16c.	Total T-Lymphocytes.....	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	%	<input type="checkbox"/>	
Comments: For each comment, please specify item number. <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> <hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/>						
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	April 19, 2001		
			SAMPLE	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	
hivnet/forms/HIV024_chorio/forms/lab_results_mother.fm				Language	Staff Initials / Date	

See SSP for AE and SAE reporting guidelines. Enter on illness/AE Log forms as necessary.

9.4.11 Mother's Specimen Collection (MSC-1)


Description and Purpose

The *Mother's Specimen Collection* form documents specimens collected for storage and processing at a later time at outside laboratories and is completed at the Enrollment and First Antenatal study visits. It may also be used to document specimens collected at interim visits.

Form-Specific Instructions

- The date in the top right-hand corner is the date that the specimens were collected.
- Mark the "collected" box for each specimen collected at a particular visit.
- If the specimen is not required at that visit, mark the "N/A" (Not applicable) box. The reason need not be recorded.
- If a specimen is required at a visit, but was *not* collected, mark the "not collected" box and write a brief reason why it was not collected on the line next to the "not collected" box. Please do not write something like "see comments" on these lines as the reason will not become part of the database.
- Items 4 (cervical-vaginal swab for syphilis and gonorrhea LCR) and 6 (plasma for vitamins and zinc) have been deleted from the form due to changes in specimen collection in the protocol.

Figure 9-9
Mother's Specimen Collection (MSC-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)										Mother's Specimen Collection (MSC-1)					
										Visit Code		<input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/>	
HIV 024 Chorio (051)					MSC-1 (006)					Page 1 of 1					
Participant ID										Specimen Collection Date					
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> - <input type="text"/>			Mother's Specimen Collection				<input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> <input type="text"/>				
Site Number			Participant Number				Chk		Cohort		da mm yy				
<p>Instructions: Use this form to document all specimens collected for storage.</p>															
										collected	NA	not collected	Reason not collected		
1. Gram stain slide.....										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____		
2. Cervical-vaginal swab — FFN										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____		
3. Cervical-vaginal swab — HIV viral load										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____		
4. Cervical-vaginal swab for LCR for gonorrhea and chlamydia										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____		
5. Plasma for HIV viral load.....										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____		
6. Plasma for vitamins and zinc										<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> →	_____		
<p>Comments: For each comment, please specify item number.</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>															
<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>		August 23, 2001				SAMPLE				<input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/>			
hivnet/forms/HIV024_chorio/forms/specimen_collection_mother.fm										Language		Staff Initials / Date			

9.4.12 Mother's First Antenatal Study Visit (AVA-1 - AVA-3)

Description and Purpose

The *Mother's 1st Antenatal Study Visit* form documents procedures and exams performed during the First Antenatal Study Visit, including weight, blood pressure, medical history, HIV symptoms, and study drug adherence. ***This form must be completed for all mothers who are not considered to be lost-to-follow-up prior to the labor and delivery visit, even if the visit to not take place.***

Form-Specific Instructions

- The date recorded in the top right-hand corner is the date the visit took place. If the visit did not take place draw a line through the data boxes.
- If any item under 3 or 4 is marked "yes", complete an *Illness/AE Log* form for each illness, diagnosis, or condition.
- If item 5 is marked "yes", update the Mother's Concomitant Medications Log with any medications, except study drug, that the mother has taken since enrollment.
- Item 7 is a question about the number of sexual partners the participant has had since the last visit. The number of partners should include all men with which she has had sexual intercourse since her last study visit, ***including*** her husband (but only if she has actually had sexual intercourse with him during that time period).
- If a participant requires more antenatal study drug because it is lost or left behind, open the small envelope in the participant's study drug kit to obtain her emergency drug supply code. ***Open this envelope only if the participant needs more study drug.*** If drug has been dispensed from the emergency supply bottle, mark item 10 as "yes" and record the number of capsules dispensed from the emergency supply bottle, the number returned, and letter of the emergency supply code from the bottle extra study drug was dispensed (letters A - F).
- Item 11 documents the pill count. If the participant returns her blister cards, count the number returned, subtract that number from the number dispensed, and enter the total number taken, including capsules from the emergency supply, if dispensed.
- If the participant has forgotten her blister cards, or they have been lost, cross out the boxes under "# returned", and mark "NA" next to the boxes. Do not enter "# returned" as "00" if she did not bring her blister cards in. Complete the number of pills taken based on information she gives you about how many pills she took each day.
- If the participant has taken all her study drug, or tells you she has taken all of the study drug, skip to item 13. If she has not taken all of her drug, complete item 12 after interviewing the participant about why she did not take all of the study drug.
- Item 13 is the date the participant last took antenatal study drug.
- Items 14 - 16 document dispensing of all study drugs at this visit. If nevirapine or nevirapine placebo is dispensed at this visit record the lot number in the space provided under item 16.

Special Trial Closure Instructions

For participants who had the First Antenatal Study Visit after the decision to end the study early, and for whom labor study drug was never dispensed, mark item 14 as “no” and enter the reason in 14b as “*study closure*”.

See H024 Data Communiqué #7 for example case report forms.

Figure 9-10
Mother's First Antenatal Study Visit (AVA-1 - AVA-3)


Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's First Antenatal Study Visit (AVA-1)				
	HIV 024 Chorio (051)	AVA-1 (010)	Visit (201)	Page 1 of 3				
Participant ID			Visit Date					
0 0 0 - [] [] [] - [] - 0	Mother's First Antenatal Study Visit		[] []	[] []	[] []			
Site Number	Participant Number	Chk	Cohort	dd	mm	yy		
PHYSICAL EXAM								
1. Weight:	[] [] []	kilograms	2. Blood Pressure:	[] [] [] / [] [] []	mmHg			
OBSTETRIC / MEDICAL HISTORY								
3. Since your last visit have you...				yes	no			
had any vaginal bleeding?				<input type="checkbox"/>	<input type="checkbox"/>			
experienced membrane rupture?				<input type="checkbox"/>	<input type="checkbox"/>			
been diagnosed (by a blood smear) with malaria?				<input type="checkbox"/>	<input type="checkbox"/>			
had any other medical problem? Specify: _____				<input type="checkbox"/>	<input type="checkbox"/>			
			<i>If yes, see SSP for AE and SAE reporting guidelines. Enter on Illness/AE Log as necessary.</i>					
4. Have you...				yes	no			
had three or more loose, watery stools per day over the last 2 weeks?				<input type="checkbox"/>	<input type="checkbox"/>			
had fever (hot to the touch) for more than 2 weeks since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
had a cough (coughing all day) for more than 2 weeks since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
had recurrent itchy vaginal discharge since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
had <i>Herpes zoster</i> or shingles since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
received treatment for tuberculosis since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
had oral thrush since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
had unintentional weight loss since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
had swollen glands for more than one month since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
			<i>If yes, see SSP for AE and SAE reporting guidelines. Enter on Illness/AE Log as necessary.</i>					
been admitted to hospital since the last visit?				<input type="checkbox"/>	<input type="checkbox"/>			
			<i>If yes, record below and enter on Illness/AE Log.</i>					

5. Since your last visit, have you taken, or are you currently taking, any antibiotics (other than study drug) or any other medications?				yes	no			
				<input type="checkbox"/>	<input type="checkbox"/>			
6. Since your last visit, have you been treated for malaria?				<input type="checkbox"/>	<input type="checkbox"/>			
			<i>If yes, enter on Concomitant Medications Log.</i>					
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001	SAMPLE			0 1				
hivnet024mop/hiv024_chorio051/first_antenatal_visit_mother_fm				Language	Staff Initials / Date			

Figure 9-11
Mother's First Antenatal Study Visit (AVA-1 - AVA-3)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's First Antenatal Study Visit (AVA-2)			
HIV 024 Chorio (051)		AVA-2 (011)		Visit (201)		Page 2 of 3	
Participant ID				Mother's First Antenatal Study Visit			
0	0	0	-	-	-	-	0
<small>Site Number</small>	<small>Participant Number</small>		<small>Chk</small>	<small>Cohort</small>			
SEXUAL HISTORY							
7. How many sexual partners, including your spouse, have you had since your last visit?				<small>number of partners</small> [][]		→ If 0 partners, go to item 9.	
8. Since your last visit, how often did your spouse and other sexual partners use condoms? <i>Mark only one.</i>				<small>never</small> <input type="checkbox"/>	<small>sometimes</small> <input type="checkbox"/>	<small>always</small> <input type="checkbox"/>	
9. Since your last visit, have you been treated for:				<small>yes</small> <input type="checkbox"/>		<small>no</small> <input type="checkbox"/>	
syphilis?				<input type="checkbox"/>		<input type="checkbox"/>	
genital ulcers?				<input type="checkbox"/>		<input type="checkbox"/>	
abnormal vaginal discharge?				<input type="checkbox"/>		<input type="checkbox"/>	
				→ If any yes, enter treatment on Concomitant Medications Log.			
PILL COUNT							
10. Did participant require study drug from emergency supply?				<small>yes</small> <input type="checkbox"/>	<small>no</small> <input type="checkbox"/>		
				→ If no, go to item 11.			
Metronidazole from emergency supply							
Number dispensed:		[][]		# returned:		[][]	
Erythromycin from emergency supply							
Number dispensed:		[][]		# returned:		[][]	
				<input type="checkbox"/> <small>letter code</small>			
11. Did the participant return her blister cards?				<small>yes</small> <input type="checkbox"/>	<small>no</small> <input type="checkbox"/>		
				→ If no, complete number taken based on participant's report.			
Metronidazole							
# dispensed at enrollment:		[2][1]		# returned:		[][]	
				Total # taken (including from emergency supply):		[][]	
Erythromycin							
# dispensed at enrollment:		[2][1]		# returned:		[][]	
				Total # taken (including from emergency supply):		[][]	
				→ If total number taken is ≥ 21 for both drugs, go to item 13.			
12. Why didn't participant take all her study drug? <i>Mark all that apply.</i>							
<input type="checkbox"/> abdominal pain		<input type="checkbox"/> lost blister cards					
<input type="checkbox"/> forgot to take		<input type="checkbox"/> other, specify: _____					
13. Date last dose of study drug taken:				[][]	[][]	[][]	
				<small>dd</small>	<small>mm</small>	<small>yy</small>	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	April 19, 2001			
				SAMPLE		[0][1]	
				<small>Lang usage</small>		<small>Staff initials / Date</small>	
hivnet/forms/HIV024_chorio/forms/1st_antenatal_visit_mother.fm							

Figure 9-12
Mother's First Antenatal Study Visit (AVA-1 - AVA-3)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)		Mother's First Antenatal Study Visit (AVA-3)	
			
HIV 024 Chorio (051)	AVA-3 (014)	Visit (201)	Page 3 of 3
Participant ID			
<input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text" value="0"/>
Site Number	Participant Number	Chk	Cohort
Mother's First Antenatal Study Visit			
STUDY DRUG ACCOUNTABILITY			
14. Were study antibiotics for labor dispensed?	yes <input type="checkbox"/>	no <input type="checkbox"/>	
	→ <i>If yes, go to item 15.</i>		
14a. Reason not dispensed:	<input type="checkbox"/> <i>refused</i> <input type="checkbox"/> <i>other, specify:</i> _____		
15. Was study nevirapine or placebo dispensed?	yes <input type="checkbox"/>	no <input type="checkbox"/>	
	→ <i>If yes, go to item 16.</i>		
15a. Reason not dispensed:	<input type="checkbox"/> <i>refused</i> <input type="checkbox"/> <i>other, specify:</i> _____		
16. Nevirapine/placebo dispensed: <i>Mark only one.</i>			
<input type="checkbox"/> <i>active drug</i>	Lot #	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
<input type="checkbox"/> <i>placebo</i>			
Comments: <i>For each comment, please specify item number.</i>			
_____ _____ _____ _____ _____ _____ _____			
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001	SAMPLE	<input type="text" value="0"/> <input type="text" value="1"/>	_____ Language Staff Initials / Date
hivnet/forms/HIV024_chorio/forms/1st_antenatal_visit_mother.fm			

9.4.13 Mother's Second Antenatal Study Visit (AVB-1, AVB-2)

Description and Purpose

The *Mother's Second Antenatal Study Visit* form documents procedures and exams performed during the second antenatal visit, including weight, blood pressure, medical history, and HIV symptoms.

Form-Specific Instructions

- The date recorded in the top right-hand corner is the date the visit took place.
- Unlike the *First Antenatal Study Visit* form (AVA) if any item under 3 or 4 is marked "yes", it may not be necessary to complete an *Illness/AE Log* form because, in general, this visit occurs more than 2 weeks after the participant took her first course of study drug (See Section 8). However, if any illness or AEs reported at the First Antenatal Visit were originally reported as "continuing," ask the participant if the condition has since resolved and update the form.
- If items 5 or 6 are marked "yes", update the Mother's Concomitant Medications Log with any medications, except study drug, that the mother has taken since the last visit.

Figure 9-13
Mother's Second Antenatal Study Visit (AVB-1, AVB-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's Second Antenatal Study Visit (AVB-1)				
HIV 024 Chorio (051)		AVB-1 (012)		Visit (301)		Page 1 of 2		
Participant ID				Visit Date				
0 0 0	- [] [] [] [] [] []	- [] []	- 0	[] [] / [] [] [] []				
<small>Site Number</small>	<small>Participant Number</small>	<small>Chk</small>	<small>Cohort</small>	Mother's Second Antenatal Study Visit				
PHYSICAL EXAM								
1. Weight: [] [] [] kilograms		2. Blood Pressure: [] [] [] / [] [] [] mmHg						
OBSTETRIC / MEDICAL HISTORY								
3. Since your last visit have you...							<i>yes</i>	<i>no</i>
had any vaginal bleeding?							<input type="checkbox"/>	<input type="checkbox"/>
experienced membrane rupture?							<input type="checkbox"/>	<input type="checkbox"/>
been diagnosed (by a blood smear) with malaria?							<input type="checkbox"/>	<input type="checkbox"/>
had any other medical problem? Specify: _____							<input type="checkbox"/>	<input type="checkbox"/>
4. Have you...							<i>yes</i>	<i>no</i>
had three or more loose, watery stools per day over the last 2 weeks?							<input type="checkbox"/>	<input type="checkbox"/>
had fever (hot to the touch) for more than 2 weeks since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
had a cough (coughing all day) for more than 2 weeks since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
had recurrent itchy vaginal discharge since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
had <i>Herpes zoster</i> or shingles since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
received treatment for tuberculosis since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
had oral thrush since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
had unintentional weight loss since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
had swollen glands for more than one month since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
been admitted to hospital since the last visit?							<input type="checkbox"/>	<input type="checkbox"/>
<i>If yes, record below and see SSP for AE and SAE reporting guidelines.</i>								
5. Since your last visit, have you taken, or are you currently taking, any antibiotics (other than study drug) or any other medications?							<i>yes</i>	<i>no</i>
							<input type="checkbox"/>	<input type="checkbox"/>
6. Since your last visit, have you been treated for malaria?							<input type="checkbox"/>	<input type="checkbox"/>
							<i>If yes, enter on Concomitant Medications Log.</i>	
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	April 19, 2001			SAMPLE		[0] [1]	_____	
<small>HivnetfomsHIV024_choriofoms2nd_antenatal_visit_mother.fm</small>						<small>Language</small>	<small>Staff initials / Date</small>	

Figure 9-14
Mother's Second Antenatal Study Visit (AVB-1, AVB-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) Mother's Second Antenatal Study Visit (AVB-2)	
	Page 2 of 2
HIV 024 Chorio (051)	AVB-2 (013)
Visit (301)	
Participant ID	
0 0 0	- [] [] [] [] [] - [] - 0
Site Number	Participant Number Chk Cohort
Mother's Second Antenatal Study Visit	
SEXUAL HISTORY	
7. How many sexual partners, including your spouse, have you had since your last visit?	number of partners [] [] [] → If 0 partners, go to item 9.
8. Since your last visit, how often did your spouse and other sexual partners use condoms? <i>Mark only one.</i>	never sometimes always <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
9. Since your last visit, have you been treated for:	yes no
syphilis?.....	<input type="checkbox"/> <input type="checkbox"/>
genital ulcers?.....	<input type="checkbox"/> <input type="checkbox"/>
abnormal vaginal discharge?	<input type="checkbox"/> <input type="checkbox"/>
	→ If any yes, enter treatment on Concomitant Medications Log.
Comments: For each comment, please specify item number.	
_____ _____ _____ _____ _____ _____ _____ _____	
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001	SAMPLE
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001	[0] [1] Language Staff Initials / Date

9.4.14 Mother's Intrapartum (MIP-1 - MIP-5)

Description and Purpose

The *Mother's Intrapartum* form documents the labor and delivery visit, including the date and time of the onset of labor, procedures, any complications, indications of chorioamnionitis, and the outcome of the pregnancy. ***This form must be completed for all mothers not considered to be lost-to-follow-up prior to delivery with as much information as available even if the mother does not give birth at the study site.***

Form-Specific Instructions

- Complete this form with information about true labor only. If the mother has an episode of false labor, do not include that information on the form submitted to DataFax.
- Unlike the *First Antenatal Study Visit* form (AVA) if any item under 1 or 2 is marked "yes", it may not be necessary to complete an *Illness/AE Log* form because this visit, in general, occurs more than two weeks after the participant took her first course of study drug (See Section 8). However, if any previously reported illnesses or AE was originally reported as "continuing," ask the participant if the condition has since resolved and update the form.
- If item 3 or 4 is marked "yes", update the *Mother's Concomitant Medications Log* with any medications, except study drug, that the mother has taken since the last visit.
- If the mother does not deliver at the study site, mark item 8 as "no" and complete as many items as possible from the mother's self-report or from medical records. Any items that are unknown may be crossed out and marked "unknown" or "NA." If the mother does not return to the study site until the 4-6 week visit, items 1 through 4 should be skipped, and completed on the *Mother's Follow-up* form instead, so that these symptoms are not documented on two different forms.
- Item 9, time of onset of labor in many cases will need to be provided by the mother.
- Item 16, if the mother was given any non-study antibiotics during labor and delivery, mark this item as "yes", record the time, and update her Concomitant Medications Log.
- Item 21, if no obstetric complications or procedures, mark item 21a (*none*) and go to item 22. If there were obstetric complications or procedures, document them by marking the appropriate box and completing an *Illness/AE Log* form for each complication, diagnosis, or condition. If the mother was diagnosed with hypertension sometime before the Labor/Delivery visit, and it hasn't become worse since treatment with study drug, then mark the "Hypertension diagnosed before the start of labor" item to the right as "yes" and an *Illness/AE Log* form will not be expected.
- Item 24, in the case of singleton births, the infant is "infant A." In the case of twins or triplets, "infant A" is the first born, "infant B" is second born, and "infant C" is third born. If more than three infants, call the Protocol Operations Coordinator at the Statistical Center for instructions.

- For item 25, enter an infant's Participant ID number (*see section 9.2*) for each live birth. The Infant Participant ID numbers are identical to their mother's, but the last digit will be a 1, 2 or 3 where the mother has a "0." If the pregnancy results in a stillbirth, do not assign a participant ID number to the stillborn infant and do not complete any Infant data collection forms. The stillbirth should be reported as an Adverse Experience on the Mother's *Illness/AE Log* form, using the mother's participant ID number.
- If a stillbirth is part of a set of twins or triplets, do not change the assignment of the Infant Participant ID numbers. The second born, if born alive, is always assigned a Participant ID that ends in "2", and the third born, if born alive, is always assigned a Participant ID that ends in "3", even if an earlier sibling was stillborn and the Participant ID that ends in "1" is not assigned.
- Item 28 is the weight of the placenta. In the case of multiple birth, if there is more than one placenta, record the combined weight of all placentas.
- Item 29 documents the placental tissue has been collected. If the placenta was not collected write a brief reason why on the line provided.
- Item 30 (collection of colostrum sample) has been deleted due to changes in the protocol.

Figure 9-15
Mother's Intrapartum (MIP-1 - MIP-5)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)				Mother's Intrapartum (MIP-1)		
						Page 1 of 5
Participant ID <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;">0</div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;">0</div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;">0</div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;"></div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;"></div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;"></div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;"></div> <div style="margin: 0 5px;">-</div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;">0</div> </div> <div style="margin-left: 10px;"> Mother's Intrapartum </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 5px; font-size: small;"> <div style="width: 15%;">Site Number</div> <div style="width: 40%;">Participant Number</div> <div style="width: 10%;">Chk</div> <div style="width: 10%;">Cohort</div> </div>				Delivery Date <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;"></div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;"></div> <div style="border: 1px solid black; padding: 2px 5px;"></div> </div> <div style="display: flex; justify-content: space-around; margin-top: 5px; font-size: x-small;"> dd mm yy </div>		
OBSTETRIC / MEDICAL HISTORY						
1. Since your last visit have you...						
had any vaginal bleeding?	<input type="checkbox"/>	<input type="checkbox"/>	yes	no		
experienced membrane rupture?	<input type="checkbox"/>	<input type="checkbox"/>				
been diagnosed (by a blood smear) with malaria?	<input type="checkbox"/>	<input type="checkbox"/>				
had any other medical problem? Specify: _____	<input type="checkbox"/>	<input type="checkbox"/>				
2. Have you...						
had three or more loose, watery stools per day over the last 2 weeks?	<input type="checkbox"/>	<input type="checkbox"/>	yes	no		
had fever (hot to the touch) for more than 2 weeks since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
had a cough (coughing all day) for more than 2 weeks since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
had recurrent itchy vaginal discharge since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
had Herpes zoster or shingles since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
received treatment for tuberculosis since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
had oral thrush since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
had unintentional weight loss since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
had swollen glands for more than one month since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
been admitted to hospital since the last visit?	<input type="checkbox"/>	<input type="checkbox"/>				
<i>If yes, indicate reason:</i>						

3. Since your last visit, have you taken, or are you currently taking, any antibiotics (other than study drug) or any other medications?						
<input type="checkbox"/>	<input type="checkbox"/>	yes	no			
4. Since your last visit, have you been treated for malaria?						
<input type="checkbox"/>	<input type="checkbox"/>					
<i>If yes, enter on Concomitant Medications Log.</i>						
Comments: <i>For each comment, please specify item number.</i>						

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	April 19, 2001	SAMPLE	<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;">0</div> <div style="border: 1px solid black; padding: 2px 5px; margin-right: 5px;">1</div> </div> <div style="display: flex; justify-content: space-between; font-size: x-small; margin-top: 5px;"> Language Staff initials / Date </div>
hivnetforms/HIV024_chorioforms/intrapartum_mother.fm						

Figure 9-16
Mother's Intrapartum (MIP-1 - MIP-5)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's Intrapartum (MIP-2)			
HIV 024 Chorio (051)		MIP-2 (032)		Visit (401)		Page 2 of 5	
Participant ID							
0	0	0	-	-	-	0	Mother's Intrapartum
<small>Site Number</small>	<small>Participant Number</small>	<small>Chk</small>	<small>Cohort</small>				
SEXUAL HISTORY							
5. How many sexual partners, including your spouse, have you had since your last visit?			number of partners		If 0 partners, go to item 7.		
			[][]				
6. Since your last visit, how often did your spouse and other sexual partners use condoms? <i>Mark only one.</i>			<small>never</small>	<small>sometimes</small>	<small>always</small>		
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7. Since your last visit, have you been treated for:			<small>yes</small>		<small>no</small>		
syphilis?			<input type="checkbox"/>	<input type="checkbox"/>			
genital ulcers?			<input type="checkbox"/>	<input type="checkbox"/>			
abnormal vaginal discharge?			<input type="checkbox"/>	<input type="checkbox"/>			
			If any yes, enter treatment on Concomitant Medications Log.				
DELIVERY HISTORY							
8. Did the mother deliver at a study clinic or hospital?			<small>yes</small>	<small>no</small>	If no, complete as many items as possible.		
			<input type="checkbox"/>	<input type="checkbox"/>			
9. Onset of labor (regular contractions about 10 minutes apart):			<small>Date:</small>			<small>Time: 24-hour clock</small>	
			<small>dd</small>	<small>mm</small>	<small>yy</small>	<small>hr</small>	<small>min</small>
			[][]	[][]	[][]	[][]	[][]
10. Admission to labor room/ward or clinic:			[][]	[][]	[][]	[][]	[][]
11. Membranes ruptured:			[][]	[][]	[][]	[][]	[][]
12. Cervical dilation at admission:			[][]	<small>cm</small>			
13. Rupture of membranes was: <i>Mark only one.</i>			<small>spontaneous</small>		<small>artificial</small>		
			<input type="checkbox"/>	<input type="checkbox"/>			
14. Type of amniotic fluid: <i>Mark all that apply.</i>			<small>clear</small>		<small>meconium</small>	<small>bloody</small>	<small>foul smelling</small>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15. Use of oxytocin:			<small>yes</small>	<small>no</small>	<small>induction of labor</small>		<small>acceleration of labor</small>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>
			If yes, indicate reason:				
Comments: <i>For each comment, please specify item number.</i>							
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001 SAMPLE <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>							
<small>mivnetfomsHIV024_choriofomsintrapartum_mother.fm</small>						<small>Language</small>	<small>Staff Initials / Date</small>

Figure 9-17
Mother's Intrapartum (MIP-1 - MIP-5)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)
Mother's Intrapartum (MIP-3)

HIV 024 Chorio (051)
MIP-3 (033)
Visit (401)
Page 3 of 5

Participant ID

0	0	0	-	-	-	0	Mother's Intrapartum	
Site Number	Participant Number	Chk		Cohort				

16. Did the participant take antibiotics, other than study drug, during labor and delivery? *yes* *no*

dd *mm* *yy* *24 hour clock*

hr min

: :

If yes, indicate date/time above and update Concomitant Medications Log.

17. Vulvar/Vaginal Exam: *normal* *abnormal*

If abnormal, record below. Mark all that apply.

warts *ulcers*

 other, specify: _____

yes *no*

18. Was an episiotomy performed?

19. Were there vaginal tears?

20. Type of delivery: *vaginal* *cesarean*

 Go to item 20b.

20a. Vaginal birth: *Mark all that apply.*

spontaneous vertex delivery *forceps*

breech *vacuum extraction*

other, specify _____

20b. Cesarean Section: *elective* *emergency*

Please record the date/time of initiation of surgery:

24-hour clock

dd mm yy hr min

: :

Comments: *For each comment, please specify item number.*

April 19, 2001 **SAMPLE**

01

Lang uage Staff initials / Date

hivnet/forms/HIV024_chorio/forms/intrapartum_mother.fm

Figure 9-18
Mother's Intrapartum (MIP-1 - MIP-5)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)			Mother's Intrapartum (MIP-4)		
HIV 024 Chorio (051)		MIP-4 (034)		Visit (401)	
				Page 4 of 5	
Participant ID					
0	0	0	-	-	0
<small>Site Number</small>	<small>Participant Number</small>	<small>Chk</small>	<small>Cohort</small>	Mother's Intrapartum	
21. Obstetric complications and procedures: <i>Mark none or all that apply.</i>					
21a. None.....	<input type="checkbox"/>	→ Go to item 22.			
21b. Fever during labor	<input type="checkbox"/>	→ highest temperature	<input type="text"/>	<input type="text"/>	°C
21c. Fever postpartum	<input type="checkbox"/>	→ highest temperature	<input type="text"/>	<input type="text"/>	°C
21d. Antenatal hemorrhage	<input type="checkbox"/>	→ if yes, record below. Mark only one.			
		<small>placenta previa</small>	<small>abruptio placenta</small>	<small>other, specify:</small>	
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	
21e. Postpartum hemorrhage	<input type="checkbox"/>				
21f. Hypertension (> 140/90) without proteinuria	<input type="checkbox"/>	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> Was hypertension diagnosed before the start of labor? yes no <input type="checkbox"/> <input type="checkbox"/> ↓ if yes, do not report hypertension as an AE. </div>			
21g. Hypertension (> 140/90) with proteinuria (preeclampsia)	<input type="checkbox"/>				
21h. Eclampsia (preeclampsia plus seizure or coma).....	<input type="checkbox"/>				
21i. Malpresentation	<input type="checkbox"/>				
21j. Cord presentation/prolapse	<input type="checkbox"/>				
21k. Fetal distress resulting in a forceps delivery or cesarean section	<input type="checkbox"/>				
21l. Prolongation of 1 st or 2 nd stage resulting in forceps delivery or cesarean section	<input type="checkbox"/>				
21m. Postpartum endometritis (fever with abdominal pain and tenderness)	<input type="checkbox"/>				
21n. Other, specify: _____	<input type="checkbox"/>				
22. Diagnostic criteria for chorioamnionitis		<small>yes</small>	<small>no</small>		
22a. Fever during labor > 38° C.....	<input type="checkbox"/>	<input type="checkbox"/>			
22b. Abdominal tenderness	<input type="checkbox"/>	<input type="checkbox"/>			
22c. Purulent cervical discharge.....	<input type="checkbox"/>	<input type="checkbox"/>			
22d. Fetal heart rate > 160 BPM	<input type="checkbox"/>	<input type="checkbox"/>			
22e. Foul smelling infant or placenta.....	<input type="checkbox"/>	<input type="checkbox"/>			
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001 SAMPLE <input type="text" value="0"/> <input type="text" value="1"/> _____ <small>Language</small> <small>Staff Initials / Date</small>					
<small>mivnet\forms\HIV024_chorio\forms\intrapartum_mother.fm</small>					

Figure 9-19
Mother's Intrapartum (MIP-1 - MIP-5)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)				Mother's Intrapartum (MIP-5)			
HIV 024 Chorio (051)		MIP-5 (035)		Visit (401)		Page 5 of 5	
Participant ID							
0 0 0			0	Mother's Intrapartum			
<small>Site Number</small>	<small>Participant Number</small>	<small>Chk</small>	<small>Cohort</small>				
		singleton	twin	triplet			
23. Birth was: <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>							
24. Outcome of pregnancy:							
	<i>liveborn infant</i>	<i>fresh stillbirth</i>	<i>macerated stillbirth</i>	25. Enter Infant's Participant ID for each live birth:			
<i>Firstborn infant</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				1
<i>Secondborn infant</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				2
<i>Thirdborn infant</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				3
				<i>dd</i>	<i>mm</i>	<i>yy</i>	
26. Was the placenta delivered spontaneously? <input type="checkbox"/> <i>yes</i> → Record date and time:							
					:		<i>24-hour clock</i>
				<i>hr</i>	<i>min.</i>		
						<i>yes</i>	<i>no</i>
				Was evacuation of uterus performed?		<input type="checkbox"/>	<input type="checkbox"/>
27. Condition of placenta(s): <i>Mark all that apply</i>							
	<i>normal</i>	<i>oedematous</i>	<i>infarcts/ calcifications</i>	<i>foul smelling</i>			
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
28. Total weight of placenta(s): grams							
29. Was placental tissue collected for histological analysis? <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i> → If no, indicate reason:							

				<i>placenta</i>	<i>membranes</i>	<i>cord</i>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If yes, indicate types. Mark all that apply.							
30. Was colostrum/milk collected? This item removed.							
Comments: For each comment, please specify item number.							

<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> August 23, 2001				SAMPLE		0 1 Language Staff Initials / Date	
hivnetforms\HIV024_chorio\forms\intrapartum_mother.fm							

9.4.15 Labor Dosing (LD-1 - LD2)

Description and Purpose

The *Labor Dosing* form documents dosing of the mother with study drug during labor and delivery. ***This form must be completed as much as possible even if the mother does not give birth at the study site and did not take the intrapartum doses of study drug.***

Form-Specific Instructions

- Unlike the *Mother's Intrapartum* form, include information about all labor study drug dosing, during both false and true labor, on this form.
- If the participant was dispensed extra study drug to replace lost drug before coming in for labor and delivery, either from her study drug kit or from the intrapartum study drug emergency supply, mark item 1 as yes and complete the number of capsules dispensed, the number returned and the letter code of the extra study drug dispensed. If the extra drug is from the study drug kit rather than the emergency supply, cross out the box for the letter code and mark as "na".
- Item 2, if the participant brought her blister cards of labor study drug with her, mark this as "yes." The pill count documents how much study drug was taken prior to arrival at the study site Labor Ward.
- Count and record the number of capsules returned. The number taken is the number dispensed, less the number returned. Based on an interview with the mother, for each dose she took prior to arrival at the labor ward record the number of capsules, date and time she took them, and mark the "Self Report" box.

If the participant did not bring her blister cards with her, mark item 1 as "no", and complete the pill count based on an interview with the mother. If the participant was given extra study drug from her kit or the emergency supply enter the total number of capsules taken, from all sources.

- If the participant delivered at home and brought the blister cards into the study site after delivery record as "Taken" only the study drug taken before delivery. ***Do not record any doses of study drug given after delivery.***
- Items 3 - 5 record dosing of the mother with nevirapine or nevirapine placebo, including whether she was redosed with nevirapine due to vomiting or false labor.
- Items 6 - 20 record all doses of study drug taken during labor. Interview the participant and record the date and time of all doses taken before arrival at the Labor Ward and for these doses mark the "Self-report" box. Then record all doses given in the Labor Ward as they are given, marking the "Labor Ward" box. After delivery, if the participant is admitted to the hospital of clinic for complications and study drug is continued as a three-times a day antibiotic, then mark all doses given in hospital or clinic as "Labor Ward". ***Do not record any doses of study drug given after delivery.***
- Item 21, if the participant was redosed with study drug during labor for any reason, mark the "yes" box and indicate the reason for redosing.

- Item 22, if the participant does not bring her blister cards with her, and requires more study drug during the course of labor and delivery, dispense more study drug either from the participant's study drug kit or from the intrapartum emergency supply according to the letter code in the participant's study drug supply. Record the letter code in the box provided.
- If in rare event that the participant experiences false labor or prolonged labor and requires more than 15 doses of study drug, complete a second Labor Dosing form to document all doses. Complete items 20 and 21 on the first page, and cross them out and mark as "NA" on the second page.

Special Trial Closure Instructions

- If the participant had Labor study drug dispensed at the First Antenatal Study Visit (Visit 2.0) that was later retrieved before delivery due to the decision to end the trial early, mark item 2 as "yes" and enter the number of capsules returned as "09" and the number taken as "00". Write a note in the Comments section that indicates the study drug was retrieved early and write the date retrieved.
- If the participant never had Labor study drug dispensed at the First Antenatal Study Visit (Visit 2.0), mark item 2 as "no", cross out the pre-printed number dispensed and write "00" above it, cross out the # returned boxes and mark as "NA", and enter the # taken as "00". Do not cross out # taken and mark as "NA", a number must always be entered. Add a note in the Comments section that indicates the study drug was not dispensed due to trial closure.
- See H024 Data Communiqué #7 for example case report forms.

Figure 9-20
 Labor Dosing (LD-1 - LD2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)			Labor Dosing (LD-1)
HIV 024 Chorio (051)	LD-1 (028)	Visit (401)	Page 1 of 2
Participant ID			
Site Number	Participant Number	Chk	Cohort
Labor Dosing			
<i>Instructions: Record pill count and nevirapine dosing below. Record all doses of study antibiotics, including those taken before arrival and any refills, on page 2. Mark all doses taken before arrival as "Self-report" and all doses taken after admission until delivery as "Laborward."</i>			
1. Did participant require extra study drug after dispensing but before labor and delivery (from emergency bottle or study drug kit)? yes <input type="checkbox"/> no <input type="checkbox"/> → <i>if no, go to item 2.</i>			
Extra Metronidazole			
Number dispensed: <input type="text"/> <input type="text"/>		# returned: <input type="text"/> <input type="text"/>	
Extra Ampicillin			
Number dispensed: <input type="text"/> <input type="text"/>		# returned: <input type="text"/> <input type="text"/>	
<input type="text"/> letter code			
2. Did participant return her blister cards? yes <input type="checkbox"/> no <input type="checkbox"/> → <i>if no, complete number taken based on participant's report.</i>			
Metronidazole			
# dispensed: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 9		# returned: <input type="text"/> <input type="text"/>	
		Total # taken (including from extra supply): <input type="text"/> <input type="text"/>	
Ampicillin			
# dispensed: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> 9		# returned: <input type="text"/> <input type="text"/>	
		Total # taken (including from extra supply): <input type="text"/> <input type="text"/>	
Nevirapine Dosing			
3. The mother... took nevirapine or placebo prior to arrival <input type="checkbox"/>			
was given nevirapine upon arrival <input type="checkbox"/> → Lot #: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			
was not given nevirapine or placebo <input type="checkbox"/> → Go to page 2.			
Date Dose Taken Time Dose Taken			
<small>dd mm yy 24-hour clock hr min</small>			
4. First Dose: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> self-report			
5. Was the mother redosed with nevirapine due to false labor, vomiting, or other causes? yes <input type="checkbox"/> no <input type="checkbox"/> → <i>if no, go to page 2.</i>			
false labor vomiting other, specify:			
5a. What was the cause of redosing? <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____			
Date Dose Taken Time Dose Taken			
<small>da mm yy 24-hour clock hr min</small>			
5b. Dose #2: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>			
Comments: For each comment, please specify item number.			
_____ _____			
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> November 13, 2001 <input type="text"/> <input type="text"/> Language <input type="checkbox"/> Staff Initials / Date			
hivnet/forms/HIV024_chorio/forms/labour_dosing_mother.fm			

Figure 9-21
Labor Dosing (LD-1 - LD2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)						Labor Dosing (LD-2)																							
HIV 024 Chorio (051)		LD-2 (029)		Visit (401)		Page 2 of 2																							
Participant ID <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; padding: 2px;"> <table style="border-collapse: collapse;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td style="font-size: 8px;">Site Number</td> <td style="font-size: 8px;">Participant Number</td> <td style="font-size: 8px;">Chk</td> <td colspan="7" style="font-size: 8px;">Cohort</td> </tr> </table> </div> <div style="margin-left: 20px;"> Labor Dosing </div> </div>																				Site Number	Participant Number	Chk	Cohort						
Site Number	Participant Number	Chk	Cohort																										
Instructions: Record Metronidazole and Ampicillin dosing every 4 hours during labor until delivery.																													
	Number of Capsules		Date Dose Taken			Time Dose Taken		Self-report	Labor ward	Nurse code																			
	Metro	Amp	dd	mm	yy	24-hour clock hr	min																						
6. Dose #1:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
7. Dose #2:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
8. Dose #3:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
9. Dose #4:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
10. Dose #5:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
11. Dose #6:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
12. Dose #7:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
13. Dose #8:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
14. Dose #9:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
15. Dose #10:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
16. Dose #11:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
17. Dose #12:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
18. Dose #13:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
19. Dose #14:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
20. Dose #15:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>																			
21. Was participant redosed with study drugs due to false labor, vomiting within one hour of dosing, or other causes?						<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	If yes, specify below. Mark only one.																						
<input type="checkbox"/> <i>false labor</i> <input type="checkbox"/> <i>vomiting</i> <input type="checkbox"/> <i>other, specify:</i> _____																													
22. Did participant require study drug from emergency supply after presenting for labor and delivery?						<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	If yes, specify letter code: <input type="text"/>																						
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> November 13, 2001						<input type="text"/> <input type="text"/> Language		<input type="text"/> <input type="text"/> Staff initials / Date																					
hivnet024/HIV024_chorio029/labor_dosing_motherfm																													

9.4.16 Mother's Discharge (MD-1)

Description and Purpose

The *Mother's Discharge* form documents exams performed at discharge and the mother's status at discharge, whether discharge from the labor ward or from the postnatal ward. ***This form must be completed as much as possible even if the mother does not give birth at the study site.***

Form-Specific Instructions

- Item 4, if the answer to this is "yes" update the *Mother's Concomitant Medications Log*.
- Item 5, if the mother had any illnesses or adverse experiences since the onset of labor, mark this as "yes" and record each illness, diagnosis, or condition on *Illness/AE Log* forms.
- Item 7, if the mother dies before or after delivery, complete a *Mother's Termination* form and an *Illness/AE Log* form. Enter the medical condition that caused the death on the *Illness/AE Log* form, rather than the death itself.
- Item 9, on discharge dispense to the participant any study drug that is left after labor dosing. Record the number of capsules dispensed. If all study drug was taken before discharge, enter "00" for the number of capsules dispensed. If there was no study drug left to dispense at discharge, the *Postpartum Pill Count* form (see *Section 9.12*) does not need to be completed or faxed to DataFax.

Special Trial Closure Instructions

If Labor study drug was never dispensed due to trial closure, or dispensed and retrieved before delivery, be sure to enter "00" in item 9 for the number of capsules dispensed at discharge. Do not cross out and mark as "NA". This item must be entered as a number. If "00" is entered as the number of capsules dispensed at discharge then the *Postpartum Pill Count* is not completed and faxed.

Figure 9-22
Mother's Discharge (MD-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)				Mother's Discharge (MD-1)			
HIV 024 Chorio (051)		MD-1 (019)		Visit (401)		Page 1 of 1	
Participant ID <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> - <input type="text"/> <input type="text"/>				Form Completion Date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>			
Site Number		Participant Number		Chk	Cohort		
				<input type="checkbox"/>	<input type="checkbox"/>		
				<i>normal</i>	<i>abnormal</i>		
Mother's Discharge 1. Physical Exam at discharge: <input type="checkbox"/> <input type="checkbox"/> → <i>If abnormal, record below. Mark all that apply.</i>							
<input type="checkbox"/> generalized wasting		<input type="checkbox"/> infected abdominal wound					
<input type="checkbox"/> generalized lymphadenopathy		<input type="checkbox"/> fresh vaginal bleeding					
<input type="checkbox"/> genital ulcers		<input type="checkbox"/> infected episiotomy or tear					
<input type="checkbox"/> Herpes zoster		<input type="checkbox"/> infected lochia					
<input type="checkbox"/> other, specify: _____							
2. Has the mother been diagnosed with puerperal sepsis?.....				<input type="checkbox"/>	<input type="checkbox"/>	<i>yes</i>	<i>no</i>
3. Has the mother received a blood transfusion at or since delivery?				<input type="checkbox"/>	<input type="checkbox"/>		
4. Has the mother taken any medications, other than study drug or nevirapine, since onset of labor?				<input type="checkbox"/>	<input type="checkbox"/>		
5. Has the mother had any illnesses or adverse experiences since onset of labor?				<input type="checkbox"/>	<input type="checkbox"/>	→ <i>If yes, update Concomitant Medications Log.</i>	
6. Was the mother admitted (for > 48 hours for vaginal delivery or > 7 days for CS) to the Postnatal Ward?				<input type="checkbox"/>	<input type="checkbox"/>	→ <i>If yes, enter each on Illness/AE Log.</i>	
				<input type="checkbox"/>	<input type="checkbox"/>	→ <i>If yes, indicate reason below. Mark all that apply.</i>	
<input type="checkbox"/> retained products of conception		<input type="checkbox"/> offensive discharge					
<input type="checkbox"/> postpartum bleeding		<input type="checkbox"/> infected wound					
<input type="checkbox"/> abdominal pain/ tenderness		<input type="checkbox"/> transfusion					
<input type="checkbox"/> urinary tract infection		<input type="checkbox"/> fever → <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> °C				Record highest temperature	
<input type="checkbox"/> pneumonia		<input type="checkbox"/> other, specify: _____					
7. Mother's status on discharge (from Labor ward, Postnatal ward): <i>Mark only one.</i>							
<input type="checkbox"/> alive and well							
<input type="checkbox"/> alive and unwell		→		<i>Enter on Illness/AE Log</i>			
<input type="checkbox"/> died before delivery		→		<i>Complete Termination form and update Illness/AE Log, go to item 10.</i>			
<input type="checkbox"/> died after delivery							
8. Mother's weight at discharge: <input type="text"/> <input type="text"/> <input type="text"/> kilograms							
9. Number of study drug capsules dispensed at discharge:				Metronidazole <input type="text"/> <input type="text"/>		Ampicillin <input type="text"/> <input type="text"/>	
10. Date and time of discharge (or death):							
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>			
		<i>dd mm yy</i>		<i>hr min</i>			
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>		April 19, 2001		SAMPLE			
						<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	
						Language Staff Initials / Date	

9.4.17 Mothers Postpartum Pill Count (PPC-1)

Description and Purpose

The *Mother's Postpartum Pill Count* form is used to document the amount of study drug taken after labor and delivery. ***It is not necessary to complete or fax this form if, after labor dosing, no study drug is left to dispense to the mother at discharge.***

Form-Specific Instructions

- Item 1 documents the pill count. If the participant returns her blister cards, count the number returned, subtract that number from the number dispensed, and enter the number taken.
- If the participant has forgotten her blister cards, or they have been lost, complete the number taken based on information she gives you about how many pills she took each day.
- If the participant has not taken all her study drug, or tells you she has not taken all of her study drug, complete item 2 after interviewing the participant about why she did not take all of the study drug.
- Item 3 is the last date the participant took intrapartum/post delivery study drug.

Figure 9-23
Mothers Postpartum Pill Count (PPC-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)				Mother's Postpartum Pill Count (PPC-1)																																											
HIV 024 Chorio (051)		PPC-1 (020)		Visit (501)		Page 1 of 1																																									
Participant ID <div style="display: flex; justify-content: space-between;"> <div style="width: 40%;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; text-align: center;">0</td> <td style="border: 1px solid black; width: 20px; text-align: center;">0</td> <td style="border: 1px solid black; width: 20px; text-align: center;">0</td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> </tr> <tr> <td style="font-size: 8px;">Site Number</td> <td colspan="4" style="font-size: 8px;">Participant Number</td> <td style="font-size: 8px;">Chk</td> <td colspan="6" style="font-size: 8px;">Cohort</td> </tr> </table> </div> <div style="width: 60%; text-align: right;"> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> <td style="border: 1px solid black; width: 20px;"></td> </tr> <tr> <td colspan="2" style="font-size: 8px;">dd</td> <td colspan="2" style="font-size: 8px;">mm</td> <td colspan="4" style="font-size: 8px;">yy</td> </tr> </table> </div> </div>				0	0	0										Site Number	Participant Number				Chk	Cohort														dd		mm		yy				Mother's Postpartum Pill Count 4-6 Week Visit			
0	0	0																																													
Site Number	Participant Number				Chk	Cohort																																									
dd		mm		yy																																											
<i>Instructions: If participant was not dispensed study drug at discharge, this form does not need to be completed or faxed.</i>																																															
<div style="display: flex; justify-content: space-between;"> yes no </div> <p>1. Did the participant return with her blister cards? <input type="checkbox"/> <input type="checkbox"/> → <i>If no, go to item 2.</i></p> <p>Metronidazole Number returned: <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/></p> <p>Ampicillin Number returned: <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/></p> <div style="display: flex; justify-content: space-between;"> yes no </div> <p>2. Did the participant take all her study drug? <input type="checkbox"/> <input type="checkbox"/> → <i>If no, mark reason below. Mark all that apply.</i></p> <p>2a. Reasons:</p> <div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"><input type="checkbox"/> abdominal pain</div> <div style="width: 50%;"><input type="checkbox"/> lost blister cards</div> <div style="width: 50%;"><input type="checkbox"/> forgot to take</div> <div style="width: 50%;"><input type="checkbox"/> other, specify: _____</div> </div> <p>3. Date last dose of study drug taken: <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/></p> <div style="display: flex; justify-content: space-around; font-size: 8px;"> dd mm yy </div> <p>Comments: <i>For each comment, please specify item number.</i></p> <hr/> <hr/> <hr/>																																															
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001				SAMPLE		<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; text-align: center;">0</td> <td style="border: 1px solid black; width: 20px; text-align: center;">1</td> </tr> <tr> <td style="font-size: 8px;">Lang uage</td> <td style="font-size: 8px;">Staff Initials / Date</td> </tr> </table>		0	1	Lang uage	Staff Initials / Date																																				
0	1																																														
Lang uage	Staff Initials / Date																																														
hivnet/forms/HIV024_chorio/forms/post_pill_count_mother.fm																																															

9.4.18 Mother's Follow-up Visit (MFU-1)


Description and Purpose

The *Mother's Follow-up Visit* form is used to document HIV symptoms, the use of non-study antibiotics, and the mother's health at all follow-up visits after delivery. It may also be used to document any interim visits between regularly scheduled visits after the Labor and Delivery Visit.

Form-Specific Instructions

- The date in the top right-hand corner is the date the visit occurred, not the date the form was completed.
- If the response to any
- If the response to item 2 is "yes", complete an entry on the *Mother's Concomitant Medications Log* for each antibiotic or medication taken since her last study visit.
- If the response to item 3 is "yes" at the 4-6 Week Follow-up Visit, all illnesses and adverse experiences since Labor and Delivery must be entered on *Illness/AE Log* forms. **After the 4-6 Week Visit see Section 8 of this manual regarding which illnesses or conditions need to be reported as an adverse experience.**
- Item 4 (collection of breastmilk) has been deleted due to changes in the protocol.

Mother's Follow-up Visit (MFU-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's Follow-up Visit (MFU-1)			
				Visit Code		<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>	
HIV 024 Chorio (051)		MFU-1(021)		Page 1 of 1			
Participant ID				Visit Date			
<input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> - <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> - <input type="text" value=""/> - <input type="text" value="0"/>		Mother's Follow-up Visit		<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>		<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>	
<small>Site Number</small>		<small>Participant Number</small>		<small>Chk</small>		<small>Cohort</small>	
				<small>dd</small>		<small>mm</small>	
				<small>yy</small>			
1. Have you...							
						<small>yes</small>	<small>no</small>
had painful, swollen, or warm breasts (mastitis) since the last visit?						<input type="checkbox"/>	<input type="checkbox"/>
had cracked nipples since the last visit?.....						<input type="checkbox"/>	<input type="checkbox"/>
had three or more loose, watery stools per day over the last 2 weeks?.....						<input type="checkbox"/>	<input type="checkbox"/>
had fever (hot to the touch) for more than 2 weeks since the last visit?						<input type="checkbox"/>	<input type="checkbox"/>
had a cough (coughing all day) for more than 2 weeks since the last visit?.....						<input type="checkbox"/>	<input type="checkbox"/>
had recurrent itchy vaginal discharge since the last visit?.....						<input type="checkbox"/>	<input type="checkbox"/>
had <i>Herpes zoster</i> or shingles since the last visit?.....						<input type="checkbox"/>	<input type="checkbox"/>
received treatment for tuberculosis since the last visit?						<input type="checkbox"/>	<input type="checkbox"/>
had oral thrush in the last month?						<input type="checkbox"/>	<input type="checkbox"/>
had unintended or unusual weight loss in the last month?						<input type="checkbox"/>	<input type="checkbox"/>
had swollen glands for more than one month since the last visit?.....						<input type="checkbox"/>	<input type="checkbox"/>
been admitted to hospital since the last visit?.....						<input type="checkbox"/>	<input type="checkbox"/>
<i>If yes, indicate reason and enter on Illness/AE Log:</i> _____							
2. Have you taken any antibiotics or other medications since the last visit?						<small>yes</small>	<small>no</small>
						<input type="checkbox"/>	<input type="checkbox"/>
						<i>If yes, enter on Concomitant Medications Log.</i>	
3. Have you had any illnesses since the last visit?						<input type="checkbox"/>	<input type="checkbox"/>
						<i>If yes, see SSP for AE and SAE reporting guidelines. Enter on Illness/AE Log as necessary.</i>	
4. Was breastmilk removed?							
<i>This item removed.</i>							
<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> August 23, 2001				SAMPLE		<input type="text" value="0"/> <input type="text" value="1"/>	
<small>hivnetformsHIV024_chorioformsfollow_up_mother.fm</small>				<small>Language</small>		<small>Staff Initials / Date</small>	

Infant's Forms

9.4.19 Infant Birth (IB-1)

Description and Purpose

The *Infant Birth* form documents the date and time of birth, gestational age, health status, and any illnesses or adverse experiences. ***This form must be completed as much as possible even if the infant is not born at the study site.***

Note: this does not apply to stillborn infants (see *Section 9.4.13 - Mother's Intrapartum*), do not complete an *Infant Birth* form for stillbirths.

Form-Specific Instructions

- The date at the top right-hand corner is the date of the infant's birth, not the date the form is completed. This date must be completed, even if the infant is not born at a study site.
- Item 1, if the infant is not born at the study site, mark this as "no" and complete as many items as possible based on an interview with the mother when she comes in, or from medical records. Indicate in the boxes to the right whether the information is from medical records or from an interview with the mother.
- Item 10, if the infant has had an illness or other adverse experience since birth, mark this as "yes" and complete an *Illness/AE Log* form for each illness, diagnosis, or condition.
- Item 11, if the infant has been given any medications since birth, mark this as "yes" and complete entries on the *Infant Concomitant Medications Log* form.
- Item 12, if the infant was admitted to the nursery mark this as "yes" and mark the appropriate reasons below. Check to make sure that these items have been entered on *Illness/AE Log* forms if appropriate.
- Item 13, if the infant is born alive but dies before discharge complete an *Infant's Termination* form and an *Illness/AE Log* form for the cause of death.

Figure 9-24
Infant Birth (IB-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)				Infant Birth (IB-1)		
HIV 024 Chorio (052)		IB-1 (001)		Visit (401)		Page 1 of 1
Participant ID <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> - <input type="text"/>				Infant Birth yes no		Birth Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Site Number		Participant Number		Chk		Cohort
						dd mm yy
1. Was the infant delivered at the study site hospital? <input type="checkbox"/> yes <input type="checkbox"/> no						
→ <i>If no, complete as many items as possible. Completed from:</i> <input type="checkbox"/> <i>medical records</i> <input type="checkbox"/> <i>mother's self report</i>						
2. Time of birth: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <i>24-hour clock</i>						
3. Sex: <input type="checkbox"/> <i>male</i> <input type="checkbox"/> <i>female</i>						
4. Birthweight: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>grams</i>						
5. Gestational age (Ballard score): <input type="text"/> <input type="text"/> <i>weeks</i>						
6. Crown-heel length: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>cm.</i>						
7. Head circumference: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>cm.</i>						
8. APGAR at one minute: <input type="text"/> <input type="text"/>						
9. APGAR at 5 minutes: <input type="text"/> <input type="text"/>						
10. Has the infant had any illness or adverse experience since birth? <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>						
→ <i>If yes, enter on Illness/AE Log.</i>						
11. Has the infant been given any medications other than nevirapine? <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>						
→ <i>If yes, update the Concomitant Medications Log.</i>						
12. Was infant admitted to the nursery? <input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>						
→ <i>If yes, mark reasons below. Mark all that apply.</i>						
<input type="checkbox"/> low APGAR score						
<input type="checkbox"/> low birth weight (< 2.5 kg)						
<input type="checkbox"/> preterm (< 37 weeks)						
<input type="checkbox"/> respiratory distress syndrome						
<input type="checkbox"/> asphyxia						
<input type="checkbox"/> meconium aspiration						
<input type="checkbox"/> seizures						
<input type="checkbox"/> other, specify: _____						
<input type="checkbox"/> poor sucking						
<input type="checkbox"/> pneumonia						
<input type="checkbox"/> hypoglycemia						
<input type="checkbox"/> congenital abnormality						
<input type="checkbox"/> jaundice						
<input type="checkbox"/> eye discharge						
<input type="checkbox"/> fever > 38 °C (Record highest temperature.) → <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> °C						
<input type="checkbox"/> clinical neonatal sepsis						
<input type="checkbox"/> cold injury (hypothermia)						
<input type="checkbox"/> omphalitis (umbilical flare)						
<input type="checkbox"/> foul smelling infant						
<input type="checkbox"/> suspected meningitis						
13. Infant's status on discharge:						
<input type="checkbox"/> alive and well						
<input type="checkbox"/> alive and unwell → <i>Enter on Illness/AE Log.</i>						
<input type="checkbox"/> died → <i>Complete Termination form and enter on Illness/AE Log.</i>						
14. Date and time of discharge or death: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <i>24-hour clock</i>						
		dd mm yy		hr min		
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001		SAMPLE		<input type="text" value="0"/> <input type="text" value="1"/>		_____ Staff Initials / Date
hivnetforms\HIV024_chorio\forms\birth_infant.fm						

9.4.20 Infant Nevirapine Dosing (IND-1)

Description and Purpose

The purpose of the *Infant Nevirapine Dosing* form is to document dosing of the infant with nevirapine. This form is completed even if the infant was not born to an HIV uninfected mother and not given nevirapine

Form-Specific Instructions

- Item 1, if the infant received nevirapine go to item 2. If the infant did not receive nevirapine, mark the appropriate reason below.
- Item 2, record the amount of nevirapine given the baby, as well as the date and time the dose was administered.
- If the infant was redosed with nevirapine mark item 3 as “yes”, mark the appropriate reason, and indicate the date and time the infant was redosed.

Figure 9-25
Infant Nevirapine Dosing (IND-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Infant Nevirapine Dosing (IND-1)			
HIV 024 Chorio (052)		IND-1(009)		Visit (401)		Page 1 of 1	
Participant ID							
0	0	0	-	-	-	Infant Nevirapine Dosing	
<small>Site Number</small>	<small>Participant Number</small>		<small>Chk</small>	<small>Cohort</small>			
				<small>yes</small>	<small>no</small>		
1. Did infant receive nevirapine?				<input type="checkbox"/>	<input type="checkbox"/>	→ <i>if no, indicate reason below.</i>	
<input type="checkbox"/> mother is HIV-negative							
<input type="checkbox"/> severe congenital malformations or other conditions not compatible with life.							
<input type="checkbox"/> documented or suspected serious infectious, cardiac, respiratory, or metabolic illness, or other immediate life threatening conditions, making the infant unable to tolerate oral medication by 72 hours of life.							
<input type="checkbox"/> mother refused							
<input type="checkbox"/> other, specify: _____							
→ <i>End of form</i>							
2. First dose given: <input type="text"/> . <input type="text"/> <input type="text"/> ml Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>							
<small>24-hour clock</small>							
<small>dd mm yy hr min</small>							
3. Was the infant redosed due to vomiting or other causes?				<input type="checkbox"/>	<input type="checkbox"/>	→ <i>if no, end of form.</i>	
3a. Why was infant redosed?							
<input type="checkbox"/> vomiting							
<input type="checkbox"/> other, specify: _____							
3b. Dose #2: <input type="text"/> . <input type="text"/> <input type="text"/> ml Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> Time: <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>							
<small>24-hour clock</small>							
<small>dd mm yy hr min</small>							
Comments: <i>For each comment, please specify item number.</i>							

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001				SAMPLE		<input type="text"/> <input type="text"/>	
<small>hivnet\forms\HIV024_chorio\forms\nevirapine_infant.fm</small>				<small>Language</small>		<small>Staff Initials / Date</small>	

9.4.21 Infant's Laboratory Results (ILR-1)

Description and Purpose

The *Infant's Laboratory Results* form documents CBC results and Dried Blood Spot specimen collection for later HIV PCR analysis. It is required at all Infant visits, except the 6 Month and 9 Month Visits, and may also be used to document laboratory tests done at Interim Visits.

Form-Specific Instructions

- *This form was revised March 25, 2002 and is to be put into use by all sites no later than May 10, 2001.*
- The date at the top right-hand corner is the date that specimens were collected, not the date the form was completed.
- CBC, if the specimen was not collected at a visit mark the "Not Collected" boxes. If the specimen was collected but results are not available because the sample was insufficient or lost, then do not mark the "Not Collected" box, instead draw a line through the results boxes, write "NA" and initial and date.
- Items 5 and 6 document specimens collected for HIV testing, the EIA is to be done by the site laboratory on a specimen collected at the 12 month visit, and the Dried Blood Spot is collected at birth, 4-6 weeks, and 12 months (more often if a confirmatory test is necessary, see the protocol for more details). If the DBS specimen is not required at this visit (and not needed for confirmation) mark this item as "N/A" for not applicable. If the specimen is supposed to be collected at this visit but was not then mark this item as "no" and indicate the reason the specimen was not obtained.
- If items 1, 4 or 7 (hemoglobin, platelets, ALT) have abnormal results that meet DAIDS Toxicity criteria of **Grade 2 or greater** (*please note this is a change from the first version of this form*), mark and "x" in the "≥ Grade 2" box to the right of the results. According to the new DAIDS SAE Reporting Manual included in your SSP, **Lab results that are grade 2 or greater may need to be reported as a Serious Adverse Experience and recorded on an Illness/AE Log form if not associated with an already reported diagnosis (see Section 8)**. For example, a grade 3 hemoglobin value would not be reported as a separate AE if associated with an already reported AE of malaria, but a grade 2 platelet count not known to be associated with any other diagnosis would be reported as an AE if within 8 weeks of the last dose of study drug and as an SAE if the problem was thought to be related to study drug. **After the 4-6 Week Visit see Section 8 of this manual regarding which illnesses or conditions need to be reported as a Serious Adverse Experience.**

Figure 9-26
Infant's Laboratory Results (ILR-1)

Statistical Center for HIV/AIDS Research & Prevention				Infant's Laboratory Results (ILR-1)			
				Visit Code		1	
HIV 024 Chorio (052)		ILR-1 (104)		Page 1 of 1			
Participant ID				Specimen Collection Date			
000		- - - - -		- - - - -		- - - - -	
Site Number		Participant Number		Chk		Cohort	
Infant's Laboratory Results				dd		mm yy	
CBC							
Not Done/Not Collected				≥ Grade 2			
<input type="checkbox"/>	1	Hemoglobin		g/dl	<input type="checkbox"/>	See SSP for AE and SAE reporting guidelines. Enter on illness/AE Log as necessary.	
<input type="checkbox"/>	2	Hematocrit		%	<input type="checkbox"/>		
<input type="checkbox"/>	3	Platelets		10 ³ /μL	<input type="checkbox"/>		
<input type="checkbox"/>	4	WBC		10 ³ /μL	<input type="checkbox"/>		
HIV-RELATED							
Not Done/Not Collected				positive negative indeterminate			
<input type="checkbox"/>	5	HIV EIA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
SPECIMEN COLLECTION							
				collected NA not collected reason not collected			
<input type="checkbox"/>	6	Dried Blood Spot for HIV PCR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	_____	
CHEMISTRIES							
Not Done/Not Collected				≥ Grade 2			
<input type="checkbox"/>	7	ALT (SGPT)		IU/liter	<input type="checkbox"/>	See SSP for AE and SAE reporting guidelines. Enter on illness/AE Log as necessary.	
Comments: For each comment, please specify item number.							

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> March 25, 2002		SAMPLE		01		Language Staff Initials/Date	
hivnetforms\HIV024_chorio\forms\lab_results_infant.fm							

9.4.22 Infant's Follow-up Visit (IFU-1, IFU-2)

Description and Purpose

The *Infant's Follow-up Visit* form is used to document all Infant study visits after birth. It may also be used to document interim visits.

Form-Specific Instructions

- Items 1 - 5 document the follow-up examinations of the infant.
- Item 5, General Exam, if the exam is normal, then only mark the "normal" box and nothing else. If the exam is abnormal, mark exam box as "abnormal" and as many abnormalities as appropriate. Please note that many of these abnormalities should be reported on an *Illness/AE Log* form if there has been onset before or at the 4-6 Week Visit (or 3 Month Visit for serious adverse experiences) - see Section 8 for more information.
- Items 6 - 8 record information about breast feeding. Date last breastfed should be provided only if the infant has been weaned and will not receive any more breastmilk.
- If the response to item 9 is "yes" at the 4-6 Week Follow-up Visit, all illnesses and adverse experiences since Labor and Delivery must be entered on *Illness/AE Log* forms. After the 4-6 Week Visit illnesses and conditions may need to be reported as an AE, especially if considered serious - see Section 8 for more information.
- Item 10, if the infant has been hospitalized since the last visit, mark this "yes." In general, hospitalizations are considered to be a Serious Adverse Experience, see Section 8 to determine if the condition that caused hospitalization should be reported as AE.
- Item 11, if illness occurs before or at the 4-6 Week Visit, each illness, diagnosis or condition must be reported on an *Illness/AE Log* form. **After the 4-6 Week Visit see Section 8 of this manual regarding which illnesses or conditions need to be reported as an adverse experience.**
- Item 12, if the infant has been given any new medications since the last visit, mark this as "yes" and record the medication(s) on the Infant's Concomitant Medications Log form.
- Item 13, record the number of each vaccination given to the infant since the last visit.

Figure 9-27
Infant's Follow-up Visit (IFU-1, IFU-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Infant's Follow-up Visit (IFU-1)			
				Visit Code		<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
HIV 024 Chorio (052)		IFU-1 (002)		Page 1 of 2			
Participant ID				Visit Date			
<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>				<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>			
Site Number		Participant Number		Chk		Cohort	
Infant's Follow-up Visit				<i>dd</i> <i>mm</i> <i>yy</i>			
Physical Exam							
1. Current weight <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> kilograms							
2. Crown-heel length <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> centimeters							
3. Head circumference <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> . <input style="width: 20px; height: 20px;" type="text"/> centimeters							
4. Does the infant have any enlarged lymph nodes (> 1cm)?							
<div style="display: flex; justify-content: space-around; width: 100%;"> yes no </div> <input type="checkbox"/> <input type="checkbox"/>							
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> occipital <input type="checkbox"/> submandibular / submental <input type="checkbox"/> cervical / supraclavicular </div> <div style="width: 45%;"> <input type="checkbox"/> axillary <input type="checkbox"/> inguinal </div> </div>							
<div style="text-align: right; margin-right: 20px;"> → If yes, mark regions below. <i>Mark all that apply.</i> </div>							
5. General Exam: <i>normal</i> <i>abnormal</i>							
<input type="checkbox"/> <input type="checkbox"/> → If abnormal, record below. Mark all that apply.							
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> diaper rash <input type="checkbox"/> oral thrush <input type="checkbox"/> otitis media <input type="checkbox"/> retraction of intercostal muscles <input type="checkbox"/> wheezes <input type="checkbox"/> palpable liver present <input type="checkbox"/> tenderness to palpation <input type="checkbox"/> generalized rigidity <input type="checkbox"/> other, specify: _____ <input type="checkbox"/> other, specify: _____ </div> <div style="width: 45%;"> <input type="checkbox"/> generalized eczematoid dermatitis <input type="checkbox"/> Herpes stomatitis <input type="checkbox"/> cough <input type="checkbox"/> active alae nasi (nasal flaring) <input type="checkbox"/> rales <input type="checkbox"/> palpable spleen present <input type="checkbox"/> generalized weakness or paresis </div> </div>							
<hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/> <hr style="border: 0; border-top: 1px solid black; margin-bottom: 5px;"/>							
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001				SAMPLE		<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	
<small>HivnetForms\HIV024_chorio\forms\follow_up_infant.fm</small>				Language		Staff Initials / Date	

Figure 9-28
Infant's Follow-up Visit (IFU-1, IFU-2)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Infant's Follow-up Visit (IFU-2)	
				Visit Code <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text" value="1"/>
HIV 024 Chorio (052)		IFU-2 (003)		Page 2 of 2	
Participant ID					
<input style="width: 20px; height: 20px;" type="text" value="0"/> <input style="width: 20px; height: 20px;" type="text" value="0"/> <input style="width: 20px; height: 20px;" type="text" value="0"/>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	<input style="width: 20px; height: 20px;" type="text"/>	Infant's Follow-up Visit	
Site Number	Participant Number	Chk	Cohort		
Medical History Since Last Study Visit					
6. Is this infant still receiving any breast milk?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	<input type="checkbox"/> <i>no</i> → If yes, go to item 9.			
7. Has this infant received any breastmilk since the last visit?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	<input type="checkbox"/> <i>no</i> → If no, go to item 9.			
8. Date last received breast milk. <i>Estimate date if uncertain.</i>	<input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/>	<i>dd mm yy</i>			
9. Has this infant had an illness or adverse experience since the last visit?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	<input type="checkbox"/> <i>no</i> → If yes, see SSP for AE and SAE reporting guidelines. Enter on Illness/AE Log as necessary.			
10. Has the infant been hospitalized since the last visit?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	<input type="checkbox"/> <i>no</i> → If yes, see SSP for AE and SAE reporting guidelines. Enter on Illness/AE Log as necessary.			
11. Has the infant been taken to the clinic for an illness since the last visit, or is the infant currently ill?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	<input type="checkbox"/> <i>no</i> → If yes, record illness below. Mark all that apply. If yes, see SSP for AE and SAE reporting guidelines. Enter on Illness/AE Log as necessary.			
<input type="checkbox"/> seizures <input type="checkbox"/> neonatal sepsis <input type="checkbox"/> meningitis <input type="checkbox"/> pneumonia <input type="checkbox"/> diarrhea <input type="checkbox"/> respiratory problems other than pneumonia <input type="checkbox"/> malaria <input type="checkbox"/> other, specify: _____					
12. Has the infant been given any medications since the last visit, or at this visit?	<input type="checkbox"/> <i>yes</i> <input type="checkbox"/> <i>no</i>	<input type="checkbox"/> <i>no</i> → If yes, update the Concomitant Medications Log.			
13. How many doses of the following vaccines has the infant received since the last visit, including today?					
BCG	<input style="width: 20px; height: 20px;" type="text"/>	DPT	<input style="width: 20px; height: 20px;" type="text"/>		
OPV	<input style="width: 20px; height: 20px;" type="text"/>	Measles	<input style="width: 20px; height: 20px;" type="text"/>		
Comments: <i>For each comment, please specify item number.</i>					
_____ _____					
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001	SAMPLE		<input style="width: 20px; height: 20px;" type="text" value="0"/> <input style="width: 20px; height: 20px;" type="text" value="1"/>	_____ Language Staff Initials /Date	
hivnet.forms.HIV024_chorio/forms/follow_up_infant.fm					

Forms for Mothers and Infants

9.4.23 Transfer (MT-1 / IT-1)

Description and Purpose

Mother and/or *Infant Transfer* forms are used to notify SCHARP that a study participant is transferring from one study site to another. The Transferring Study Site completes and faxes the *Transfer* form and is responsible for maintaining copies of all transferred documents and assuring that all transfer documents are completed accurately. When both Transfer and Receipt forms have been completed and received by DataFax, the participant is officially transferred and will appear in the database and QC reports for the receiving site.

Form-Specific Instructions

- This form is completed by the Transferring Study Site staff.
- Record the name of the Receiving Study Site.
- Complete the form using the visit date and visit code of the last completed visit at the Transferring Study Site.
- Record the date when the participant's records were sent to the Receiving Study Site.
- Mark which items have been sent to the Receiving Site.
- Enter the date the Study Drug kit was sent to the Receiving Site, if applicable.
- Enter the visit code of the next scheduled visit.

Figure 9-29
Transfer (MT-1 / IT-1)



Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's Transfer (MT-1)	
				1	
HIV 024 Chorio (051)		MT-1 (061)		Page 1 of 1	
Participant ID <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/>			Mother's Transfer <input type="text"/> - <input type="text"/> - <input type="text"/> - <input type="text"/>		
Site Number	Participant Number	Chk	Cohort	Form Completion Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
				da	mm yy
(To be completed by the <i>Transferring Study Site</i>)					
Instructions:					
<ul style="list-style-type: none"> • Complete this form for a participant transferring to another HPTN study site. • Fax the form to SCHARP DataFax. • All QCs are the responsibility of the transferring study site until all study materials are received at receiving study site and Receipt form is submitted to SCHARP DataFax. 					
Transferring Study Site					
1. Name of receiving study site: _____					
2. Date of last completed visit: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> → Visit code of last completed visit: <input type="text"/> <input type="text"/> <input type="text"/>					
3. Date study materials sent to receiving study site: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>					
Study materials sent:					
<input type="checkbox"/> copies of case report forms					
<input type="checkbox"/> copies of source documents / clinic notes					
<input type="checkbox"/> specimen tracking ID labels					
<input type="checkbox"/> copy of original consent form					
<input type="checkbox"/> blank case report forms with transferring site number					
<input type="checkbox"/> other, specify: _____					
4. Date study drug kit sent to receiving study site: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> OR <input type="checkbox"/> not applicable					
5. Visit code of next scheduled study visit: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>					
Comments: _____ _____					
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> November 1, 2001 <small>hivnet/forms/HIV024_chorio/forms/transfer_mother.fm</small>				<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Language Staff Initials / Date	

Figure 9-30
Transfer (MT-1 / IT-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Infant's Transfer (IT-1)
		1
HIV 024 Chorio (052) IT-1 (061)		Page 1 of 1
Participant ID [] [] [] - [] [] [] [] - [] - [] Infant's Transfer		Form Completion Date [] [] [] [] [] [] <i>dd mm yy</i>
Site Number Participant Number Chk Cohort		
(To be completed by the Transferring Study Site)		
Instructions: <ul style="list-style-type: none"> • Complete this form for a participant transferring to another HPTN study site. • Fax the form to SCHARP DataFax. • All QCs are the responsibility of the transferring study site until all study materials are received at receiving study site and Receipt form is submitted to SCHARP DataFax. 		
Transferring Study Site		
1. Name of receiving study site: _____		
2. Date of last completed visit: <i>dd mm yy</i> [] [] [] [] [] [] → Visit code of last completed visit: [] [] []		
3. Date study materials sent to receiving study site: [] [] [] [] [] []		
Study materials sent: <ul style="list-style-type: none"> <input type="checkbox"/> copies of case report forms <input type="checkbox"/> copies of source documents / clinic notes <input type="checkbox"/> specimen tracking ID labels <input type="checkbox"/> copy of original consent form (Mother's records) <input type="checkbox"/> blank case report forms with transferring site number <input type="checkbox"/> other, specify: _____ 		
4. Visit code of next scheduled study visit: [] [] []		
Comments: _____ _____		
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> November 1, 2001 <small>hivnetforms/HIV024_chorio/forms/transfer_infant_fm</small>		[] [] [] [] [] Language Staff Initials / Date

9.4.24 Receipt (MR-1 / IR-1)

Description and Purpose

The *Mother and Infant Receipt* form documents receipt of a participant who has transferred to another study site. The Receiving Study Site is responsible for maintaining copies of all transfer documents and ensuring that all future forms for the participant are completed accurately.

Form-Specific Instructions

- This form is completed by the Receiving Study Site staff.
- Record the participant ID provided by the Transferring Study Site. ***Do not assign a new participant ID number.***
- Item 1, Record the Receiving Study Site's (your site's) 3-digit ID and study site name.
- For Item 2, record the date that your site received the participant's records from the Transferring Study Site. Mark all study materials that have been received.
- For Item 3, mark the date the Study Drug kit was received. If the participant is transferred after the labor & delivery visit, mark the "NA" box.
- For Item 5, mark "yes" or "no" to indicate whether you obtained informed consent from the participant at your study site. If informed consent was obtained, enter the date that the participant signed informed consent. If informed consent was not obtained, then you will need to either complete a Termination (TM-1) form or specify a reason why there is a delay in obtaining informed consent. If you later obtain informed consent from the participant, modify this form by crossing a single line through your previous entries, marking the appropriate responses, and initialing and dating any changes. If you have completed a Termination form and the participant later consents to participate in the study at your site, contact the SCHARP for instructions.
- Item 6 is the date that all study materials have been received, and the participant has signed informed consent at the Receiving Study Site.

Figure 9-31
Receipt (MR-1 / IR-1)



Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Mother's Receipt (MR-1)
 HIV 024 Chorio (051) MR-1 (071)		1 Page 1 of 1
Participant ID [][] - [][][][] - [] - [] Site Number Participant Number Chk Cohort		Form Completion Date [][] [][] [][] dd mm yy
Mother's Receipt (To be completed by the Receiving Study Site)		
INSTRUCTIONS: <ul style="list-style-type: none"> • Complete this form for a participant who was transferred from another SCHARP Study Site. • Participant ID: Record Participant ID assigned by the transferring Study Site. Note: Do not assign a new Participant ID. • Fax the form to SCHARP DataFax. 		
Receiving Study Site Site ID		
1. Receiving Study Site:	[][][]	Site Name: _____
2. Date study materials received:	[][] [][] [][]	
Study materials received: <ul style="list-style-type: none"> <input type="checkbox"/> copies of case report forms <input type="checkbox"/> copies of source documents / clinic notes <input type="checkbox"/> specimen tracking ID labels <input type="checkbox"/> copy of original consent form <input type="checkbox"/> blank case report forms with transferring site number <input type="checkbox"/> other, specify: _____ 		
3. Date study drug kit received:	[][] [][] [][]	OR <input type="checkbox"/> not applicable
4. Participant seen at site?	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> no → If no, specify reason in Comments; end of form.
5. Did participant sign informed consent at the receiving site?	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> no → If no, complete Termination form; end of form.
5a. Date consent signed:	[][] [][] [][]	
6. Date transfer completed:	[][] [][] [][]	
(Date when all study materials received and informed consent signed by participant.)		
Comments: _____ _____		
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> November 1, 2001 hivnet/forms/HIV024_chorio/forms/receipt_mother.fm		[][] [][] [] Language Staff Initials / Date

Figure 9-32
Receipt (MR-1 / IR-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Infant's Receipt (IR-1)			
				1			
HIV 024 Chorio (052)		IR-1 (071)		Page 1 of 1			
Participant ID <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> - <input type="text"/>				Form Completion Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			
Site Number	Participant Number	Chk	Cohort	Infant's Receipt	<i>dd</i>	<i>mm</i>	<i>yy</i>
<i>(To be completed by the Receiving Study Site)</i>							
INSTRUCTIONS:							
<ul style="list-style-type: none"> • Complete this form for a participant who was transferred from another SCHARP Study Site. • Participant ID: Record Participant ID assigned by the transferring Study Site. Note: Do not assign a new Participant ID. • Fax the form to SCHARP DataFax. 							
Receiving Study Site							
		<i>Site ID</i>					
1. Receiving Study Site:	<input type="text"/> <input type="text"/> <input type="text"/>	Site Name: _____					
	<i>dd</i>	<i>mm</i>	<i>yy</i>				
2. Date study materials received:	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>				
Study materials received:							
<input type="checkbox"/> copies of case report forms							
<input type="checkbox"/> copies of source documents / clinic notes							
<input type="checkbox"/> specimen tracking ID labels							
<input type="checkbox"/> copy of original consent form (Mother's records)							
<input type="checkbox"/> blank case report forms with transferring site number							
<input type="checkbox"/> other, specify: _____							
3. Participant seen at site?	<i>yes</i>	<i>no</i>					
	<input type="checkbox"/>	<input type="checkbox"/>	➔ If no, specify reason in Comments; end of form.				
4. Did mother sign informed consent at the receiving site?	<input type="checkbox"/>	<input type="checkbox"/>	➔ If no, complete Termination form; end of form.				
4a. Date consent signed:	<i>dd</i>	<i>mm</i>	<i>yy</i>				
	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>				
5. Date transfer completed:	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>				
(Date when all study materials received and informed consent signed by mother.)							
Comments:							

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> November 1, 2001				<input type="text"/> <input type="text"/>		<input type="text"/>	
<small>hivnetforms/HIV024_chorioforms/receipt_infant_fm</small>				<small>Language</small>		<small>Staff Initials / Date</small>	

9.4.25 Concomitant Medications Log (CM-1)

Description and Purpose

The *Concomitant Medications Log* documents **all** non-study medications, including prescription, over-the-counter, herbal, and naturopathic preparations taken by a participant while on-study. It also includes medications prescribed or administered by a clinician to treat an adverse experience. Up to four medications can be reported on a single page.

Form-Specific Instructions

Fax the Concomitant Medications Log to DataFax when the participant completes the study (a good rule of thumb is to fax the Concomitant Medications Log whenever you fax the Termination form) or if requested by the Statistical Center.

Page: Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.

No medications taken throughout study: Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. Record “Staff Initials/Date” and “Form Completion Date.”

Medication: For prescription combination medications (e.g., Combivir or Bactrim), record the trade name. For non-prescription combination medications (e.g., cold medicine), record brand name. For multivitamins, record “multivitamin.”

Date Started: At a minimum, the year is required. If the participant is unable to recall the exact date, obtain participant’s best estimate.

Date Stopped: At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked.

Dose/Units: If the participant does not know the dose or units, record “UNK.” For prescription combination medications (e.g., Combivir), record the dosage of all active ingredients (e.g., 150/300 mg). For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).

Route and Frequency: Below is a list of common route and frequency abbreviations.

Route Abbreviations:

PO oral	IM intramuscular	IV intravenous	TOP topical	IHL inhaled
----------------	-------------------------	-----------------------	--------------------	--------------------

Frequency Abbreviations:

prn as needed	qd everyday	tid three times daily	qhs at bedtime
once one time	bid twice daily	qid four times daily	qxx every x hours

Mark the “Taken for Illness/AE?” box only if the medication was taken for a condition that was reported as an Adverse Experience on an Illness/AE form. If this box is marked a page number corresponding the Illness/AE form must be entered.

Figure 9-33
Concomitant Medications Log (CM-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP) Mother's Concomitant Medications Log (CM-1)

HIV 024 Chorio (051) CM-1 (423)

Page

Participant ID

- - -

Site Number Participant Number Chk. Cohort

Mother's Concomitant Medications Log

Note: Number pages sequentially (01, 02, 03) for each participant.

No medications taken throughout study. → (Fill out Form Completion Date only if no medications taken.)

Form Completion Date:

End of form. Fax form to SCHARP DataFax.

Instructions: List each medication separately. Fax to SCHARP DataFax for enrolled participants only. Fax when participant terminates from the study.

Medication	Dose/Units	Route/Frequency	Date Started
			<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>
Indication		Staff Initials/Log Entry Date	Continuing medication at end of study: <input type="checkbox"/> or <input type="checkbox"/>
Date Ended		Date	
<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>		<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>	
Taken for Illness/AE? <input type="checkbox"/> yes <input type="checkbox"/> no page # <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>			

→ **If yes, record illness/AE page(s)**

Medication	Dose/Units	Route/Frequency	Date Started
			<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>
Indication		Staff Initials/Log Entry Date	Continuing medication at end of study: <input type="checkbox"/> or <input type="checkbox"/>
Date Ended		Date	
<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>		<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>	
Taken for Illness/AE? <input type="checkbox"/> yes <input type="checkbox"/> no page # <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>			

→ **If yes, record illness/AE page(s)**

Medication	Dose/Units	Route/Frequency	Date Started
			<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>
Indication		Staff Initials/Log Entry Date	Continuing medication at end of study: <input type="checkbox"/> or <input type="checkbox"/>
Date Ended		Date	
<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>		<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>	
Taken for Illness/AE? <input type="checkbox"/> yes <input type="checkbox"/> no page # <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>			

→ **If yes, record illness/AE page(s)**

Medication	Dose/Units	Route/Frequency	Date Started
			<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>
Indication		Staff Initials/Log Entry Date	Continuing medication at end of study: <input type="checkbox"/> or <input type="checkbox"/>
Date Ended		Date	
<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>		<input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>	
Taken for Illness/AE? <input type="checkbox"/> yes <input type="checkbox"/> no page # <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/> <input type="text" value=""/>			

→ **If yes, record illness/AE page(s)**

April 17, 2002 **SAMPLE**

Language Staff Initials/Date _____

hivnetformsHIV024_chorioformsconnmed_mother.fm

Figure 9-34
Concomitant Medications Log (CM-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Infant's Concomitant Medications Log (CM-1)	
		Page 	
HIV 024 Chorio (052)		CM-1 (423)	
Participant ID 0 0 0 - - - 			
Site Number	Participant Number	Chk	Cohort
Infant's Concomitant Medications Log			
<input type="checkbox"/> No medications taken throughout study.		(Fill out Form Completion Date only if no medications taken.)	
Staff Initials / Date _____		Form Completion Date / / 	
		End of form. Fax form to SCHARP DataFax.	
<i>Instructions: List each medication separately. Fax to SCHARP DataFax for enrolled participants only. Fax when participant terminates from the study.</i>			
Medication	Dose/Units	Route/Frequency	Date Started
			 / /
Indication		Staff Initials/Log Entry Date	Continuing medication at end of study:
			<input type="checkbox"/> or <input type="checkbox"/>
Taken for Illness/AE? <input type="checkbox"/> yes <input type="checkbox"/> no		page # 	Date Ended / /
		If yes, record illness/AE page(s) 	
Medication	Dose/Units	Route/Frequency	Date Started
			 / /
Indication		Staff Initials/Log Entry Date	Continuing medication at end of study:
			<input type="checkbox"/> or <input type="checkbox"/>
Taken for Illness/AE? <input type="checkbox"/> yes <input type="checkbox"/> no		page # 	Date Ended / /
		If yes, record illness/AE page(s) 	
Medication	Dose/Units	Route/Frequency	Date Started
			 / /
Indication		Staff Initials/Log Entry Date	Continuing medication at end of study:
			<input type="checkbox"/> or <input type="checkbox"/>
Taken for Illness/AE? <input type="checkbox"/> yes <input type="checkbox"/> no		page # 	Date Ended / /
		If yes, record illness/AE page(s) 	
Medication	Dose/Units	Route/Frequency	Date Started
			 / /
Indication		Staff Initials/Log Entry Date	Continuing medication at end of study:
			<input type="checkbox"/> or <input type="checkbox"/>
Taken for Illness/AE? <input type="checkbox"/> yes <input type="checkbox"/> no		page # 	Date Ended / /
		If yes, record illness/AE page(s) 	
<input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 17, 2002		SAMPLE	
hivnet/forms/HIV024_chorio/forms/connmed_infant.fm		0 1	Language _____ Staff Initials / Date _____

9.4.26 Adverse Experience Log (AE-1)

Description and Purpose

Any Adverse Experience (AE) reported by the participant or clinically observed after initiation of study product, regardless of whether or not it is related to study product, must be documented any time during study participation.

Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency.

Form-Specific Instructions

Page: Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.

Adverse Experience (AE): Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, “decreased hematocrit” or “increased ALT.”

Onset Date: At minimum, month and year are required. Record one of the following, as appropriate:

- the date on which the participant reports first experiencing the AE;
- if the AE is discovered during the study visit exam, record the date of the study visit exam;
- if the AE is an abnormal lab result, record the date on which the specimen was collected.

Severity: To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading Severity of Adverse Experiences* (also referred to as the “Toxicity Table”).

Relationship to Study Product:

- **Definitely related:** The exposure to study product and the onset of the AE are related in time; a direct association between the study product and the AE can be demonstrated (i.e., the AE shows a pattern consistent with previous knowledge of the study product).
- **Probably related:** The exposure to study product and the onset of the AE are reasonably related in time; the AE is more likely explained by the study product than by another cause but cannot be considered “definitely related.”
- **Possibly related:** The exposure to study product and the onset of the AE are reasonably related in time but relationship does not meet criteria for being defined as “probably related”; the AE could be due to another equally likely cause.
- **Not related:** The exposure to study product and onset of the AE are not considered to be reasonably related in time, or there is another obvious cause of the AE.

Study Product Administration: N/A (not applicable) should be marked if the AE occurred after the participant had completed all administration of the study agent, or the study product is held for a different AE, or the AE is Grade 5 - Death.

Status/Outcome:

- **Continuing:** AE is continuing at the time it is reported.
- **Resolved:** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
- **Death:** Mark this box only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to “continuing at end of study participation.”
- **Severity/frequency increased:** If an AE increases in severity or frequency after it has been reported on the AE Log, line through the “Continuing” box previously marked and mark “Severity/frequency increased.” Record the date of increase in the “Status/Outcome Date.” Report the increase in severity or frequency as a new AE. For this new AE, the “Onset Date” will be the date that the severity or frequency increased. Note that decreases in severity should not be recorded as new AEs.
- **Continuing at end of study participation:** Mark this box whenever an AE is continuing at the time of participant study termination.

Status/Outcome Date: At minimum, month and year are required. Record one of the following, as appropriate:

- the date on which the participant no longer experienced the AE; or
- the date of the study visit or specimen collection at which the change in status/outcome is first noted.


AE Revisions and Updates:

If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words “Delete due to diagnosis on AE page #” (specify page number of diagnosis AE).

Figure 9-35

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Mother's Illness/AE Log (AE-1)		
				Page <input style="width: 20px;" type="text"/>		
HIV 024 Chorio (051)		AE-1 (420)				
Participant ID			Mother's Illness/AE Log			
<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>	<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>	<input style="width: 20px;" type="text"/>	<input style="width: 20px;" type="text"/>	Date Reported to Site		
Site Number	Participant Number	Chk	Cohort	da	mm	yy
<p>Instructions: Fax this form to SCHARP DataFax whenever a new Illness/AE is recorded or information on this form is updated. Fax only pages with new entries or revisions.</p>						
Illness / Adverse Experience Reported				Onset Date		
_____				<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>		
<i>Diagnosis or Symptom (Diagnosis is preferred)</i>				dd mm yy		
Severity		Relationship to Study Drug		Study Drug Administration		
<input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 - Life-threatening <input type="checkbox"/> Grade 5 - Death		<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related		<input type="checkbox"/> No change <input type="checkbox"/> Held <input type="checkbox"/> Permanently discontinued <input type="checkbox"/> N/A <input type="checkbox"/> Change in administration <i>Comment below.</i>		
Outcome			Treatment <i>Mark "None" or mark all that apply.</i>			
<input type="checkbox"/> Continuing <input type="checkbox"/> Resolved <input type="checkbox"/> Death <input type="checkbox"/> Severity/frequency increased <i>Report as new A.E.</i> <input type="checkbox"/> Continuing at end of study participation			<input type="checkbox"/> None <input type="checkbox"/> Medication(s) <i>Report on Concomitant Medications Log.</i> <input type="checkbox"/> New/Prolonged hospitalization <input type="checkbox"/> Procedure/Surgery <i>Comment below.</i> <input type="checkbox"/> Other <i>Comment below.</i>			
Outcome Date <i>Leave blank for "Continuing."</i>			yes no			
<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>			Has this Illness/AE been reported to ROC as a Serious Adverse Experience? <input type="checkbox"/> <input type="checkbox"/>			
This illness/AE was reported at visit: <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>			Comments: _____ _____ _____ _____			
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001		SAMPLE		<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>		
hivnet/forms/HIV024_chorio/forms/illness_ae_mother.fm		Language		Staff Initials / Date		

Figure 9-36

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Infant's Illness/AE Log (AE-1)			
 HIV 024 Chorio (052) AE-1 (420)				Page <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <i>Note: Number pages sequentially (01, 02, 03) for each participant.</i>			
Participant ID <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> - <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>				Date Reported to Site <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>			
Site Number		Participant Number		Chk		Cohort	
Infant's Illness/AE Log							
Instructions: Fax this form to SCHARP DataFax whenever a new illness/AE is recorded or information on this form is updated. Fax only pages with new entries or revisions.							
Illness / Adverse Experience Reported						Onset Date	
_____ <i>Diagnosis or Symptom (Diagnosis is preferred)</i>						<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>	
Severity		Relationship to Study Drug		Study Drug Administration			
<input type="checkbox"/> Grade 1 - Mild <input type="checkbox"/> Grade 2 - Moderate <input type="checkbox"/> Grade 3 - Severe <input type="checkbox"/> Grade 4 - Life-threatening <input type="checkbox"/> Grade 5 - Death		<input type="checkbox"/> Definitely related <input type="checkbox"/> Probably related <input type="checkbox"/> Possibly related <input type="checkbox"/> Not related		<input type="checkbox"/> No change <input type="checkbox"/> Held <input type="checkbox"/> Permanently discontinued <input type="checkbox"/> N/A <input type="checkbox"/> Change in administration <i>Comment below.</i>			
Outcome				Treatment <i>Mark "None" or mark all that apply.</i>			
<input type="checkbox"/> Continuing <input type="checkbox"/> Resolved <input type="checkbox"/> Death <input type="checkbox"/> Severity/frequency increased <i>Report as new A.E.</i> <input type="checkbox"/> Continuing at end of study participation				<input type="checkbox"/> None <input type="checkbox"/> Medication(s) <i>Report on Concomitant Medications Log.</i> <input type="checkbox"/> New/Prolonged hospitalization <input type="checkbox"/> Procedure/Surgery <i>Comment below.</i> <input type="checkbox"/> Other <i>Comment below.</i>			
				Outcome Date <i>Leave blank for "Continuing."</i>			
				<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> / <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>			
						yes no	
Has this illness/AE been reported to ROC as a Serious Adverse Experience?						<input type="checkbox"/> <input type="checkbox"/>	
This illness/AE was reported at visit:						<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>	
Comments: _____ _____ _____ _____							
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001				SAMPLE		<input style="width: 20px;" type="text"/> <input style="width: 20px;" type="text"/>	
hivnet/forms/HIV024_chorio/forms/illness_ae_infant.fm				Language		Staff Initials / Date	

9.4.27 Missed Visit (MV-1)

Description and Purpose

The *Missed Visit* form is completed whenever site staff are confident that a required scheduled visit will not be conducted within the parameters included in the Study Specific Procedures.

Submission of a *Missed Visit* form will turn off the DataFax expectations indicating the form set of a scheduled visit has not been received; however, even after submission of a *Missed Visit* form, continued attempts should be made to reschedule the participant and complete protocol-required visits unless deemed permanently missed.

Form-Specific Instructions

- Consult the protocol or study specific procedures to determine when a visit will be considered permanently missed.
- If a visit is completed after submitting a *Missed Visit* form, mark the previously-submitted Missed Visit form with a large X, write the word “delete” at the top of the form, and refax it to DataFax.
- Mark only one checkbox to indicate the reason the visit was missed.
 - The “date of last contact with participant” means the date that you last spoke to, heard from, or have seen the participant.
 - If you do not know the reason and have had regular contact with the participant, mark “missed scheduled appointment(s).”
- Use the comments section at the bottom of the form to record any additional information.

Figure 9-37
Missed Visit (MV-1)



Statistical Center for HIV/AIDS Research & Prevention (SCHARP)										Mother's Missed Visit (MV-1)				
										Visit Code		<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	
HIV 024 Chorio (051)					MV-1 (463)					Page 1 of 1				
Participant ID										Form Completion Date				
<input type="text"/> <input type="text"/> <input type="text"/>			<input type="text"/> <input type="text"/> <input type="text"/>			<input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/>		<input type="text"/>				
Site Number			Participant Number			Chk.		Cohort		<i>dd</i> <i>mm</i> <i>yy</i>				
Mother's Missed Visit														
<p>Instructions: Complete this form when a participant has missed a scheduled visit. For Visit Code, enter the visit code of the scheduled visit that was missed. Fax the form to SCHARP DataFax according to the timeline included in the Study Specific Procedures.</p>														
<p>Reason Visit Missed:</p> <p>Mark only one.</p>														
										<i>dd</i>	<i>mm</i>	<i>yy</i>		
										<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>		
<p><input type="checkbox"/> Unable to contact participant; date of last contact with participant:</p>														
<p><input type="checkbox"/> Missed scheduled appointment(s).</p>														
<p><input type="checkbox"/> Refused visit.</p>														
<p><input type="checkbox"/> Incarcerated.</p>														
<p><input type="checkbox"/> Institutionalized.</p>														
<p><input type="checkbox"/> Withdrawn from the study. → Complete a Termination form.</p>														
<p><input type="checkbox"/> Deceased. → Complete a Termination form (entry on illness/AE Log may also be required).</p>														
<p><input type="checkbox"/> Other, please specify: _____</p>														
<p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>														
										<input type="text"/> <input type="text"/> <input type="text"/> <input checked="" type="checkbox"/>	April 19, 2001			
										SAMPLE				
										<input type="text"/> <input type="text"/>	Lang usage			
										<input type="text"/> <input type="text"/>			Staff Initials / Date	
<p><small>hivnet/forms/HIV024_chorio/forms/missed_visit_mother.fm</small></p>														

Figure 9-38
Missed Visit (MV-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)				Infant's Missed Visit (MV-1)			
				Visit Code		<input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/>	
HIV 024 Chorio (052)		MV-1 (463)		Page 1 of 1			
Participant ID				Form Completion Date			
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> - <input type="text"/>		Infant's Missed Visit		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
Site Number		Participant Number		Chk		Cohort	
						<i>dd mm yy</i>	

Instructions: Complete this form when a participant has missed a scheduled visit. For Visit Code, enter the visit code of the scheduled visit that was missed. Fax the form to SCHARP DataFax according to the timeline included in the Study Specific Procedures.

Reason Visit Missed:
Mark only one.

Unable to contact parent(s); date of last contact with parent(s):
dd mm yy

Missed scheduled appointment(s).

Parent(s) refused visit.

Withdrawn from the study. → **Complete a Termination form.**

Deceased. → **Complete a Termination form (entry on illness/AE Log may also be required).**

Other, please specify: _____

Vital Status Update:
Mark only one.

Alive. → Date last known to be alive:
dd mm yy

Deceased. → Approximate date of death:
dd mm yy

Unknown.

Comments: _____

April 19, 2001 **SAMPLE**
hivnet/forms/HIV024_chorio/forms/missed_visit_infant.fm Language Staff Initials / Date

9.4.28 Termination (TM-1)

Description and Purpose

The *Termination* form documents termination of a participant's study participation, because of:

- completion of scheduled Exit Visit or End of Study
- death
- early withdrawal from the study

Form-Specific Instructions

- Do not complete and fax the *Termination* form for early withdrawal from the trial until you are certain that the participant will not be returning for study visits.
- The Termination Date is the date the site determined that the participant was no longer in the study.
- Mothers who are terminated from the study early due to the death of their infant, stillbirth or abortion should all have "death of infant" marked as the reason for termination.
- When a mother or infant is terminated due to their death the cause of death on the Termination form must match all Illness/AE forms for fatal (grade 5) events.
- Do not submit any data with a date after the Termination Date. For example, an unreported AE found during a monitoring visit, the "Date Reported to Site" should be the date the condition was noted in the source documents, not the date the AE report was completed.
- After the participant's last visit, mothers may be terminated before their infant. For example, infant has a visit 9.1 due to the need for a second DBS specimen. Mother is terminated at visit 9.0 since no more data will be submitted for her.

Special Trial Closure Instructions

For all participants who terminate before the 12 month visit due to trial closure:

- Do not mark the Termination form as "*Scheduled exit visit/End of Study*" unless they have completed the 12 Month Visit. Instead, mark as an "***Early Termination.***"

Participant decides to end participation in trial after notification of results but before study site IRB has approved Version 5 of protocol:


- Mark the termination as an early termination with the reason "***Participant refused further participation***"

Participant completes the 3, 6 or 9 Month Visit after study site IRB has approved Version 5 of protocol:

- Mark the termination as an early termination with the reason "***Other, specify***" and specify "***Study Closure***" as the specified reason.


See H024 Data Communiqué #7 for example case report forms.

Figure 9-39
Termination (TM-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)		Mother's Termination (TM-1)
		Page 1 of 1
HIV 024 Chorio (051) TM-1 (490)		
Participant ID 0 0 0 - [] [] [] - [] - 0 Mother's Termination		Form Completion Date [] [] [] [] [] [] <i>dd mm yy</i>
Site Number	Participant Number	Chk. Cohort
Instructions: Complete this form whenever a participant terminates from the study.		
<i>dd mm yy</i>		
1. Termination Date:	[] [] [] [] [] []	
(Date the site determined that the participant was no longer in the study.)		
2. Reason for termination: <i>Mark only one.</i>		
<input type="checkbox"/> 2a. Scheduled exit visit/End of study.		
<input type="checkbox"/> 2b. Death (please indicate date and cause if known).		
Cause of death _____ OR <input type="checkbox"/> Cause unknown		
Date of death [] [] [] [] [] [] OR <input type="checkbox"/> Date unknown		
<i>dd mm yy</i>		
<input type="checkbox"/> 2c. Early termination. Please indicate primary reason below. <i>Mark only one.</i>		
<input type="checkbox"/> Participant refused further participation.		
<input type="checkbox"/> Participant relocated, no remote follow-up planned.		
<input type="checkbox"/> Investigator decision, please specify: _____		
<input type="checkbox"/> Unable to contact participant.		
<input type="checkbox"/> Death of infant.		
<input type="checkbox"/> Other reason, please specify: _____		
Comments: _____		

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> April 19, 2001 SAMPLE		0 1 Language Staff Initials / Date
hivnet/forms/HIV024_chorio/forms/termination_mother.fm		

Figure 9-40
Termination (TM-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)		Infant's Termination (TM-1)	
			
HIV 024 Chorio (052) TM-1(490)		Page 1 of 1	
Participant ID			
0 0 0	- [] [] [] [] - [] - []	Infant's Termination	
Site Number	Participant Number	Chk	Cohort
Instructions: Complete this form whenever a participant terminates from the study.			
da mm yy			
1. Termination Date:	[] []	[] []	[] []
(Date the site determined that the participant was no longer in the study.)			
2. Reason for termination: <i>Mark only one.</i>			
<input type="checkbox"/> 2a. Scheduled exit visit/End of study.			
<input type="checkbox"/> 2b. Death (please indicate date and cause if known).			
Cause of death _____		OR	<input type="checkbox"/> Cause unknown
Date of death [] [] [] [] [] [] [] []		OR	<input type="checkbox"/> Date unknown
dd mm yy			
<input type="checkbox"/> 2c. Early termination. Please indicate primary reason below. <i>Mark only one.</i>			
<input type="checkbox"/> Parent(s) refused further participation.			
<input type="checkbox"/> Parent(s) and/or infant relocated, no remote follow-up planned.			
<input type="checkbox"/> Investigator decision, please specify: _____			
<input type="checkbox"/> Unable to contact parent(s).			
<input type="checkbox"/> Other reason, please specify: _____			
Comments: _____			

<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/>	April 19, 2001	SAMPLE	[] []
hivnet/forms/HIV024_chorio/forms/termination_infant.fm		Language	Staff Initials /Date

9.4.29 Comments (COM-1)

Description and Purpose

The *Comments* form allows site staff to record additional information about a specific participant or to clarify data recorded on another form.

Form-Specific Instructions

- For Visit Code, enter the visit code of the form or visit on which you are commenting.
- Do not use this form to make corrections of data on other forms. All corrections and verifications of data must be made to the original form, initialed and dated, and refaxed to the DataFax.

9.4.30 End of Study Inventory (MEI-1 and IEI-1)

Description and Purpose

The End of Study Inventory forms document the total number of pages of log-style forms that have been completed and submitted for an individual participant. As each log-style form may have a variable number of pages completed, this information is used by SCHARP to ensure that all pages have been received.

Form-Specific Instructions

- Item 1, visit code, for both MEI-1 and IEI-1, is the last visit code before termination for which data has been entered on a form and submitted to SCHARP. Do not enter a visit code for a visit at which a participant was seen by site staff but no data were submitted to SCHARP.

Example: Infant and mother return to site for EIA results at visit 9.1 and infant blood is drawn for a DBS. Infant and mother return to site at visit 9.2 for final results and counseling. The visit code to be entered on the IEI-1 form would be 9.1. Similarly, the visit code to be entered on the Mother's End of Study Inventory form would be 9.0 since no maternal data was entered onto case report forms and faxed to SCHARP for visits 9.1 or 9.2.

- Pre-existing Conditions and Concomitant Medication Log forms must always have at least one page submitted, therefore page "00" is not acceptable.
- Always enter the last Illness/AE Log page submitted, even if one or more of the log pages has been deleted. If no Illness/AE log pages have been submitted mark the "none" box, do not enter "00" pages.

Example: five Illness/AE Log pages were faxed into DataFax but it was determined that the condition on page 2 was not actually an adverse experience and it was deleted from the database. Page "05" is still entered on the End of Study Inventory form as the last page submitted.

Figure 9-43
End of Study Inventory (MEI-1 and IEI-1)


Statistical Center for HIV/AIDS Research & Prevention (SCHARR)		Mother's End of Study Inventory (MEI-1)																												
																														
HIV 024 Chorio (051)		MEI-1 (489)																												
		Page 1 of 1																												
Participant ID		Form Completion Date																												
<table border="1" style="border-collapse: collapse; width: 100%;"> <tr> <td style="width: 25px; text-align: center;">0</td> <td style="width: 25px; text-align: center;">0</td> <td style="width: 25px; text-align: center;">0</td> <td style="width: 25px; text-align: center;">-</td> <td style="width: 25px; text-align: center;"> </td> <td style="width: 25px; text-align: center;"> </td> <td style="width: 25px; text-align: center;">-</td> <td style="width: 25px; text-align: center;"> </td> <td style="width: 25px; text-align: center;">-</td> <td style="width: 25px; text-align: center;">0</td> </tr> <tr> <td style="font-size: 8px;">Site Number</td> <td colspan="3" style="font-size: 8px;">Participant Number</td> <td style="font-size: 8px;">Chk</td> <td colspan="4" style="font-size: 8px;">Cohort</td> </tr> </table>		0	0	0	-			-		-	0	Site Number	Participant Number			Chk	Cohort				<table border="1" style="border-collapse: collapse; width: 100%;"> <tr> <td style="width: 25px; text-align: center;"> </td> <td style="width: 25px; text-align: center;"> </td> <td style="width: 25px; text-align: center;"> </td> <td style="width: 25px; text-align: center;"> </td> </tr> <tr> <td style="font-size: 8px;">dd</td> <td style="font-size: 8px;">mm</td> <td colspan="2" style="font-size: 8px;">yy</td> </tr> </table>						dd	mm	yy	
0	0	0	-			-		-	0																					
Site Number	Participant Number			Chk	Cohort																									
dd	mm	yy																												
Mother's End of Study Inventory																														
<i>Instructions: Complete this form whenever a participant terminates from the study.</i>																														
1.	What is the visit code of the participant's last visit?	Visit Code	<input type="text"/> <input type="text"/> . <input type="text"/>																											
2.	What was the last Pre-existing Conditions page number submitted for this participant?	<input type="text"/> <input type="text"/>	page #																											
3.	What was the last Illness/AE Log page number submitted for this participant?	<input type="text"/> <input type="text"/>	page # OR <input type="checkbox"/> none																											
4.	What was the last Concomitant Medications Log page number submitted for this participant?	<input type="text"/> <input type="text"/>	page #																											
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> September 20, 2002		SAMPLE																												
hivnet/forms/HIV024_chorio/forms/end_of_study_mother.fm		<table border="1" style="border-collapse: collapse; width: 40px;"> <tr> <td style="width: 20px; text-align: center;">0</td> <td style="width: 20px; text-align: center;">1</td> </tr> <tr> <td colspan="2" style="font-size: 8px;">Language</td> </tr> </table>	0	1	Language		<hr style="width: 80px; margin: 0 auto;"/> Staff Initials / Date																							
0	1																													
Language																														

Figure 9-44
End of Study Inventory (MEI-1 and IEI-1)

Statistical Center for HIV/AIDS Research & Prevention (SCHARR)				Infant's End of Study Inventory (IEI-1)					
				Page 1 of 1					
HIV 024 Chorio (052)		IEI-1 (489)							
Participant ID				Form Completion Date					
<input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>			
Site Number	Participant Number	Chk	Cohort	Infant's End of Study Inventory			dd	mm	yy
Instructions: Complete this form whenever a participant terminates from the study.									
1. What is the visit code of the participant's last visit?	Visit Code	<input type="text"/> <input type="text"/> <input type="text"/>							
2. What was the last Illness/AE Log page number submitted for this participant?	<input type="text"/> <input type="text"/>	page #	OR	<input type="checkbox"/> none					
3. What was the last Concomitant Medications Log page number submitted for this participant?	<input type="text"/> <input type="text"/>	page #							
<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input checked="" type="checkbox"/> September 20, 2002				SAMPLE		<input type="text" value="0"/> <input type="text" value="1"/>			
hivnet/forms/HIV024_chorio/forms/end_of_study_infant.fm				Language		Staff Initials / Date			

10. Clinical and Laboratory Procedures

10.1 Specimen Collection and Management

As the transmission of HIV and other blood-borne pathogens can occur through contact with contaminated needles, blood, and blood products, appropriate blood and secretion precautions will be employed by all personnel in the drawing of blood and shipping and handling of all specimens for this study, as currently recommended by the Centers for Disease Control (CDC).

Each site should have a least one person who is certified by IATA or SaftPak (CD), to prepare the shipments. Failure to do so is breaking the law and subsequent to stiff penalties which will be borne by the individual and not HIVNET, FHI or the individual project sites. HIV is no longer considered a “Dangerous Good” and can be shipped as a Diagnostic Specimen. However, all IATA regulations concerning packaging remain in effect. The labeling of the package should say “Diagnostic Specimens Packed in Compliance with IATA Packing Instruction 650.”

10.1.1 Preparation of vaginal Gram stain

All slides have been shipped to UAB for evaluation.

10.1.2 Collection and storage of cervical swab for HIV viral load evaluation

The swabs should be stored in a sealed vial at -70°C . The samples should be shipped to UNC, where they will be processed. Include LDMS shipping manifest (paper and electronic) with each shipment. The lab should be notified that the shipment is en route. Please note that there are infectious substances.

10.1.3 FFN storage and testing






The swabs should be stored in a sealed vial at -70°C . The samples should be shipped to UAB. From there, they will be shipped to Adeza, where they will be processed. Include LDMS shipping manifest (paper and electronic) with each shipment. The lab should be notified that the shipment is en route. Although potentially infectious, the actual infectious status of the ffNs is unknown; they should be shipped as “diagnostic samples”.

10.1.4 DBS preparation and storage

Clean infant’s heel with alcohol swab. Use safety lancet to puncture skin. Collect blood in five 50 heparinized microliter tubes. Make 5 blood spots on the filter paper (see below), one spot per microcapillary tube. Label filter paper with Chorio project ID number, date of birth, and date of collection (on both sides of vertical line). Allow filter paper cards to air dry at room temperature for at least 2 hours (do not place filter paper in heat or sun; spread cards in one layer – they should not be placed on top of one another). Laboratory technicians will place dry filter paper in ziplock bag with dessicant. Store samples at room temperature, not in sun or exposed to heat.

Two blood spots will be put to the left of the vertical line, three to the right. The laboratory technician will split the paper at the vertical line. The side of paper with two spots will be archived, the side with three will be sent to the virology lab at UNC. Use the small preprinted PTID and collection date labels on the DBS cards. Write the Date of Birth on the front or back of card as space allows. PTID and date of collection should NOT be handwritten to minimize the chances of transcription errors.

Example:

 	  
ID number Date of Birth Date of Collection	ID number Date of Birth Date of Collection

10.1.5 Collection of venous blood for viral load analysis

Collect maternal viral load analysis in EDTA (purple) vacutainer. The sample should be shipped to UNC to be tested. Include LDMS shipping manifest (paper and electronic) with each shipment. The lab should be notified that the shipment is en route.

10.1.6 Preparation and evaluation of placenta (for chorio and malaria)

One of the primary outcomes for the Project is the status of the placenta, cord and membranes, after birth. The evaluation of these tissues will allow the Project to search for evidence of inflammation in each specimen and should indicate the microbial infection status of the tissues before birth.

Very mild inflammation may occur when the placenta detaches itself from the mother's uterine wall after the child has been born. Therefore, great care must be taken when handling the placenta for histological preparation to ensure no additional damage is done.

Handling of Placenta

Each site has its own protocol for retrieval and dissection of placental specimens based on the sampling instructions below. The Pathologist and the histopathology units will process the tissue into wax blocks that will be labeled and packed ready to be shipped to Zambia.

Sampling of Placenta

1. After delivery of the placenta, the placenta should be placed in a bucket labeled with the participant's study ID number and date of collection.
2. As soon after delivery as possible (must be within 6 hours) the placenta will be placed on a flat surface. The umbilical cord will be identified and at a distance beginning 2 cm from the insertion into the placenta, a length of cord equal to approximately 2 cm will be separated using a sharp instrument, and placed in a formalin container.
3. With the placenta still on the flat surface and the umbilical cord side up, the membranes, still attached to the placenta, will then be stretched out so that the torn edge is furthest from the placenta. A 3 cm width of a typical membrane segment will be identified. A scissor will then be used to make two cuts toward the placenta, cutting until a point 1 cm from the placenta is reached. A transverse cut should then be made, creating a rectangular piece of membrane. Starting from the outside, the membrane piece will then be rolled, as if one were rolling up a piece of paper. Two pins should be placed at each end to hold the roll in place, or if pins are not available, each end may be tied with a piece of string. The rolled membrane and both pins will then be placed in the same formalin container.

4. With the placenta still on the flat surface with cord-side down, from a representative or typical area, a triangular wedge (2 x 2 x 2 cm) of the full placental thickness will be removed using a sharp instrument and placed in formalin. This wedge will run 2 cm along the placental margin and the triangular wedge will be created by two cuts of 2 cm each coming to a point toward the center of the placenta. The wedge should have a 0.5 to 1 cm piece of chorioamnion attached. If, on gross examination, there is specific pathology in a non-representative section such as hemorrhage or infarct, a second placental section should be taken from that area and processed as was the original section.
5. Each of the three (or four) specimens should be placed in the same plastic container with enough 10% neutral buffered formalin to completely cover the specimens. The container will be permanently labeled with the participant's study ID number and delivery date. Use preprinted ID and collection date labels from SCHARP or from LDMS.

Processing of placental samples:

The placenta bucket should have been logged into LDMS. As the placenta is processed into the formalin container and paraffin blocks/cassettes, all steps should be tracked in LDMS.

1. After the specimens are fixed in formalin, the specimens will be processed by embedding an appropriate portion of each of the three specimens into paraffin. Two paraffin blocks should be made of each portion, with one remaining on-site and one being shipped to CIDRZ.
2. The portion of the cord to be embedded in paraffin will include a full cord circumference. The 2 paraffin blocks should be labeled in pencil with the participant's study ID number. For all single births, the cassette should be labeled with the mother's PID# but dropping the first two site digits and excluding dashes. E.g. PID# 526-0043-0-1. The cassette will read: 6004301. This number will be written in pencil on the front "label" area of the cassette. For multiple births, label the front of the cassette with the infant's PID# (dropping the first two site digits and excluding dashes).
3. The portion of the membranes to be embedded in paraffin will be a full circumference of the roll. The 2 paraffin block should be labeled in pencil with the participant's study ID number. For all single births, the cassette should be labeled with the mother's PID# but dropping the first two site digits and excluding dashes. E.g. PID# 526-0043-0-1. The cassette will read: 6004301. This number will be written in pencil on the front "label" area of the cassette. For multiple births, label the front of the cassette with the infant's PID# (dropping the first two site digits and excluding dashes).

The portion of the placenta to be embedded in paraffin will include the full thickness from the membrane through the villi taken along one of the sides of the wedge. The 2 paraffin blocks should be labeled with the participant's study ID number.

Each formalin container with the remaining tissue will be stored and retained at least until the slides are read, and when written permission for discarding the specimen is provided.

The paraffin blocks will be made into slides and read at the Centre for Infectious Diseases Research in Zambia (CIDRZ).

Sample SOP of Health and Safety Requirements, Disposal and Q/C

The following SOP has been provided by CIDRZ as a template and may be adapted for use at any of the other sites.

Health and Safety Requirements

- Protective clothing must be worn at all times without exception. Work methodically and tidily to avoid unnecessary spillage of blood and technical errors.
- Formalin is a poisonous and irritating chemical and great care should be taken when using it. Prolonged exposure to formalin can lead to respiratory tract complications. Sensitivity to the solution can occur and the user must avoid skin contact at all times. If contact does arise, wash the area with copious amounts of water.

Disposal

- All biological material must be disposed of in the correct containers. Sharps such as needles, scalpel blades or lancets, should be first disinfected for thirty minutes in a solution of 10% bleach, before being placed in the sharps bin.
- Disposable material such as swabs, cotton etc should be placed directly into a bin marked for hazardous waste and incinerated.
- When disposing of the bleach/blood mix, it should be carefully poured down a designated waste sink, followed by bleach and then copious amounts of water. The sink will be allocated by the head of the Central Lab CIDRZ, head of Histopathology Lab and by the SIC at UTH.
- Formalin should be disposed of in a sink situated within a fume hood and followed by copious amounts of water. The sink will be allocated by the head of the Central Lab CIDRZ, head of Histopathology Lab and by the SIC at UTH.
- Cloths used to wipe down machinery or to contain blood/tissue spills should be disinfected with 10% formalin for thirty minutes before being cleaned.

Quality Control

- Ensure the forms are filled in completely and correctly.
- Check that both the lid and the bucket are labeled with the Patient ID#, Date of collection and weight of placenta.
- Ensure all other specimens collected at Labour and Delivery are also correctly labeled.
- Log all stages of placental specimen processing into LDMS and use this system to track storage and shipping.
- Check the participant ID and collection date on the placenta bucket vs. the information on the formalin container, the paraffin blocks/cassettes and the shipping manifest to catch any transcription errors before shipping to CIDRZ. If the information on the bucket is handwritten, it may also need to be checked against patient records for accuracy before shipping.

10.2 Summary: Specimen Collection and Shipment

As of August 5th, 2002, all active participants in HIVNET 024 had delivered (June 16th in Lusaka, Zambia; July 16th in Dar es Salaam, Tanzania; July 24th in Lilongwe, Malawi; and as of August 5th in Blantyre, Malawi). As all infants are beyond the 4-6 week follow-up visit, this summary will include laboratory evaluations for 3 months and beyond. The following summary applies only to HIV-exposed infants of unknown HIV status.

Please note that there are NO further samples to be collected on the following 3 groups:

- Mothers, whether HIV infected or not
- Infants with a confirmed HIV diagnosis (2 consecutive positive HIV-RNA tests drawn on different days)
- Infants born to women enrolled as HIV uninfected

HIV-exposed infants of unknown HIV status: 3 month, 6, 9 month visit

Sample	Test	Collection Needed	Instructions
Infant Blood	HIV-RNA	From blood draw collect 5- 50 heparinized microliter tubes, to make 5 blood spots.	3 blood spots from each filter paper should be shipped to UNC for testing. The remaining 2 spots should be stored on site at room temp.
<ul style="list-style-type: none"> • If the DBS confirms that the infant is HIV infected, no further testing is necessary. • If the DBS is positive and a confirmatory sample is necessary, repeat in 4 to 6 weeks. 			

HIV-exposed infants of unknown HIV status: 12 month visit

Sample	Tests	Collection Needed	Instructions
Infant Blood	1. ELISA 2. HIV-RNA	1. From blood draw collect 5- 50 heparinized microliter tubes, to make 5 blood spots. 2. From same blood draw, collect sample for ELISA	1. Local ELISA (x1) 2. If ELISA is reactive, 3 blood spots from each filter paper should be shipped to UNC for testing. The remaining 2 spots should be stored on site at room temp.
<ul style="list-style-type: none"> • If the ELISA is negative, no further testing is necessary and NO DBS should be shipped to UNC. • If the DBS confirms that the infant is HIV infected, no further testing is necessary. • If the DBS is positive and a confirmatory sample is necessary, repeat as soon as possible. 			

10.3 Specimen Shipping

For all shipments, notify the receiving laboratory in advance that specimens are en route and include the date that specimens were shipped, the shipper and the airbill number. Email addresses and phone numbers of contacts are provided. Include an LDMS shipping manifest (both electronic and paper) in each specimen shipment. You may also attach the electronic manifest to the email notification.

The infant DBS sample obtained at birth and 6 weeks should be sent directly to the UNC Retrovirology Laboratory as soon as possible. Sites may collect 10 to 20 of the filter cards for shipment on an every 2-week basis. However, no card should be held for more than 2 weeks. This schedule may be revised by the UNC virology lab depending on the volume of samples received from the sites. Samples for maternal viral load (plasma and cervical swabs) should also be shipped to UNC.

Samples	Shipping Address
<ul style="list-style-type: none"> • Infant DBS filter cards • Maternal plasma for viral load (UNC) • Maternal cervical swabs for viral load (UNC) 	Susan Fiscus Retrovirology Core Laboratory University of North Carolina at Chapel Hill Department of Microbiology & Immunology 709 Mary Ellen Jones Building Manning Drive and West Drive Chapel Hill, NC 27599-7140 TEL (919)-966-6867 FAX (919)-966-9873 email: retro_lab@med.unc.edu or fiscussa@med.unc.edu

Gram stain slides and vaginal swab for FFN should be shipped to UAB. It is recommended that the gram stain slides be shipped when approximately 100 have been collected. The FFN swabs must be kept frozen. Shipping instructions are pending on these.

Samples	Shipping Address
<ul style="list-style-type: none"> • Gram stain (UAB)* • Vaginal swabs for FFN (UAB) <p>*Please be certain that the slides are securely fastened in whatever mailer is being used. These containers should then be wrapped in bubble wrap or other cushioned material.</p>	OB-GYN Infectious Disease Research Lab University of Alabama at Birmingham Attention: DeeDee Lyon 618 South 20th Street Old Hillman Building 440 Birmingham, AL 35233-7333 (205) 934-4226

The paraffin blocks are to be sent to the University Teaching Hospital in Lusaka, Zambia, for histologic analysis. The following protocol should be adhered to.

1. Collect and process placental tissue as per site protocol and store as paraffin blocks.
2. Enter into the LDMS system at each individual site.
3. Ensure each histology cassette is labeled clearly and correctly with the PID# and date. Please use quality cassettes so that labeling with a pencil can be performed easily.
4. **A hard copy of the LDMS shipping manifest is sufficient to include in the shipping box.** The list should include the PID#, date the sample was taken, single or multiple birth should be specified, the tissues obtained (membranes, cord, placenta) and how many blocks there are for each tissue type.
5. Once enough blocks have been collected, they should be packed in a suitable container that is UN certified, and surrounded with a small amount of absorbent material and enough shock absorbent material to prevent too much movement of blocks and breakage. There are no real guidelines on how they should be packed other than to do so sensibly, to avoid wax being chipped in the transport process. Remember that the handlers at the airport do not show respect for most luggage.
6. A “This way up” sign should be on two sides of the box, “Handle with care” should also be placed on two sides of the box. No other labels are required, as fixed placental blocks are not classed as Infectious substances.
7. Send shipments either once a month or every two months depending on the amount of specimens received at each site. Ensure it is cost effective.

8. The CDC permit is not required in this shipment as the placenta wax cartridges do not fall under hazardous materials shipping regulations. However, an individual at each site should be identified and contact information included with the shipment in the event that the package is somehow opened or damaged. That contact person should be either the 024 Coordinator or the Investigator of Record.
9. Include the shipping disk (if you have one) and **the hard copy of the LDMS shipping manifest**. Ensure you keep duplicates of everything sent.
10. Tape the box securely and send it by whatever means is cost effective to the Zambian address below.
11. Communicate to Ali Taylor, the Zambian site Lab Manager, informing her of the shipment and include the sample listing as an attachment by email.
12. Ali Taylor will send confirmation when the sample shipment arrives.
13. The samples will be entered into LDMS in Zambia, QC'd against cassettes and list/disk and then transported to UTH who will also check them in.
14. Dr. Mudenda will microscopically read the placentas and fill out the Data Fax forms.
15. All placental blocks will be stored at UTH until further notice.
16. Data Fax forms will be collected from UTH and sent from the CIDRZ offices to the States.

Sample	Shipping Address
<ul style="list-style-type: none"> • Paraffin blocks of cord, membranes and choriamnion samples 	<p>CIDRZ/LUDHMT Plot 5977 Benakale Road, Northmead Lusaka, Zambia Contact: Ali Taylor, CIDRZ Lab Manager E: alit@zamnet.zm Office: 260 1 293661, 293783, 293772, 293766 Lab Phone/Fax: 260 1 253130</p>

HPTN Clinic and Local LDMS Laboratory Specimen Collection, Labeling, Storage and Shipping for the HPTN 024 Protocol

1. SCHARP Printing of Specimen and Tracking Sheet Labels:

SCHARP will prepare Specimen Tracking Sheets and two sets of labels for shipment to each study site prior to the start of a protocol. During study visits, one set of labels will be applied to the Specimen Tracking Sheet, and one set of labels will go on the specimen containers.

A) Labels for Tracking Sheets: Two **barcoded** labels are applied to a Specimen Tracking Sheet at the time of a study visit.

- **Participant ID labels:** One page of larger-size labels is provided for each study participant. These labels have the group, ID and protocol number bar-coded, with readable information below each barcode. These bar-coded labels will be applied to the top of the Specimen Tracking Sheet, which will accompany each specimen shipment to the LDMS laboratory.
- **Specimen Collection Date Labels:** Larger size labels will have the date bar-coded, with readable information below each barcode. These labels will be applied to the bottom of the Specimen Tracking Sheet, which will accompany each specimen shipment to the LDMS laboratory. One or more pages of date labels will be provided for each day when study visits are expected.

B) Labels for Specimens: Two **non-barcoded** labels are applied to each specimen.

- **Participant ID labels:** One or more pages of small labels will be prepared for each assigned study participant ID. These labels will identify the protocol and participant study ID and will not be bar-coded. The size is small enough to fit on all specimens, from Gram Stain Slides to 5ml Tubes.
- **Specimen Collection Date Labels:** One or more pages of small labels will be prepared for each potential study day and will not be bar-coded. The size is small enough to fit on all specimens, from Gram Stain Slides to 5ml Tubes. Enough date labels will be printed to accommodate the largest anticipated need for a peak participant visit day.

Study Clinic Specimen Procedures¹

Prior to a participant visit, the clinic should place both types of Specimen Collection Date labels and the Specimen Tracking Sheets in the location where specimens will be labeled. The participant ID label pages should be placed in the participant's folder once a participant has been assigned an ID number. Both the small participant ID label sheet and the large bar-coded participant ID label sheet should be placed in the folder.

¹ See LDMS-Figure 1: 'Clinic Specimen Collection, Labeling and shipping to LDMS lab' flow diagram.

Each day, the clinic staff will make sure that the specimen collection date label sheets (both the small specimen collection date label sheet and the larger bar-coded specimen date label sheet) are for the current date. At the end of each day, unused labels for that day are discarded.

2. **Labeling Specimens:** On the day of a participant visit, the participant ID labels will be taken out of the participant's folder and brought to the specimen preparation location, where the date labels and the blank Specimen Tracking Sheets are kept. The study clinic will place one small participant ID label and one small specimen collection date label on each specimen container. The date labels should be checked to ensure that the date is correct.

For Gram Stain slides, the labels should be placed on the bottom of the slide, because the stains used can bleed into the label and obscure the printed information.

For Dried Blood Spot cards, a total of 6 labels should be placed on each card: a set of date label and ID labels on each end, and a set in the middle aligned under the center dot. This will ensure all parts of the card are labelled when the card is cut for shipping.

3. **Specimen Tracking Sheet:** One of the large bar-coded participant ID labels will be applied to the top of a Specimen Tracking Sheet in the space shown on the sheet for a participant ID number. One of the large bar-coded date labels will be applied at the bottom of the sheet over the location with the date boxes. The visit code will be written and the appropriate visit box/ barcode will be checked.

On the right side of the Specimen Tracking Sheet, each type of specimen that will be sent to the LDMS laboratory will be checked and the number of specimens will be written. All types of blood vacutainers are entered under the 'BLD' primary type. Specimens that are going directly to a local lab for immediate processing and not going through the LDMS lab should not be entered on the Specimen Tracking Sheet. The purpose of the Specimen Tracking Sheet is to assist the LDMS lab technician in entering the specimens received into LDMS.

4. The clinic staff will place all specimens collected for that participant visit day for a given protocol into an appropriate specimen transfer container along with the LDMS Specimen Tracking Sheet that describes those specimens. If more than one participant visit specimen collection was done that day, each set of specimens will be packaged together with its own Specimen Tracking Sheet. The LDMS lab should be notified that a specimen shipment is coming so they will be ready for processing upon arrival.

LDMS Laboratory Specimen Processing²

5. When the specimen shipment is received at the local LDMS Laboratory, each package in the shipment will be checked to ensure that the all specimens in the package are for the same ID as the barcode ID label on the Specimen Tracking Sheet and that the type and number of each type of specimen marked on the Specimen Tracking Sheet is correct. If discrepancies are noticed, the clinic staff should be contacted and local procedures for QC and correction followed.
6. The LDMS laboratory tech will then open the LDMS Specimen Management window and position the cursor at the Group box. Using the barcode scanner, the LDMS laboratory tech will scan the bar-coded Group (HPTN) field at the top of the Specimen Tracking Sheet. Next, the bar-coded Participant ID number will be scanned, then the protocol number, and then the visit code will be scanned. On older tracking sheets, scanning does not automatically advance the cursor to the next field. In this case scan the tab symbol printed on the tracking sheet to advance. After scanning the visit number, if the visit unit does not automatically input, type “v” and “Vst” will be input for unit. Newer tracking sheets will automatically input “Vst” for unit and advance to the next field. At this point the cursor will be in the "Spec Date" field.

This finishes entry of participant information and begins the primary specimen information entry. The bar-coded specimen collection date will then be scanned. If the receipt date is the same as the specimen collection date, then scan the collection date barcode into the receipt date field; otherwise, hand-enter the receipt date. At this point the technician is through with the barcode reader. The rest of the information will be entered by hand, following the HPTN LDMS User Manual (Section 3, Specimen Management). Each type of specimen will then be logged in and the appropriate number of labels will be generated for that specimen type.
7. If the specimen is to be aliquoted and frozen, LDMS-generated labels will be prepared using the LDMS system and printed on the LDMS printer using label stock certified for long term freezer storage and/or dry ice shipping. The Central Laboratory will specify all label stock to be used. Some specimens will not need relabeling.
8. The LDMS-generated labels will be applied to each cryovial, using standard procedures and placed into a freezer box that has already been created in the LDMS.
9. Each aliquot in the box will be stored in the LDMS system using the Storage Management screen. Similar procedures will be followed for specimens that will be stored at room temperature, such as Gram Stain slides and Dried Blood Spot Cards. They will also be given assigned locations in identified containers and those containers added to the previously prepared storage structures in LDMS.

² See LDMS-Figure 2: ‘LDMS Laboratory Specimen Logging, Cryovialing, Storage and Shipping to Central Labs’ flow diagram.

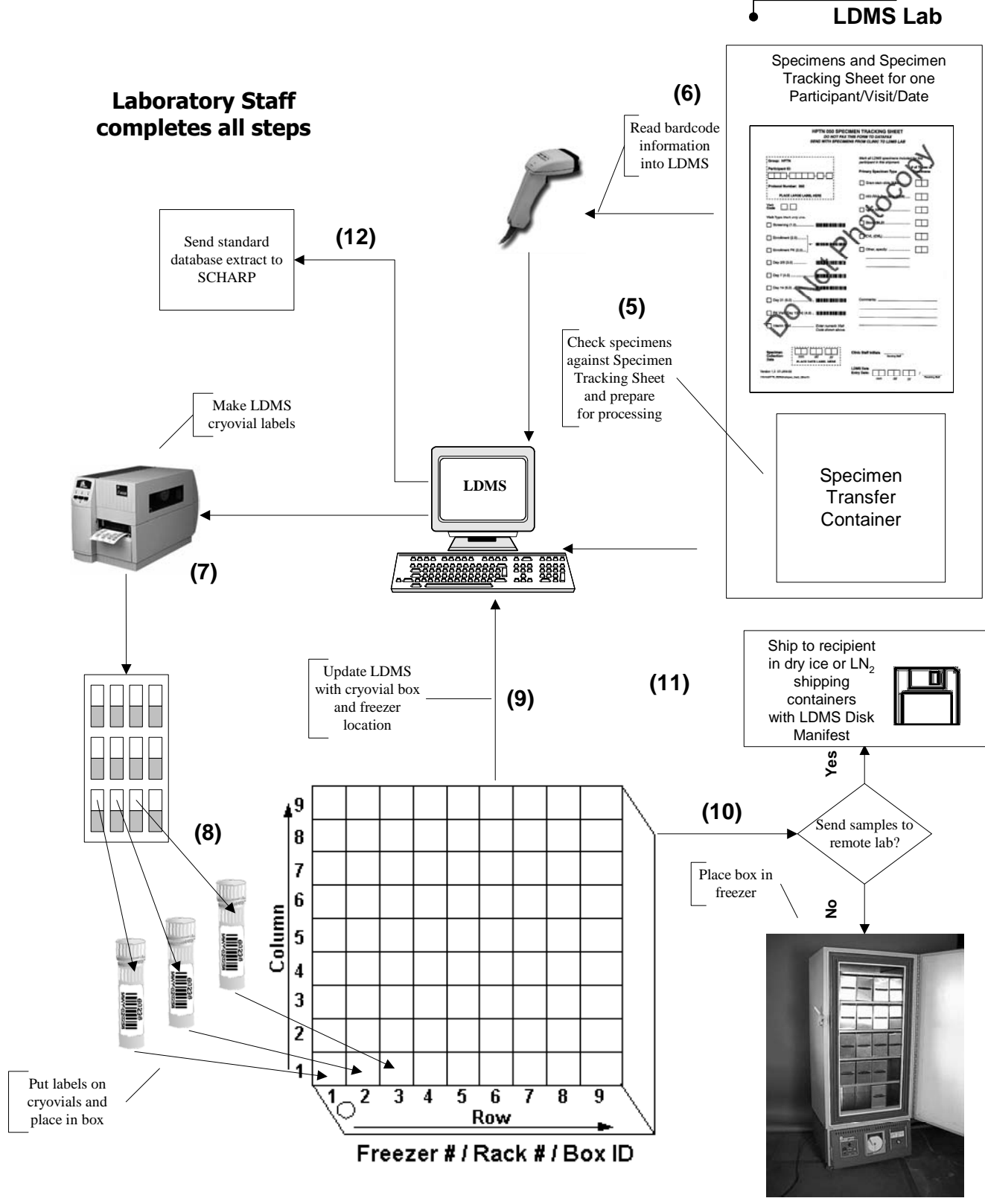
10. Each container will then be placed into the LDMS-assigned freezer location or other assigned storage structure, according to LDMS specifications. Specimens that do not need freezing (ex. Gram Stain Slides, DBS cards) can be checked into 'virtual' freezers for specimen tracking purposes.

11. If specimens are designated by the protocol to be shipped either to the Central Laboratory or a specialty lab (such as UNC), the specimens will be checked out of the local freezer storage and logged into an appropriate shipping container using the LDMS system. The shipping containers and packing and labeling procedures appropriate to the type of specimen will be defined by the Central Laboratory. Shipments to the Central Lab or protocol-specific labs will follow instructions in the protocol Study Specific Procedure manual.

An electronic shipping manifest will be created for each shipment by the LDMS system. The electronic manifest disk will be placed in the shipping container prior to final packing and pickup. After pickup, the electronic shipping manifest will also be sent as an e-mail attachment to the intended recipient of the shipment. The email will include the name of the shipper and the shipment tracking number, so that the receiving laboratory can contact the shipper if the shipment does not arrive on schedule.

LDMS-Figure 2

LDMS Laboratory Specimen Logging, Cryovialing, Storage and Shipping to Central Labs



11. Study Blinding/Unblinding

Blinding of study participants' should remain in place until a study is closed. As a general guideline, study participants are unblinded only after all data are entered into the database, all study endpoints and other data included in the final analysis have been verified and cleaned, and the data are determined to be ready for final analysis.

Participants are informed of their treatment assignment only after study closure. Therefore, participants who complete the study prior to closure will need to wait until study closure for unblinding. This should be made clear to participants at the time of recruitment.

Participants experiencing possible side effects to the study drugs should be treated as if they have received the active agent. Study drugs should be stopped in participants experiencing a serious reaction possibly related. When a participant has experienced a serious reaction possibly related to the study drug, the field director will notify the protocol specialist, who will notify the protocol chairs, medical officers, protocol operations coordinator, and protocol pharmacist. The team will make a determination regarding whether the participant requires unblinding so she may be advised of her allergy. The randomization code will not be kept on site.