Section 14. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-008 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact Corey Miller (corey@scharp.org).

For this study, the SDMC (Statistical and Data Management Center) is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, WA, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN-008 team members, along with their job roles and e-mail addresses, are listed below.

Role on MTN-008	Name	E-mail address
Protocol Statistician	James Dai	jdai@scharp.org
Project Manager	Corey Miller	corey@scharp.org
Statistical Research Associate	Joleen Borgerding	jborgerd@scharp.org
Clinical Affairs Safety Associate	Jenny Tseng	jenny@scharp.org
Protocol Programmer	Julie Zhuo	jzhuo@scharp.org
Reporting Programmer	Cathy Kirkwood	ckirkwoo@scharp.org
Laboratory Programmer	Della Wilson	della@scharp.org
CASI Programmer	Lynda McVarish	lmcv@scharp.org
Data Coordinator	Debbie Lands	dlands@scharp.org
Document Specialist	Donna Fulcher	donna@scharp.org

14.1 DataFax Overview

DataFax is the data management system used by SCHARP to receive and manage data collected at study sites. The site faxes an electronic image of each case report form (CRF) to SCHARP DataFax, and the original hard copy CRF is retained by the site.

CRF Transmission

Case report forms can be transmitted to SCHARP in one of two ways: faxed using a fax machine connected to a land phone line (fax to phone number 206.667.4805) or faxed using a fax machine connected to the internet (fax to e-mail <datafax@scharp.org>).

SCHARP's Information Systems Technology (IST) group is available to consult with the site to determine the best method for data transmission. The SCHARP IST group can be contacted via e-mail at support@scharp.org. The SCHARP IST group should also be contacted anytime the site has technical questions or problems with their fax equipment.

Data Entry/Quality Control

Once a CRF image is received by SCHARP DataFax, the following occurs:

- DataFax identifies the study to which each CRF belongs using the barcode at the top of the form. It reads and enters the data into the study database and stores each CRF on a computer disk.
- Each CRF is then reviewed by at least two members of SCHARP's Data Operations Group. Problems such as missing or potentially incorrect data are identified and marked with Quality Control notes (QCs).

- QCs are compiled into QC reports that are sent via e-mail to the study site on a regular basis. Sites are asked to correct or clarify any problems identified on the QC reports and refax the corrected CRFs to SCHARP DataFax.
- When the re-faxed pages are received, SCHARP staff review the corrected pages and resolve the QCs.

If a change is made to a CRF but the updated page is not re-faxed to SCHARP DataFax, the change will **not** be entered and the study database will continue to contain incomplete or incorrect data. Additionally, if the change was prompted by a QC, the QC will continue to appear on subsequent QC reports until the modified CRF is received at SCHARP. Therefore, it is very important that the site refax updated CRF pages to SCHARP DataFax **any time** a change is made to a CRF, regardless of whether or not the change was made in response to a QC report.

14.2 DataFax Form Completion

14.2.1 Guidelines

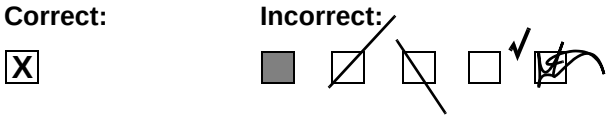
Based on the use of fax technology and Good Clinical Practices (GCPs), the following guidelines should be used for completing DataFax CRFs:

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.
- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible while staying within the boundaries of the boxes.
- Record data on the front of CRFs only. DataFax cannot read the back of CRFs.
- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction “Mark all that apply.”
- A response is required for every item unless instructed otherwise by a skip pattern.
- **Never** obscure, mark over, or punch holes through the barcode at the top of each CRF. DataFax requires the barcode to identify the CRF.
- **Never** use correction fluid (“white-out”) or correction tape on CRFs.
- Remove any paper clips, staples, or other attachments before faxing CRFs.
- The site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.
- Fax forms as soon as possible after they have been completed and reviewed. Ideally, completed forms will be faxed to SCHARP within 1–2 days of completing the visit, though up to 5 days is allowed.

14.2.2 How to Mark Response Boxes

Many items on DataFax CRFs have a box or series of boxes for recording a response. Mark the box clearly with an **X**. Do not fill in the box with shading or mark it with a slash or other character.

Correct: **Incorrect:**



Mark only one response box for each item unless the "Mark all that apply" instruction is present.

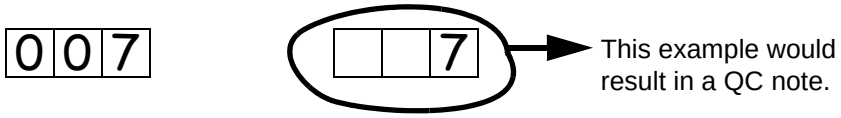
14.2.3 How to Record Numbers

Some questions on DataFax CRFs include boxes for recording a numeric response. DataFax can only read the numbers in these boxes if they are recorded clearly. The following instructions should be followed when recording numeric responses:

- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

  The following example shows how a value of 7 is recorded when three response boxes are provided:

  Correct: **Incorrect:**

- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

  In the following example, the 4 could be misinterpreted as a 7 or a 1 because DataFax can only read what is *inside* the box:

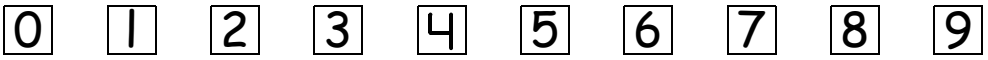
  Correct: **Incorrect:**

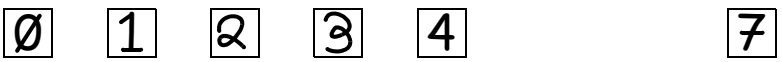
- Write the number(s) simply, with few loops.

  The following example shows the format in which numbers will be most easily read by DataFax. Also included are some commonly used formats that may be difficult for DataFax to identify.

  Easily Identified:

  Difficult to Identify:

14.2.4 How to Record Dates

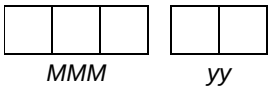
Dates are recorded using the "dd MMM yy" format, where "dd" represents the two-digit day, "MMM" represents the three-letter abbreviation of the month (in capital letters), and "yy" represents the last two digits of the year.

The month field must be filled in with the three-letter abbreviation *in English* for the date to be read in DataFax. Abbreviations are shown below:

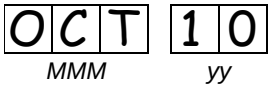
Month	Abbreviation	Month	Abbreviation
January	**JAN**	July	**JUL**
February	**FEB**	August	**AUG**
March	**MAR**	September	**SEP**
April	**APR**	October	**OCT**
May	**MAY**	November	**NOV**
June	**JUN**	December	**DEC**

For example, June 6, 2011 is recorded as:

Sometimes, only a month and a year are required (e.g., diagnosis date for a pre-existing condition), in which case the response boxes will look like this:

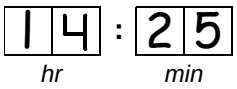


A diagnosis date of October, 2010 would be recorded as follows:



14.2.5 How to Record Time

Time is recorded on DataFax CRFs using the 24-hour clock (00:00-23:59), in which hours are designated from 0–23. For example, in the 24-hour clock 2:25 p.m. translates to 14:25 (2 p.m. = 14), which would be recorded as follows:



Midnight is recorded as 00:00, not 24:00.

The following chart shows equivalencies between the 12- and 24-hour clocks:

12-hour clock (a.m.)	24-hour clock
Midnight	00:00
1:00 a.m.	01:00
2:00 a.m.	02:00
3:00 a.m.	03:00
4:00 a.m.	04:00
5:00 a.m.	05:00
6:00 a.m.	06:00
7:00 a.m.	07:00
8:00 a.m.	08:00
9:00 a.m.	09:00
10:00 a.m.	10:00
11:00 a.m.	11:00

12-hour clock (p.m.)	24-hour clock
Noon	12:00
1:00 p.m.	13:00
2:00 p.m.	14:00
3:00 p.m.	15:00
4:00 p.m.	16:00
5:00 p.m.	17:00
6:00 p.m.	18:00
7:00 p.m.	19:00
8:00 p.m.	20:00
9:00 p.m.	21:00
10:00 p.m.	22:00
11:00 p.m.	23:00

14.2.6 Data Corrections and Additions

Sometimes, data on a DataFax CRF may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a QC report or as a result of site review of the CRF before faxing.

It is important to make these changes to the original CRF—***never*** copy data onto a new form. After making the change, the CRF *must* be re-faxed to SCHARP DataFax.

Note: If a correction or addition is made to one page of a multiple-page CRF, only refax the page that was changed.

Note: Never write over an entry once it is recorded. Use the standards outlined in the following paragraphs when changing, clarifying, or amending data.

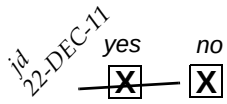
Whenever an entry on a DataFax CRF is changed, do the following:

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),
- place the correct or clarified answer near the box, and
- initial and date the correction as shown below:

Correct: **Incorrect:**

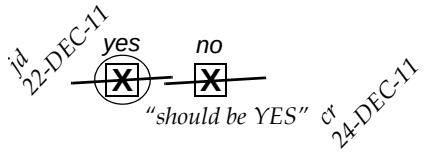
If an **X** is marked in the wrong response box, correct it by doing the following:

- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and
- initial and date the correction as shown below:



If the correct answer has previously been crossed out, do the following:

- circle the correct item,
- write an explanation in the white space near the item, and
- initial and date all corrections as shown below:

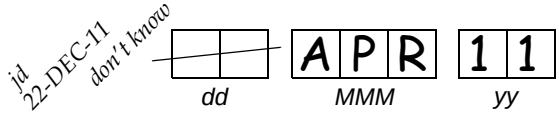


The standards above must ***always*** be followed whenever a CRF is changed, clarified, or amended, even if the change is made ***before*** the CRF is faxed to SCHARP for the first time.

14.2.7 How to Handle Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer, draw a single horizontal line through the blank boxes and initial and date the item. It is helpful to write "don't know," "refuses to answer," "UNK" (unknown), "N/A" (not applicable), or "REF" (refused) near the blank boxes.

For example, when recording a date, if the exact day is not known, draw a single horizontal line through the "dd" boxes and write "don't know" next to the response boxes, as shown below:



A skip pattern is the **only** valid reason to leave a response blank. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial form completion, or as an update to the form.

14.3 MTN-008 Study-Specific Data Collection Information

14.3.1 Participant IDs (PTIDs)

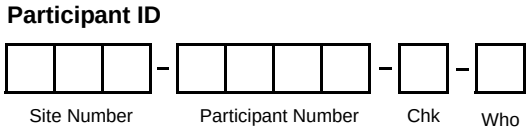
DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. SCHARP provides each site with a list of PTIDs prior to study start-up. The site should assign one PTID to each participant enrolled in the study. The PTIDs are assigned in sequential order as participants enroll in the study. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, she maintains that same PTID throughout the entire study.

PTID boxes are located near the upper left corner of each CRF page.

Site staff are responsible for maintaining a log linking PTIDs to participant names (PTID-Name Link log) in accordance with Section 3 of this manual.

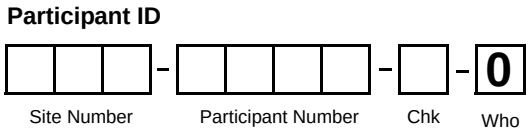
The PTIDs used for this study are nine digits and formatted as "WWW-XXXX-Y-Z." The PTID consists of four parts: the site number (WWW), the participant number (XXXX), a numerical check digit (Y) and the "who" identifier (Z). The check digit (Y) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. The who identifier is used to identify each participant as the mother (0) or infant (1) Below are examples of the PTID structures used in MTN-008.

General PTID Structure



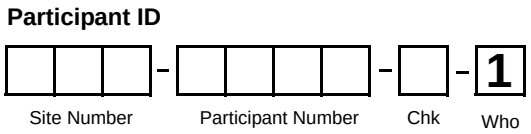
Mother PTID Structure

SCHARP provides each site with a list of Mother PTIDs prior to study start-up. The who identifier for mothers will always be "0."



Infant PTID Structure

The Infant PTID is identical to it's mother's PTID with the exception of the last digit, the who identifier. For infants, this number will always be 1.



14.3.2 Study Visit Timing

Study Visits

Screening Visit

The Screening Visit is defined as the day the participant provides written informed consent to be screened for the study. Screening may take place up to 4 weeks (28 days) prior to the Enrollment Visit, and if necessary, multiple visits may be conducted to complete required screening procedures.

If the participant later re-screens (starts another screening attempt), all screening procedures (except PTID assignment), evaluations, and forms must be repeated, including provision of written informed consent. Once a PTID is assigned to a participant, the same PTID is used for that participant for the entire duration of the study. If a participant re-screens, only case report forms from the successful Screening Visit are faxed to SCHARP DataFax.

Enrollment Visit (Day 0)

The Enrollment Visit (Day 0) must take place no later than 28 days after the Screening Visit. For MTN-008, a participant is considered enrolled as follows:

- Mothers (and their unborn infants) in the Pregnancy Cohort will be considered enrolled in MTN-008 when the Clinic Randomization Envelope is assigned.
- Mothers in the Lactation Cohort will be considered enrolled in MTN-008 once the authorized clinician completes the study product prescription order form on Day 0.
- Infants in the Lactation Cohort will be considered enrolled in MTN-008 simultaneously, when their mothers are enrolled.

Assignment of the MTN-008 Clinic Randomization Envelopes for the Pregnancy Cohort will be documented using the MTN-008 Clinic Randomization Envelope Tracking Record provided to each site by SCHARP.

Follow-up Visits: Mothers

Maternal participants enrolled in the Pregnancy Cohort for MTN-008 are required to complete 6 follow-up visits: 3 follow-up phone calls, 1 clinic visit, the Delivery Visit, and the Post-delivery Assessment. Maternal participants enrolled in the Lactation Cohort for MTN-008 are required to complete 4 follow-up visits: 3 follow-up phone calls and 1 clinic visit. The visit type, visit code, target visit day, and visit windows for required MTN-008 follow-up visits are listed in Table 14-1.

Follow-up Visits: Infants

Infant participants enrolled in the Pregnancy Cohort for MTN-008 are required to complete 2 follow-up visits: the Delivery Visit and the Post-delivery Assessment. Infant participants enrolled in the Lactation Cohort for MTN-008 are required to complete 4 follow-up visits: 3 follow-up phone calls and 1 clinic visit. The visit type, visit code, target visit day, and visit windows for required MTN-008 follow-up visits are listed in Table 14-1.

Table 14-1: MTN-008 List of Visits, Visit Codes, Target Visit Dates, and Target Visit Windows

All visit windows are in days; Enrollment = Day 0

Visit	Visit Code	Day Target Window Opens	Target Date	Day Target Window Closes
Screening	01.0	Day -28	**N/A**	Day 0
Enrollment	02.0	n/a	**Day 0**	n/a
Day 1 phone call	03.0	Day 1	**Day 1**	Day 2
Day 3 phone call	04.0	Day 3	**Day 3**	Day 4
Day 6 visit	05.0	Day 6	**Day 6**	Day 7
Day 14 phone call	06.0	Day 8	**Day 14**	Day 21
Delivery visit*	55.0	n/a	**varies**	n/a
Post-delivery assessment*	56.0	7 days post-delivery	**varies**	21 days post-delivery
** Pregnancy Cohort only*				

Target Dates and Visit Windows

All attempts must be made to schedule and complete visits on the target date for the visit. Visit target dates are set based on the enrollment date (Day 0) and do not change if subsequent actual visits take place before or after the target date. Visits completed within the target window will appear on the MTN-008 Retention Reports as being completed "on-time."

There may be cases where it is not possible to complete the visit on the target date. Therefore, follow up visits may be completed within a visit window around the target date. The visit window for the Day 1 and Day 3 phone calls is +1 day. The visit window for the Day 14 phone call is -6 days — +7days. For example, if a participant enrolls into MTN-008 on 16 March 2011, her Day 3 phone call target date is 19 March 2011. However, if she is unreachable that day, the Day 3 phone call can be completed on 20 March 2011. The visit window for the Day 6 Visit is +1 day. For example, if a participant enrolls into MTN-008 on 11 June 2011, her Day 6 Visit target date is 17 June 2011. However, if she is unable to come to the clinic that day for an unforeseen reason, the Day 6 Visit can be completed on 18 June 2011. For participants who do not complete scheduled visits within the target window, the visit will be considered "missed" and relevant CRFs will be completed to document the missed visit.

SCHARP will provide sites with an Excel spreadsheet tool that may be used to generate individual participant follow-up visit calendars. The spreadsheet requires that the participant's enrollment date be entered. Once the enrollment date is entered, the target date and visit windows for the follow-up visits will appear in the spreadsheet, which can then be printed and added to the participant's study notebook.

Missed Visits

In those cases where a participant is not able to complete any part of a required follow-up visit within the visit window, the visit is considered missed. For example, if the same participant who enrolls into MTN-008 on 22 March 2011 cannot be reached for her Day 3 phone call on March 25th or March 26th (within the acceptable visit window). In this case, since the visit window for that participant's Day 3 phone call has "closed," the Day 3 phone call is considered missed, and is documented by completing a Missed Visit form.

Interim Visits

A study visit is considered an interim visit when a participant completes a phone call or presents at the site for additional clinical/laboratory assessments and/or procedures *outside* of the required evaluations for a scheduled study visit. Interim visits may be performed at any time during the study for any reason such as: administrative reasons (a participant has study-related questions for the staff), product-related (a participant needs additional study product), lab-related (a participant needs a lab test repeated for confirmation), or clinical follow-up (a participant needs additional clinical follow-up for an Adverse Experience). If any data are required to be reported on a DataFax CRF as a result of an interim contact/ visit, an Interim Visit form must be completed and faxed to SCHARP DataFax. If no DataFax forms are required for the interim visit (for example, the participant comes to the clinic to obtain more panty liners), the interim visit may be documented by a chart note only (no CRFs required).

For example, a participant completes the Day 1 and Day 3 phone calls as scheduled. She comes to the clinic on Day 5 to report that she is experiencing some new symptoms, she is noticing redness and irritation near the area of the vagina where gel is inserted. Additional follow-up is performed to assess the newly-reported redness and irritation. Since this visit to the clinic on Day 5 is not part of the required follow-up visit schedule and data will be recorded on a DataFax form (e.g. Adverse Experience Log form), this is considered an interim visit and an Interim Visit form is completed to document the visit. Visit code assignment for interim visits is covered in Section 14.3.3.

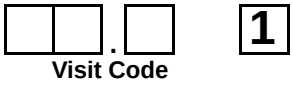
Unscheduled phone contact (i.e. a phone call on a day other than Day 1, Day 3, or 14) with a participant is also considered an interim visit if 1) the phone contact results in the reporting of a new AE, or 2) during the phone contact, the participant is instructed by site staff to temporarily or permanently discontinue product use. For example, a site is unable to contact a participant for the Day 3 phone call, the Day 3 phone call is considered missed. However, two days later on Day 5, the site is able to reach the participant by telephone and she reports a new symptom, which results in the reporting of a new AE. The phone contact where the new symptom is reported is considered an interim visit.

For questions about phone contacts and assignment of visit codes to such contacts, please contact the SCHARP MTN-008 Project Manager.

14.3.3 Visit Codes, and Page Numbers

Visit Codes

Some DataFax CRFs will include boxes in the upper right corner for a visit code and have the following visit code structure:



DataFax uses the visit code to identify the visit at which a CRF is completed. However, not all DataFax CRFs include boxes for visit codes. If a form is only completed once during a study (for example, the Enrollment form or the Termination form), the visit code will be automatically assigned in DataFax.

When visit code boxes are provided, site staff are responsible for entering the visit code in the boxes provided in the upper right corner of each page. For multiple-paged CRFs, site staff need to make sure that all the pages of the CRF are marked with the same visit code for given participant and visit. Please see Table 14-1 for specific visit codes used for the study visits.

Visit codes for interim visits

In addition to the scheduled, protocol-required visits listed in Table 14-1, interim visits may occur once the participant is enrolled (see Section 14.3.2 for a definition and examples of unscheduled/interim visits). Interim visit codes are assigned using the following guidelines:

- In the box to the left of the decimal point, record the one-digit visit code for the most recent scheduled visit (whether that visit was completed or missed).
- Use the guide below to complete the box to the right of the decimal point:
  - ##.1 = the first interim visit after the most recent scheduled visit,
  - ##.2 = the second interim visit after the most recent scheduled visit, and so on.

Example: A participant returns to the site clinic on Day 4 to report new symptoms which require a new AE Log form to be completed. This current visit is considered and interim visit and is assigned the following interim visit code:

Visit Code for this Interim Visit:

Visit Code 0 4 . 1

NOTE: *<u>Not</u> all interim visits are assigned visit codes. An interim visit should be assigned an interim visit code only if data collected at the visit warrants completion of a new DataFax form, such as an AE Log form or Product Hold/Discontinuation Log form. An Interim Visit form must be completed for each and every visit that is assigned an interim visit code.*

Page numbers

Other CRFs, such as log forms (i.e., Adverse Experience Log form, Concomitant Medications Log form, Product Hold./Discontinuation Log form), include boxes in the upper-right corner for recording page numbers, as shown below:

Page ☐☐

Assign page numbers in sequential order, starting with 01 (or 001 for Adverse Experience Log forms). For example, the second Concomitant Medications Log page would be assigned page number 02, the third page would be assigned 03, and so on throughout study participation.

14.3.4 Staff Initials/Date

Most CRFs include a line in the lower-right corner for a staff member's initials and the date on which the form was completed. When more than one staff member records data on a CRF, the site should designate the staff member who has primary responsibility for the form. This individual completes the staff initials/ date field. The individual not identified in the staff initials/date field writes his/her initials and date next to each data element for which he/she is responsible.

14.3.5 Case Report Form Completion Schedule

The SCHARP-provided case report forms for this study include DataFax forms (forms that are completed and faxed to SCHARP DataFax) and non-DataFax forms (forms that are completed but **not** faxed to SCHARP DataFax).

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. The following tables (Table 13-2 and Table 13-3) lists the DataFax and non-DataFax forms that are **required** to be completed at each MTN-008 study visit for the Pregnancy and Lacation Cohorts, respectively.

Table 14-2: Case Report Form Completion Schedule for Pregnancy Cohort

Screening Visit (within 28 days prior to Enrollment)		Visit Code: 01.0
Form Acronym	**Form Name**	**Plate #**
Required		
Non-DataFax	Enrollment Eligibility: Pregnancy Cohort	n/a
DEM-1	Demographics	001
Non-DataFax	Mother: Participant-reported Baseline Medical and Menstrual History	n/a
Non-DataFax	Mother Targeted Physical Exam	n/a
PR-1	Pregnancy Report and History	440
PE-1	Pelvic Exam	141
PLR-1	Pelvic Laboratory Results	143
Non-DataFax	Pelvic Exam Diagrams	n/a
SLR-1	STI Laboratory Results	131
SL-1, SL-2	Safety Laboratory Results	151, 152
CM-1	Concomitant Medications Log	423
Non-DataFax	MTN-008 Maternal PK-LDMS Specimen Tracking Sheet	n/a
Enrollment Visit (Day 0)		**Visit Code: 02.0**
Form Acronym	**Form Name**	**Plate #**
Required		
ENR-1	Enrollment (Mother)	70
ENR-1	Enrollment (Infant)	70
PRE-1	Pre-existing Conditions (Mother)	012
Non-DataFax	Mother Targeted Physical Exam	n/a
PE-1	Pelvic Exam	141
PLR-1	Pelvic Laboratory Results	143
Non-DataFax	Pelvic Exam Diagrams	n/a
SL-1, SL-2	Safety Laboratory Results	151, 152
PKM-1	Maternal Pharmacokinetics	061
FC-1	Flow Cytometry	064
Non-DataFax	MTN-008 Maternal PK-LDMS Specimen Tracking Sheet	n/a
As Needed		
AE-1	Adverse Experience Log (Mother)	460
CM-1	Concomitant Medications Log (Mother)	423

Day 1 Phone Call		Visit Code: 03.0
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
As Needed		
AE-1	Adverse Experience Log (Mother)	460
CM-1	Concomitant Medications Log (Mother)	423
Day 3 Phone Call		**Visit Code: 04.0**
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
As Needed		
AE-1	Adverse Experience Log (Mother)	460
CM-1	Concomitant Medications Log (Mother)	423
Day 6 Visit		**Visit Code: 05.0**
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
Non-DataFax	Mother Targeted Physical Exam	n/a
PE-1	Pelvic Exam	141
PLR-1	Pelvic Laboratory Results	143
Non-DataFax	Pelvic Exam Diagrams	n/a
SL-1, SL-2	Safety Laboratory Results	151, 152
PKM-1	Maternal Pharmacokinetics	061
FC-1	Flow Cytometry	064
PER-1	Participant Evaluability and Replacement	145
PDC-1	Participant-reported Dosing and Collection	260
SPR-1	Study Product Returns	415
Non-DataFax	MTN-008 Maternal PK-LDMS Specimen Tracking Sheet	n/a
As Needed		
AE-1	Adverse Experience Log (Mother)	460
CM-1	Concomitant Medications Log (Mother)	423
Day 14 Phone Call		**Visit Code: 06.0**
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
As Needed		
AE-1	Adverse Experience Log (Mother)	460
CM-1	Concomitant Medications Log (Mother)	423

Delivery Visit		Visit Code: 55.0
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit (Mother)	121
FV-1	Follow-up Visit (Infant)	121
PO-1, PO-2, PO-3	Pregnancy Outcome	442, 443, 444
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
Non-DataFax	Mother Targeted Physical Exam	n/a
SL-1, SL-2	Safety Laboratory Results	151, 152
PKM-1	Maternal Pharmacokinetics	061
FC-1	Flow Cytometry	064
Non-DataFax	MTN-008 Maternal PK-LDMS Specimen Tracking Sheet	n/a
CM-1	Concomitant Medications Log (Infant)	423
PKI-1	Infant Pharmacokinetics	062
Non-DataFax	MTN-008 Infant PK-LDMS Specimen Tracking Sheet	n/a
As Needed		
AE-1	Adverse Experience Log (Mother)	460
CM-1	Concomitant Medications Log (Mother)	423
AE-1	Adverse Experience Log (Infant)	460
Post-delivery Assessment Visit		**Visit Code: 66.0**
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit (Mother)	121
FV-1	Follow-up Visit (Infant)	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
TM-1	Termination (Mother)	490
TM-1	Termination (Infant)	490
ESI-1	End of Study Inventory (Mother)	489
ESI-1	End of Study Inventory (Infant)	489
As Needed		
Non-DataFax	Infant Medical History Log	n/a
AE-1	Adverse Experience Log (Mother)	460
AE-1	Adverse Experience Log (Infant)	460
CM-1	Concomitant Medications Log (Mother)	423
CM-1	Concomitant Medications Log (Infant)	423

Table 14-3: Case Report Form Completion Schedule for Lactation Cohort

Screening Visit (within 28 days prior to Enrollment)		Visit Code: 01.0
Form Acronym	**Form Name**	**Plate #**
Required		
Non-DataFax	Enrollment Eligibility: Lactation Cohort: Mother	n/a
Non-DataFax	Enrollment Eligibility: Lactation Cohort: Infant	n/a
DEM-1	Demographics	001
Non-DataFax	Mother: Participant-reported Baseline Medical and Menstrual History	n/a
Non-DataFax	Mother Targeted Physical Exam	n/a
Non-DataFax	Infant Medical History Log	n/a
PE-1	Pelvic Exam	141
PLR-1	Pelvic Laboratory Results	143
Non-DataFax	Pelvic Exam Diagrams	n/a
SLR-1	STI Laboratory Results	131
SL-1, SL-2	Safety Laboratory Results	151, 152
CM-1	Concomitant Medications Log (Mother)	423
CM-1	Concomitant Medications Log (Infant)	423
Non-DataFax	MTN-008 Maternal PK-LDMS Specimen Tracking Sheet	n/a
Enrollment Visit (Day 0)		**Visit Code: 02.0**
Form Acronym	**Form Name**	**Plate #**
Required		
ENR-1	Enrollment (Mother)	70
ENR-1	Enrollment (Infant)	70
PRE-1	Pre-existing Conditions (Mother)	012
PRE-1	Pre-existing Conditions (Infant)	012
Non-DataFax	Mother Targeted Physical Exam	n/a
PE-1	Pelvic Exam	141
PLR-1	Pelvic Laboratory Results	143
Non-DataFax	Pelvic Exam Diagrams	n/a
SL-1, SL-2	Safety Laboratory Results	151, 152
PKM-1	Maternal Pharmacokinetics	061
PKI-1	Infant Pharmacokinetics	062
FR-1	Feeding Record	250
FC-1	Flow Cytometry	064
Non-DataFax	MTN-008 Maternal PK-LDMS Specimen Tracking Sheet	n/a
Non-DataFax	MTN-008 Infant PK-LDMS Specimen Tracking Sheet	n/a
As Needed		
Non-DataFax	Infant Medical History Log	n/a
AE-1	Adverse Experience Log (Mother)	460
AE-1	Adverse Experience Log (Infant)	460
CM-1	Concomitant Medications Log (Mother)	423
CM-1	Concomitant Medications Log (Infant)	423

Day 1 Phone Call		Visit Code: 03.0
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit (Mother)	121
FV-1	Follow-up Visit (Infant)	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
As Needed		
Non-DataFax	Infant Medical History Log	n/a
AE-1	Adverse Experience Log (Mother)	460
AE-1	Adverse Experience Log (Infant)	460
CM-1	Concomitant Medications Log (Mother)	423
CM-1	Concomitant Medications Log (Infant)	423
Day 3 Phone Call		**Visit Code: 04.0**
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit (Mother)	121
FV-1	Follow-up Visit (Infant)	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
As Needed		
Non-DataFax	Infant Medical History Log	n/a
AE-1	Adverse Experience Log (Mother)	460
AE-1	Adverse Experience Log (Infant)	460
CM-1	Concomitant Medications Log (Mother)	423
CM-1	Concomitant Medications Log (Infant)	423
Day 6 Visit		**Visit Code: 05.0**
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit (Mother)	121
FV-1	Follow-up Visit (Infant)	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
Non-DataFax	Mother Targeted Physical Exam	n/a
PE-1	Pelvic Exam	141
PLR-1	Pelvic Laboratory Results	143
Non-DataFax	Pelvic Exam Diagrams	n/a
SL-1, SL-2	Safety Laboratory Results	151, 152
PKM-1	Maternal Pharmacokinetics	061
PKI-1	Infant Pharmacokinetics	062
FR-1	Feeding Record	250
FC-1	Flow Cytometry	064
PER-1	Participant Evaluability and Replacement	145
PDC-1	Participant-reported Dosing and Collection	260
SPR-1	Study Product Returns	415
Non-DataFax	MTN-008 Maternal PK-LDMS Specimen Tracking Sheet	n/a
Non-DataFax	MTN-008 Infant PK-LDMS Specimen Tracking Sheet	n/a

As Needed		
Non-DataFax	Infant Medical History Log	n/a
AE-1	Adverse Experience Log (Mother)	460
AE-1	Adverse Experience Log (Infant)	460
CM-1	Concomitant Medications Log (Mother)	423
CM-1	Concomitant Medications Log (Infant)	423
Day 14 Phone Call		**Visit Code: 06.0**
Form Acronym	**Form Name**	**Plate #**
Required		
FV-1	Follow-up Visit (Mother)	121
FV-1	Follow-up Visit (Infant)	121
Non-DataFax	Mother: Participant-reported Follow-up Medical and Menstrual History	n/a
TM-1	Termination (Mother)	490
TM-1	Termination (Infant)	490
ESI-1	End of Study Inventory (Mother)	489
ESI-1	End of Study Inventory (Infant)	489
As Needed		
Non-DataFax	Infant Medical History Log	n/a
AE-1	Adverse Experience Log (Mother)	460
AE-1	Adverse Experience Log (Infant)	460
CM-1	Concomitant Medications Log (Mother)	423
CM-1	Concomitant Medications Log (Infant)	423

14.3.6 Site Review of DataFax Forms

Each form must be reviewed for completeness and legibility before being faxed to SCHARP DataFax. As part of the review, the site should check the following:

- Other than the participant ID number (PTID), there is no information on the form that could identify the participant (e.g., name, phone number, national identification number, or any other personal identifiers).
- A response has been recorded for each item, unless the item was skipped as instructed by a skip pattern or the item was marked as missing or unknown as described in 14.2.7.
- All text responses are clearly recorded.
- There are no marks on or above the DataFax barcode at the top of each DataFax page.
- There are no:
  - missing dates,
  - missing visit codes,
  - incorrect PTIDs,
  - incorrect visit codes,
  - missing data for items beginning a series of skip patterns, and/or
  - inconsistent or discrepant data.

While CRFs are being reviewed, it is important that they are stored and tracked systematically. It is also necessary to have a system to identify whether a CRF has been faxed to SCHARP DataFax. Such a system may include using a stamp to date the back of the CRF, or utilizing the SCHARP CRF Tracking System (see SSP Section 14.3.7 for more information).

Important: If a date stamp is used to document when the form is faxed, *only* stamp the back of the CRF, *never* the front. Be sure to date stamp the back of the CRF each time it is faxed, including re-faxes.

14.3.7 Faxing DataFax Forms

To streamline the submission of DataFax forms, the site should identify which staff members will be responsible for faxing forms to SCHARP DataFax and receiving and responding to QC reports.

It is important that the sites fax completed DataFax CRFs to SCHARP within the time period specified in the site's MTN-008 Data Management SOP, and that they respond promptly to requests for clarifications and corrections included in QC reports. Early detection of recurrent problems provides an opportunity to reduce errors and improve data quality.

For sites wishing to confirm the receipt of faxed forms at SCHARP, the CRF Tracking System (CTS) is available. This system generates two types of e-mails listings: 1) the number of form pages received at SCHARP; and 2) which specific forms were received at SCHARP for a given PTID and visit. Please contact the MTN-008 Project Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

14.3.8 Non-DataFax Forms

MTN-008 sites will receive non-DataFax forms from SCHARP. These forms will be easily identifiable because there will not be a DataFax barcode along the top of the CRF. In place of the barcode, the following text will appear: "NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX."

These forms should **not** be faxed to SCHARP DataFax. Instead, they should be kept in the participant's file as a record of the activities recorded on the form. The form completion guidelines described in sections 14.3.1 through 14.3.4 should be applied when completing non-DataFax CRFs.

14.4 Form Supply and Storage

14.4.1 Form and Specimen Label Supply

An initial supply of case report forms needed for the study will be supplied by SCHARP using form visit packets, where the packet contains all of the required CRFs for the visit. For example, the Pregnancy Cohort: Screening Visit packet will include all of the CRFs listed for this visit in the Case Report Form Completion Schedule table (Table 14-2). In addition to form packets for each visit listed in Table 14-2, bulk supplies of "as needed" CRFs will be provided to the site (for example, Adverse Experience Log forms, Concomitant Medications Log forms, etc.). Subsequent supplies of forms will be available for download and printing at each site as needed via the ATLAS website. The resupplied forms will likely only be available in white.

SCHARP will also ensure sites have access to specimen labels (printed on-site). Specimen labels should be used for all primary specimen collection containers. Please refer to the Laboratory section of the manual for more information on laboratory specimen collection and labeling.

14.4.2 Form Storage

Specifications for form storage will be detailed in the site's MTN-008 Data Management SOP. It is recommended that for each participant, study CRFs be stored in a hard-cover notebook. SCHARP can provide a template for use in creating notebook cover labels and spine labels. SCHARP can also provide a template that can be used to create tab dividers.

It is suggested that Concomitant Medications Log forms, Adverse Experience Log forms, and Product Hold/Discontinuation Log forms be kept in their own tabbed sections within the participant study notebook. This makes page numbering and updating of these forms easier than if these forms are stored by visit within the participant's study notebook.

14.5 Form Completion Instructions

Detailed form completion instructions for each form are provided on the back of each form page. These instructions include the purpose of each form as well as how each form should be completed. Some items on forms are straightforward and do not require specific instructions. Therefore, specific form instructions are not always provided for each item on the form. Rather, instructions are provided only for those items requiring additional clarification for the purpose of form completion.

Below are some additional instructions for the Pre-existing Conditions, Concomitant Medications Log, and Adverse Experience Log forms.

Pre-existing Conditions and Concomitant Medication Log

- For the Pre-existing Conditions and Concomitant Medication Log forms, note that you should fax each page to SCHARP any time a new entry is added or modified, even if the page is not complete. You should not wait to complete all entries on a page before faxing to SCHARP.

Adverse Experience Log (AE Log)

- For the Adverse Experience Log form, do not wait until the AE resolves before faxing the form page to SCHARP.
- Always make changes, corrections, and updates to the originally-completed Adverse Experience Log form page. Once an AE Log form page has been started and faxed to SCHARP, the data from that page should never be transcribed onto another AE Log form page.

For item 1, note that planned procedures or surgeries are not AEs. For example, a tonsillectomy is not an AE; rather, it is a treatment that will be collected in item 7 of the form. Any adverse experiences associated with the planned procedure or surgery are AEs.

Safety Laboratory Results

- Depending on a site's normal reference ranges, it is possible that a participant can have a value that falls within the normal range, but is still gradable per the DAIDS Toxicity Table. Always refer to the DAIDS Toxicity Table when determining whether or not a lab value is gradable and should be reported as an AE.

14.6 Case Report Forms

This section contains each MTN-008 case report form developed for the study. Detailed form completion instructions for each form are provided on the back of each form page.

Refer to the Visit Checklist of a given visit for a suggested order in which the forms should be completed at that visit.

Sample

Note: Number pages sequentially (001, 002, 003) for each participant. **Page** ☐☐☐

MTN 008 (1[illegible]0) AE-1 (460)

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ☐

Site Number | Participant Number | Chk | Who

Adverse Experience Log

Date Reported to Site

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Adverse Experience (AE)

_____

Record diagnosis (in English) if available. Include anatomical location, if applicable.

2. Onset Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

3. Severity

- ☐ Grade 1 – Mild
- ☐ Grade 2 – Moderate
- ☐ Grade 3 – Severe
- ☐ Grade 4 – Potentially life-threatening
- ☐ Grade 5 – Death

4. Relationship to Study Product

- ☐ Related
- ☐ Not related
  Record rationale or alternative etiology in Comments.

5. Study Product Administration

- ☐ No change
- ☐ Held
- ☐ Permanently discontinued
- ☐ N/A *If study product completed or previously discontinued, mark N/A.*

6. Status/Outcome

- ☐ Continuing
- ☐ Resolved
- ☐ Death
- ☐ Severity/frequency increased
  Report as a new AE.
- ☐ Continuing at end of study participation

6a. **Status/Outcome Date**
Leave blank if Status/Outcome is "Continuing."

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

7. Treatment *Mark "None" or all that apply.*

- ☐ None
- ☐ Medication(s)
  Report on Concomitant Medications Log.
- ☐ New/Prolonged hospitalization
  Comment below.
- ☐ Procedure/Surgery
  Comment below.
- ☐ Other
  Comment below.

		yes	*no*
8.	Is this an SAE according to ICH guidelines?	☐	☐
9.	Has/will this AE be reported as an EAE?	☐	☐
10.	At which visit was this AE first reported? ..... ☐☐.☐ *Visit code required (regular or interim).*		
11.	Did this AE result in ICU admission greater than 24 hours?	☐	☐

Comments: _____

_____

_____

☐ ☐ ☐ ☒ 14-FEB-11

0 1
Language

Staff Initials / Date

Adverse Experience Log (AE-1)

Purpose: To document any Adverse Experience (AE) reported by the participant or clinically observed as defined by the protocol.

General Information/Instructions: 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. 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).

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.
- **Item 1:** 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."
- **Item 2:** 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.
- **Item 3:** To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *Addendum 1 (Female Genital Grading Table for Use in Microbicide Studies)*.
- **Item 4:** Mark the assessment of the relationship between the AE and the study agent. Mark "Related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "Not related" if there is not a reasonable possibility that the AE is related to the study agent. If "Not related," record an alternative etiology, diagnosis, or explanation in the "Comments" field. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
- **Item 5:**
  - ***No change***: Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation.
  - ***Held:*** Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark "Held" for the AE(s) that contributed to the product hold.
  - ***Permanently discontinued:*** Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, only mark "Permanently discontinued" for the AE that contributed to the permanent discontinuation.
  - ***N/A (not applicable):*** Mark if the AE occurred after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is Grade 5-death.
- **Item 6:**
  - ***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 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. Update EAE form if applicable. 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.
- **Item 6a:** 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.
- **Item 7:** Indicate if treatment was clinically indicated for the AE, regardless of whether the treatment was actually used. Also mark this item if the participant self-treated.
- **Items 8 and 9:** For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
- **Item 11:** If the AE being reported resulted in admission in an Intensive Care Unit (ICU) for more than 24 hours mark the "yes" box.

Sample

MTN 008 (180) CM-1 (423)

Note: Number pages sequentially (01, 02, 03) for each participant **Page** ☐☐

Participant ID

☐☐☐-☐☐☐☐-☐-☐

Site Number Participant Number Chk Who

Concomitant Medications Log

☐ **No medications taken at Screening/Enrollment.** Staff Initials/Date
→ ***Fax to SCHARP DataFax.***

☐ **No medications taken throughout study.** Staff Initials/Date
→ ***End of form. Fax to SCHARP DataFax.***

1.

Medication *(generic name)* | **Staff Initials/Log Entry Date**

Indication

Taken for a reported AE? ☐ *yes* ☐ *no*
→ ***Record AE Log page(s):*** ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

Date Started ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

Date Stopped ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* **OR** ☐ Continuing at end of study

Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____

Dose/Units

Route *Mark only one.* ☐ *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *other, specify:* _____

2.

Medication *(generic name)* | **Staff Initials/Log Entry Date**

Indication

Taken for a reported AE? ☐ *yes* ☐ *no*
→ ***Record AE Log page(s):*** ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

Date Started ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

Date Stopped ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* **OR** ☐ Continuing at end of study

Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____

Dose/Units

Route *Mark only one.* ☐ *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *other, specify:* _____

3.

Medication *(generic name)* | **Staff Initials/Log Entry Date**

Indication

Taken for a reported AE? ☐ *yes* ☐ *no*
→ ***Record AE Log page(s):*** ☐☐☐ ☐☐☐ ☐☐☐ ☐☐☐

Date Started ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

Date Stopped ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* **OR** ☐ Continuing at end of study

Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____

Dose/Units

Route *Mark only one.* ☐ *PO* ☐ *IM* ☐ *IV* ☐ *TOP* ☐ *IHL* ☐ *VAG* ☐ *REC* ☐ *other, specify:* _____

☐☐☐☒ 14-FEB-11

0 1 Language

Concomitant Medications Log (CM-1)

Purpose: All medication(s) that are used by the participant during the study including the protocol-defined screening period, other than study product, must be documented on this form. This includes, but is not limited to, prescription medications, non-prescription (i.e., over-the-counter) medications, preventive medications and treatments (e.g., allergy shots, flu shots, and other vaccinations), herbal preparations, vitamin supplements, naturopathic preparations, and recreational drugs.

General Information/Instructions: When to fax this form:

- once the participant has enrolled in the study;
- when pages have been updated or additional Log pages have been completed (only fax updated or new pages);
- when the participant has completed study participation; and/or
- when instructed by SCHARP.

Item-specific instructions:

- **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 at Screening/Enrollment:** Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01.
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study.
- **Medication:** For combination medications, record the first three main active ingredients.
- **Indication:** For health supplements, such as multivitamins, record "general health." For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). For recreational drugs, record "recreation."
- **Date Started:** If the participant is unable to recall the exact date, obtain participant's best estimate. At a minimum, the year is required.
- **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. At a minimum, the month and year are required.
- **Frequency:** Below is a list of common frequency abbreviations:

prn as needed	**qd** every day	**tid** three times daily	**qhs** at bedtime
once one time	**bid** twice daily	**qid** four times daily	

  - Use "other, specify" for alternate dosing schedules.

- **Route:** Below is a list of common route abbreviations:

PO oral	**IM** intramuscular	**IV** intravenous	**TOP** topical	**IHL** inhaled	**VAG** vaginal	**REC** rectal

- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon).

Sample

MTN 008 (100) DEM-1 (001)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Demographics

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

1. What is the participant's date of birth?..... [ ][ ] [ ][ ][ ] [ ][ ] → If unknown, record age: [ ][ ]

dd *MMM* *yy* *years*

male *female*

2. What is the participant's gender? ..... [ ] [X]

3. Does the participant consider herself to be Latina or of Hispanic origin? ..... *yes* [ ] *no* [ ]

4. What does the participant report as her race? *Mark all that apply.*

- [ ] 4a. American Indian or Alaskan Native
- [ ] 4b. Asian
- [ ] 4c. Black or African American
- [ ] 4d. Native Hawaiian or other Pacific Islander
- [ ] 4e. White
- [ ] 4f. other, specify: _____

*(**Note**: Latina is not a race.)*

Comments: _____

[ ][ ][ ][X] 14-FEB-11

[0][1] Language

_____ Staff Initials / Date

Demographics (DEM-1)

Purpose: This form is used to document maternal participant demographic information.

General Information/Instructions: This form is completed only once for each maternal study participant, at the Screening Visit.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant's estimate of their age. Do not complete both answers.
- **Item 2:** This item does not require a response. This item (gender) has been hard-coded as "female" for all study participants.
- **Item 4:** Record the participant's race based on self-definition. In the case of mixed race, mark all that apply and/or "other" and indicate the mixed race background.

Sample

MTN 008 (180) ESI-1 (489)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [ ]

Site Number | Participant Number | Chk | Who

End of Study Inventory

Form Completion Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

1. What is the **highest** visit code (scheduled or interim) for this participant, recorded on a form submitted via DataFax?..... *visit code* [ ][ ] . [ ]

2. How many interim visits were conducted for this participant during the study and recorded on a form submitted via DataFax?..... *# of interim visits* [ ][ ]

3. Indicate the **highest** page number submitted for this participant for each of the following forms:

		page #		*no pages submitted*
3a.	Adverse Experience Log (AE-1)	[ ][ ][ ]	**OR**	[ ]
3b.	Concomitant Medications Log (CM-1)	[ ][ ]		
3c.	Pre-existing Conditions (PRE-1)	[ ][ ]		
3d.	Product Hold/Discontinuation Log (PH-1)	[ ][ ]	**OR**	[ ]

Comments: _____

[ ][ ][ ][X] 14-FEB-11

[0][1] Language

_____ Staff Initials / Date

End of Study Inventory (ESI-1)

Purpose: This form is used to confirm that SCHARP has received all study data for a given participant.

General Information/Instructions: Complete this form once for each enrolled participant after the participant has terminated from the study (as documented by a Termination form). This form must be completed for both the maternal and infant participant.

Item-specific instructions:

- **Form Completion Date:** A complete date is required.
- **Item 1:** Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.
- **Item 2:** Record the total number of Interim Visit DataFax forms submitted for this participant. If no Interim Visit forms were submitted for the participant, record "00" in the boxes.
- **Item 3:** The forms listed in item 3 are specific to the PTID recorded on this form.
- **Item 3a:** Record the highest page number of the Adverse Experience Log submitted for this participant, even if that page was marked for deletion.

Sample

MTN 008 (100) ENR-1 (070)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [ ]

Site Number | Participant Number | Chk | Who

Enrollment

1. Date the informed consent form for enrollment was marked or signed: ..... dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

2. Is this a replacement participant? ..... *yes* ☐ *no* ☐ → ***If no, go to item 3.***

   2a. PTID of participant being replaced: ..... [ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [ ]
   Site Number | Participant Number | Chk | Who

3. This participant is enrolling into which study cohort?

   ☐ 3a. Mother Pregnancy Cohort Group 1 (37 $^{0}/_{7}$ – 39 $^{1}/_{7}$ weeks inclusive)

   ☐ 3b. Mother Pregnancy Cohort Group 2 (34 $^{0}/_{7}$ – 36 $^{6}/_{7}$ weeks inclusive)

   ☐ 3c. Mother Lactation Cohort

   ☐ 3d. Infant Pregnancy Cohort Group 1 (37 $^{0}/_{7}$ – 39 $^{1}/_{7}$ weeks inclusive)

   ☐ 3e. Infant Pregnancy Cohort Group 2 (34 $^{0}/_{7}$ – 36 $^{6}/_{7}$ weeks inclusive)

   ☐ 3f. Infant Lactation Cohort

   → ***If infant, end of form.***

4. Was the mother able and willing to provide written informed consent for specimen storage and future research? ..... *yes* ☐ *no* ☐ *not yet consented* ☐ → ***If no or not yet consented, go to item 5.***

   4a. Date the informed consent form for specimen storage and future research was marked or signed: ..... dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

5. Did the mother complete the CASI Baseline Behavioral and Acceptability Questionnaire? ..... *yes* ☐ *no* ☐ → ***If no, specify reason in Comments.***

6. ***For mothers assigned to Pregnancy Cohort only:***
   Was a clinic randomization envelope assigned? ..... ☐ ☐ → ***If no, specify reason in Comments. End of form.***

   6a. Clinic randomization envelope number: ..... [ ][ ][ ]

   6b. Date assigned: ..... dd [ ][ ] MMM [ ][ ][ ] yy [ ][ ]

   6c. Time assigned: ..... hr [ ][ ] : min [ ][ ] *24-hr clock*

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

Language: 0 1

Staff Initials / Date

Enrollment (ENR-1)

Purpose: This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants determined to be eligible for the study.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant is enrolled [that is, she is provides informed consent (Lactation Cohort) and is assigned a clinic randomization envelope (Pregnancy Cohort)], and only after completion of the Enrollment Visit.

Note: *There is no visit code field on this form since this form is only completed at the Enrollment Visit.*

Item-specific Instructions:

- **Item 1:** If the participant marks the informed consent using her thumbprint, record the date the thumbprint was made.
- **Item 4:** Mark the "yes" box only if the participant gave consent to have her and her infant's lab specimens stored for future research testing. Mark the "not yet consented" box if the participant is not asked for informed consent for specimen storage at enrollment (rather, it is deferred to a later visit). When the participant is asked to provide informed consent for specimen storage, update the response to item 1 and initial, date, and refax the form to SCHARP.
- **Item 5:** Completion of the CASI Baseline Behavioral and Acceptability Questionnaire is required for all maternal participants at the Enrollment Visit. If the required questionnaire was not done, specify the reason on the Comments line.
- **Item 6:** For Pregnancy Cohort only. If a clinic randomization envelope was not assigned to a mother in the Pregnancy Cohort, mark the "no" box and specify the reason on the Comments line, then end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax if a clinic randomization envelope was not assigned to a mother in the Pregnancy Cohort.
- **Item 6a:** Record the 3-digit clinic randomization envelope number present on the clinic randomization envelope assigned to this participant.
- **Item 6b:** Record the date the clinic randomization envelope was assigned to the participant. This date should match the "date assigned" recorded for this envelope on the MTN-008 Clinic Randomization Envelope Tracking Record.
- **Item 6c:** Record the time (using a 24-hour clock) the clinic randomization envelope was assigned to the participant. This time should match the "time assigned" recorded for this envelope on the MTN-008 Clinic Randomization Envelope Tracking Record.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [1]

Site Number | Participant Number | Chk | Who

Enrollment Eligibility—Lactation Cohort: Infant

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

		yes	*no*	
1.	Did mother consent for participation of both self **and infant** in Lactation Cohort?	☐	☐	
2.	Is the infant in general good health, as determined by clinical judgment of IoR/designee?	☐	☐	
3.	Is the infant between the ages of 4 and 26 weeks (inclusive) at Screening and Enrollment (Day 0)?	☐	☐	***If no, participant is ineligible.***
4.	At screening or enrollment (Day 0), does the infant have any social or medical condition that, in the investigator's opinion, would make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?	*yes* ☐	*no* ☐	***If yes, participant is ineligible.***

☐ ☐ ☐ ☒ 14-FEB-11

[0][1] Language

Staff Initials / Date

Enrollment Eligibility—Lactation Cohort: Infant (non-DataFax) - Page 1 of 1

Purpose: This form is used to document the infant participant's eligibility for the Lactation Cohort. This form is completed based on review of all clinical documentation from the participant's Screening and Enrollment Visits in addition to other protocol-specified inclusion and exclusion criteria.

General Information/Instructions: Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Sample **Not a DataFax form. Do not fax to DataFax.**

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Enrollment Eligibility—Lactation Cohort: Mother

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

		yes	*no*
1.	Is the participant age 18 through 40 years (inclusive) at screening?	☐	☐
2.	Is the participant willing and able to provide written informed consent to be screened for and take part in the study?	☐	☐
3.	Is the participant willing and able to provide adequate locator information, as defined in site SOP?	☐	☐
4.	Is the participant willing and able to communicate in written and spoken English?	☐	☐
5.	Is the participant HIV-uninfected (per HIV Testing Algorithm, Appendix II)?	☐	☐
6.	Is the participant currently primarily breastfeeding a single healthy infant between the ages of 4 and 26 weeks (inclusive) according to guidelines specified in the *MTN-008 SSP Manual*?	☐	☐
7.	Is the participant intending to breastfeed during the period of anticipated study participation?	☐	☐
8.	Is the participant using an effective method of contraception at enrollment (Day 0), and intending to use an effective method for the duration of scheduled study participation; effective methods include hormonal methods, abstinence, male condoms, intrauterine device, and sterilization (of participant or her sexual partner or partners, as applicable and with verification as defined in site SOPs)?	☐	☐
9.	Does the participant have a Pap result consistent with Grade 0 according the Female Genital Grading Table for Use in Microbicide Studies or satisfactory evaluation of a non-Grade 0 Pap result, per clinical judgment of Site Investigator or Record (IoR)/designee) within the 12 calendar months prior to Enrollment (Day 0)?	☐	☐
10.	Is the participant willing to abstain from the following during study participation?		
10a.	non-prescribed intravaginal products and practices (including douching and sex toys)	☐	☐
10b.	other investigational agent or device study	☐	☐ → ***If no, participant is ineligible.***

		yes	*no*
11.	Was the participant enrolled in the Pregnancy Cohort?	☐	☐
12.	Is the infant excluded from participation in the MTN 008 Lacatation Cohort?	☐	☐
13.	Does the participant report of any of the following?		
13a.	history of adverse reaction to any component of tenofovir 1% gel	☐	☐
13b.	enrollment in any other investigational drug or device trial within 30 days prior to the Enrollment Visit (Day 0)	☐	☐
13c.	within 48 hours prior to Screening or Enrollment (Day 0), use of vaginal medication(s) (participant may return to complete study procedures after 48 hours have passed since use of vaginal medication)	☐	☐
13d.	within 7 days prior to Screening or Enrollment (Day 0), more than two infant feedings in a single day with nutrition other than own breast milk (e.g., formula, solids)	☐	☐ → ***If yes, participant is ineligible.***

[ ][ ][ ][X] 14-FEB-11

[0][1] Language

Staff Initials / Date

Enrollment Eligibility—Lactation Cohort: Mother (non-DataFax) - Page 1 of 2

Purpose: This form is used to document the maternal participant's eligibility for the Lactation Cohort. This form is completed based on review of all clinical and lab test results documentation from the participant's Screening and Enrollment Visits in addition to other protocol-specified inclusion and exclusion criteria.

General Information/Instructions: Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (1.00)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Enrollment Eligibility—Lactation Cohort: Mother

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

	yes	*no*
14. Does the participant, at the time of Enrollment (Day 0), report or have clinical evidence according to the judgment of the IoR/designee of any of the following conditions?		
14a. insufficient milk supply	☐	☐
14b. mastitis	☐	☐
15. As determined by the IoR/designee, does the participant have any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease?	☐	☐
16. Does the participant have any of the following laboratory results?		
16a. positive urine pregnancy test	☐	☐
16b. serum creatinine at screening greater than 1.0 mg/dL	☐	☐
16c. AST and/or ALT at screening greater than 1.5 ULN (upper limit of normal)	☐	☐
16d. Hepatitis B surface antigen (HBsAg) positivity at screening	☐	☐
17. By participant report or review of medical record, in the past 8 weeks prior to Day 0, does the participant have a diagnosis of sexually transmitted infection, including chlamydia, gonorrhea, and/or trichomoniasis?	☐	☐
18. At the time of Enrollment (Day 0), does the participant have a diagnosis of symptomatic vaginitis, including bacterial vaginosis and vulvovaginal candidiasis (asymptomatic evidence of bacterial vaginosis and/or yeast is not exclusionary)?	☐	☐
19. At Screening and Enrollment (Day 0) , on pelvic exam does the participant have…	☐	☐
19a. incomplete postpartum involution of the uterus?	☐	☐
19b. a clinically apparent Grade 2 or higher pelvic exam finding?	☐	☐
20. At screening or within 7 days of enrollment (Day 0), has the participant used oral and/or vaginal preparations of antibiotic or antifungal medications?	☐	☐
21. At Screening or Enrollment (Day 0), does the participant have any social or medical condition that, in the investigator's opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?	☐	☐

If yes, participant is ineligible.

[ ][ ][ ][X] 14-FEB-11

[0][1] Language

Staff Initials / Date

Enrollment Eligibility—Lactation Cohort: Mother (non-DataFax) - Page 2 of 2

No additional instructions.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (1.00)

Participant ID

Site Number - Participant Number - Chk - Who (0)

Enrollment Eligibility—Pregnancy Cohort

Visit Date dd MMM yy

		yes	no	
1.	Is the participant age 18 through 40 years (inclusive) at screening?	☐	☐	
2.	Is the participant willing and able to provide written informed consent to be screened for and take part in the study, including participation of the infant after delivery?	☐	☐	
3.	Is the participant willing and able to provide adequate locator information, as defined in site SOP?	☐	☐	
4.	Is the participant willing and able to communicate in written and spoken English?	☐	☐	
5.	Is the participant HIV-uninfected (per HIV Testing Algorithm, Appendix II)?	☐	☐	
6.	Is the participant currently pregnant with the following characteristics?			
6a.	viable	☐	☐	
6b.	singleton	☐	☐	***If no, participant is ineligible.***

		yes	no	N/A	
7.	Is the gestational age consistent with the following guidelines?				
7a.	for Pregnancy Cohort Group 1, between 37 0/7 and 39 1/7 weeks (inclusive) at the Enrollment Visit (Day 0)	☐	☐	☐	
7b.	for Pregnancy Cohort Group 2, between 34 0/7 and 36 6/7 weeks (inclusive) at the Enrollment Visit (Day 0)	☐	☐	☐	***If no, participant is ineligible.***

		yes	no	
8.	Does the participant have a Pap test result consistent with Grade 0 according to the *Female Genital Grading Table for Use in Microbicide Studies* or satisfactory evaluation of a non-Grade 0 Pap result, per clinical judgment of Site Investigator or Record (IoR)/designee) within the 12 calendar months prior to enrollment?	☐	☐	
9.	Is the participant willing to abstain from the following during study participation?			
9a.	non-prescribed intravaginal products and practices (including douching and sex toys)	☐	☐	
9b.	other investigational agent or device study	☐	☐	***If no, participant is ineligible.***

		yes	no	
10.	Does the participant report of any of the following?			
10a.	history of adverse reaction to any component of tenofovir 1% gel	☐	☐	
10b.	enrollment in any other investigational drug or device trial within 30 days prior to the Enrollment Visit (Day 0)	☐	☐	
10c.	currently breastfeeding	☐	☐	
10d.	within 48 hours prior to Screening or Enrollment (Day 0), use of vaginal medications (participant may return to complete study procedures after 48 hours have passed since use of vaginal medication)	☐	☐	***If yes, participant is ineligible.***

☐ ☐ ☐ ☒ 14-FEB-11

0 1 Language

Staff Initials / Date

Enrollment Eligibility—Pregnancy Cohort (non-DataFax) - Page 1 of 2

Purpose: This form is used to document the maternal participant's eligibility for the Pregnancy Cohort. This form is completed based on review of all clinical and lab test results documentation from the participant's Screening and Enrollment Visits in addition to other protocol-specified inclusion and exclusion criteria.

General Information/Instructions: Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (1.00)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Enrollment Eligibility—Pregnancy Cohort

Visit Date

[ ][ ] dd [ ][ ][ ] MMM [ ][ ] yy

11. Is the participant documented to have any of the following during the current pregnancy?

		yes	no
11a.	ultrasound evidence of significant fetal congenital anomaly (in the opinion of the IoR or designee)	☐	☐
11b.	known rupture of the amniotic membranes	☐	☐
11c.	known placental/fetal abnormalities that could affect placental transfer (e.g., placental abruption, placenta previa, placenta accreta, intrauterine growth restriction, two-vessel cord, etc.)	☐	☐
11d.	known maternal disease with predictable negative effect on placental function (e.g., hypertension, diabetes mellitus, collagen vascular disease)	☐	☐

If yes, participant is ineligible.

12. Does the participant have any of the following laboratory abnormalities noted at screening?

		yes	no
12a.	hemoglobin value of Grade 3 or higher according to *DAIDS Toxicity Table*	☐	☐
12b.	serum creatinine greater than 1.0 mg/deciliter (dL)	☐	☐
12c.	AST and/or ALT greater than 1.5 ULN (upper limit of normal)	☐	☐
12d.	Hepatitis B surface antigen (HBsAg) positivity	☐	☐

If yes, participant is ineligible.

		yes	no
13.	By participant report or review of medical record, in the past 8 weeks prior to enrollment (Day 0), does the participant have a diagnosis of sexually transmitted infection, including chlamydia, gonorrhea, and/or trichomoniasis?	☐	☐
14.	At the time of enrollment (Day 0), does the participant have a diagnosis of symptomatic vaginitis, including bacterial vaginosis and vulvovaginal candidiasis (asymptomatic evidence of bacterial vaginosis and/or yeast is not exclusionary)?	☐	☐
15.	At enrollment (Day 0) , does the participant have a clinically apparent Grade 2 or higher pelvic exam finding?	☐	☐
16.	At screening or within 7 days of enrollment (Day 0), has the participant used oral and/or vaginal preparations of antibiotic or antifungal medications?	☐	☐
17.	At screening or enrollment (Day 0), does the participant have any social or medical condition that, in the investigator's opinion, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives?	☐	☐

If yes, participant is ineligible.

Enrollment Eligibility—Pregnancy Cohort (non-DataFax) - Page 2 of 2

No additional instructions.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (100) FR-1 (250)

Participant ID

☐☐☐-☐☐☐☐-☐-1

Site Number | Participant Number | Chk | Who

Feeding Record

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Infant Feeding #1

Not done ☐

	breast	*formula*	*24-hour clock hr*	*min*
1. Method of feeding:	☐	☐		
2. Start time:			☐☐ :	☐☐
3. End time:			☐☐ :	☐☐

Infant Feeding #2

Not done ☐

	breast	*formula*	*24-hour clock hr*	*min*
4. Method of feeding:	☐	☐		
5. Start time:			☐☐ :	☐☐
6. End time:			☐☐ :	☐☐

Infant Feeding #3

Not done ☐

	breast	*formula*	*24-hour clock hr*	*min*
7. Method of feeding:	☐	☐		
8. Start time:			☐☐ :	☐☐
9. End time:			☐☐ :	☐☐

Infant Feeding #4

Not done ☐

	breast	*formula*	*24-hour clock hr*	*min*
10. Method of feeding:	☐	☐		
11. Start time:			☐☐ :	☐☐
12. End time:			☐☐ :	☐☐

Infant Feeding #5

Not done ☐

	breast	*formula*	*24-hour clock hr*	*min*
13. Method of feeding:	☐	☐		
14. Start time:			☐☐ :	☐☐
15. End time:			☐☐ :	☐☐

Infant Feeding #6

Not done ☐

	breast	*formula*	*24-hour clock hr*	*min*
16. Method of feeding:	☐	☐		
17. Start time:			☐☐ :	☐☐
18. End time:			☐☐ :	☐☐

Comments: _____

☐☐☐☒ 14-FEB-11

01 Language

Staff Initials / Date

Feeding Record (FR-1)

Purpose: This form is used to document infant feedings between maternal dosing and the 6-hour post-dose infant specimen collection for pharmacokinetics testing.

General Information/Instructions: This form is only completed for maternal participants in the Lactation Cohort. This form is completed at the Enrollment Visit (Day 0) and the Day 6 Visit.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Items 1, 4, 7, 10, 13, 16:** Mark the appropriate response box to document if infant feeding was given using breast milk or formula.
- **Items 2–18:** Record the method, start time, and end time for each feeding done between the maternal dosing and when the 6 hour post-dose infant specimen is drawn. The form includes space to record up to 6 feedings, if less than 6 feedings are done, mark the "not done" box accordingly. When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12).

Sample

Visit Code ☐☐.☐ 1

MTN 008 (180) FC-1 (064)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

Flow Cytometry

Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Specimen Collection Time

hr *min*

☐☐:☐☐ *24-hour clock*

Not done/ Not collected ☐

1. FLOW CYTOMETRY

		%	Absolute Count		MFI	
1a.	Lymphocyte		☐☐☐☐ *cells/mm³*			
1b.	CD3 (CD3/CD4)	☐☐	**AND** ☐☐☐☐ *cells/mm³*			
1c.	CD4 (CD3/CD4)	☐☐	**AND** ☐☐☐☐ *cells/mm³*			
1d.	CD38 (CD3/CD4/CD38).....	☐☐	**AND** ☐☐☐☐ *cells/mm³*	**AND**	☐☐☐☐☐☐	
1e.	HLA-DR (CD3/CD4/HLA-DR)	☐☐	**AND** ☐☐☐☐ *cells/mm³*	**AND**	☐☐☐☐☐☐	
1f.	Dual Positive ..... (CD3/CD4/CD38/HLA-DR)	☐☐	**AND** ☐☐☐☐ *cells/mm³*			

AND *MFI: x-axis (HLA-DR)* ☐☐☐☐☐☐ *MFI: y-axis (CD38)* ☐☐☐☐☐☐

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

0 1
Language

Staff Initials / Date

Flow Cytometry (FC-1)

Purpose: This form is used to document maternal flow cytometry laboratory results.

Item-specific Instructions:

- **Visit Code**: Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Specimen Collection Time:** When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12).
- **Not done/Not collected:** Mark this box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Specify the reason on the Comments lines.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (180) FV-1 (121)

Participant ID

☐☐☐-☐☐☐☐-☐-☐

Site Number Participant Number Chk Who

Follow-up Visit

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Which follow-up study visit/phone call is being completed?

- ☐ Day 1 phone call
- ☐ Day 3 phone call
- ☐ Day 6 visit
- ☐ Day 14 phone call
- ☐ Delivery visit ***(Pregnancy Cohort only)***
- ☐ Post-delivery Assessment ***(Pregnancy Cohort only)***

2. Were any **new** adverse experiences reported for this PTID during this follow-up visit/phone call?..... *yes* ☐ *no* ☐ → ***If no, go to item 3.***

2a. How many **new** AE Log pages were completed for this PTID for this visit?..... ☐☐ *# of pages*

ITEMS 3 AND 4 FOR MATERNAL PARTICIPANTS ONLY

3. Did the mother complete the CASI Follow-up Acceptability and Adherence Questionnaire at this visit? ..... *yes* ☐ *no* ☐ *not required* ☐ → ***If no or not required, go to item 4.***

3a. Date the CASI Follow-up Acceptability and Adherence Questionnaire was completed: ..... ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

4. Did the mother complete the CASI Gel Use Experiences Questionnaire? ..... *yes* ☐ *no* ☐ *not required* ☐ → ***If no or not required, end of form.***

4a. Date the CASI Gel Use Experiences Questionnaire was completed: ..... ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

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Language

_____
Staff Initials / Date

Follow-up Visit (FV-1)

Purpose: This form is used to document completion of all required follow-up visits and phone calls for maternal and infant study participants.

General Information/Instructions: This form is completed for each maternal and infant study participant, at the Day 1 Phone Call, the Day 3 Phone Call, the Day 6 Visit, the Day 14 Phone Call, the Delivery Visit (Pregnancy Cohort only), and the Post-delivery Assessment (Pregnancy Cohort only).

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Items 3 and 4:** For maternal participants only. Completion of the CASI Follow-up Behavioral and Acceptability Questionnaire and the CASI Gel Use Experiences Questionnaire are required for all maternal participants at the Day 6 Visit. If the required questionnaire was not done, specify the reason on the Comments line.
- **Item 4a:** This is the date the participant completed the questionnaire, not the date the responses were entered into the computer.

Sample
MTN 008 (180)

Not a DataFax form. Do not fax to DataFax.

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 1

Site Number Participant Number Chk Who

Infant Medical History Log

Page ☐☐☐

Medical Condition	**Onset Date** (dd-MMM-yy)	**Staff Initials/Log Entry Date**
	Resolve Date (dd-MMM-yy)	
Comments		

Medical Condition	**Onset Date** (dd-MMM-yy)	**Staff Initials/Log Entry Date**
	Resolve Date (dd-MMM-yy)	
Comments		

Medical Condition	**Onset Date** (dd-MMM-yy)	**Staff Initials/Log Entry Date**
	Resolve Date (dd-MMM-yy)	
Comments		

Medical Condition	**Onset Date** (dd-MMM-yy)	**Staff Initials/Log Entry Date**
	Resolve Date (dd-MMM-yy)	
Comments		

☐ ☐ ☐ ☒ 14-FEB-11

0 1
Language

Staff Initials / Date

Infant Medical History Log (non-DataFax) – Page 1 of 1

Purpose: This form is used to document and track all medical conditions experienced by the infant participant at screening and while on-study. This includes diagnosed medical conditions as well as participant self (guardian/mother)-reported symptoms.

General Information/Instructions: Review this log at every visit. If a condition has no Resolve Date listed, assess the status of that condition at the visit. This form is a non-DataFax form. Do not fax to SCHARP DataFax.

Item-specific Instructions:

- **Page:** This is a log form. Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers.
- **Medical Condition:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms.
- **Onset Date:** At a minimum, month and year are required.
- **Staff Initials/Log Entry Date:** Enter the staff initials and date of the staff member who records the onset date.
- **Resolve Date:** At a minimum, month and year are required. Record one of the following, as appropriate:
  - the date on which the participant no longer experiences the medical condition,
  - the date of the study visit or specimen collection at which the change in status/resolution is first noted,

  or

  - if condition is continuing at end of study, record “CES” in the space provided.

Sample

Visit Code . 1

MTN 008 (1[illegible]) PKI-1 (062)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [1]

Site Number | Participant Number | Chk | Who

Infant Pharmacokinetics

Specimen Collection Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

1. Participant length: ..... [ ][ ][ ] *cm*
2. Participant weight: ..... [ ][ ][ ] *kg*

INFANT BLOOD COLLECTION (PREGNANCY COHORT)

Not done/ Not collected		*24-hour clock* hr	min
☐	3. Delivery Visit cord blood	[ ][ ] :	[ ][ ]
☐	4. Delivery Visit blood	[ ][ ] :	[ ][ ]

INFANT BLOOD COLLECTION (LACTATION COHORT)

Not done/ Not collected		*24-hour clock* hr	min
☐	5. 6-hour post-gel maternal dosing blood	[ ][ ] :	[ ][ ]

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

[0][1] Language

_____ Staff Initials / Date

Infant Pharmacokinetics (PKI-1)

Purpose: This form is used to document infant pharmacokinetics and stored specimen collection.

General Information/Instructions: This form is completed for each infant study participant, at the Enrollment Visit (Day 0) (Lactation Cohort only), the Day 6 Visit (Lactation Cohort only), and the Delivery Visit (Pregnancy Cohort only).

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Items 1 and 2:** Use leading zeros when needed.
- **Item 4:** Infant blood is only collected when cord blood cannot be collected.
- **Items 3–5:** If any of the specimens listed in items 3–5 were not collected, mark the "Not done/Not collected" box and specify the reason on the Comments line. When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12).

  ***Note**: Items 3 and 4 are only completed for infants in the Pregnancy Cohort. Item 5 is only completed for infants in the Lactation Cohort.*

Sample

Participant ID ☐☐☐-☐☐☐☐-☐-1

Site Number | Participant Number | Chk | Who

Visit Code ☐☐.☐

PK SPECIMEN TIME	PRIMARY SPECIMEN TYPE	DATE COLLECTED dd-MMM-yy	TIME COLLECTED hh:mm	NUMBER OF TUBES COLLECTED	INSTRUCTIONS FOR PROCESSING LAB
INFANT BLOOD COLLECTION (PREGNANCY COHORT)					
Delivery Visit	Infant Cord Blood **(CRD)**			☐ **Non** (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
Delivery Visit	Infant Blood **(BLD)**			☐ **Non** (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
INFANT BLOOD COLLECTION (LACTATION COHORT)					
6 hour post maternal dosing	Infant Blood **(BLD)**			☐ **Non** (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER

Comments: _____

Initials: _____ (Sending Staff) _____ (Receiving Staff) **LDMS Data Entry Date:** ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy* / _____ LDMS Staff

Infant PK - LDMS Specimen Tracking Sheet (nonDataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN-008 infant PK blood specimens into the Laboratory Data Management System (LDMS).

General Information/Instructions: A copy of this form accompanies infant PK blood specimens (in their original specimen collection containers) to the LDMS entry laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS entry laboratory. If the site chooses, a copy of this completed form may be made once the specimens have been entered into LDMS and the copy kept in the participant's study notebook. This is not required, however. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the LMDS specimens were collected.
- **NUMBER OF TUBES COLLECTED**: In the box to the left of each additive type, record the total number of tubes collected. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials - Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date - LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

Sample

MTN 008 (350) IV-1 (350)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐-☐-☐

Site Number Participant Number Chk Who

Interim Visit

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. What is the reason for this interim visit? *Mark all that apply.*

- ☐ 1a. in-person visit to report new symptoms → ***Complete Adverse Experience Log, if applicable.***
- ☐ 1b. phone call from participant to report new symptoms → ***Complete Adverse Experience Log, if applicable.***
- ☐ 1c. follow-up of symptoms and/or AE(s) → ***Update Adverse Experience Log, if applicable.***
- ☐ 1d. participant needs study product
- ☐ 1e. participant is returning unused study product
- ☐ 1f. report pregnancy outcomes → ***Complete Pregnancy Outcome form.***
- ☐ 1g. other, specify: _____

2. Besides this Interim Visit form, what other DataFax forms were completed at this visit? *Mark "none" or all that apply.*

- ☐ 2a. none → ***End of form.***
- ☐ 2b. Pelvic Exam
- ☐ 2c. Pelvic Laboratory Results
- ☐ 2d. Safety Laboratory Results
- ☐ 2e. STI Laboratory Results
- ☐ 2f. Infant Pharmacokinetics
- ☐ 2g. Participant Evaluability and Replacement
- ☐ 2h. Adverse Experience Log (new) → 2h1. How many **new** AE Log pages were completed for this visit? *# of pages* ☐☐
- ☐ 2i. Product Hold/Discontinuation Log (new) → 2i1. How many **new** PH Log pages were completed for this visit? ☐☐
- ☐ 2j. Pregnancy Outcome
- ☐ 2k. Study Product Returns
- ☐ 2l. other, specify: _____

Comments: _____

_____

_____

☐☐☐☒ 14-FEB-11

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Language

_____
Staff Initials / Date

Interim Visit (IV-1)

Purpose: Complete this form when an Interim Visit occurs during study follow-up for maternal and infant participants.

General Information/Instructions: Any other forms completed for this visit must have the same Visit Code as this Interim Visit form.

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:
  - Record the visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was the Day 1 Phone Call (Visit Code = 03.0), record "03" to the left of the decimal point in the visit code field.
  - Record the number that corresponds to the Interim Visit in the second box (the box to the right of the decimal point):

    XX.1 = First Interim Visit after the most recent scheduled regular visit.

    XX.2 = Second Interim Visit after the most recent scheduled regular visit.

Item-specific instructions:

- **Item 1d:** If participant received additional study product, record the amount of study product dispensed on the Comments line.
- **Item 1e:** If participant returned unused study product, record the amount of unused study product that was returned on the Comments line. Also complete a Study Product Returns form.
- **Item 2:** Note that marking a box other than "none" indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.
  - **Item 2a:** Mark the "none" box if the Interim Visit form is the **only** DataFax form completed for this visit.
  - **Item 2h:** Mark this box if a new (previously unreported) AE is reported or observed at this visit. If the box to the left of "Adverse Experience Log (new)" is marked, record how many **new** AE Log pages were completed for this visit in item 2h1. For example, if two new AEs were reported, record "02." Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
  - **Item 2i:** Mark this box if a new (previously unreported) product hold/discontinuation is reported at this visit. If the box to the left of "Product Hold/Discontinuation Log (new)" is marked, record how many **new** PH Log pages were completed for this visit in item 2i1. For example, if two new product holds were reported, record "02." Note that the Visit Code recorded in item 1 of these two PH Log pages should be the same as the Visit Code recorded on this form.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (180) PKM-1 (061)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number Participant Number Chk Who

Maternal Pharmacokinetics

Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Participant height: ..... ☐☐☐ *cm*
2. Participant weight: ..... ☐☐☐ *kg*

MATERNAL BLOOD COLLECTION AND GEL ADMINISTRATION—PREGNANCY AND LACTATION COHORTS

Not done/ Not collected			*serum*	*PBMC*	*24-hour clock* *hr*	*min*
☐	3.	Pre-gel blood draw	☐	☐	☐☐ :	☐☐
☐	4.	Gel administration.....			☐☐ :	☐☐
			serum	*PBMC*	*hr*	*min*
☐	5.	1-hour post-gel blood draw.....	☐	☐	☐☐ :	☐☐
☐	6.	2-hour post-gel blood draw.....	☐	☐	☐☐ :	☐☐
☐	7.	4-hour post-gel blood draw.....	☐	☐	☐☐ :	☐☐
☐	8.	6-hour post-gel blood draw.....	☐	☐	☐☐ :	☐☐
☐	9.	8-hour post-gel blood draw.....	☐	☐	☐☐ :	☐☐

MATERNAL BLOOD COLLECTION—PREGNANCY COHORT

Not done/ Not collected			*serum*	*PBMC*	*24-hour clock* *hr*	*min*
☐	10.	Blood collection at delivery visit	☐	☐	☐☐ :	☐☐

MATERNAL BREAST MILK AND GEL ADMINISTRATION—LACTATION COHORT

Not done/ Not collected			*24-hour clock* *hr*	*min*
☐	11.	Pre-gel milk specimen	☐☐ :	☐☐
☐	12.	Gel administration.....	☐☐ :	☐☐
☐	13.	2-hour post-gel milk specimen	☐☐ :	☐☐
☐	14.	4-hour post-gel milk specimen	☐☐ :	☐☐
☐	15.	6-hour post-gel milk specimen	☐☐ :	☐☐

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

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Language

Staff Initials / Date

Maternal Pharmacokinetics (PKM-1)

Purpose: This form is used to document maternal pharmacokinetics and stored specimen collection as well as study gel administration information.

General Information/Instructions: This form is completed for each maternal study participant, at the Enrollment Visit (Day 0), the Day 6 Visit, and the Delivery Visit (Pregnancy Cohort only).

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Items 1 and 2:** Use leading zeros when needed.
- **Items 3–15:** If any of the specimens/procedures listed in items 3–15 were not collected or performed, mark the "Not done/Not collected" box and specify the reason on the Comments line. For items 3 and 5–10, mark the corresponding box to indicate that serum and/or PBMCs were **stored**. When recording time, use a 24-hour clock (e.g., 8:12 p.m. is recorded as 20:12).

  ***Note**: Item 10 is only completed for mothers in the Pregnancy Cohort. Items 11–15 are only completed for mothers in the Lactation Cohort.*

MTN-008 Maternal PK- LDMS Specimen Tracking Sheet

Sample

*For login of **maternal** MTN-008 stored specimens into LDMS*

Participant ID ☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

Visit Code ☐☐.☐

Specimen Collection Date ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

MATERNAL PK BLOOD COLLECTION (PREGNANCY AND LACTATION COHORTS)

PK SPECIMEN TIME	PRIMARY SPECIMEN TYPE	TIME COLLECTED hh:mm *24-hr clock*	NUMBER OF TUBES COLLECTED	INSTRUCTIONS FOR PROCESSING LAB
Pre-gel	Maternal Blood **(BLD) Tenofovir Level**		☐ **Non** (red top)	Process within eight hours of collection. Freeze immediately after centrifugation. Store with derivative SER
	Maternal Blood **(BLD) PBMC**		☐ **CPS** (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
1 Hour	Maternal Blood **(BLD) Tenofovir Level**		☐ **Non** (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood **(BLD) PBMC**		☐ **CPS** (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
2 Hour	Maternal Blood **(BLD) Tenofovir Level**		☐ **Non** (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood **(BLD) PBMC**		☐ **CPS** (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
4 Hour	Maternal Blood **(BLD) Tenofovir Level**		☐ **Non** (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood **(BLD) PBMC**		☐ **CPS** (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.

MTN-008 Maternal PK- LDMS Specimen Tracking Sheet

*For login of **maternal** MTN-008 stored specimens into LDMS*

Participant ID ☐☐☐-☐☐☐☐-☐-0
Site Number | Participant Number | Chk | Who

Visit Code ☐☐.☐

Specimen Collection Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

6 Hour	Maternal Blood **(BLD) Tenofovir Level**		☐ **Non** (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood **(BLD) PBMC**		☐ **CPS** (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
8 Hour	Maternal Blood **(BLD) Tenofovir Level**		☐ **Non** (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood **(BLD) PBMC**		☐ **CPS** (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
Delivery visit	Maternal Blood **(BLD) Tenofovir Level**		☐ **Non** (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Maternal Blood **(BLD) PBMC**		☐ **CPS** (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.

MATERNAL PK BREAST MILK COLLECTION (LACTATION COHORT)

PK SPECIMEN TIME POINT	PRIMARY SPECIMEN TYPE	TIME COLLECTED hh:mm *24-hr clock*	NUMBER OF TUBES COLLECTED	INSTRUCTIONS FOR PROCESSING LAB
Pre-gel	Breast milk **(BMK)**		☐ Non (cryovial)	Freeze immediately. Store with derivative BMK.
2 Hour	Breast milk **(BMK)**		☐ Non (cryovial)	Freeze immediately. Store with derivative BMK.
4 Hour	Breast milk **(BMK)**		☐ Non (cryovial)	Freeze immediately. Store with derivative BMK.
6 Hour	Breast milk **(BMK)**		☐ Non (cryovial)	Freeze immediately. Store with derivative BMK.

MTN-008 Maternal PK- LDMS Specimen Tracking Sheet

Sample

*For login of **maternal** MTN-008 stored specimens into LDMS*

Participant ID ☐☐☐-☐☐☐☐-☐-0
Site Number | Participant Number | Chk | Who

Visit Code ☐☐.☐

Specimen Collection Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

ALL OTHER MATERNAL SPECIMENS

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADDITIVE/ DERIVATIVE	NOTES FOR LAB
☐	Blood **(BLD)** *Plasma* **Collection Time:** __ __: __ __ *hour : min*	**EDT** (purple top)	**PLA**	**N/A**	Store in aliquots of 1-2 ml. If held at room temperature, plasma must be frozen within 4 hours of collection. If refrigerated or on ice, plasma must be frozen within 8 hours of collection.
☐	Endo-cervical Swab (**CXS**) **Collection Time:** __ __: __ __ *hour : min*	**PBS** (Phosphate buffered saline)	**CXS**	**N/A**	Place swab in crovial with PBS. Freeze within 8 hours of collection.
☐	Vaginal Swab (**VAG**) **Collection Time:** __ __: __ __ *hour : min*	**PBS** (Phosphate buffered saline)	**VAG**	**N/A**	Place swab in crovial with PBS. Freeze within 8 hours of collection.
☐	Vaginal Gram Stain Slide **(VAG)**	**NON** (no additive)	**SLD**	**GRS**	Re-label with LDMS label. Store duplicate slides (one for on-site storage, and one for shipping and testing at MTN Network Lab).

Comments: _____

Initials: _____ (Sending Staff) _____ (Receiving Staff) **LDMS Data Entry Date:** ☐☐ ☐☐☐ ☐☐ / _____
dd *MMM* *yy* LDMS Staff

MTN-008 Maternal PK- LDMS Specimen Tracking Sheet

*For login of **maternal** MTN-008 stored specimens into LDMS*

Maternal PK - LDMS Specimen Tracking Sheet (nonDataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN-008 maternal PK blood and breast milk specimens into the Laboratory Data Management System (LDMS).

General Information/Instructions: A copy of this form accompanies maternal PK blood and breast milk specimens (in their original specimen collection containers) to the LDMS entry laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS entry laboratory. If the site chooses, a copy of this completed form may be made once the specimens have been entered into LDMS and the copy kept in the participant's study notebook. This is not required, however. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the LMDS specimens were collected.
- **NUMBER OF TUBES COLLECTED**: In the box to the left of each additive type, record the total number of tubes collected. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials - Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date - LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

Sample

Visit Code [ ][ ].[0] [1]

MTN 008 (180) MV-1 (463)

Participant ID

[ ][ ][ ]-[ ][ ][ ][ ]-[ ]-[ ]

Site Number Participant Number Chk Who

Missed Visit

Form Completion Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

dd *MMM* *yy*

1. Target Visit Date: [ ][ ] [ ][ ][ ] [ ][ ]

Comments: _____

_____

_____

_____

[ ][ ][ ][X] 14-FEB-11

[0][1]
Language

_____
Staff Initials / Date

Missed Visit (MV-1)

Purpose: Complete this form whenever a maternal or infant participant misses a required visit according to the visit window outlined in the protocol or Study Specific Procedures (SSP).

General Information/Instructions: If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a Missed Visit form. Fax this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the Visit Code of the visit that was missed. Record the date that the form was completed. This will not necessarily be the date of the missed visit. A complete date is required.

Item-specific Instructions:

- **Item 1:** Record the target date of the visit. A complete date is required.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mother Targeted Physical Exam

Exam Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

Items 1–4 are required. If not evaluated or abnormal, please specify.

VITAL SIGNS

		yes	*no*	
1.	Were vital signs done?	☐	☐ →	***If no, specify:*** _____

Oral Temp [ ][ ] . [ ] *°C*

BP [ ][ ][ ] / [ ][ ][ ] *mmHg*

Pulse [ ][ ][ ] *per minute*

_____
Vital Signs: Staff Initials / Date

FINDINGS

not evaluated	*normal*	*abnormal*		
☐	☐	☐	2.	General appearance _____
☐	☐	☐	3.	Abdomen _____
☐	☐	☐	4.	Breast Exam _____

Items 5–15 are optional. If abnormal, please specify.

☐	☐	☐	5.	HEENT _____
☐	☐	☐	6.	Neck _____
☐	☐	☐	7.	Lymph Nodes _____
☐	☐	☐	8.	Heart _____
☐	☐	☐	9.	Lungs _____
☐	☐	☐	10.	Extremities _____
☐	☐	☐	11.	Neurological _____
☐	☐	☐	12.	Skin _____
☐	☐	☐	13.	Other, specify: _____
☐	☐	☐	14.	Other, specify: _____
☐	☐	☐	15.	Other, specify: _____

If any are abnormal and ongoing at Enrollment, record findings on Pre-existing Conditions form. If abnormal during follow-up, update or complete Adverse Experience Log when applicable.

_____
Findings: Staff Initials / Date

[ ][ ][ ][X] 14-FEB-11

[0][1]
Language

_____
Staff Initials / Date

Mother Targeted Physical Exam (non-DataFax) – Page 1 of 1

Purpose: This form is used to document the maternal participant's vital signs and targeted physical exam findings.

General Information/Instructions: This form is completed each time a targeted physical exam is performed. Because this is a non-DataFax form, do NOT fax to SCHARP DataFax.

Item-specific Instructions:

- **Vital Signs:** Use leading zeros when needed. The staff member who completes these items should initial and date in the space provided.
- **Findings:** The staff member who completes these items should initial and date in the space provided.
- **Items 13–15:** Use these items to list any additional organ systems that were evaluated. If no other organ systems other than the ones listed in items 2–12 were evaluated, mark items 13–15 as "not evaluated."

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mother: Participant-reported Baseline Medical and Menstrual History

Visit Date

[ ][ ] dd [ ][ ][ ] MMM [ ][ ] yy

	Medical problem? yes	no	*If yes, onset date* MMM	yy	***Description:***	***Ongoing?*** yes	no	***Severity Grade***
HE (head/eyes)	☐	☐				☐	☐	
	☐	☐				☐	☐	
ENT (ears/ nose/throat)	☐	☐				☐	☐	
	☐	☐				☐	☐	
Lymphatic	☐	☐				☐	☐	
	☐	☐				☐	☐	
Cardiovascular	☐	☐				☐	☐	
	☐	☐				☐	☐	
Respiratory	☐	☐				☐	☐	
	☐	☐				☐	☐	
Liver	☐	☐				☐	☐	
	☐	☐				☐	☐	
Renal *(including urinary symptoms)*	☐	☐				☐	☐	
	☐	☐				☐	☐	
Gastrointestinal	☐	☐				☐	☐	
	☐	☐				☐	☐	
Musculoskeletal *(including bone fractures)*	☐	☐				☐	☐	
	☐	☐				☐	☐	

If yes to any at the time of enrollment, record on Pre-existing Conditions form.

[ ][ ][ ][X] 14-FEB-11

[0][1] Language

Staff Initials / Date

Mother: Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 1 of 7

Purpose: This form is used to document a maternal participant's baseline medical history, since becoming sexually active. It is first completed at the Screening Visit. It is then updated again at the Enrollment Visit. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

General Information/Instructions: It may be helpful to use a calendar as a probe to help participants recall dates.

Note: *This form should contain information on the participant's medical history through the Enrollment Visit only. Do* ***not*** *update this form during follow-up unless the participant recalls additional information related to her medical history at baseline. Be sure to record all conditions that were ongoing at enrollment on the Pre-existing Conditions form.*

Item-specific Instructions:

- **Medical problem:** For each organ system/disease listed, mark the "yes" box if there is evidence (either by participant report or by medical records) that the participant has ever experienced any medical problem involving that organ system/disease since becoming sexually active. Mark the "no" box for conditions not reported or documented in medical records.
- **If yes, onset date:** For each organ system/disease marked "yes," record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing:** For each diagnosed or reported condition, determine if it is ongoing or resolved. Mark the "yes" box if the condition is ongoing (not resolved), and "no" if the condition is resolved. Review all ongoing conditions at the participant's Enrollment Visit. For conditions ongoing at Enrollment, record the condition on the participant's Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences Addenda 1 and 3 (Female Genital and Rectal Grading Tables for Use in Microbicide Studies)*, as appropriate. AEs not included in those tables will be graded by the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Experiences*. If a condition is not gradable, write "NG."

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mother: Participant-reported Baseline Medical and Menstrual History

	Medical problem? *yes*	*no*	*If yes, onset date* *MMM*	*yy*	***Description:***	***Ongoing?*** *yes*	*no*	***Severity Grade***
Neurologic	☐	☐				☐	☐	
	☐	☐				☐	☐	
Skin	☐	☐				☐	☐	
	☐	☐				☐	☐	
Endocrine/ Metabolic	☐	☐				☐	☐	
	☐	☐				☐	☐	
Hematologic	☐	☐				☐	☐	
	☐	☐				☐	☐	
Cancer	☐	☐				☐	☐	
	☐	☐				☐	☐	
Drug Allergy	☐	☐				☐	☐	
	☐	☐				☐	☐	
Other Allergy	☐	☐				☐	☐	
	☐	☐				☐	☐	
Mental Illness	☐	☐				☐	☐	
	☐	☐				☐	☐	

If yes to any at the time of enrollment, record on Pre-existing Conditions form.

Mother: Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 2 of 7

Item-specific Instructions:

- **Medical problem:** For each organ system/disease listed, mark the "yes" box if there is evidence (either by participant report or by medical records) that the participant has ever experienced any medical problem involving that organ system/disease since becoming sexually active. Mark the "no" box for conditions not reported or documented in medical records.
- **If yes, onset date:** For each organ system/disease marked "yes," record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing:** For each diagnosed or reported condition, determine if it is ongoing or resolved. Mark the "yes" box if the condition is ongoing (not resolved), and "no" if the condition is resolved. Review all ongoing conditions at the participant's Enrollment Visit. For conditions ongoing at Enrollment, record the condition on the participant's Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences Addenda 1 and 3 (Female Genital and Rectal Grading Tables for Use in Microbicide Studies)*, as appropriate. AEs not included in those tables will be graded by the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Experiences*. If a condition is not gradable, write "NG."

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mother: Participant-reported Baseline Medical and Menstrual History

	Description:	*Ongoing?* yes	no	*Severity Grade*
History of Alcohol Use:		☐	☐	
History of Recreational Drug Use:		☐	☐	

	Medical problem? yes	no	*If yes, onset date* MMM	yy	*Description:*	*Ongoing?* yes	no	*Severity Grade*
STI/RTI	☐	☐				☐	☐	

☐ symptomatic vaginal candidiasis ☐ abnormal pap ☐ symptomatic BV ☐ PID

☐ HSV-1/HSV-2 ☐ Syphilis ☐ Gonorrhea ☐ Chlamydia

☐ HPV ☐ Trichomoniasis ☐ other vaginitis ☐ chancroid

☐ cervicitis ☐ other

STI/RTI	☐	☐				☐	☐	

☐ symptomatic vaginal candidiasis ☐ abnormal pap ☐ symptomatic BV ☐ PID

☐ HSV-1/HSV-2 ☐ Syphilis ☐ Gonorrhea ☐ Chlamydia

☐ HPV ☐ Trichomoniasis ☐ other vaginitis ☐ chancroid

☐ cervicitis ☐ other

STI/RTI	☐	☐				☐	☐	

☐ symptomatic vaginal candidiasis ☐ abnormal pap ☐ symptomatic BV ☐ PID

☐ HSV-1/HSV-2 ☐ Syphilis ☐ Gonorrhea ☐ Chlamydia

☐ HPV ☐ Trichomoniasis ☐ other vaginitis ☐ chancroid

☐ cervicitis ☐ other

If yes to any at the time of enrollment, record on Pre-existing Conditions form.

Mother: Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 3 of 7

Item-specific Instructions:

- **Medical problem:** Mark the "yes" box for each STI/RTI (evidenced by participant report or by medical records) that the participant has ever experienced since becoming sexually active, if any. For each STI/RTI reported, mark the box that corresponds to the specific STI/RTI the participant experienced (e.g.,"Gonorrhea"). Mark the "no" box for the remaining STI/RTI items.
- **If yes, onset date:** For each organ system/disease marked "yes," record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing:** For each diagnosed or reported condition, determine if it is ongoing or resolved. Mark the "yes" box if the condition is ongoing (not resolved), and "no" if the condition is resolved. Review all ongoing conditions at the participant's Enrollment Visit. For conditions ongoing at Enrollment, record the condition on the participant's Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences Addenda 1 and 3 (Female Genital and Rectal Grading Tables for Use in Microbicide Studies)*, as appropriate. AEs not included in those tables will be graded by the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Experiences*. If a condition is not gradable, write "NG."

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (1.00)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mother: Participant-reported Baseline Medical and Menstrual History

Genital Symptoms	*yes*	*no*	***If yes, onset date*** *MMM*	*yy*	***Description:***	***Ongoing?*** *yes*	*no*	***Severity Grade***
Vaginal dryness?	☐	☐				☐	☐	
Genital/vaginal itching?	☐	☐				☐	☐	
Genital/vaginal burning?	☐	☐				☐	☐	
Genital/vaginal pain? (other than during sex)	☐	☐				☐	☐	
Pain during sex? (dyspareunia)	☐	☐				☐	☐	
Pain during urination? (dysuria)	☐	☐				☐	☐	
Abnormal genital/ vaginal discharge?	☐	☐				☐	☐	
Unusual genital/ vaginal odor?	☐	☐				☐	☐	
Other genital symptoms? Specify: _____	☐	☐				☐	☐	

If yes to any, evaluate for STIs/RTIs.

If yes to any, evaluate for eligibility. If yes to any at time of Enrollment, record on Pre-existing Conditions form.

	yes	*no*	***If yes, onset date*** *MMM*	*yy*	***Description:***	***Ongoing?*** *yes*	*no*	***Severity Grade***
Blood-tinged discharge?	☐	☐				☐	☐	

If yes, evaluate for eligibility.

If yes at the time of Enrollment, record on Pre-existing Conditions form.

Other medical problem?	*yes*	*no*	***If yes, onset date*** *MMM*	*yy*	***Description:***	***Ongoing?*** *yes*	*no*	***Severity Grade***
Other?	☐	☐				☐	☐	
Other?	☐	☐				☐	☐	
Other?	☐	☐				☐	☐	

If yes to any at the time of Enrollment, record on Pre-existing Conditions form.

[ ][ ][ ][X] 14-FEB-11

[0][1]
Language

Staff Initials / Date

Mother: Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 4 of 7

Item-specific Instructions:

- **Genital Symptoms:** These questions refer to any genital symptoms the participant may have experienced since becoming sexually active. For each item marked "yes," complete the adjacent item, "If yes: Is she currently experiencing this symptom?" For items marked "no," leave the adjacent item "If yes: Is she currently experiencing this symptom?" blank. For any item marked "yes," evaluate the participant for STIs/RTIs per the protocol and SSP. If the participant is diagnosed with a STI/RTI that is exclusionary per protocol, do not enroll the participant. Provide treatment as necessary (per WHO guidelines).
- **If yes, onset date:** For each item marked "yes," record the month and year the participant was diagnosed with the condition or began experiencing symptoms.
- **Ongoing:** For each reported symptom or condition, determine if it is ongoing or resolved. Review all ongoing symptoms/conditions at the participant's Enrollment Visit and determine eligibility. For symptoms/conditions ongoing at Enrollment, record the condition on the participant's Pre-existing Conditions form.
- **Severity Grade:** Assign a severity grade to all diagnosed conditions that are ongoing. To grade the severity, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences Addenda 1 and 3 (Female Genital and Rectal Grading Tables for Use in Microbicide Studies)*, as appropriate. AEs not included in those tables will be graded by the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Experiences*. If a condition is not gradable, write "NG."
- **Other medical problem (yes/no):** For each "other" symptom or condition that the participant has ever experienced since becoming sexually active (either by participant report or by medical records), mark the "yes" box. Mark the "no" box for the remaining "other?" items.
- **Other:** Record any symptom or condition reported by the participant that is not recorded elsewhere on this form.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mother: Participant-reported Baseline Medical and Menstrual History

Menstrual History

	dd	*MMM*	*yy*
First day of last menstrual period:	[ ][ ]	[ ][ ][ ]	[ ][ ]
Last day of last menstrual period:	[ ][ ]	[ ][ ][ ]	[ ][ ]

If participant's last menstrual period was more than one month ago, record relevant clinical history (include severity grade, if missed menses is unexpected).

_____

_____

	regular	*irregular*
Usual menstrual cycle:	☐	☐

Usual number of days between menses: ..... [ ][ ] *# of days*

	minimum		*maximum*	
Usual number of bleeding days (record range):	[ ][ ]	*# of days*	***TO*** [ ][ ]	*# of days*

Age of menarche: ..... [ ][ ] *years*

	light	*moderate*	*heavy*
Usual type of menstrual flow (at the heaviest day of menses):	☐	☐	☐

Usual menstrual symptoms (document start date, type and severity, if any): _____

_____

Usual non-menstrual genital bleeding pattern (document start date, frequency, duration, type of flow, and associated symptoms, if any):

_____

History of any other menstrual problems not recorded above (record severity grade, if ongoing):

_____

_____

_____

☐ ☐ ☐ ☒ 14-FEB-11

[0][1] Language

_____ Staff Initials / Date

Mother: Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 5 of 7

Item-specific Instructions:

- **First/Last day of last menstrual period:** Record the dates relating to the participant's most recently completed menses regardless of how long ago it occurred. At minimum, month and year are required.
- **Usual number of days between menses:** If the participant is amenorrheic, refer to her previous menstrual cycles that occurred prior to the amenorrhea.
- **Usual number of bleeding days:** If the participant is amenorrheic, refer to her previous menstrual cycles that occurred prior to the amenorrhea.
- **Usual menstrual symptoms:** Document the type and severity of any and all reported symptoms the participant commonly experiences in association with her menses. If the participant is amenorrheic, document any usual menstrual symptoms she experienced prior to becoming amenorrheic.
- **Usual non-menstrual genital bleeding pattern:** Document the frequency of bleeding, duration of bleeding, type of flow (e.g., light, moderate, or heavy), and associated symptoms (if any) of any and all reported non-menstrual bleeding commonly experienced by the participant. This includes intermenstrual bleeding (IMB) and/or any breakthrough genital bleeding/spotting associated with the participant's contraceptive use.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ]-[ ][ ][ ][ ]-[ ]-[0]

Site Number | Participant Number | Chk | Who

Mother: Participant-reported Baseline Medical and Menstrual History

Pregnancy History

Preg #	Outcome Date	Outcome *(fullterm, preterm, ectopic, SAB, TAB, etc.)*	Type of Delivery *(vag, cesarean, D&C)*	Alive now?	Congenital anomalies or problems with pregnancy *(describe)*
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

Contraceptive History

Current Method(s)	Approx. Dates of Use	Any problems?
Previously Used Method(s)	**Approx. Dates of Use**	**Any problems?**

Mother: Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 6 of 7

Item-specific Instructions:

- **Pregnancy History:** Record the outcome date, outcome (for example, full-term live birth, premature live birth, spontaneous abortion, etc.) and other relevant information regarding each of the participant's pregnancies.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mother: Participant-reported Baseline Medical and Menstrual History

History of sexual assault (if any):_____

History of any other obstetric, gynecologic, or reproductive problems, and/or procedures not recorded elsewhere on this form (record severity grade, if ongoing):

Mother: Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 7 of 7

No additional instructions.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mothers: Participant-reported Follow-up Medical and Menstrual History

Visit Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

	Medical problem since last visit? *yes*	*no*	***If yes, onset date*** *dd*	*MMM*	***OR*** *yy*	***continuing from previous visit***	***Description*** *(include severity grade and outcome date, if applicable)*
HE (head/eyes)	☐	☐				☐	
	☐	☐				☐	
ENT (ears/ nose/throat)	☐	☐				☐	
	☐	☐				☐	
Lymphatic	☐	☐				☐	
	☐	☐				☐	
Cardiovascular	☐	☐				☐	
	☐	☐				☐	
Respiratory	☐	☐				☐	
	☐	☐				☐	
Liver	☐	☐				☐	
	☐	☐				☐	
Renal *(including urinary symptoms)*	☐	☐				☐	
	☐	☐				☐	
Gastrointestinal	☐	☐				☐	
	☐	☐				☐	
Musculoskeletal *(including bone fractures)*	☐	☐				☐	
	☐	☐				☐	

Update or complete Adverse Experience Log when applicable.

[ ][ ][ ][X] 14-FEB-11

[0][1] Language

Staff Initials / Date

Mothers: Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 1 of 4

Purpose: This form is used to document a maternal participant's follow-up medical history during the study (that is, her medical history since her last study visit). It is completed at each regularly scheduled follow-up visit. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

General Information/Instructions: It may be helpful to use a calendar as a probe to help participants recall dates.

Note: *Each Follow-up Medical History form should contain medical information reported by the participant at the time the form was completed. If, at a subsequent study visit, the participant reports additional medical information related to the time period covered on a previous Follow-up Medical History form,* ***do not*** *update the previous form. Instead, record the new information on the current Follow-up Medical History form and explain the discrepancy in the "Additional Notes" section (may be documented in the participant's chart notes as well). If the participant reports additional medical information related to her baseline medical history,* ***do*** *update the Baseline Medical History (non-DataFax) form and the Pre-existing Conditions form (for conditions present at enrollment).*

Item-specific Instructions:

- **Yes/No boxes:** The first time this form is completed for a participant (at her first follow-up visit), review the participant's Pre-existing Conditions form. For each ongoing condition, review the condition with the participant and record updated information about the condition on this form. For all visits after the first follow-up visit, review the Follow-up Medical History form completed at the previous visit and record updated information on all conditions that were ongoing at the last visit on the Follow-up Medical History form for the current visit.
- **If yes, onset date:** For each item marked "yes," record the day, month, and year the participant was diagnosed with the condition or began experiencing symptoms. When applicable, complete an Adverse Experience Log form for the condition recording this date as the AE Onset Date (item 2 of the Adverse Experience Log form).
- **Continuing from previous visit:** Mark this box for items that are continuing from a previous visit (that is, the onset date of the condition is recorded on a previously-completed medical history form). If this box is marked, leave the "If yes, onset date" boxes blank. If an onset date is recorded, leave the "continuing from previous visit" box blank.
- **Update or complete Adverse Experience Log when applicable:** For each item diagnosed, complete an Adverse Experience Log form (if applicable) if this is the **first time** the condition has been reported since the participant enrolled in the study. If this **not** the first time the condition has been reported since enrollment, an AE Log should already have been completed for this condition—review the previously completed AE Log and either update any relevant information, or complete a new AE Log as necessary (e.g., in cases where a previously reported AE has increased in severity or frequency). If the condition was first reported on the participant's Baseline Medical History and Pre-existing Conditions forms and it has not increased in severity or frequency, **do not** complete an AE Log—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mothers: Participant-reported Follow-up Medical and Menstrual History

	Medical problem since last visit? *yes*	*no*	***If yes, onset date*** *dd*	*MMM*	***OR*** *yy*	***continuing from previous visit***	***Description*** *(include severity grade and outcome date, if applicable)*
Neurologic	☐	☐				☐	
	☐	☐				☐	
Skin	☐	☐				☐	
	☐	☐				☐	
Endocrine/ Metabolic	☐	☐				☐	
	☐	☐				☐	
Hematologic	☐	☐				☐	
	☐	☐				☐	
Cancer	☐	☐				☐	
	☐	☐				☐	
Drug Allergy	☐	☐				☐	
	☐	☐				☐	
Other Allergy	☐	☐				☐	
	☐	☐				☐	
Mental Illness	☐	☐				☐	
	☐	☐				☐	

Update or complete Adverse Experience Log when applicable.

Any changes in alcohol use since last study visit?

Any changes in recreational drug use since last study visit?

☐ ☐ ☐ ☒ 14-FEB-11

[0][1] Language

Staff Initials / Date

Mothers: Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 2 of 4

Item-specific Instructions:

- **Yes/No boxes:** The first time this form is completed for a participant (at her first follow-up visit), review the participant's Pre-existing Conditions form. For each ongoing condition, review the condition with the participant and record updated information about the condition on this form. For all visits after the first follow-up visit, review the Follow-up Medical History form completed at the previous visit and record updated information on all conditions that were ongoing at the last visit on the Follow-up Medical History form for the current visit.
- **If yes, onset date:** For each item marked "yes," record the day, month, and year the participant was diagnosed with the condition or began experiencing symptoms. When applicable, complete an Adverse Experience Log form for the condition recording this date as the AE Onset Date (item 2 of the Adverse Experience Log form).
- **Continuing from previous visit:** Mark this box for items that are continuing from a previous visit (that is, the onset date of the condition is recorded on a previously-completed medical history form). If this box is marked, leave the "If yes, onset date" boxes blank. If an onset date is recorded, leave the "continuing from previous visit" box blank.
- **Update or complete Adverse Experience Log when applicable:** For each item diagnosed, complete an Adverse Experience Log form (if applicable) if this is the **first time** the condition has been reported since the participant enrolled in the study. If this **not** the first time the condition has been reported since enrollment, an AE Log should already have been completed for this condition—review the previously completed AE Log and either update any relevant information, or complete a newAE Log as necessary (e.g., in cases where a previously reported AE has increased in severity or frequency). If the condition was first reported on the participant's Baseline Medical History and Pre-existing Conditions forms and it has not increased in severity or frequency, **do not** complete an AE Log—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mothers: Participant-reported Follow-up Medical and Menstrual History

Since her last study visit, has the participant experienced any of the following symptoms:

Genital Symptoms

	yes	no	If yes, onset date dd	MMM	yy	OR continuing from previous visit	Description (include severity grade and outcome date, if applicable)
Vaginal dryness?	☐	☐	☐☐	☐☐☐	☐☐	☐	
Genital/vaginal itching?	☐	☐	☐☐	☐☐☐	☐☐	☐	
Genital/vaginal burning?	☐	☐	☐☐	☐☐☐	☐☐	☐	
Genital/vaginal pain? (other than during sex)	☐	☐	☐☐	☐☐☐	☐☐	☐	
Pain during sex? (dyspareunia)	☐	☐	☐☐	☐☐☐	☐☐	☐	
Pain during urination? (dysuria)	☐	☐	☐☐	☐☐☐	☐☐	☐	
Abnormal genital/ vaginal discharge?	☐	☐	☐☐	☐☐☐	☐☐	☐	
Unusual genital/ vaginal odor?	☐	☐	☐☐	☐☐☐	☐☐	☐	
Other genital symptoms? Specify: _____	☐	☐	☐☐	☐☐☐	☐☐	☐	

→ *If yes to any, conduct pelvic exam if clinically indicated. Update or complete Adverse Experience Log when applicable.*

	yes	no	If yes, onset date dd	MMM	yy	OR continuing from previous	Description (include severity grade and outcome date, if applicable)
Blood-tinged discharge?	☐	☐	☐☐	☐☐☐	☐☐	☐	

→ *Conduct pelvic exam if indicated. Update or complete Adverse Experience Log when applicable.*

Other medical problem since last visit?

	yes	no	If yes, onset date dd	MMM	yy	OR continuing from previous	Description (include severity grade and outcome date, if applicable)
Other?	☐	☐	☐☐	☐☐☐	☐☐	☐	
Other?	☐	☐	☐☐	☐☐☐	☐☐	☐	

→ *Update or complete Adverse Experience Log when applicable.*

Mothers: Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 3 of 4

Item-specific Instructions:

- **Genital Symptoms:** For any item marked "yes," conduct a pelvic exam if clinically indicated (and not already required for the visit). Evaluate the participant for STIs/RTIs per the protocol and SSP. If the participant is diagnosed with a STI/RTI, provide treatment as necessary (as per WHO guidelines).
- **Menstrual symptoms worse than her usual menstrual symptoms:** This item is intended to capture dysmenorrhea reported during follow-up visits. If the participant reports dysmenorrhea and/or any other symptom(s) related to menstruation, probe for further information (i.e., type and severity of symptoms), then compare to the participant's usual baseline menstrual symptoms to determine whether an AE should be reported.
- **Genital Bleeding:** If the participant reports vaginal bleeding or spotting between usual menstrual periods, blood-tinged genital/vaginal discharge, or any post-coital bleeding, refer to the Study-Specific Procedures (SSP) Manual.
- **If yes, onset date:** For each item marked "yes," record the day, month, and year the participant was diagnosed with the condition or began experiencing symptoms. When applicable, complete an Adverse Experience Log form for the condition recording this date as the AE Onset Date (item 2 of the Adverse Experience Log form).
- **Continuing from previous visit:** Mark this box for items that are continuing from a previous visit (that is, the onset date of the symptom or condition is recorded on a previously-completed medical history form). If this box is marked, leave the "If yes, onset date" boxes blank. If an onset date is recorded, leave the "continuing from previous visit" box blank.
- **Update or complete Adverse Experience Log when applicable:** For each item, complete an Adverse Experience Log form (if applicable) if this is the **first time** the symptom or condition has been reported since the participant enrolled in the study. If this **not** the first time the symptom/condition has been reported since enrollment, an AE Log should already have been completed for this symptom/condition—review the previously completed AE Log and either update any relevant information, or complete a new AE Log as necessary (e.g., in cases where a previously reported AE has increased in severity or frequency). If the symptom/condition was first reported on the participant's Baseline Medical History and Pre-existing Conditions forms and it has not increased in severity or frequency, **do not** complete an AE Log—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.
- **Other:** Record any symptom or condition reported by the participant that is not recorded elsewhere on this form.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (100)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Mothers: Participant-reported Follow-up Medical and Menstrual History

Any changes to contraception/family planning use not recorded elsewhere on this form? ..... *yes* ☐ *no* ☐ → ***If yes, specify below. Include start and stop dates. Update Contraceptives Log when applicable.***

Any changes to obstetric/gynecologic/reproductive history since last study visit? ..... *yes* ☐ *no* ☐ → ***If yes, specify below.***

Additional Notes:

Mothers: Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 4 of 4

No additional instructions.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (145) PER-1 (145)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

Participant Evaluability and Replacement

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Is this participant evaluable? That is, did the mother receive at least 4 doses of study gel and did the mother complete the Day 6 Visit? ..... *yes* ☐ *no* ☐ → ***If yes, end of form.***

2. Why is this participant not evaluable? *Mark all that apply.*

   ☐ she did not receive at least 4 doses of study gel

   ☐ she did not complete the Day 6 Visit

   ☐ other, specify:

   _____

3. Will this participant be replaced? ..... *yes* ☐ *no* ☐ → ***If no, specify reason in Comments.***

Comments: _____

☐☐☐☒ 14-FEB-11

0 1 Language

_____ Staff Initials / Date

Participant Evaluability and Replacement (PER-1)

Purpose: This form is used to document whether the maternal participant was evaluable based on study criteria and, if not, whether she was replaced. Do not complete this form for infant participants.

General Information/Instructions: This form is completed once for each enrolled maternal study participant once evaluability is determined.

Item-specific Instructions:

- **Item 1:** Mark the “yes” box if the participant met both criteria stated in item 1. If the participant met only one or neither of the criteria in item 1, mark the “no” box.
- **Item 2:** Mark the reason the participant is not evaluable. If the “other, specify” box is marked, specify the reason the participant is not evaluable in the space provided.
- **Item 3:** If the “no” box is marked, specify the reason the non-evaluable participant will not be replaced on the Comments line.

Sample

MTN 008 (180) PRC-1 (466)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [ ]

Site Number Participant Number Chk Who

Participant Receipt

Form Completion Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

***Note: Do not** assign a new Participant ID. Record the Participant ID assigned by the original study site.*

1. Name of receiving study site: _____

2. Name of transferring study site: _____

3. Date informed consent signed at receiving study site: [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

yes *no*

4. Did participant provide informed consent for specimen storage at receiving study site? [ ] [ ] → ***If no, end of form.***

4a. Date informed consent for specimen storage signed: [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

Comments: _____

_____

[ ] [ ] [ ] [X] 14-FEB-11

[0][1]
Language

_____
Staff Initials / Date

Participant Receipt (PRC-1)

Purpose: Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site. This form must be completed for both the maternal and infant participant.

General Information/Instructions: The Participant Receipt form is completed by the receiving site (the site at which the participant will be continuing his or her study visits).

For more information on Participant Transfer and Receipt, refer to the protocol, Study Specific Procedures (SSPs), and/or Manual of Operations (MOP).

Item-specific instructions:

- **Participant ID: Do not** assign a new Participant ID. Record the Participant ID assigned by the original study site.
- **Item 3:** A complete date is required.
- **Item 4a:** A complete date is required.

Sample

MTN 008 (180) PT-1 (465)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [ ]

Site Number Participant Number Chk Who

Participant Transfer

Form Completion Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

1. Name of transferring study site: _____

2. Name of receiving study site: _____

3. Visit Code of last completed contact with participant: ..... [ ][ ] . [ ]

4. Date participant records were sent to receiving study site: [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

Comments: _____

_____

[ ] [ ] [ ] [X] 14-FEB-11

[0][1] Language

_____ Staff Initials / Date

Participant Transfer (PT-1)

Purpose: Complete this form when a participant is transferring to another study clinic/site. This form must be completed for both the maternal and infant participant.

General Information/Instructions: The Participant Transfer form is completed by the transferring site (the site that the participant is leaving).

For more information on Participant Transfer and Receipt, refer to the protocol, Study Specific Procedures (SSPs), and/or Manual of Operations (MOP).

Item-specific instructions:

- **Item 4:** A complete date is required.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (1[illegible]) PDC-1 (260)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

Participant-reported Dosing and Collection

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Home Dosing

Study Gel Not Inserted	Day #	Dosing Date (*dd* *MMM* *yy*)	Dosing Time (*24-hour clock*) (*hr* : *min*)	Was this dosing time provided from the source document? (*yes* / *no*)
☐	1. Day 1	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐ ☐
☐	2. Day 2	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐ ☐
☐	3. Day 3	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐ ☐
☐	4. Day 4	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐ ☐
☐	5. Day 5	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐ ☐

Home Breast Milk Specimen Collection (LACTATION COHORT ONLY)

Not Collected	Sample #	Specimen Collection Date (*dd* *MMM* *yy*)	Specimen Collection Time (*24-hour clock*) (*hr* : *min*)	Not Stored
☐	6. Sample 1	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐
☐	7. Sample 2	☐☐ ☐☐☐ ☐☐	☐☐ : ☐☐	☐

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

0 1
Language

Staff Initials / Date

Participant-reported Dosing and Collection (PDC-1)

Purpose: This form is used to document daily home dosing dates and times for mothers in the Pregnancy Cohort and the Lactation Cohort. This form is also used to document home breast milk specimen collection dates and times for mothers in the Lactation Cohort.

General Information/Instructions: This form is completed for all maternal participants. Clinic staff will transcribe all relevant information from the participant’s Home Dosing Log and Home Collection of Breast Milk Specimens Log.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Items 1-5**: Transcribe the date and time of each daily dosing recorded on the participant’s Home Dosing Log form. The date must be transcribed using the SCHARP DataFax standard, dd MMM yy. The time must be transcribed using the 24-hour clock.

  If the participant marked the “I did not insert study gel today” box on her log, mark the “Study Gel Not Inserted” box, and leave all other items for that specific day blank.

  For each day that dosing information is recorded, mark “yes” if the time of dosing is provided on the source documentation (i.e., the Home Dosing Log form). If the source documentation is blank or not available, but the participant is able to report an estimated dosing time record the estimated time, and mark the “no” box.
- **Items 6 and 7**: These items are for maternal participants in the Lactation Cohort only.

  Transcribe the date and time of each breast milk sample collection recorded on the participant’s Home Collection of Breast Milk Specimens Log. The date must be transcribed using the SCHARP DataFax standard, dd MMM yy. The time must be transcribed using the 24-hour clock.

  If the participant marked the “none collected” box on her log, mark the “Not Collected” box and leave the date, time, and “Not Stored” box for that specific day blank/unmarked.

  If the participant did collect the specimen, but the clinic/lab does not store the specimen, complete the date and time, and mark the “Not Stored” box for that specific day.
- **Comments**: Any relevant information from the participant’s log(s) may be transcribed here. You may leave this space blank if there are no additional relevant comments.

Version 1.0, 14-FEB-11

N:\hivnet\forms\MTN_008\forms\m008_dosing_collection_ppt_report.fm

Sample

Visit Code ☐☐.☐ 1

MTN 008 (180) PE-1 (141)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

Pelvic Exam

Exam Date

☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

1. Pelvic exam assessment:..... *not done* ☐ *abnormal findings* ☐ *no abnormal findings* ☐ → ***If no abnormal findings, end of form.***

   → ***If not done, comment below. End of form.***

1a. Abnormal findings. *Mark all that apply.*

☐ enlarged/tender inguinal lymph nodes	☐ laceration	☐ mass
☐ abnormal vaginal discharge	☐ abrasion	☐ warts
☐ abnormal cervical discharge	☐ peeling	☐ adnexal tenderness
☐ blood-tinged discharge	☐ petechia	☐ cervical motion tenderness
☐ blood in vagina—no identified source	☐ ecchymosis	☐ uterine tenderness
☐ blood from cervical os	☐ vesicles	☐ cervical friability
☐ bleeding from site of epithelial disruption	☐ edema	☐ vulvar rash
☐ erythema	☐ abnormal cysts	☐ vulvovaginitis
☐ ulceration	☐ lesions	☐ cervicitis
		☐ other abnormal findings, specify: _____

If any are abnormal and ongoing at Enrollment, record findings on Pre-existing Conditions form. If abnormal during follow-up, update or complete Adverse Experience Log when applicable.

Specimen Collection Date

dd	*MMM*	*yy*		*not required*	*stored*	*not stored*	*Reason:*
☐☐	☐☐☐	☐☐	2. Gram stain (vaginal)	☐	☐	☐ →	_____
☐☐	☐☐☐	☐☐	3. Cervical swab	☐	☐	☐ →	_____
					→ ☐ *# of swabs*		
				not required	*stored*	*not stored*	*Reason:*
☐☐	☐☐☐	☐☐	4. Vaginal swab	☐	☐	☐ →	_____
					→ ☐ *# of swabs*		

Comments: _____

☐☐☐☒ 14-FEB-11

0 1 Language

_____ Staff Initials / Date

Pelvic Exam (PE-1)

Purpose: This form is used to document maternal pelvic exams conducted and genital specimens collected for the Network Laboratory during the study.

General Information/Instructions: This form is completed each time a pelvic exam is performed.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.

Sample

Not a DataFax form. Do not fax to DataFax.

MTN 008 (1.00)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]

Site Number | Participant Number | Chk | Who

Pelvic Exam Diagrams

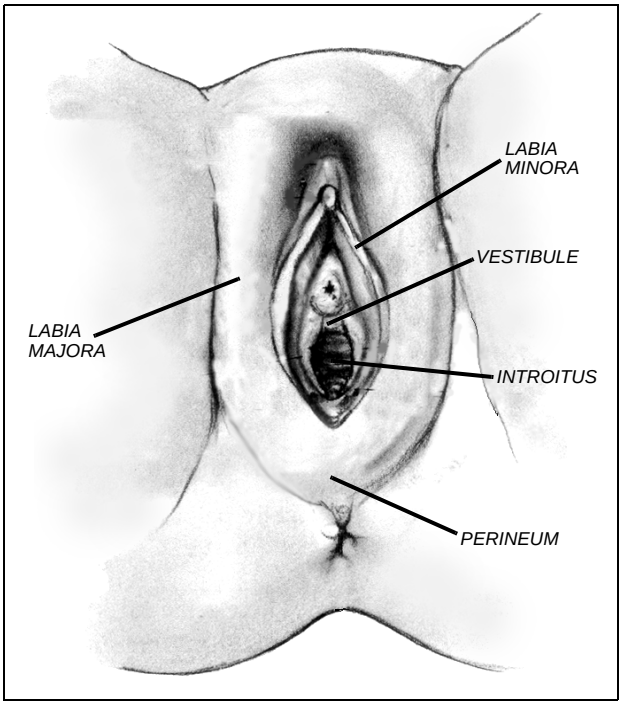
Exam Date

[ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

☐ no normal variants or abnormal findings observed

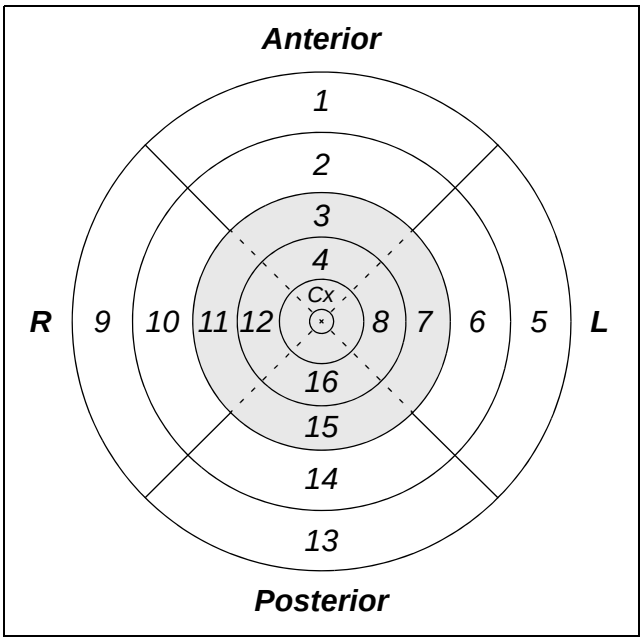
External Genitalia



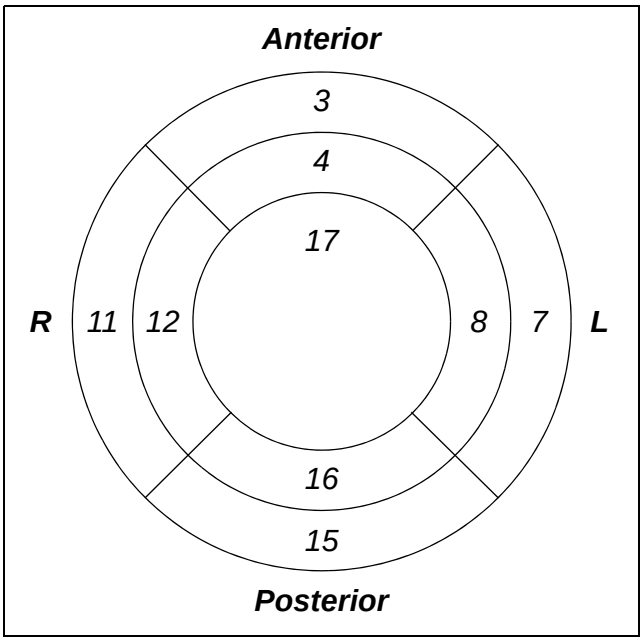
Legend for Vagina/Cervix

1. Anterior vagina, distal half
2. Anterior vagina, proximal half
3. Anterior fornix
4. Cervical trunk, anterior
5. Left lateral vagina, distal half
6. Left lateral vagina, proximal half
7. Left lateral fornix
8. Cervical trunk, left lateral
9. Right lateral vagina, distal half
10. Right lateral vagina, proximal half
11. Right lateral fornix
12. Cervical trunk, right lateral
13. Posterior vagina, distal half
14. Posterior vagina, proximal half
15. Posterior fornix
16. Cervical trunk, post
17. Cervical face

Vagina



Cervix



☐ ☐ ☐ ☒ 14-FEB-11

[0][1]
Language

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax) – Page 1 of 1

Purpose: This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through study exit).

General Information/Instructions: This form is completed each time a pelvic exam is performed unless the site is using another document as source for the pelvic exam. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

- All variants of normal (normal findings) and all abnormal findings must be documented on this form. Variants of normal need only be recorded on this form, and not on any of the DataFax Pelvic Exam forms. The following findings are considered normal variants:
  - anatomic variants
  - mucus retention cysts
  - atrophic changes
  - Nabothian cysts
  - gland openings
  - Gartner's duct cysts
  - skin tags
  - ectopies
- If there are no variants of normal or abnormal findings observed mark the "no normal variants or abnormal findings observed" box.
- Documenting findings on the cervix: If helpful, draw the os in the center of the diagram labeled "Cervix" (lower right corner).

Sample

Visit Code ☐☐.☐ 1

MTN 008 (143) PLR-1 (143)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number Participant Number Chk Who

Pelvic Laboratory Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Not done/ Not collected ☐ **Alternate Collection Date** *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

1. VAGINAL WET PREP STUDIES

		negative	*positive*
Not done ☐	1a. Homogeneous vaginal discharge	☐	☐
☐	1b. pH ☐.☐ → ***If > 4.5 mark as positive.*** →		☐
☐	1c. Whiff test	☐	☐
☐	1d. Clue cells > 20%	☐	☐
☐	1e. *Trichomonas vaginalis*	☐	☐
☐	1f. Buds and/or hyphae (yeast)	☐	☐

Wet Prep: _____ Staff Initials/Date

2. HSV Culture .....

Not done/ Not collected ☐

negative	*positive*
☐	☐

HSV Culture: _____ Staff Initials/Date

3. PAP SMEAR

Not done/ Not collected ☐ **Alternate Collection Date** *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

- ☐ negative for intraepithelial lesion or cancer (malignancy)
- ☐ ASC-US
- ☐ ASC-H
- ☐ SIL–low grade (LSIL)
- ☐ SIL–high grade (HSIL)
- ☐ AGC
- ☐ AGC–favor neoplastic
- ☐ cancer

Pap Smear: _____ Staff Initials/Date

Comments: _____

☐☐☐☒ 14-FEB-11

0 1 Language

Pelvic Laboratory Results (PLR-1)

Purpose: This form is used to document results of specimens collected during the Screening, Enrollment, and follow-up pelvic exams.

General Information/Instructions: Record test results on this form as they become available. Fax this form to SCHARP DataFax once results for **all** collected specimens are recorded on this form.

If a test result(s) recorded on this form indicates that the participant has a laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as either a pre-existing condition on the Pre-existing Conditions form (for Enrollment test result(s) only), or an adverse experience on the Adverse Experience (AE) Log (for follow-up visit test result(s) only).

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Alternate Collection Date**: This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. A complete date is required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the Comments line.
- **Item 1:** If a vaginal wet prep was performed but not all assays were completed, mark the "Not done" box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments line.
- **Item 1a:** Mark the "positive" box if homogeneous vaginal discharge was observed. If homogeneous discharge was observed and is considered to be abnormal, mark "abnormal vaginal discharge" in item 1a of the Screening and Enrollment Pelvic Exam form, or the Follow-up Pelvic Exam form completed for this pelvic exam.
- **Item 3:** If done, record the Pap Smear result. Mark only one box.
  - **negative for intraepithelial lesion or cancer (malignancy):** Includes all normal findings and any findings of infection (trichomonas, candida, etc.), reactive changes/inflammation, glandular changes due to hysterectomy, or atrophic changes.
  - **ASC-US:** Mark this box when abnormal/atypical squamous cells of undetermined significance are reported.
  - **ASC-H:** Mark this box when abnormal/atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesion (HSIL) are reported.
  - **SIL-low grade (LSIL):** Mark this box when low-grade squamous interepithelial lesions are reported. This category includes presence of human papillomavirus (HPV) infection, mild dysplasia, and cervical interepithelial neoplasia (CIN 1).
  - **SIL-high grade (HSIL):** Mark this box when high-grade squamous interepithelial lesions are reported. This category includes the presence of moderate to severe dysplasia, carcinoma in situ (CIS), CIN 2, and CIN 3, or changes suspicious for invasive cancer.
  - **AGC:** Mark this box when atypical/abnormal glandular cells are reported. This category includes endocervical (from cervical canal) atypical cells; endometrial atypical cells; glandular atypical cells.
  - **AGC-favor neoplastic:** Mark this box when atypical/abnormal glandular cells that favor cell growth (neoplastic changes) are reported. This category includes endocervical cells and glandular cells.
  - **cancer:** Mark this box when cancer or adenocarcinoma is reported. This includes endocervical, endometrial, extrauterine, and other (not specified) cancers/adenocarcinomas.

Sample

MTN 008 (180) PRE-1 (012)

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

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ☐

Site Number | Participant Number | Chk | Who

Pre-existing Conditions

☐ **No pre-existing conditions reported or observed.** _____ Staff Initials / Date → ***End of form. Fax to SCHARP DataFax.***

1.

Description	**Date of Diagnosis/ Surgery** *MMM* ☐☐☐ *yy* ☐☐
Comments	**Severity Grade** ☐ ☐ *not gradable* **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date

2.

Description	**Date of Diagnosis/ Surgery** *MMM* ☐☐☐ *yy* ☐☐
Comments	**Severity Grade** ☐ ☐ *not gradable* **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date

3.

Description	**Date of Diagnosis/ Surgery** *MMM* ☐☐☐ *yy* ☐☐
Comments	**Severity Grade** ☐ ☐ *not gradable* **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date

4.

Description	**Date of Diagnosis/ Surgery** *MMM* ☐☐☐ *yy* ☐☐
Comments	**Severity Grade** ☐ ☐ *not gradable* **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date

5.

Description	**Date of Diagnosis/ Surgery** *MMM* ☐☐☐ *yy* ☐☐
Comments	**Severity Grade** ☐ ☐ *not gradable* **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date

6.

Description	**Date of Diagnosis/ Surgery** *MMM* ☐☐☐ *yy* ☐☐
Comments	**Severity Grade** ☐ ☐ *not gradable* **Is condition ongoing?** *yes* ☐ *no* ☐ _____ Staff Initials / Date

☐ ☐ ☐ ☒ 14-FEB-11

0 1 Language

Pre-existing Conditions (PRE-1)

Purpose: This form is used to document the participant's pre-existing medical conditions.

General Information/Instructions: Only medical conditions experienced up to study product initiation should be recorded unless otherwise specified in the protocol or Study-Specific Procedures (SSPs). Include current medical conditions and any ongoing conditions such as mental illness, alcoholism, drug abuse, and chronic conditions (controlled or not controlled by medication).

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
- **Description:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. 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."
- **Date of Diagnosis/Surgery:** If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.
- **Comments:** This field is optional. Use it to record any additional relevant information about the condition.
- **Severity Grade:** For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark the "not gradable" box.
- **Is condition ongoing?:** Mark "yes" if condition is ongoing at enrollment.
- **Pre-existing Conditions Revisions and Updates:** If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s) to SCHARP DataFax.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (1[illegible]) PO-1 (442)

Participant ID

☐☐☐-☐☐☐☐-☐-☐

Site Number Participant Number Chk Who

Pregnancy Outcome

☐ **Outcome unobtainable**
→ ***End of form.***

1. How many pregnancy outcomes resulted from this reported pregnancy?..... ☐ 1

2. Outcome Date: ..... *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

3. Place of delivery/outcome:

- ☐ home
- ☐ hospital

  clinic **NOT APPLICABLE FOR THIS PROTOCOL.**
- ☐ unknown
- ☐ other, specify: _____

4. Specify Outcome: *Mark only one.*

- ☐ 4a. full term live birth (≥ 37 $^{0}/_{7}$ weeks)
- ☐ 4b. premature live birth (< 37 $^{0}/_{7}$ weeks)
- ☐ 4c. stillbirth/intrauterine fetal demise (≥ 20 $^{0}/_{7}$ weeks)
- ☐ 4d. spontaneous abortion (< 20 $^{0}/_{7}$ weeks)
- ☐ 4e. ectopic pregnancy
- ☐ 4f. therapeutic/elective abortion
- ☐ 4g. other, specify: _____

→ 4a1. **Method:** *scheduled C-section* ☐ *unscheduled C-section* ☐ *standard vaginal* ☐ *operative vaginal* ☐

If C-section was due to or resulted in maternal complications, report complications on Adverse Experience Log and EAE Reporting form for mother, if applicable.

5. Provide a brief narrative of the circumstances: _____

_____

_____

☐☐☐☐ 14-FEB-11

☐☐ Language

_____ Staff Initials / Date

Pregnancy Outcome (PO-1)

Purpose: This form is used to report pregnancy outcome information for the enrolled pregnancy. Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that pregnancy outcome is unobtainable.

General Information/Instructions: A Pregnancy Outcome form is required for each maternal participant in the Pregnancy Cohort. If the participant is in the Lactation Cohort, contact SCHARP.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Outcome unobtainable:** If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and fax all three pages of this form to SCHARP DataFax.
- **Item 4a1:** The C-section itself is not an Adverse Experience. If the C-section is performed due to or resulting from maternal complication(s), report each complication as an AE on an AE Log if the onset date is prior to study termination. If a maternal complication AE meets the requirements for EAE reporting, complete an EAE Reporting form. "Operative vaginal" delivery includes delivery with forceps and/or vacuum.
- **Items 4c, 4d, and 4e:** Refer to the protocol and Study Specific Procedures (SSP) for EAE and AE reporting requirements for pregnancy losses.
- **Item 4f:** If the outcome is therapeutic/elective abortion, the abortion itself is not an Adverse Experience. If the abortion is performed due to a maternal pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under "Treatment."
- **Item 5:** Record whether labor was "spontaneous" or "induced." If labor was induced, record the indication. Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (1[illegible]) PO-2 (443)

Participant ID

☐☐☐-☐☐☐☐-☐-☐

Site Number Participant Number Chk Who

Pregnancy Outcome

☐ No data recorded on this page.

6. Were any fetal/infant congenital anomalies identified? ..... *yes* ☐ *no* ☐ *unknown* ☐

If no or unknown, go to item 7.

6a. Congenital anomalies identified. *Mark all that apply.* ***Complete Adverse Experience Log and EAE Reporting form for the infant.***

- ☐ 6a1. Central nervous system, cranio-facial
- ☐ 6a2. Central nervous system, spinal
- ☐ 6a3. Cardiovascular
- ☐ 6a4. Renal
- ☐ 6a5. Gastrointestinal
- ☐ 6a6. Pulmonary
- ☐ 6a7. Musculoskeletal/extremities
- ☐ 6a8. Physical defect
- ☐ 6a9. Skin
- ☐ 6a10. Genitourinary
- ☐ 6a11. Chromosomal
- ☐ 6a12. Craniofacial (structural)
- ☐ 6a13. Hematologic
- ☐ 6a14. Infectious
- ☐ 6a15. Endocrine/metabolic
- ☐ 6a16. Other

6b. Describe the congenital anomaly/defect: _____

_____

7. Infant gender: ..... *male* ☐ *female* ☐ *unknown* ☐

8. Infant birth weight: ..... ☐☐.☐ *kg* **OR** *unavailable* ☐

9. Infant gestational age based on obstetric assessment: ..... *weeks* ☐☐ *days* ☐ **OR** *unavailable* ☐

10. Classification of the newborn by birth weight and gestational age (obstetric or by examination):

- ☐ Large for gestational age (> 90%)
- ☐ Appropriate for gestational age
- ☐ Small for gestational age (< 10%)
- ☐ Intrauterine growth restriction (< 3%)
- ☐ Classification not available

Pregnancy Outcome (PO-2)

Item-specific Instructions:

- **Visit Code:** Record the visit code that is present on page 1 of this form.
- **No data recorded on this page:** This box must only be marked if all items on the page are left blank.
- **Item 6a:** If a woman on study has a baby with a congenital anomaly, report the event on an Adverse Experience (AE) Log for the corresponding infant (i.e. the AE Log form will have the infant's PTID), if prior to termination. Also submit an Expedited Adverse Event (EAE) Reporting form.
- **Item 8:** Record the infant's birth weight as documented in medical records. If no medical record documentation of infant birth weight is available, complete this item based on participant report. Mark the "unavailable" box if no medical record documentation is available and the participant does not know the infant's birth weight.
- **Item 9:** If the infant's gestational age is determined using the Ballard method, please record "0" in the "days" box. Mark the "unavailable" box if no medical record documentation of the infant's gestational age is available.

Sample

MTN 008 (444) PO-3 (444) **Visit Code** ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐-☐-☐
Site Number Participant Number Chk Who

Pregnancy Outcome

☐ No data recorded on this page.

11. Were there any pregnancy or postpartum complications related to the pregnancy outcome? ..... *yes* ☐ *no* ☐ → ***If no, go to item 12.***

11a. Pregnancy-related or postpartum complications. *Mark all that apply.* → ***Complete Adverse Experience Log for the mother when applicable.***

- ☐ 11a1. postpartum hemorrhage
- ☐ 11a2. postpartum endometritis
- ☐ 11a3. chorioamnionitis
- ☐ 11a4. third trimester bleeding
- ☐ 11a5. other, specify: _____
- ☐ 11a6. none of the above

11b. Was the rupture of membranes:

11b1. preterm premature (prior to the onset of labor? ..... *yes* ☐ *no* ☐

dd	*MMM*	*yy*	*24-hr clock* *hr*	*min*
☐☐	☐☐☐	☐☐	☐☐ :	☐☐

11b2. term premature (prior to the onset of labor? ..... *yes* ☐ *no* ☐

dd	*MMM*	*yy*	*24-hr clock* *hr*	*min*
☐☐	☐☐☐	☐☐	☐☐ :	☐☐

12. Date and time (24-hr clock) of onset of labor:

dd	*MMM*	*yy*	*hr*	*min*
☐☐	☐☐☐	☐☐	☐☐ :	☐☐

Comments: _____

☐☐☐☐ 14-FEB-11

☐☐ Language

_____ Staff Initials / Date

Pregnancy Outcome (PO-3)

Item-specific Instructions:

- **Visit Code:** Record the visit code that is present on page 1 of this form.
- **No data recorded on this page:** This box must only be marked if all items on the page are left blank.
- **Items 11b1 and 11b2:** Record the complete date and time. Record the time using a 24-hour clock.
- **Item 12:** Record the complete date and time of onset of labor, that is, admission to hospital for L&D management, which also would include induction. Record the time using a 24-hour clock.

Sample

Visit Code ☐☐.☐ 1

MTN 008 ([illegible]) PR-1 (440)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

Pregnancy Report and History

PREGNANCY REPORT

		dd	*MMM*	*yy*
1.	Date of onset of last menstrual period:	☐☐	☐☐☐	☐☐
2.	Estimated date of delivery:	☐☐	☐☐☐	☐☐

PREGNANCY HISTORY

		yes	*no*	
3.	Has the participant ever been pregnant before?	☐	☐ →	***If no, end of form.***
3a.	Is this the participant's first pregnancy since enrollment in this study?	☐	☐ →	***If no, end of form.***
3b.	Number of full term live births (≥ 37 weeks):	☐☐		
3c.	Number of premature live births (< 37 weeks):	☐☐		
3d.	Number of spontaneous fetal deaths and/or still births (≥ 20 weeks):	☐☐		
3e.	Number of spontaneous abortions (< 20 weeks):	☐☐		
3f.	Number of therapeutic/elective abortions:	☐☐		
3g.	Number of ectopic pregnancies:	☐☐		
4.	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before study enrollment?	☐	☐ →	***If yes, document in participant's records.***

Comments: _____

☐☐☐☒ 14-FEB-11

01 Language

Staff Initials / Date

Pregnancy Report and History (PR-1)

Purpose: Complete this form for each maternal participant in the Pregnancy Cohort. If a maternal participant in the Lactation Cohort becomes pregnant post enrollment, but before study termination, contact SCHARP.

General Information/Instructions: Record the visit code of the visit at which study staff became aware that the participant is/was pregnant.

Item-specific instructions:

- **Item 1:** A complete date is required. Record best estimate if date not known.
- **Item 2:** A complete date is required.

Sample

MTN 008 (1[illegible]0) PH-1 (410)

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

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number | Participant Number | Chk | Who

Product Hold/Discontinuation Log

1. Date and visit code when study product hold was initiated: ☐☐ ☐☐☐ ☐☐ *visit code* ☐☐.☐
   dd *MMM* *yy*

2. Why is study product being held? *Mark all that apply.*

   ☐ 2a. mother unable or unwilling to comply with required study procedures

   ☐ 2b. mother may be put at undue risk

   ☐ 2c. mother has gone into labor

   ☐ 2d. adverse experience → *AE Log page #* ☐☐☐ *AE Log page #* ☐☐☐ *AE Log page #* ☐☐☐

   ☐ 2e. other, specify: _____

3. Date of last study product use: ..... ☐☐ ☐☐☐ ☐☐
   dd *MMM* *yy*

4. Was the participant instructed to resume study product use? ..... *yes* ☐ *no (permanently discontinued)* ☐

   4a. Date and visit code when participant was instructed to resume or permanently discontinue study product use: ☐☐ ☐☐☐ ☐☐ *visit code* ☐☐.☐
   dd *MMM* *yy*

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

0 1
Language

_____
Staff Initials / Date

Product Hold/Discontinuation Log (PH-1)

Purpose: This form is used to document temporary holds and early permanent discontinuations of study product use for maternal participants.

General Information/Instructions: This form is completed each time a maternal participant is instructed to temporarily stop (hold) or permanently discontinue study product use prior to her Day 6 Visit. If, at the same study visit, a product hold/discontinuation is initiated for more than one reason, complete a single Product Hold/Discontinuation Log page and mark all applicable reasons.

In the case of temporary product holds, do not wait for information about product resumption to fax the form—fax this form to SCHARP DataFax as soon as items 1–3 have been completed. Refax the page once item 4 has been completed.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Product Hold/Discontinuation Log pages after faxing, unless instructed by SCHARP.
- **Item 2:** Mark the box to the left of the reason why the participant is being instructed to hold or permanently discontinue study product use. If product is being held or discontinued due to an adverse experience, record the page number of the AE Log documenting the product hold or permanent discontinuation. If the product hold/discontinuation is due to a reason other than the ones listed, mark the “other, specify” box and record the reason for the hold/discontinuation on the line provided.
- **Item 3:** Record the date the participant last used study product. Use a best estimate if the actual date cannot be determined.
- **Item 4:** Complete this item once study staff have determined that the participant can resume study product use or have determined that she is permanently discontinued from study product use. Mark this item “yes” if study staff instructed the participant that she can resume use of study product. If the participant was permanently discontinued from study product use, mark the “no (permanently discontinued)” box.
- **Item 4a:** Record the date and visit code on which the participant was told by a study staff member that she could resume or that she should permanently discontinue study product use.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (180) SL-1 (151)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

Safety Laboratory Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

LACTATION COHORT

	negative	*positive*	*not done*
1. hCG for pregnancy	☐	☐	☐

If negative or positive, go to item 2.

1a. Specify the reason the pregnancy test was not done: _____

PREGNANCY AND LACTATION COHORTS

Not done/ Not collected ☐ **2. HEMOGRAM** — **Alternate Collection Date** *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

	Not reported			Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
2a. Hemoglobin	☐	.....	☐☐.☐ *g/dL*	☐	☐☐☐	OR ☐
2b. Hematocrit	☐	.....	☐☐.☐ *%*			
2c. MCV	☐	.....	☐☐☐.☐ *fL*			
2d. Platelets	☐	.....	☐☐☐☐.☐ *x10^3/mm^3*	☐	☐☐☐	OR ☐
2e. WBC	☐	.....	☐☐☐.☐ *x10^3/mm^3*	☐	☐☐☐	OR ☐

Not done

DIFFERENTIAL ☐ → ***If not done, go to item 3 on page 2.***

	Not reported	Percentage		Absolute Count *cells/mm3*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
2f. Neutrophils	☐	☐☐.☐	OR	☐☐☐☐☐	☐	☐☐☐	OR ☐
2g. Lymphocytes	☐	☐☐.☐	OR	☐☐☐☐	☐	☐☐☐	OR ☐
2h. Monocytes	☐	☐☐.☐	OR	☐☐☐☐			
2i. Eosinophils	☐	☐☐.☐	OR	☐☐☐☐			
2j. Basophils	☐	☐☐.☐	OR	☐☐☐☐			
2k. Bands	☐	☐☐.☐	OR	☐☐☐☐			
2l. Atypical lymphocytes	☐	☐☐.☐	OR	☐☐☐☐			
2m. other, specify:	☐	☐☐.☐	OR	☐☐☐☐			

Safety Laboratory Results (SL-1)

Purpose: To document maternal safety laboratory results as required or clinically indicated during screening, enrollment, and follow-up.

Initial Specimen Collection Date: Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.

Alternate Collection Date: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. Record a complete date.

Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments line.
- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
    - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
    - Treat all missing digits in the lab value as zeros.
    - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.

AE Log Page #: If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

Not Reportable as an AE: Only mark this box if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

Item-specific Instructions:

- **Items 2f–2m**: If lab results are available in both percentage and absolute count, absolute count should be recorded.

Sample

MTN 008 (180) SL-2 (152) **Visit Code** ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number Participant Number Chk Who

Safety Laboratory Results

Not done/ Not collected	Alternate Collection Date dd	MMM	yy	3. CHEMISTRIES	U/L	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
☐	☐☐	☐☐☐	☐☐	3a. AST (SGOT)	☐☐☐☐	☐	☐☐☐	OR ☐
☐	☐☐	☐☐☐	☐☐	3b. ALT (SGPT)	☐☐☐☐	☐	☐☐☐	OR ☐
☐	☐☐	☐☐☐	☐☐	3c. Creatinine	*mg/dL* ☐☐.☐	☐	☐☐☐	OR ☐

SPECIMEN STORAGE

Alternate Collection Date dd	MMM	yy		*not required*	*stored*	*not stored*	*Reason:*
☐☐	☐☐☐	☐☐	4. Plasma	☐	☐	☐→	_____

Comments: _____

☐☐☐☒ 14-FEB-11

0 1 Language

_____ Staff Initials / Date

Safety Laboratory Results (SL-2)

Initial Specimen Collection Date: Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.

Alternate Collection Date: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. Record a complete date.

Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments line.
- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
    - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade in the appropriate box next to the results.
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
    - Treat all missing digits in the lab value as zeros.
    - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- There may be situations in which a lab value falls within a site's lab normal ranges and also within a gradable range per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.

AE Log Page #: If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

Not Reportable as an AE: Only mark this box if the lab value is gradable per the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (180) SLR-1 (131)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

STI Laboratory Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. HIV TEST RESULTS

Not done/ Not collected	Alternate Collection Date dd	MMM	yy		kit	negative	positive
☐	☐☐	☐☐☐	☐☐	1a. HIV Rapid test	☐☐	☐	☐

If negative, go to item 2.

Not done/ Not collected	dd	MMM	yy		negative	positive	indeterminate
☐	☐☐	☐☐☐	☐☐	1b. HIV Western Blot	☐	☐	☐

If negative or indeterminate, consult MTN Network Lab.

2. STI SEROLOGY

Not done/ Not collected	Alternate Collection Date dd	MMM	yy		non-reactive	reactive
☐	☐☐	☐☐☐	☐☐	2a. Syphilis screening test	☐	☐

If non-reactive, go to item 3.

2a1. Syphilis titer ..... **1:** ☐☐☐☐

					negative	positive
				2b. Syphilis confirmatory test	☐	☐

3. OTHER STI TESTS

Not done/ Not collected	Alternate Collection Date dd	MMM	yy		negative	positive
☐	☐☐	☐☐☐	☐☐	3a. *N. gonorrhea*	☐	☐
☐	☐☐	☐☐☐	☐☐	3b. *C. trachomatis*	☐	☐
					non-reactive	reactive
☐	☐☐	☐☐☐	☐☐	3c. Hepatitis B Surface Antigen	☐	☐

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

0 1
Language

_____
Staff Initials / Date

STI Laboratory Results (SLR-1)

Purpose: This form is used to document maternal STI laboratory results as required or clinically indicated during screening, enrollment, and follow-up.

Initial Specimen Collection Date: Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. Record a complete date.

Alternate Collection Date: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. Record a complete date.

Results Reporting

- If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation on the Comments line.
- If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
- If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%.
- It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL.
    - If the site lab does not produce test results in the units used on this form, *first* perform the conversion, *then* round the converted result if necessary.

Item-specific Instructions:

- **Item 1a:** Record the assigned two-digit rapid test code. Record result of rapid HIV EIA.

Rapid Test	Kit Code
OraSure OraQuick	01

- **Items 2a–3c:** If a result is positive/reactive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log form.

Sample

Visit Code ☐☐.☐ 1

MTN 008 (180) SPR-1 (415)

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number | Participant Number | Chk | Who

Study Product Returns

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

		yes	*no, specify:*
1.	Was study product returned?	☐	☐ → ***End of form.***
2.	Date product was returned by participant:	☐☐ *dd*	☐☐☐ *MMM* ☐☐ *yy*
3.	Number of **unused** applicators returned:	☐	***unused** applicators returned*

Comments: _____

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_____ Staff Initials / Date

Study Product Returns (SPR-1)

Purpose: This form is used to document unused product returns for all maternal participants.

General Information/Instructions: This form should be completed once for each maternal participant after she has completed the product use period.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Item 1:** If study product was not returned, record the reason on the line provided.
- **Item 2:** Record the exact day, month, and year unused study product was returned by the participant.

Sample

MTN 008 (100) TM-1 (490)

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [ ]

Site Number | Participant Number | Chk | Who

Termination

1. Termination Date: *dd* [ ][ ] *MMM* [ ][ ][ ] *yy* [ ][ ]

Date the site determined that the participant was no longer in the study.

2. Reason for termination. *Mark only one.*

- ☐ 2a. scheduled exit visit/end of study → ***End of form.***
- ☐ 2b. death, *indicate date and cause if known*
  - 2b1. date of death *dd* [ ][ ] *MMM* [ ][ ][ ] *yy* [ ][ ] **OR** ☐ date unknown
  - 2b2. cause of death _____ **OR** ☐ cause unknown

  → ***Complete or update Adverse Experience Log.***
- ☐ 2c. participant refused further participation, specify: _____
- 2d. participant unable to adhere to visit schedule **NOT APPLICABLE FOR THIS PROTOCOL.**
- ☐ 2e. participant relocated, no follow-up planned
- ☐ 2f. investigator decision, specify: _____
- ☐ 2g. unable to contact participant
- 2h. HIV infection **NOT APPLICABLE FOR THIS PROTOCOL.**
- ☐ 2i. inappropriate enrollment → ***End of form.***
- ☐ 2j. invalid ID due to duplicate screening/enrollment → ***End of form.***
- ☐ 2k. other, specify: _____
- ☐ 2l. early study closure → ***End of form.***
- ☐ 2m. mother terminated from MTN-008

3. Was termination associated with an adverse experience? ..... *yes* ☐ *no* ☐ *don't know* ☐ → ***If no or don't know, end of form.***

3a. Record AE Log page: [ ][ ][ ]

Comments: _____

☐ ☐ ☐ ☒ 14-FEB-11

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Language

_____
Staff Initials / Date

Termination (TM-1)

Purpose: This form should be completed for every enrolled maternal and infant study participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

General Information/Instructions: This form must be completed for both the maternal and infant participant.

Item-specific Instructions:

- **Item 1:** A complete date is required.
- **Item 2:** Mark only the primary reason for termination.
  - **Item 2a:** Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
  - **Item 2b1:** At a minimum, the month and year are required.
  - **Item 2l:** Early study closure: Only mark 2l when instructed by SCHARP.
- **Item 3a:** Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the “specify” line.