Section 13. Data Collection

The purpose of this document is to provide site staff with the information they need to successfully complete and submit MTN-016 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-016 team members, along with their job roles and e-mail addresses, are listed below.

Role on MTN-016	Name	E-mail address
Protocol Statistician	Ben Masse	bmasse@scharp.org
Project Manager	Corey Miller	corey@scharp.org
Statistical Research Associate	Sharavi Gandham	sharavi@scharp.org
Protocol Programmer	Shuhuan Zhang	shuhuan@scharp.org
Data Coordinator	Suzanne Cullers	scullers@scharp.org
Document Specialist	Donna Fulcher	donna@scharp.org
Reporting Programmer	Deb Bassuk	dbassuk@scharp.org
Laboratory Programmer	Laura Robins-Morris	lrobins@scharp.org

13.1 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.
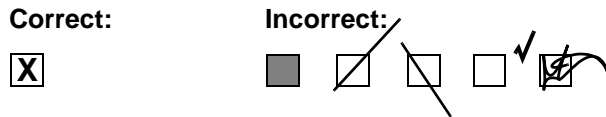
13.2 DataFax Form Completion

13.2.1   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.

13.2.2   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.
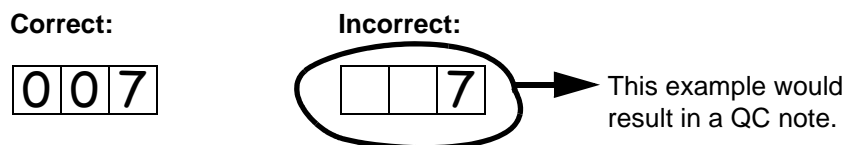
Correct: **Incorrect:**

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

13.2.3   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:**

This example would result in a QC note.

- 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:

0 1 2 3 4 5 6 7 8 9

Difficult to Identify:

0 1 2 3 4   7

13.2.4 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, 2009 is recorded as:

```
0 6   J U N   0 9
 dd    MMM     yy
```

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:

```
         
 MMM    yy
```

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

```
O C T   1 0
 MMM     yy
```

13.2.5 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:

```
1 4 : 2 5
 hr    min
```

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

13.2.6   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.

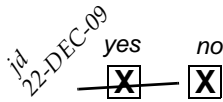Whenever an entry on a DataFax CRF is changed, do the following:

• 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:

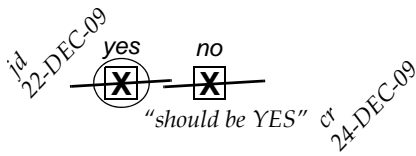**Correct:**   **Incorrect:**

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
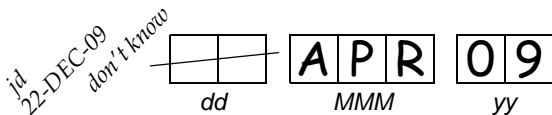
• initial and date all corrections as shown below:

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.

13.2.7   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.

13.3 MTN-016 Study-Specific Data Collection Information
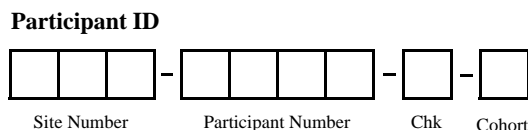
13.3.1   Participant IDs (PTIDs)

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.
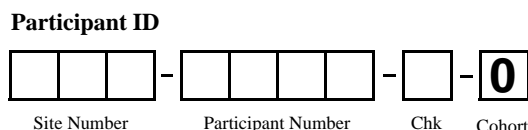
The PTIDs used for this study are nine digits and formatted as "WWW-XXXX-Y-Z." The PTID consists of four parts: the site number (WWW), the participant number (XXXX), a numerical check digit (Y) and the cohort number (Z). The check digit (Y) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. The cohort number is used to identify each participant as the woman (0) or infant (1,2,3, etc.) Below are examples of the PTID structures used in MTN-016.

General PTID Structure

Participant ID

Site Number   Participant Number   Chk   Cohort

Woman PTID Structure

SCHARP provides each site with a list of Woman PTIDs prior to study start-up. The cohort number for women will always be "0."

Participant ID

Site Number   Participant Number   Chk   Cohort   **0**

Infant PTID Structure

The Infant PTID is identical to it's mother's PTID with the exception of the last digit, the cohort number. For infants, the cohort number will be 1, 2, 3, etc. For the first infant born **and enrolled** to a woman enrolled in MTN-016 the cohort number will be "1." For the second infant born **and enrolled** to a woman enrolled in MTN-016 the cohort number will be "2." If the woman (PTID 301-1234-9-0) has multiple infants throughout her enrollment in MTN-016, but only chooses to enroll the 1st and 4th born, the PTIDs for the enrolled infants will be 301-1234-9-1 and 301-1234-9-2, respectively.

Participant ID

Site Number   Participant Number   Chk   Cohort   **1**

13.3.2   Study Visit Timing

Women Study Visits

Screening and Enrollment Visit

The Screening and Enrollment Visit is defined as Day 0 for the woman participant. This is the day she provides written informed consent to be screened and enrolled in the study.

For MTN-016, a woman participant is considered enrolled once the participant has met all eligibility criteria and provided informed consent.

Quarterly Visits

While the woman is still pregnant, she will follow a quarterly visit follow-up schedule. The number of follow-up visits for this study will vary per participant, as it will depend upon how far along in the pregnancy she is. The greatest number of possible quarterly visits is 3 based on the maximum gestational period. See Table 13-1 for details regarding the target dates and visit windows for each Quarterly Visit.

Pregnancy Outcome Visit

In cases when the woman enrolls into MTN-016 *prior* to the pregnancy outcome, the Pregnancy Outcome Visit will be part of a regularly scheduled Quarterly Visit or Interim Visit (see Interim Visits section below), and will be approximately when the outcome of the pregnancy becomes known to study staff. All procedures of the Quarterly Visit must be completed if the visit occurs within the Quarterly Visit window, plus completion of the Pregnancy Outcome form.

In cases when the woman enrolls *after* the pregnancy outcome, the Pregnancy Outcome Visit will be completed on the same day as the Screening and Enrollment Visit. In these case, Quarterly Visit will not be completed.

The Pregnancy Outcome Visit does not signify termination from the study, but does signify the end of follow-up until a subsequent pregnancy is reported or a valid reason for termination occurs.

Note: MTN-016 allows for a woman to enroll in the study within one year after her pregnancy outcome.

Pregnancy Cycles

As stated in the MTN-016 Protocol, Section 5.1, "participants and their infants can be enrolled for subsequent pregnancies; subsequent pregnancies of an EMBRACE participant will require a separate informed consent process to be initiated." For a given woman participant, each pregnancy which meets the eligibility criteria for MTN-016 is referred to as a cycle. Each subsequent pregnancy may happen at any time after the initial pregnancy is completed. Please see Table 13-3 for the required CRFs to be completed at the beginning of each pregnancy cycle.

Table 13-1: MTN-016 List of Visits, Visit Codes, Target Visit Dates, and Target Visit Windows: WOMEN

All visit windows are in days; Enrollment date = Day 0

Visit	Visit Code	Day Target Window Opens	Target Date	Day Target Window Closes
Enrollment	1.0	N/A	**0**	N/A
Quarterly #1	2.0	46	**90**	135
Quarterly #2	3.0	136	**180**	225
Quarterly #3	4.0	226	**270**	315

Infants Study Visits

Newborn/Initial Visit

When possible, this visit should occur during the first ten days of life. The infant date of birth is defined as Day 0 for the infant participant.

For MTN-016, an infant participant is considered enrolled once consented **and** born.

Months 1, 6, and 12 Visits

There are 3 scheduled follow-up visits for the infants in MTN-016; Month 1, 6, and 12. There is no formal Termination or Study Exit Visit in MTN-016. Therefore, study exit procedures will be part of the Month 12 Visit procedures. See Table 13-2 for details regarding the target dates and visit windows for each follow-up visit.

Table 13-2: MTN-016 List of Visits, Visit Codes, Target Visit Dates, and Target Visit Windows: INFANTS

All visit windows are in days; Date of birth = Day 0

Visit	Visit Code	Day Target Window Opens	Target Date	Day Target Window Closes
Newborn	1.0	0	**0**	10
Month 1	2.0	16	**30**	44
Month 6	3.0	152	**182**	212
Month 12	4.0	334	**364**	394

Target Dates and Visit Windows

Whenever possible, visits should be completed within the target window. Ideally, visits will be completed on the target date for the visit. For *women participants*, follow-up visits in MTN-016 are targeted to occur quarterly (Day 90, Day 180, and Day 270) throughout the pregnancy following the participant's enrollment date into the study (Day 0). Women participant target dates are set based on the enrollment date and do not change if subsequent actual visits take place before or after the target date. For *infant participants*, follow-up visits in MTN-016 are targeted to occur at Month 1 (Day 30), Month 6 (Day 182), and Month 12 (Day 364) following the participant's date of birth (Day 0). Infant participant target dates are set based on the date of birth 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-016 Retention Reports as being completed "on-time."

It is not always 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 *women participants'* follow-up visits is 45 days before or after the target date (i.e. +/- 45 days). For example, if a woman participant enrolls into MTN-016 on 15 September 2009, her first Quarterly Visit target date is 14 December 2009. However, she can complete her Quarterly Visit #1 any time between 31 October 2009 and 28 January 2010. The visit windows for the *infant participants'* follow-up visits are as follows: Newborn Visit can be completed within 10 days after the infant's date of birth, the Month 1Visit has a 2 week window before or after the target date (i.e. +/- 2 weeks), the Month 6 and Month 12 Visits have a 30 day window before or after the target date (i.e. +/- 30 days). For example, if an enrolled infant participant was born on 22 February 2010, the Month 1 target date is 24 March 2010. However, the Month 1 Visit can be completed any time between 10 March 2010 and 07 April 2010. 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 (for women participants) or date of birth (for infant participants) be entered. Once the enrollment date/birthdate 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. The women participant calendar tool provides potential visit scheduling for up to 4 pregnancy cycles for each woman.

Split Visits

In cases where a participant is not able to complete all required visit evaluations on the same day, the participant may come back and complete the remaining evaluations on another day, as long as the evaluations are completed within the visit window for that particular visit (see Tables 13-1 and 13-2 for specific visit windows). For example, if an infant participant comes for the Month 6 Visit on the target date and completes all required evaluations except for the developmental screening assessment, the infant can return up to 30 days later to complete the developmental screening assessment. See Section 13.3.3 for information on assigning visit codes to split visits.

Missed Visits

In those cases where a participant is not able to complete any part of a required visit within the target visit window, the visit is considered missed. For example, if the same participant who enrolls into MTN-016 on 15 September 2009 shows up for her first Quarterly Visit on 29 January 2010, her Quarterly Visit #1 is considered missed, as she is now in the target window for her second Quarterly Visit (29 January 2010 - 28 April 2010). In this case, since the target visit window for that participant's first Quarterly Visit has "closed", the Quarterly Visit #1 is considered missed, and is documented by completing a Woman Missed Visit case report form.

Interim Visits

A study visit is considered an interim visit when a participant 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), clinical follow-up, etc. Given the specification of visit windows for this study, interim visits will occur when more than one visit takes place within a target visit window. The following are examples of interim visits for MTN-016:

1. A participant completes all required evaluations for the scheduled study visit within the target window. The participant then returns to the site clinic within the same target window to report a pregnancy outcome.

2. A participant completes all required evaluations, including an ultrasound exam, for the scheduled study visit within the target window. The participant then returns to the site clinic within the same target window for a repeat follow-up ultrasound exam.

Phone contact with a participant may also be considered an interim visit if the phone contact results in reporting a pregnancy outcome or a new social harm.

Assignment of visit codes to Interim Visits is covered later in the next section, section 13.3.3.

For questions about phone contacts and assignment of visit codes to such contacts, please contact the SCHARP MTN-016 Project Manager.

13.3.3   Pregnancy Number, Visit Codes, and Page Numbers

Some DataFax CRFs will include boxes in the upper right corner for a visit code. Many of the case report forms for the women participants having the following visit code structure:

Pregnancy #   **Visit Code**   **1**

The CRFs for the infant participants use the standard visit code structure and do not include the Pregnancy Number.

Pregnancy Number

This phrase is synonymous with *pregnancy cycle*. As stated earlier is Section 13.3.2, women in MTN-016 may have multiple pregnancy cycles; that is she may have more than one eligible and enrolled pregnancy during the time of MTN-016. The first enrolled pregnancy will be Pregnancy Number 01. The next eligible **and enrolled** pregnancy will be Pregnancy Number 02, etc. If the woman participant has multiple pregnancies throughout her enrollment in MTN-016, but only chooses to consent for her 1st and 3rd pregnancies, the Pregnancy Numbers for the eligible and enrolled pregnancies will be 01 and 02, respectively.

Visit Codes

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 Woman Enrollment form or the Infant 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. Please see Tables 13-1 and 13-2 for specific visit codes used for the woman and infant visits, respectively.

Visit Codes for Split Visits

See Section 13.3.2 for the definition of split visits. When a split visit occurs, the case report forms completed for the visit are all assigned the same visit code (even though some forms and evaluations will have different visit dates). For example, an infant participant comes in for the Month 6 Visit on the target date of 23 July 2010 and completes all required evaluations except for the infant physical exam (the mother did not have time to stay at the clinic for all procedures to be completed). The infant returns on 25

July 2010 and completes the physical exam. All case report forms completed on 23 and 25 July are assigned a visit code of 3.0 (since all evaluations are Month 6 evaluations).

Visit codes for interim visits

In addition to the scheduled, protocol-required visits listed in Table 13-1 and 13-2, interim visits may occur once the participant is enrolled (see Section 13.3.2 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,

    - #.3 = the third interim visit after the most recent scheduled visit, and so on.

Example: A woman participant returns to the site clinic two weeks after completing her first Quarterly Visit to report a pregnancy outcome. If she is still in the Quarterly #1 Visit window, this current visit is considered and interim visit and is assigned the following interim visit code:

Visit Code for this Interim Visit:

Visit Code **2** . **1**

Page numbers

Other CRFs, such as log forms (i.e., Concomitant Medications Log, Social Harms Assessment Log), include boxes in the upper right corner for recording page numbers, as shown below:

Page ☐ ☐

Assign page numbers in sequential order, starting with 01. Assign numbers in sequential order (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. Do not restart page numbering with a subsequent consent (i.e. pregnancy cycle). For example, if a participant reported 2 separate social harms (pages 01 and 02) during her first pregnancy, and then during her second pregnancy she reports another social harm, the newest social harm will be page 03.

13.3.4   Staff Initials/Date

Most forms 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.

13.3.5 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 13-3 and Table 13-4) list the DataFax and non-DataFax forms that are **required** to be completed at each MTN-016 study visit for Women and Infants.

Table 13-3: Case Report Form Completion Schedule: WOMEN

Form Acronym	Form Name	Plate #
SCREENING AND ENROLLMENT	**PREGNANCY # / VISIT CODE: 1.0 / 1.0**	
Required		
WEN-1	Woman Enrollment	070
DEM-1	Woman Demographics	001
PPP-1	Parent Protocol Participation	080
GSH-1–GSH-5	Genetic Screening History	101–105
UR-1	Ultrasound Results	120
PR-1	Pregnancy Report and History	440
CM-1	Woman Concomitant Medications Log	423
Non-DataFax	Woman Medical History Log	N/A
As Needed		
PO-1–PO-3	Pregnancy Outcome	441–443
QUARTERLY VISITS	**PREGNANCY # / VISIT CODES: 1.0 / 2.0, 3.0, 4.0**	
Required		
WFU-1	Woman Follow-up Visit	125
UR-1	Ultrasound Results	120
GSH-1–GSH-5	Genetic Screening History (*updated*)	101–105
CM-1	Woman Concomitant Medications Log (*updated*)	423
Non-DataFax	Woman Medical History Log (*updated*)	N/A
As Needed		
SHA-1	Social Harms Assessment Log	155
PO-1–PO-3	Pregnancy Outcome	441–443
MV-1	Woman Missed Visit	463
SUBSEQUENT CONSENT (PREGNANCY CYCLES)	**PREGNANCY # / VISIT CODE: 2.0 (3.0, 4.0) / 1.0**	
Required		
WSC-1	Woman Subsequent Consent	075
GSH-1–GSH-5	Genetic Screening History	101–105
UR-1	Ultrasound Results	120
PR-1	Pregnancy Report and History	440
CM-1	Woman Concomitant Medications Log (*updated*)	423
Non-DataFax	Woman Medical History Log (*updated*)	N/A
As Needed		
PO-1–PO-3	Pregnancy Outcome	441–443
TERMINATION/STUDY EXIT		**NO VISIT CODE**
Required		
TM-1	Woman Termination	490
ESI-1	Woman End of Study Inventory	489
INTERIM VISIT	**PREGNANCY # / VISIT CODE: varies**	
Required		
IV-1	Woman Interim Visit	350
As Needed		
SHA-1	Social Harms Assessment Log	155
GSH-1–GSH-5	Genetic Screening History (*updated*)	101–105
UR-1	Ultrasound Results	120

PO-1–PO-3	Pregnancy Outcome	441–443
CM-1	Woman Concomitant Medications Log (*updated*)	423
Non-DataFax	Woman Medical History Log (*updated*)	N/A

Table 13-4: Case Report Form Completion Schedule: INFANTS

Form Acronym	Form Name	Plate #
NEWBORN/INITIAL VISIT	**VISIT CODE: 1.0**	
Required		
IEN-1	Infant Enrollment	070
IFV-1	Infant Visit	125
IPE-1	Infant Physical Exam	130
CM-1	Infant Concomitant Medications Log	423
Non-DataFax	Infant Medical History Log	N/A
As Needed		
HTR-1	Infant HIV Test Results	135
Non-DataFax	MTN-016 LDMS Specimen Tracking Sheet	N/A
MV-1	Infant Missed Visit	463
MONTH 1 VISIT	**VISIT CODE: 2.0**	
Required		
IFV-1	Infant Visit	125
IPE-1	Infant Physical Exam	130
CM-1	Infant Concomitant Medications Log (*updated*)	423
Non-DataFax	Infant Medical History Log (*updated*)	N/A
As Needed		
HTR-1	Infant HIV Test Results	135
Non-DataFax	MTN-016 LDMS Specimen Tracking Sheet	N/A
MV-1	Infant Missed Visit	463
SHA-1	Social Harms Assessment Log	155
MONTH 6 VISIT	**VISIT CODE: 3.0**	
Required		
IFV-1	Infant Visit	125
IPE-1	Infant Physical Exam	130
IDS-1	Infant Developmental Screening	132
CM-1	Infant Concomitant Medications Log (*updated*)	423
Non-DataFax	Infant Medical History Log (*updated*)	N/A
As Needed		
HTR-1	Infant HIV Test Results	135
Non-DataFax	MTN-016 LDMS Specimen Tracking Sheet	N/A
MV-1	Infant Missed Visit	463
SHA-1	Social Harms Assessment Log	155
MONTH 12 VISIT	**VISIT CODE: 4.0**	
Required		
IFV-1	Infant Visit	125
IPE-1	Infant Physical Exam	130
IDS-1	Infant Developmental Screening	132
CM-1	Infant Concomitant Medications Log (*updated*)	423
TM-1	Infant Termination	490
ESI-1	Infant End of Study Inventory	489
Non-DataFax	Infant Medical History Log (*updated*)	N/A
As Needed		
HTR-1	Infant HIV Test Results	135
Non-DataFax	MTN-016 LDMS Specimen Tracking Sheet	N/A
MV-1	Infant Missed Visit	463
SHA-1	Social Harms Assessment Log	155
INTERIM VISIT	**VISIT CODE: VARIES**	
Required		
IV-1	Infant Interim Visit	350
As Needed		

IPE-1	Infant Physical Exam	130
HTR-1	Infant HIV Test Results	135
Non-DataFax	MTN-016 LDMS Specimen Tracking Sheet	N/A
IDS-1	Infant Developmental Screening	132
SHA-1	Social Harms Assessment Log	155
CM-1	Infant Concomitant Medications Log (*updated*)	423
Non-DataFax	Infant Medical History Log (*updated*)	N/A

13.3.6   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 13.2.7.

- 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 13.3.7 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.

13.3.7   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-016 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-016 Project Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

13.3.8   Non-DataFax Forms

MTN-016 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 13.3.1 through 13.3.4 should be applied when completing non-DataFax CRFs.

13.4 Form Supply and Storage

13.4.1   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 Woman: Screening and Enrollment Visit packet will include all of the CRFs listed for this visit in the Case Report Form Completion Schedule table (Table 13-3). In addition to form packets for each visit listed in Table 13-3, bulk supplies of "as needed" CRFs will be provided to the site (for example, Woman Subsequent Consent, Infant HIV Test Results, Social Harms Assessment Log, etc.). the forms provided by SCHARP will be color coded to help differentiate the forms used for women (white pages) from those used for infants (green pages). 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.

13.4.2   Form Storage

Specifications for form storage will be detailed in the site's MTN-016 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 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.

13.5 How to Complete Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is critical that participant interviews be conducted with a non-biased, non-judgmental approach. Study staff should help a participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.

Interviewing Techniques

An interviewer uses both verbal and non-verbal techniques to obtain the most honest, accurate, and thorough responses from participants. These techniques are discussed in the sections below.

Welcoming the Participant

- When a new participant arrives at the clinic, everything about the study is new. Help make the participant feel comfortable.

- Perhaps offer the participant a glass of water or other beverage.

- Introduce yourself, and try to create rapport (connection) between yourself and the participant to help her feel comfortable during the interview.

- Some DataFax forms include introduction statements before certain items to help prepare the participant for sensitive questions. Read each of these introductions as they appear on the forms.

Asking Sensitive Questions

Your level of comfort with asking sensitive questions will affect the participant's comfort and answers. If you ask the questions in a confident and supportive manner, the participant will feel more confident and comfortable answering the questions. Make eye contact with the participant to let her know that you are listening to her and aware that she is being asked difficult questions. Avoid apologizing for questions or making facial gestures that might show you feel any way but neutral about a question or the participant's response. If the participant feels judged for her behavior, she will be less likely to share honestly with you.

Recording Participants' Responses Verbatim

Often, interviewer-administered questions will have a list of response categories provided to capture the participant's response. Almost always, an "other, specify" box is included as one of the response categories in order to capture participant responses that do not fit into one of the categories already listed. When a participant's response does not match or fit into one of the listed response categories, record the participant's response in English.

Pacing the Interview

Every participant is different. Some will know or say the answer to questions very quickly. Others may have to think longer to come up with answers, or may change their answers after giving more thought to the subject. Always account for this variety when doing an interview. Read items slowly. Let the participant finish thinking before you record her response and go on to the next item.

Reading Items Aloud

For MTN-016 we have not translated the interviewer-administered forms as they are more clinical in nature. You must review each item on the relevant CRFs with the participant. If an item is not understood, provide explanation or interpretation, if necessary. Avoid tangential—though related—counseling and educational discussions during data collection. When applicable, acknowledge questions and concerns raised by the participant during the interview, and state that the subject can be discussed after the end of the interview.

Vary your tone of voice, so that you don't sound automated. Emphasize the important words in an item, so that the meaning of the question comes through.

When given the option, choose "clinical" versus "street" or "vernacular" language based on participant preferences/cues.

For items with multiple sub-items, review all sub-items with the participant and mark the appropriate response for each, based on participant report.

Probing

One of the major goals of the study's interviews is to obtain accurate genetic history for each woman enrolled. These interviews ask participants to recall many aspects of their family medical history. However, participants may not remember or know the answer to every question. The technique for helping a participant remember an answer, clarify a response, decide between two similar but different answers, or report something more precisely is called "probing."

Effective probing helps a participant think more about a question or refine an answer that is too general; however, probing must not bias or otherwise direct participant responses. As the interviewer, you cannot offer the participant an answer. Therefore, all probes must be neutral.

The following are some probing strategies to use when a participant initially answers "don't know" to an item or cannot refine her response enough for the item to be adequately recorded.

- **Repeat Probe:** The repeat probe is used by repeating the item or response categories (if the response categories are part of the question). Although the participant might hear you the first time you ask a question, she may need to hear the question more than once to provide an answer. Instead of rephrasing a question if you notice the participant is confused, always first repeat the item as it is written. Sometimes hearing the question a second time is all that is needed.

- **Echo Probe:** The echo probe involves repeating the participant's exact response. Sometimes hearing the answer with a different voice will help her be more precise. The echo should always be repeated in a neutral, non-judgmental style.

- **Silent Probe:** The silent probe is used by pausing briefly after a participant gives what seems to be an uncertain answer. Although silence can feel awkward, sometimes it is helpful when a participant is trying to determine the most accurate answer to a question. Use a silent probe when the participant sounds unsure of her answer and may need some extra time to think more carefully about the question.

- **Non-verbal Probe:** The non-verbal probe is used by giving hand or facial gestures that may help the participant to come up with an answer. Remember that all such gestures must be neutral and non-judgemental.

- **Specification Probe:** The specification probe is used by asking the participant to give a more precise answer. Although a participant may give an answer that he or she considers accurate, it may not be specific enough. For example, if an item asks how many times the participant did something and she answers with a range ("5 to 10"). Ranges are not acceptable for this type of interviewing. In this case, the probe, "Can you be more specific?" is often enough to help the participant choose the most accurate response.

- **Historical Probe:** The historical probe is used by asking whether the event in question occurred anytime around major holidays or personal events such as a birthday or other life event. Some items require the participant to recall dates, and initially she may be unable to recall a date. Referencing a calendar can also help the participant remember dates.

Watching for Non-verbal Cues

A participant may give you one answer verbally, but express something else using body language or facial expressions. Although you should not question a participant so as to make her feel like you don't trust her answers, be aware of whether she is giving you non-verbal cues that indicate she is not feeling comfortable, not taking the interview seriously, or not answering honestly.

Checking Your Work

During the interview it is important to use the forms instructions (those on the front and back of each page) to guide the interview. Also, make sure the participant is understanding and responding to you, and record all reported information on the forms. **After the interview and while the participant is still there**, review the forms for accuracy and completeness so you can complete an item that might have accidentally been missed.

13.6 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, you will not see all form items listed in the form-specific completion instructions, but rather, only those items needing detailed explanation.

Below are some additional instructions for the **Concomitant Medications Log** case report form.

Concomitant Medication Log

• For the Concomitant Medication Log form, 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.

13.7 Case Report Forms

This section contains each MTN-016 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: *DO NOT FAX TO DATAFAX*

▮ ▮ ▮ ▮ ▮ ▮ ▮ ▮ ▮

MTN 016 (164)　　　　DEM-1　(001)　　　　　　　　　　Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0　　**Woman Demographics**

Site Number　Participant Number　Chk　Cohort

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? .... ☐　☒

　　　　　　　　　　　　　　　　　　　　　　yes　*no*

3. Does the participant earn an income of her own?........................... ☐　☐ → **If no, go to item 4.**

　　3a. How does she earn her income? *Mark all that apply.*

　　　　☐ 3a1. formal employment

　　　　☐ 3a2. self-employed

　　　　☐ 3a3. other, specify: _____

4. What is the participant's highest level of education?

　　☐ no schooling

　　☐ primary school, not complete

　　☐ primary school, complete

　　☐ secondary school, not complete

　　☐ secondary school, complete

　　☐ attended college or university

　　　　　　　　　　　　　　　　　　　　　yes　*no*

5. Does the participant, or someone in her family, own the home she currently lives in?... ☐　☐

6. How many rooms are in the participant's household? .... ☐☐ # of rooms

　　　　　　　　　　　　　　　　　　　　　yes　*no*

7. Is the participant currently married? .... ☐　☐

8. What is the participant's ethnic group or tribe? .... ☐☐ *ethnic/tribe code*
If other, specify:
_____

U.S. SITES ONLY:

　　　　　　　　　　　　　　　　　　　　　yes　*no*

9. Does the participant consider herself to be Latina or of Hispanic origin? .... ☐　☐

☐ ☐ ☐ ☒　08-JUL-09

0 1
Language　Staff Initials / Date

Woman Demographics (DEM-1)

Purpose: This form is used to document general demographic information.

General Information/Instructions: This form is completed once for each participant, at 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 2:** This item has already been completed based on the expected study population. Please skip this item.

- **Item 3a:** Record whether the participant's source(s) of income is/are from formal employment (e.g., shop clerk, farmer, seamstress, teacher), self-employment (e.g., shop owner, artist, restaurant owner), or other type of employment.

- **Item 5:** Record whether or not the participant or someone in her family owns the home where she lives.

- **Item 8:** This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant's ethnic group or tribe. If the participant responds with "other," record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

MALAWI	SOUTH AFRICA	UGANDA	UNITED STATES	ZAMBIA	ZIMBABWE
01 - Chichewa	**07** - Zulu	**11** - Black	**18** - American Indian or Alaskan Native	**12** - Bemba	**16** - Shona
02 - Lomwe	**08** - Xhosa	**06** - White		**13** - Chewa	**17** - Ndebele
03 - Yao	**09** - Indian	**99** - Other	**19** - Asian	**14** - Tonga	**05** - Other African tribe
04 - Tumbuka	**10** - Colored		**20** - Black or African American	**15** - Lozi	**06** - White
05 - Other African tribe	**05** - Other African tribe		**21** - Native Hawaiian or other Pacific Islander	**05** - Other African tribe	**99** - Other
06 - White	**06** - White		**06** - White	**06** - White	
99 - Other	**99** - Other		**99** - Other	**99** - Other	

- **Item 9:** This item is only completed by U.S. sites. All non-U.S. sites leave this item blank.

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SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)　　　WEN-1　(070)　　　　　　　　　　　Page 1 of 1

Participant ID　　　　　　　　　　**Woman Enrollment**　　　　**Visit Date**

[ ] [ ] [ ] — [ ] [ ] [ ] [ ] — [ ] — [0]　　　　　　　　　　[ ] [ ] [ ] [ ] [ ] [ ]
Site Number　　Participant Number　　Chk　Cohort　　　　　　　　　dd　　MMM　　yy

　　　　　　　　　　　　　　　　　　　　　yes　　no

1.　Does the participant meet all eligibility criteria?..........　[ ]　[ ] ➔ *If no, participant is ineligible. End of form. Do not fax to SCHARP DataFax.*

2.　Date study informed consent signed or thumbprinted:　[ ] [ ] [ ] [ ] [ ] [ ]
　　　　　　　　　　　　　　　　　　　　　dd　　MMM　　yy

3.　During the participation in the parent protocol, did/does the participant have a known confirmed pregnancy? ....
　　　　　　　　　　　　　　　　yes　　no
　　　　　　　　　　　　　　　　[ ]　[ ] ➔ *If no, participant is ineligible. End of form. Do not fax to SCHARP DataFax.*

　　3a.　Known confirmed pregnancy was determined using at least one of the following sets of criteria (A or B):

　　　　Criteria A.

　　　　[ ] 3a1.　two consecutive monthly study visits with positive pregnancy tests

　　　　　　　　　　　　　　　　dd　　MMM　　yy
　　　　Date of 1st positive pregnancy test:　[ ] [ ] [ ] [ ] [ ] [ ]

　　　　Date of 2nd positive pregnancy test:　[ ] [ ] [ ] [ ] [ ] [ ] ➔ *Go to item 4.*

　　　　Criteria B. *Mark all that apply.*
　　　　[ ] 3b1.　auscultation of fetal heart tones

　　　　[ ] 3b2.　positive pregnancy test confirmed by clinic staff in the presence of clinically confirmed enlarged uterus

　　　　[ ] 3b3.　positive pregnancy test confirmed by clinic staff in the presence of missed menses by participant report

　　　　[ ] 3b4.　clinical assessment of fetal movement

　　　　[ ] 3b5.　demonstration of pregnancy by ultrasound

　　　　　　　　　　　　　　　yes　　no
4.　Has the pregnancy outcome been diagnosed? ....　[ ]　[ ] ➔ *If no, go to item 5.*

　　4a.　Date of diagnosis: ....　[ ] [ ] [ ] [ ] [ ] [ ]
　　　　　　　　　　　　　　　　　　　dd　　MMM　　yy

　　If equal to or greater than one year ago, participant is ineligible. End of form. Do not fax to SCHARP DataFax.

　　　　　　　　　　negative　　positive　　indeterminate　　not known　　*If not known, end of form.*

5.　Participant's HIV status: ....　[ ]　　[ ]　　[ ]　　[ ]

　　5a.　Date and source of most recent HIV test: ......
　　　　　　　　　　　　　　　　　　　　　parent protocol　　self-report
　　　　[ ] [ ] [ ] [ ] [ ] [ ]　　　　　[ ]　　　　[ ]
　　　　dd　　MMM　　yy

[ ] [ ] [ ] [x]　08-JUL-09　　　　　　　　　　[0] [1]
　　　　　　　　　　　　　　　　　　　　　　Language　Staff Initials / Date

Woman Enrollment (WEN-1)

Purpose: This form is used to document a woman participant's study enrollment. 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 eligible and provides informed consent), 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 response to this item is "no" (the participant does not meet all eligibility criteria), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.

- **Item 2:** If the participant marks the informed consent using her thumbprint, record the date the thumbprint was made.

- **Item 3:** If response to this item is "no" (the participant did/does not have a known confirmed pregnancy from the parent protocol), end the form. This participant is not eligible. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.

- **Items 3a–3b5:** These items document which criteria within A or B were met to determine the confirmed pregnancy. If item 3a1 is marked, record the dates of the two positive pregnancy tests, and go to item 4. If the confirmed pregnancy was made using criteria B, skip 3a1 and mark all that apply for items 3b1–3b5.

- **Item 4:** If the pregnancy outcome for this pregnancy has already been diagnosed, mark item 4 "yes." Complete a Pregnancy Outcome form.

- **Item 4a:** Record the date of the pregnancy outcome. All efforts should be made to obtain a complete pregnancy outcome date. If a complete date (day, month, and year) is not available, record the best estimate possible. At a minimum try to record the month and year of the pregnancy outcome. If the pregnancy outcome date is more than one year ago, the participant is not eligible. End the form and do NOT fax this or any other forms completed for this participant to SCHARP DataFax.

- **Item 5:** Record the participant's HIV status.

- **Item 5a:** Record the date **and** source of the most recent HIV test result. If the HIV test result is available from source documentation of the parent protocol mark the "parent protocol" box. Otherwise, mark the "self-report" box.

  Note: All efforts should be made to obtain HIV test result information from laboratory source documentation.

Version 1.0, 08-JUL-09

Statistical Center for HIV/AIDS Research & Prevention (SCHARP)   **Woman Subsequent Consent (WSC-1)**

SAMPLE: *DO NOT FAX TO DATAFAX*

▌▌▐▌▌▐▌▐▌▐▌

MTN 016 (164)   WSC-1   (075)

Pregnancy #   **Visit Code** ☐☐ 1.0 1

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Woman Subsequent Consent

Visit Date

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

1. Does the participant meet all eligibility criteria for this pregnancy? ....

yes ☐   *no* ☐ ➤ ***If no, end of form. Do not fax to SCHARP DataFax.***

2. Date study informed consent signed or thumbprinted:

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

3. During the participation in the parent protocol, did/does the participant have a known confirmed pregnancy? ....

yes ☐   *no* ☐ ➤ ***If no, end of form. Do not fax to SCHARP DataFax.***

3a. Known confirmed pregnancy was determined using at least one of the following sets of criteria (A or B):

Criteria A.

☐ 3a1. two consecutive monthly study visits with positive pregnancy tests

dd   MMM   yy

Date of 1st positive pregnancy test: ☐☐ ☐☐☐ ☐☐

Date of 2nd positive pregnancy test: ☐☐ ☐☐☐ ☐☐ ➤ ***Go to item 4.***

Criteria B. *Mark all that apply.*

☐ 3b1. auscultation of fetal heart tones

☐ 3b2. positive pregnancy test confirmed by clinic staff in the presence of clinically confirmed enlarged uterus

☐ 3b3. positive pregnancy test confirmed by clinic staff in the presence of missed menses by participant report

☐ 3b4. clinical assessment of fetal movement

☐ 3b5. demonstration of pregnancy by ultrasound

4. Has the pregnancy outcome been diagnosed? ....

yes ☐   *no* ☐ ➤ ***If no, go to item 5.***

4a. Date of diagnosis: .... ☐☐ ☐☐☐ ☐☐

dd   MMM   yy

If equal to or greater than one year ago, participant is ineligible. End of form. Do not fax to SCHARP DataFax. ◄

5. Participant's HIV status: ....

negative ☐   *positive* ☐   *indeterminate* ☐   *not known* ☐ ➤ ***If not known, end of form.***

5a. Date and source of most recent HIV test: ...... ☐☐ ☐☐☐ ☐☐

dd   MMM   yy

parent protocol ☐   *self-report* ☐

☐ ☐ ☐ ☒ 08-JUL-09

0 1

Language   Staff Initials / Date

N:\hivnet\forms\MTN_016\forms\forms_woman\m016_wom_subsequent_consent.fm
Version 1.0   29 July 2009

Woman Subsequent Consent (WSC-1)

Purpose: This form is used to document reconsent for any subsequent pregnancies for MTN 016 after the first pregnancy outcome.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the subsequent pregnancy is eligible for the study (that is, she is eligible and provides informed consent for this pregnancy).

Pregnancy # and Visit Code: Record the Pregnancy # and Visit Code assigned to the visit. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. The Visit Code has been pre-filled with 1.0, because this form will always be completed at the first visit for a subsequent pregnancy cycle. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1:** If response to this item is "no" (the participant does not meet all eligibility criteria for this pregnancy), end the form. Do NOT fax this or any other forms completed for this participant's subsequent pregnancy to SCHARP DataFax.

- **Item 2:** If the participant marks the informed consent using her thumbprint, record the date the thumbprint was made.

- **Item 3:** If response to this item is "no" (the participant did/does not have a known confirmed pregnancy from the parent protocol), end the form. Do NOT fax this or any other forms completed for this participant *at this visit* to SCHARP DataFax.

- **Items 3a-3b5:** These items document which criteria within A or B were met to determine the confirmed pregnancy. If item 3a1 is marked, record the dates of the two positive pregnancy tests, and go to item 4. If the confirmed pregnancy was made using criteria B, skip 3a1 and mark all that apply for items 3b1-3b5.

- **Item 4:** If the pregnancy outcome for this pregnancy has already been diagnosed, mark item 4 "yes." Complete a Pregnancy Outcome form.

- **Item 4a:** Record the date of the pregnancy outcome. All efforts should be made to obtain a complete pregnancy outcome date. If a complete date (day, month, and year) is not available, record the best estimate possible. At a minimum try to record the month and year of the pregnancy outcome. If the pregnancy outcome date is more than one year ago. the participant is not eligible. End the form and do NOT fax this or any other forms completed for this participant to SCHARP DataFax.

- **Item 5:** Record the participant's HIV status.

- **Item 5a:** Record the date **and** source of the most recent HIV test result. If the HIV test result is available from source documentation of the parent protocol mark the "parent protocol" box. Otherwise, mark the "self-report" box.

   Note: All efforts should be made to obtain HIV test result information from laboratory source documentation.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   PPP-1   (080)

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Parent Protocol Participation

Visit Date

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

1. Parent protocol network: ....

MTN   other

☐ **OR** ☐ ➤ *If other, specify in Comments. Go to item 4.*

1a. Parent protocol number: .... ☐☐☐

1b. Parent protocol Participant ID: .... ☐☐☐ - ☐☐☐☐ - ☐

Site Number   Participant Number   Chk

2. Is the participant completing a parent protocol (MTN only) visit at this MTN 016 visit? ....

yes   no

☐   ☐ ➤ *If no, go to item 3.*

2a. Visit code of parent protocol visit completed today: ....

visit code

☐☐ . ☐

3. Was/is the participant enrolled in any other MTN study in addition to the parent protocol recorded in item 1a? ....

yes   no

☐   ☐ ➤ *If no, go to item 4.*

3a. First MTN protocol number and Participant ID: ....

☐☐☐ ☐☐☐ - ☐☐☐☐ - ☐

Protocol Number   Site Number   Participant Number   Chk

3b. Second MTN protocol number and Participant ID:...

☐☐☐ ☐☐☐ - ☐☐☐☐ - ☐

Protocol Number   Site Number   Participant Number   Chk

4. Was/is the participant enrolled in any other non-MTN study with an investigational product? ....

yes   no

☐   ☐ ➤ *If no, end of form.*

4a. Record name of non-MTN study: _____

Comments: _____

_____

☐ ☐ ☐ ☒ 08-JUL-09

0 1

Language   Staff Initials / Date

Parent Protocol Participation (PPP-1)

Purpose: This form is used to document the participant's parent protocol and her previous enrollment in other MTN or non-MTN studies with investigational product(s).

General Information/Instructions: This form is completed only once for each participant, at the Enrollment Visit. Updates should be made as needed throughout MTN 016 participation.

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 parent protocol is not an MTN study, specify the non-MTN microbicide study network or group, study name, and study phase in the comments section at the bottom of the form (e.g., "Pop Council, Carraguard Phase III").

- **Items 2 and 2a**: If the participant is completing an MTN parent protocol visit (regular visit or interim visit) on this same day, mark "yes," and record the visit code (regular or interim) of the MTN parent protocol visit completed on this date.

- **Items 3a and 3b:** These items include past participation in protocols such as HPTN 055 and HPTN 035. If the participant was/is only enrolled in one other MTN study (including the studies mentioned above) in addition to the parent protocol complete item 3a and leave item 3b blank.

- **Item 4a:** Specify the non-MTN microbicide study network or group, study name, and study phase on the lines provided (e.g., "Pop Council, Carraguard Phase III").

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   GSH-1 (101)

Pregnancy #   **Visit Code** 1 . 0   1

Page 1 of 5

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Genetic Screening History

Visit Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

1. Has the participant, or members of her family, ever been diagnosed with any of the following conditions?

		yes	no	don't know	*If yes, record family relative codes:*
1a.	Cleft-Lip or Palate	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1b.	Heart Defects, specify:	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1c.	Spina Bifida *(Open Spine)*	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1d.	Muscle Disease/Muscular Dystrophy	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1e.	Mental Retardation	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1f.	Down Syndrome	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1g.	Cystic Fibrosis	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1h.	Kidney Disease	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1i.	Sickle Cell Anemia	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1j.	Hemophilia *(Bleeder's Disease)*	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1k.	Thalassemia *(Mediterranean or Cooley's Anemia)*	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐
1l.	Other, specify:	☐	☐	☐	☐☐ ☐☐ ☐☐ ☐☐

☐ ☐ ☐ ☒   08-JUL-09

0 1   Language

Staff Initials / Date

Genetic Screening History (GSH-1)

Purpose: This form is used to document significant genetic conditions of the participant (and her family), and the biological father (and his family) of the fetus/infant.

General Information/Instructions: This form is first completed at the Enrollment Visit. It is updated at each quarterly visit until the Pregnancy Outcome form is completed. All updated pages of the form must be faxed to SCHARP Data Fax. A new Genetic Screening History form is completed for each subsequent pregnancy.

Pregnancy # and Visit Code: The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. The Visit Code has been pre-filled with 1.0, because this form will always be completed at the first visit of a pregnancy cycle. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1:** Ask each participant if she, or members of her family, have been diagnosed with any of the conditions listed in items 1a–1l.

- **Items 1a–1l:** If yes, record the appropriate family code(s) for each item:

    Family relative codes:

    01 = self

    02 = parent

    03 = sibling (brother or sister)

    04 = grandparent (maternal or paternal)

    05 = aunt or uncle (maternal or paternal)

    06 = first cousin

    07 = previous child(ren)

    60 = other (none of the above mentioned relatives)

    99 = more than 4 family members

    Note: If more than four family members have been diagnosed with a specific condition, record three corresponding family codes in the first three pairs of boxes and record "99" in the fourth pair of boxes. For example, if the participant reports that she, her mother, her sister, her aunt, and her grandmother have all been diagnosed with sickle cell anemia, item 1i should be marked "yes," and the codes "01," "02," "03," and "99" should be recorded in the family relative codes for this item.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   GSH-2 (102)

Pregnancy #   **Visit Code** `1` `.` `0`   `1`

Page 2 of 5

Participant ID

`___` - `____` - `_` - `0`

Site Number   Participant Number   Chk   Cohort

Genetic Screening History

2. Has the biological father, or members of his family, ever been diagnosed with any of the following conditions?

yes   no   don't know

If yes, record family relative codes:

2a. Cleft-Lip or Palate ☐ ☐ ☐

2b. Heart Defects, specify: ☐ ☐ ☐

2c. Spina Bifida *(Open Spine)* ☐ ☐ ☐

2d. Muscle Disease/Muscular Dystrophy ☐ ☐ ☐

2e. Mental Retardation ☐ ☐ ☐

2f. Down Syndrome ☐ ☐ ☐

2g. Cystic Fibrosis ☐ ☐ ☐

2h. Kidney Disease ☐ ☐ ☐

2i. Sickle Cell Anemia ☐ ☐ ☐

2j. Hemophilia *(Bleeder's Disease)* ☐ ☐ ☐

2k. Thalassemia *(Mediterranean or Cooley's Anemia)* ☐ ☐ ☐

2l. Other, specify: ☐ ☐ ☐

☐ ☐ ☐ ☒ 08-JUL-09

`0` `1` Language   Staff Initials / Date

Genetic Screening History (GSH-2)

Item-specific Instructions:

- **Item 2:** Ask each participant if the biological father or members of his family have been diagnosed with any of the conditions listed in items 2a–2l.

- I**tems 2a–2l:** If yes, record the appropriate family code(s) for each item:

Family relative codes:

> 01 = biological father
>
> 02 = biological father's parent
>
> 03 = biological father's sibling (brother or sister)
>
> 04 = biological father's grandparent (maternal or paternal)
>
> 05 = biological father's aunt or uncle (maternal or paternal)
>
> 06 = biological father's first cousin
>
> 07 = biological father's previous child(ren)
>
> 60 = other (none of the above mentioned relatives)
>
> 99 = more than 4 family members

> *Note: If more than four family members have been diagnosed with a specific condition, record three corresponding family codes in the first three pairs of boxes and record "99" in the fourth pair of boxes. For example, if the participant reports that the biological father, his mother, his sister, his aunt, and his grandmother have all been diagnosed with sickle cell anemia, item 2i should be marked "yes," and the codes "01," "02," "03," and "99" should be recorded in the family relative codes for this item.*

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   GSH-3 (103)

Pregnancy #   **Visit Code**

$\boxed{}\boxed{}$ $\boxed{1}.\boxed{0}$ $\boxed{1}$

Page 3 of 5

Participant ID

$\boxed{}\boxed{}\boxed{}$ - $\boxed{}\boxed{}\boxed{}\boxed{}$ - $\boxed{}$ - $\boxed{0}$

Site Number   Participant Number   Chk   Cohort

Genetic Screening History

3. Is the biological father a blood relative of the participant (woman)? ....
   - yes ☐
   - no ☐
   - don't know ☐

   If no, or don't know, go to item 4.

   3a. Degree of relation: ....
   - 1st ☐
   - 2nd ☐
   - 3rd ☐
   - don't know ☐

4. Has the participant been diagnosed with diabetes? ....
   - yes ☐
   - no ☐

5. Has the participant been diagnosed with epilepsy or seizures? ....
   - ☐
   - ☐

6. Has the participant ever drunk alcoholic beverages regularly (three or more drinks each week)? ....
   - ☐
   - ☐ → *If no, go to item 7.*

   6a. During this pregnancy, did/does the participant drink alcoholic beverages?
   - ☐
   - ☐ → *If no, go to item 7.*

   6b. During this pregnancy, how often did/does the participant drink alcoholic beverages? ....
   - < once a month ☐
   - each month ☐
   - each week ☐
   - daily or almost daily ☐

   6c. During this pregnancy, how often did/does the participant drink five or more alcoholic beverages in one day? ....
   - never ☐
   - < once a month ☐
   - each month ☐
   - each week ☐
   - daily or almost daily ☐

7. Has the participant ever smoked cigarettes regularly (one or more cigarettes per week)?
   - yes ☐
   - no ☐ → *If no, go to item 8 on page 4.*

   7a. During this pregnancy, did/does the participant smoke cigarettes regularly (one or more cigarettes per week)?......
   - yes ☐
   - no ☐ → *If no, go to item 8 on page 4.*

   7b. During this pregnancy, how many cigarettes did/does the participant smoke each day? ....
   - 0–10 ☐
   - 11–20 ☐
   - > 20 ☐

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$\boxed{0}\boxed{1}$. $\boxed{}$ _____

Language   Staff Initials / Date

Genetic Screening History (GSH-3)

Item-specific Instructions:

- **Item 3a:** Mark the appropriate degree of relationship of the biological father (of the fetus/infant) to the participant.

    1st degree = father, brother, son

    2nd degree = grandfather, grandson, uncle, nephew, half brother

    3rd degree = first male cousin, great grandfather (grandfather's father), great uncle (uncle's father)

- **Items 6b, 6c, and 7b:** Mark the most accurate response box for each item.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

☐☐	1 . 0	1	
Pregnancy #	**Visit Code**		

MTN 016 (164)   GSH-4 (104)

Page 4 of 5

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Genetic Screening History

8. Has the participant ever used recreational drugs (marijuana, cocaine, heroine, etc.)?.......

yes ☐   *no* ☐ ⟶ ***If no, go to item 9 on page 5.***

8a. During this pregnancy, did/does the participant use recreational drugs?.......

☐   ☐ ⟶ ***If no, go to item 9 on page 5.***

8b. During the last 2 years, how often has the participant used the following recreational drugs?

	never	*< once a month*	*at least once a month but < once a week*	*1–2 days a week*	*3–6 days a week*	*every day*
8b1. marijuana	☐	☐	☐	☐	☐	☐
8b2. crack cocaine	☐	☐	☐	☐	☐	☐
8b3. cocaine	☐	☐	☐	☐	☐	☐
8b4. amphetamines/ methamphetamines	☐	☐	☐	☐	☐	☐
8b5. heroin	☐	☐	☐	☐	☐	☐
8b6. hallucinogens/ Ecstasy	☐	☐	☐	☐	☐	☐
8b7. unknown non-injected drug	☐	☐	☐	☐	☐	☐
8b8. other, specify:	☐	☐	☐	☐	☐	☐

_____

☐ ☐ ☐ ☒ 08-JUL-09

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Language	Staff Initials / Date

Genetic Screening History (GSH-4)

Item-specific Instructions:

- **Item 8b1–8b8:** Mark the most accurate response box for each item.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164) GSH-5 (105)

Pregnancy # **Visit Code** 1.0 1

Page 5 of 5

Participant ID

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

Site Number Participant Number Chk Cohort

Genetic Screening History

9. Does the participant report any exposures to toxic chemicals, substances, or materials such as work pollutants, contaminated water, pesticides, fertilizers, environmental toxins, cleaning agents, etc., during this pregnancy or within the year prior to this pregnancy? .... *yes* [ ] *no* [ ] → **If no, go to item 10.**

9a. If yes, describe the exposures: _____

10. Has the participant ever given birth to an infant who died within the first 8 weeks of life? .... *yes* [ ] *no* [ ] → **If no, go to item 11.**

10a. Number of infant deaths within first 8 weeks of life: .... [ ] *number of deaths*

11. Has the participant had any illnesses (including fever/rashes) during this pregnancy? .... *yes* [ ] *no* [ ]

Describe: _____

[ ][ ][ ][x] 08-JUL-09

0 1 Language Staff Initials / Date

Genetic Screening History (GSH-5)
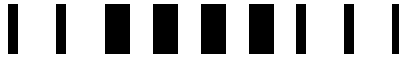
Item-specific Instructions:

- **Items 9 and 9a:** These items are used to collect information about exposure to any toxic or potentially toxic substances. Local examples should be provided to each participant when asking this question. When describing the exposures, be sure to include the substance, frequency of exposure, and duration of exposure.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   UR-1   (120)

| | | Pregnancy # | **Visit Code** | 1 |

Page 1 of 1

Participant ID

☐ ☐ ☐ - ☐ ☐ ☐ ☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Ultrasound Results

Exam Date

☐ ☐   ☐ ☐ ☐   ☐ ☐

dd   *MMM*   *yy*

1. Are ultrasound exam results available at this visit?   *yes* ☐   *no* ☐

    → *If yes, go to item 2.*

    1a. Reason ultrasound exam results not available:

        ☐ participant not pregnant at this time

        ☐ other, specify: _____

    → *End of form.*

2. Estimated gestational age
    (at time of ultrasound): ....   *weeks* ☐☐   *days* ☐

    → *If estimated gestational age is ≥ 14 0/7 weeks, go to item 2b.*

    2a. Crown-rump length: ....   ☐☐.☐ *cm*   ⟶ *Go to item 3.*

    2b. Biparietal diameter: ....   ☐☐.☐ *cm*

    Not done/ Not collected

    2c. Femur length: ....   ☐☐.☐ *cm*   **OR**   ☐

ANATOMICAL SURVEY DATA

	not visualized	*normal*	*abnormal*	*If abnormal, record description:*
3. Intracranial	☐	☐	☐	_____
4. Face/lip	☐	☐	☐	_____
5. Spine	☐	☐	☐	_____
6. Thorax	☐	☐	☐	_____
7. Four-chamber heart	☐	☐	☐	_____
8. Stomach	☐	☐	☐	_____
9. Kidneys	☐	☐	☐	_____
10. Bladder (urinary)	☐	☐	☐	_____
11. Cord insertion	☐	☐	☐	_____
12. Upper limbs	☐	☐	☐	_____
13. Lower limbs	☐	☐	☐	_____
14. Gender	☐	☐	☐	_____
15. Amniotic fluid	☐	☐	☐	_____

☐ ☐ ☒ ☐   27-OCT-09

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Language

_____
Staff Initials / Date

Ultrasound Results (UR-1)

Purpose: This form is used to document ultrasound results for each ultrasound completed during a pregnancy for MTN 016.

General Information/Instructions: This form is completed and faxed to SCHARP DataFax at each visit (that is, the Enrollment Visit and each completed Quarterly visit).

- **Pregnancy # and Visit Code:** Record the Pregnancy # and Visit Code assigned to the visit. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Exam Date:** This is the date the ultrasound is completed, not the date the results are available or reviewed.

Item-specific Instructions:

- **Item 2a:** Complete this item if the gestational age at the time of ultrasound is **less than** 14 weeks and 0 days.

- **Items 2b and 2c:** Complete these items if the gestational age at the time of ultrasound is **equal to or greater than** 14 weeks and 0 days.

- **Items 3–15:** For each item marked "abnormal," record the description of the abnormality on the corresponding line.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   WFU-1   (125)

Pregnancy #   **Visit Code** .0 1

Page 1 of 1

Participant ID

☐☐☐-☐☐☐☐-☐-0

Site Number   Participant Number   Chk   Cohort

Woman Follow-up Visit

Visit Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

1. Besides this Woman Follow-up Visit form, and the Ultrasound Results form, what other DataFax forms were completed at this visit? *Mark "none" or all that apply.*

   ☐ 1a.   none ────────▶ *If none, go to item 2.*

   ☐ 1b.   Pregnancy Outcome

   ☐ 1c.   Woman Termination

   ☐ 1d.   Woman End of Study Inventory

   ☐ 1e.   Social Harms Assessment

   ☐ 1f.   other, specify: _____

2. Is the participant completing a parent protocol (MTN only) visit at this MTN 016 visit? ....

   yes   *no*
   ☐   ☐ ────▶ *If no, go to item 3.*

   Visit Code

   2a.   Visit code of parent protocol visit completed today.......................   ☐☐.☐

3. Has the woman been tested for HIV since her last MTN 016 study visit?

   yes   *no*
   ☐   ☐ ────▶ *If no, end of form.*

   3a.   Woman's HIV status: ....

   negative   *positive*   *indeterminate*
   ☐   ☐   ☐

   3b.   Date and source of most recent HIV test: ....   ☐☐ ☐☐☐ ☐☐

   dd   *MMM*   *yy*

   parent protocol   *self-report*
   ☐   ☐

☐☐☐☒ 08-JUL-09

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Language   Staff Initials / Date

Woman Follow-up Visit (WFU-1)

Purpose: This form is used to document the required (regularly scheduled) follow-up visits. It is completed at each regularly scheduled follow-up visit conducted within visit windows as specified in the Study-Specific Procedures (SSP) Manual.

General Information/Instructions: Each time this form is completed, an Ultrasound Results form must also be completed.

- **Pregnancy # and Visit Code:** Record the Pregnancy # and Visit Code assigned to the visit. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. Refer to the SSP Manual for more specific information on assigning visit codes.

Item-specific instructions:

- **Items 2 and 2a**: If the participant is completing an MTN parent protocol visit (regular visit or interim visit) on this same day, mark "yes," and record the visit code (regular or interim) of the MTN parent protocol visit completed on this date.

- **Item 3a:** Record the participant's HIV status.

- **Item 3b:** Record the date **and** source of the most recent HIV test result. If the HIV test result is available from source documentation of the parent protocol mark the "parent protocol" box. Otherwise, mark the "self-report" box.

  Note: All efforts should be made to obtain HIV test result information from laboratory source documentation.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   SHA-1 (155)

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

Page 1 of 1

Participant ID   **Date Reported to Site**

☐☐☐-☐☐☐☐-☐-0   **Social Harms Assessment Log**   ☐☐ ☐☐☐ ☐☐

Site Number   Participant Number   Chk   Cohort   *dd*   *MMM*   *yy*

1. This form is being completed to report possible problems or social harms encountered as a result of being in this study. Which participant(s) experienced the problem(s)?

   ☐ woman only ——▶ *If woman only, go to item 2.*

   ☐ infant only

   ☐ both woman and infant

   1a. Infant Participant ID: ☐☐☐-☐☐☐☐-☐-☐

   Site Number   Participant Number   Chk   Cohort

2. Since the last visit, the participant(s) has (have) had problems with the following. *Mark all that apply.*

   ☐ 2a. primary sex partner   ☐ 2e. people at school

   ☐ 2b. people at home/family   ☐ 2f. nurse or clinician outside of study

   ☐ 2c. friends/personal relationships   ☐ 2g. landlord or property owner

   ☐ 2d. people at work   ☐ 2h. anyone else, specify:

   _____

3. Has this problem (have any of these problems) resulted in...

                                                                    yes   *no*

   3a. emotional harm to the participant(s)? For example, has (have) the participant(s) experienced increased stress, anxiety, worry, or depression as a result of this problem? ....   ☐   ☐

   3b. physical harm to the participant(s)? For example, has anyone physically hurt the participant(s) as a result of this problem? ....   ☐   ☐

   3c. economic/financial harm to the participant(s)? For example, has this problem resulted in the loss of the participant's(s') home, property, or ability to earn income? ....   ☐   ☐

   3d. physical or other harm to the participant's children? ....   ☐   ☐

                                                                    ——▶ *If no to all, end of form.*

4. Describe the problem, including outcome. ***Do not record participant's verbatim response.***

   _____

   _____

   _____

☐ ☐ ☐ ☒ 08-JUL-09

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Language   Staff Initials / Date

Social Harms Assessment Log (SHA-1)

Purpose: This log is used to document social harms—that is, problems the woman and/or infant participant may have encountered as a result of being **in the study**. Refer to the Study-Specific Procedures (SSP) Manual, Section 11.2, for more specific information about follow-up of social harms.

General Information/Instructions: If more than one enrolled infant is involved, complete a second Social Harms Assessment Log, providing the appropriate infant Participant ID and details.

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

- **Participant ID:** Complete the Participant ID using the woman participant's Participant ID. Even if the social harm is only directed at the infant, the woman's Participant ID must be recorded here.

Item-specific instructions:

- **Items 1 and 1a:** If the infant participant experienced the problem, the infant Participant ID must be recorded in item 1a.

- **Item 4:** Describe the problem and the outcome. Do not record the participant's verbatim response—describe the problem in your own words so that the nature of the problem is clear.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   IV-1   (350)

| | | Pregnancy # | Visit Code | | 1 |

Page 1 of 1

Participant ID

| | | | - | | | | | - | | - | 0 | **Woman Interim Visit**

Site Number   Participant Number   Chk   Cohort

Visit Date

| | | | | | | | |
dd   MMM   yy

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

   ☐ 1a. report pregnancy outcome

   ☐ 1b. ultrasound exam

   ☐ 1c. 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 ————————➤ **If none, go to item 3.**

   ☐ 2b. Pregnancy Outcome

   ☐ 2c. Ultrasound Results

   ☐ 2d. Woman Termination

   ☐ 2e. Woman End of Study Inventory

   ☐ 2f. Social Harms Assessment

   ☐ 2g. other, specify: _____

3. Is the participant completing a parent protocol (MTN only) visit at this MTN 016 visit?...

   yes ☐   *no* ☐ ➤ **If no, go to item 4.**

   Visit Code

   3a. Visit code of parent protocol visit completed today. .... | | . | |

4. Has the woman been tested for HIV since her last MTN 016 study visit? ....

   yes ☐   *no* ☐ ➤ **If no, end of form.**

   4a. Woman's HIV status: ....
   negative ☐   *positive* ☐   *indeterminate* ☐

   4b. Date and source of most recent HIV test: ....
   | | | | | | | |
   dd   MMM   yy
   parent protocol ☐   *self-report* ☐

| | | | x | 08-JUL-09

| 0 | 1 | _____
Language   Staff Initials / Date

N:\hivnet\forms\MTN_016\forms\forms_woman\m016_wom_std_interim_visit_29may08.fm
Version 1.0
29 July 2009

Woman Interim Visit (IV-1)

Purpose: Complete this form when an interim visit occurs during the woman's study follow-up.

General Information/Instructions:

- **Pregnancy #:** Record the Pregnancy # and Visit Code assigned to the visit. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes.

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:

  - Record the one-digit whole number visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was the first Quarterly visit (Visit Code = 2.0), record "2" 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):

    X.1 = First Interim Visit after the most recent scheduled regular visit.
    X.2 = Second Interim Visit after the most recent scheduled regular visit.

    Refer to the Study-Specific Procedures (SSP) Manual for specific information on assigning visit codes.

Item-specific instructions:

- **Items 3 and 3a**: If the participant is completing an MTN parent protocol visit (regular visit or interim visit) on this same day, mark "yes," and record the visit code (regular or interim) of the MTN parent protocol visit completed on this date.

- **Item 4a:** Record the participant's HIV status.

- **Item 4b:** Record the date **and** source of the most recent HIV test result. If the HIV test result is available from source documentation of the parent protocol mark the "parent protocol" box. Otherwise, mark the "self-report" box.

  Note: All efforts should be made to obtain HIV test result information from laboratory source documentation.

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   CM-1 (423)

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

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ⓪

Site Number   Participant Number   Chk   Cohort

Woman Concomitant Medications Log

☐ **No medications taken during pregnancy before Enrollment.**
➤ *Fax to SCHARP DataFax.*
Staff Initials/Date

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

1.

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

Indication

Date Started ☐☐ ☐☐☐ ☐☐
dd   MMM   yy

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

Frequency *Mark only one.*
☐ prn ☐ qd ☐ tid ☐ qhs ☐ qxh: every ☐☐ hrs
☐ 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

Date Started ☐☐ ☐☐☐ ☐☐
dd   MMM   yy

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

Frequency *Mark only one.*
☐ prn ☐ qd ☐ tid ☐ qhs ☐ qxh: every ☐☐ hrs
☐ 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

Date Started ☐☐ ☐☐☐ ☐☐
dd   MMM   yy

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

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

Dose/Units

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

☐ ☐ ☐ ☒   08-JUL-09

⓪1
Language

13-46
N:\hivnet\forms\MTN_016\forms\forms_woman\m016_wom_std_CM_phI_II_23dec08.fm
Version 1.0   29 July 2009

Woman Concomitant Medications Log (CM-1)

Purpose: This form is used to document all medication(s) used by the woman participant during the study including any medications taken during pregnancy. This includes, but is not limited to, prescription medications, non-prescription (that is, 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.

- **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 during pregnancy before Enrollment:** Mark this box if no medications were taken by the participant during pregnancy before 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.

Item-specific instructions:

- **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	**qxh** every x hours

- **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).

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164) PR-1 (440)

Pregnancy # | Visit Code
[ ][ ] [1].[0] [1]

Page 1 of 1

Participant ID

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

Site Number Participant Number Chk Cohort

Pregnancy Report and History

PREGNANCY REPORT

		dd	MMM	yy

1. First day of last menstrual period: .... [ ][ ] [ ][ ][ ] [ ][ ]

2. Estimated date of delivery: .... [ ][ ] [ ][ ][ ] [ ][ ]

3. What information was used to estimate the date of delivery?

    yes *no*

    3a. last menstrual period .... ☐ ☐

    3b. initial ultrasound < 20 weeks .... ☐ ☐

    3c. initial ultrasound ≥ 20 weeks .... ☐ ☐

    ➤ *If either are yes, complete Ultrasound Results form.*

    3d. physical examination .... ☐ ☐

    3e. conception date by assisted reproduction .... ☐ ☐

    3f. other, specify: _____ ☐ ☐

PREGNANCY HISTORY

    yes *no*

4. Has the participant ever been pregnant before? .... ☐ ☐ ➤ *If no, end of form.*

    4a. Is this the participant's first pregnancy since enrollment in this study?.. ☐ ☐ ➤ *If no, go to item 5.*

    4b. Number of full-term live births (≥ 37 weeks): .... [ ][ ]

    4c. Number of premature live births (< 37 weeks): .... [ ][ ]

    4d. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks): .... [ ][ ]

    4e. Number of spontaneous abortions (< 20 weeks): .... [ ][ ]

    4f. Number of therapeutic/elective abortions: .... [ ][ ]

    4g. Number of ectopic pregnancies: .... [ ][ ]

5. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? ....

    yes *no*

    ☐ ☐ ➤ *If no, end of form.*

    5a. If yes, specify: _____

    _____

Comments: _____

☐ ☐ ☐ [x] 08-JUL-09

[0][1] . _____

Language Staff Initials / Date

Pregnancy Report and History (PR-1)

Purpose: This form is used to report a pregnancy of a study participant. This form will be completed one time for each "pregnancy cycle." Refer to the Study-Specific Procedures (SSP) Manual for more specific information about pregnancy cycles.

General Information/Instructions: This form is completed at the participant's Enrollment Visit and with each subsequent consent.

- **Pregnancy # and Visit Code:** Record the Pregnancy #. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. The Visit Code has been pre-filled with 1.0 because this form will always be completed at the first visit of a pregnancy cycle. Refer to the SSP Manual for more specific information on assigning visit codes.

Item-specific instructions:

- **Item 1**: Complete date required. Record best estimate if date not known.
- **Item 2**: Complete date required.
- **Item 3d**: Physical examination includes fundal height, uterine size by pelvic exam, and/or fetal heart rate.
- **Item 5**: Include information on pregnancy complications and fetal/infant congenital anomalies experienced prior to enrolling in the study as well as any conditions experienced/reported during the study.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   PO-1   (441)

Pregnancy #   **Visit Code** 1 . 0   **Outcome Number** [ ]

Page 1 of 3

Participant ID

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

Site Number   Participant Number   Chk   Cohort

Pregnancy Outcome

[ ] **Outcome unobtainable**

➤ *End of form. Do not fax pages 2 & 3 to SCHARP DataFax.*

If Outcome Number (from upper right-hand corner) is 2 or greater, go to item 2.

1. How many pregnancy outcomes resulted from this reported pregnancy?......... [ ]

2. Outcome Date: .... [ ][ ] *dd* [ ][ ][ ] *MMM* [ ][ ] *yy*

3. At which study visit was this outcome reported? .... [ ][ ] [ ] . [ ] [1]
   Pregnancy #   **Visit Code**

4. Place of delivery/outcome:

   [ ] home

   [ ] hospital

   [ ] clinic

   [ ] unknown

   [ ] other, specify: _____

5. Specify Outcome: *Mark only one.*

   C-section   *standard vaginal*   *operative vaginal*

   [ ] full-term live birth (≥ 37 weeks)

   [ ] premature live birth (< 37 weeks)

   ➤ 5a. **Method:** [ ] [ ] [ ]
   If full-term or premature live birth, go to item 7 on page 2. If C-section, refer to the parent protocol for AE and EAE reporting requirements.

   [ ] stillbirth/intrauterine fetal demise (≥ 20 weeks)

   [ ] spontaneous abortion (< 20 weeks)

   [ ] ectopic pregnancy

   ➤ *Refer to the parent protocol for AE and EAE reporting requirements.*

   [ ] therapeutic/elective abortion

   [ ] other, specify: _____

6. Provide a brief narrative of the circumstances: _____

   _____

   _____

[ ][ ][ ][x] 08-JUL-09

[0][1]   _____
Language   Staff Initials / Date

Pregnancy Outcome (PO-1)

Purpose: This form is used to report pregnancy outcome information for a pregnancy reported post-enrollment. 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 Pregnancy Report and History form that is completed for a participant.

- **Pregnancy # and Visit Code:** Record the Pregnancy # assigned to the visit. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. The Visit Code has been pre-filled and matches to the participant's corresponding Pregnancy Report and History form. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Outcome Number:** A pregnancy outcome can be an infant or fetus. The conception of twins, for example will result in reporting of two outcomes. For a pregnancy resulting in one pregnancy outcome, record "1" here. For a pregnancy with multiple outcomes, record the outcome number matching the outcome data recorded on the form.

- **Outcome unobtainable:** If it is determined that an outcome is unobtainable (that is, the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and only fax page 1 of this form, do not fax pages 2 and 3.

Item-specific Instructions:

- **Item 1:** Item 1 is completed for Outcome Number 1, and skipped if Outcome Number is 2 or greater. If a pregnancy results in two or more outcomes, complete two or more Pregnancy Outcome forms (one for each outcome). All Pregnancy Outcome forms for **this** pregnancy will have the same Pregnancy # and Visit Code but different Outcome Numbers (for example, one Pregnancy Outcome form will have an Outcome Number = 1 and the second form will have an Outcome Number = 2).

- **Item 2:** Record the date of the pregnancy outcome. All efforts should be made to obtain a complete pregnancy outcome date. If a complete date (day, month, and year) is not available, record the best estimate possible. At a minimum try to record the month and year of the pregnancy outcome. If the pregnancy outcome date is more than one year ago the participant is not eligible. End the form and do NOT fax this or any other forms completed for this participant to SCHARP DataFax.

- **Item 5:** Refer to the parent protocol for AE and EAE reporting requirements for C-sections and pregnancy losses. If the pregnancy outcome seems to be an outcome other than those listed, contact SCHARP for further instruction.

- **Item 5a:** "Operative vaginal" delivery includes delivery with forceps and/or vacuum.

- **Item 6:** 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: *DO NOT FAX TO DATAFAX*

MTN 016 (164)	PO-2 (442)	Pregnancy #

1.0 Visit Code

Outcome Number ☐

Page 2 of 3

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - **0**

Site Number   Participant Number   Chk   Cohort

Pregnancy Outcome

	yes	no
7. Were there any complications related to the pregnancy outcome?	☐	☐ ➡ **If no, go to item 8.**

7a. Delivery-related complications. *Mark "none" or all that apply.*

☐ 7a1. none ➡ **If none, go to item 7b.**

☐ 7a2. intrapartum hemorrhage

☐ 7a3. postpartum hemorrhage

☐ 7a4. non-reassuring fetal status

☐ 7a5. chorioamnionitis

☐ 7a6. other, specify: _____

_____

7b. Non-delivery-related complications. *Mark "none" or all that apply.*

☐ 7b1. none ➡ **If none, go to item 8.**

☐ 7b2. hypertensive disorders of pregnancy

☐ 7b3. gestational diabetes

☐ 7b4. other, specify: _____

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

If no or unknown, go to statement below item 8b. ⬅

8a. Congenital anomalies identified. *Mark all that apply.* **Refer to the parent protocol for AE and EAE reporting requirements.**

☐ 8a1. Central nervous system, cranio-facial   ☐ 8a9. Skin

☐ 8a2. Central nervous system, spinal   ☐ 8a10. Genitourinary

☐ 8a3. Cardiovascular   ☐ 8a11. Chromosomal

☐ 8a4. Renal   ☐ 8a12. Craniofacial (structural)

☐ 8a5. Gastrointestinal   ☐ 8a13. Hematologic

☐ 8a6. Pulmonary   ☐ 8a14. Infectious

☐ 8a7. Musculoskeletal/extremities   ☐ 8a15. Endocrine/metabolic

☐ 8a8. Physical defect   ☐ 8a16. Other

8b. Describe the congenital anomaly/defect: _____

_____

If live birth, go to page 3. Otherwise, end of form. Do not fax page 3 to SCHARP.

☐ ☐ ☐ ☒   08-JUL-09

0 1 Language   _____ Staff Initials / Date

Pregnancy Outcome (PO-2)

General Information/Instructions: If it is determined that an outcome is unobtainable (that is, the participant refuses further contact), the "Outcome unobtainable" box at the top of page 1 must be marked. Pages 2 and 3 should not be faxed to SCHARP DataFax.

- **Pregnancy # and Visit Code:** Record the Pregnancy # assigned to the visit. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. The Visit Code has been pre-filled and matches to the participant's corresponding Pregnancy Report and History form. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Outcome Number:** A pregnancy outcome can be an infant or fetus. The conception of twins, for example will result in reporting of two outcomes. For a pregnancy resulting in one pregnancy outcome, record "1" here. For a pregnancy with multiple outcomes, record the outcome number matching the outcome data recorded on the form.

Item-specific Instructions:

- **Items 8 and 8a:** Refer to the parent protocol for AE and EAE reporting requirements for congenital anomalies.

- **Instruction at bottom of page:** "If live birth go to page 3. Otherwise, end of form. Do not fax page 3 to SCHARP." For all pregnancy outcomes other than live births this is the end of the form; only fax pages 1 and 2 to SCHARP DataFax.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   PO-3 (443)

Pregnancy #

Visit Code 1.0

Outcome Number ☐

Page 3 of 3

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Pregnancy Outcome

9. Record Infant Participant ID: ....   ☐☐☐ - ☐☐☐☐ - ☐ - ☐

Site Number   Participant Number   Chk   Cohort

not consented
OR ☐

10. Infant gender: ....

male ☐   *female* ☐   *unknown* ☐

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

12. Infant birth length: ....   ☐☐.☐ *cm*   *unavailable* **OR** ☐

13. Infant birth head circumference: ....   ☐☐.☐ *cm*   *unavailable* **OR** ☐

14. Infant birth abdominal circumference: ....   ☐☐.☐ *cm*   *unavailable* **OR** ☐

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

16. 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 retardation (< 3%)

☐ Classification not available

17. Infant APGAR score at 1 minute: ....   ☐☐   *not available* **OR** ☐

18. Infant APGAR score at 5 minutes: ....   ☐☐   *not available* **OR** ☐

19. Infant APGAR score at 10 minutes: ....   ☐☐   *not available* **OR** ☐

Comments: _____

☐ ☐ ☐ ☒ 08-JUL-09

0 1
Language   Staff Initials / Date

Pregnancy Outcome (PO-3)

General Information/Instructions: Page 3 is only completed for pregnancy outcomes resulting in a live birth. For any other pregnancy outcome, do not fax page 3 to SCHARP DataFax.

- **Pregnancy # and Visit Code:** Record the Pregnancy # assigned to the visit. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. The Visit Code has been pre-filled and matches to the participant's corresponding Pregnancy Report and History form. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Outcome Number:** A pregnancy outcome can be an infant or fetus. The conception of twins, for example will result in reporting of two outcomes. For a pregnancy resulting in one pregnancy outcome, record "1" here. For a pregnancy with multiple outcomes, record the outcome number matching the outcome data recorded on the form.

Item-specific Instructions:

- **Item 9:** If the infant corresponding to this Pregnancy Outcome form is consented for MTN 016, record the infant's Participant ID. If the infant is not consented, mark the "not consented" box.

    Note: The infant Participant ID is completed as follows:

    - *the first 8 digits are identical to the mother's Participant ID*

    - *the last digit, the cohort, is completed as follows:*
      *- for the first infant born **and** enrolled in MTN 016, cohort = 1*
      *- for the second infant born **and** enrolled in MTN 016, cohort = 2*
      *- for the third infant born **and** enrolled in MTN 016, cohort = 3*
      *- for the fourth infant born **and** enrolled in MTN 016, cohort = 4; etc.*

    - *Refer to the SSP Manual for more specific information on Participant IDs for MTN 016.*

SAMPLE: *DO NOT FAX TO DATAFAX*

■■■■ ┃ ┃ ■■■■

MTN 016 (164)   MV-1   (463)

Pregnancy #   **Visit Code**   . 0   1

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Woman Missed Visit

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

dd   *MMM*   *yy*

1. Target Visit Date: ☐☐ ☐☐☐ ☐☐

2. Reason visit was missed. *Mark only one.*

☐ 2a. unable to contact participant

☐ 2b. unable to schedule appointment within visit window

☐ 2c. participant refused visit

☐ 2d. participant incarcerated

☐ 2e. participant admitted to a health care facility

☐ 2f. participant withdrew from the study ⟶ **Complete a Termination form.**

☐ 2g. participant deceased ⟶ **Complete a Termination form.**

☐ 2h. other, specify:

_____

☐ 2i. participant relocated

Comments: _____

_____

_____

_____

☐ ☐ ☐ ☒   08-JUL-09

0 1   .

Language   Staff Initials / Date

Woman Missed Visit (MV-1)

Purpose: Complete this form whenever an enrolled woman participant misses a required visit according to the visit window outlined in the Study-Specific Procedures (SSP) Manual.

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.

- **Pregnancy # and Visit Code:** Record the Pregnancy # and Visit Code assigned to the visit. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. Refer to the SSP Manual for more specific information on assigning visit codes.

- **Form Completion Date:** Record the date the form is completed. This will not necessarily be the date of the missed visit.

Item-specific Instructions:

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

- **Item 2:** Mark the response box corresponding to the primary reason the participant missed the visit.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

■ ■ ■ | ■ | | | ■

MTN 016 (164)   PT-1   (465)

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Woman 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: ☐☐   ☐.☐   1

Pregnancy #   **Visit Code**

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

dd   MMM   yy

Comments: _____

_____

☐ ☐ ☐ ☒   08-JUL-09

0 1

Language   Staff Initials / Date

N:\hivnet\forms\MTN_016\forms\forms_woman\m016_wom_std_ppt_transfer_19apr07.fm
Version 1.0
29 July 2009

Woman Participant Transfer (PT-1)

Purpose: Complete this form when a woman participant is transferring to another study clinic/site.

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 Study-Specific Procedures (SSP) Manual, and/or MTN Manual of Operations (MOP).

Item-specific instructions:

*   **Item 3:** Record the Pregnancy # and Visit Code corresponding to the last completed contact with the participant. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. Refer to the SSP Manual for more specific information on assigning visit codes.

    Note: Do not alter or make any changes to the last box filled with a "1" as this is required for DataFax.

*   **Item 4:** Complete date required.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

██ ██ ██ █ █ █ █ █ ██

MTN 016 (164)   PRC-1   (466)

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - [0]

Site Number   Participant Number   Chk   Cohort

Woman 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

Comments: _____

_____

☐ ☐ ☐ [x]   08-JUL-09

[0][1]   _____

Language   Staff Initials / Date

Woman Participant Receipt (PRC-1)

Purpose: Complete this form when a transferred woman participant has provided informed consent at the receiving study clinic/site.

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 Study-Specific Procedures (SSP) Manual, and/or MTN 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:** Complete date required.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (164)   ESI-1   (489)

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - 0

Site Number   Participant Number   Chk   Cohort

Woman 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?...

☐☐   ☐.☐   1

Pregnancy #   **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

0 ☐☐

3. Indicate the **highest** page number submitted for this participant for each of the following form(s):

page #

3a. Woman Concomitant Medications Log .... ☐☐

page #   *no pages submitted*

3b. Social Harms Assessment Log .... ☐☐   **OR**   ☐

Comments: _____

☐ ☐ ☐ ☒   08-JUL-09

0 1

Language   Staff Initials / Date

Woman End of Study Inventory (ESI-1)

Purpose: This form is used to confirm that SCHARP has received all study data for a given woman 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 is **not** completed at the end of each pregnancy.

- **Form Completion Date:** A complete date is required.

Item-specific instructions:

- **Item 1:** Record the Pregnancy # and Visit Code corresponding to 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. The Pregnancy # refers to the pregnancy number corresponding to MTN 016 participation. Only pregnancies enrolled into MTN 016 should be counted for data purposes. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

  Note: Do not alter or make any changes to the last box filled with a "1" as this is required for DataFax.

- **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 "000" in the boxes.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

■ ■ ■ ■ I ■ I ■ I

MTN 016 (164)   TM-1   (490)

Page 1 of 1

Participant ID

[ ][ ][ ] - [ ][ ][ ][ ] - [ ] - [0]   **Woman Termination**

Site Number   Participant Number   Chk   Cohort

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

[ ] 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

[ ] 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

[ ] 2j. invalid ID due to duplicate screening/enrollment

[ ] 2k. other, specify: _____

[ ] 2l. early study closure

Comments: _____

[ ] [ ] [ ] [x]   08-JUL-09

[0][1]
Language   Staff Initials / Date

Woman Termination (TM-1)

Purpose: Complete this form **once** for each enrolled woman participant when the participant is no longer participating in the study. This form is **not** completed at the end of each pregnancy.

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 final visit as defined in the Study-Specific Procedures (SSP) Manual.

  - **Item 2b1:** At a minimum, the month and year are required.

  - **Item 2l:** Early study closure: Only mark 2l when instructed by SCHARP.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX* **Not a DataFax form. Do not fax to DataFax.**

MTN 016 (164)

Participant ID

| | | | – | | | | | – | | – | 0 |

Site Number | Participant Number | Chk | Cohort

Woman 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		

| | | | x | 08-JUL-09

| 0 | 1 |

Language

N:\hivnet\forms\MTN_016\forms\forms_woman\m016_nonDF_wom_med_hx_log.fm
Version 1.0   29 July 2009

Woman Medical History Log (non-DataFax)

Purpose: This form is used to document and track all medical conditions experienced by the woman participant while on-study. This includes diagnosed medical conditions as well as participant self-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.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (168) IEN-1 (070)

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ☐

Site Number Participant Number Chk Cohort

Infant Enrollment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Does the participant meet all eligibility criteria? ....

  yes ☐ *no* ☐ → **If no, participant is ineligible. End of form. Do not fax to SCHARP DataFax.**

2. Date study informed consent signed or thumbprinted: ....

  ☐☐ ☐☐☐ ☐☐

  dd *MMM* *yy*

  2a. Did the guardian provide informed consent for photographic documentation of suspected or confirmed anomalies? ....

  yes ☐ *no* ☐ → **If no, go to item 3.**

  2b. Date informed consent given for photographic documentation of suspected or confirmed anomalies.

  ☐☐ ☐☐☐ ☐☐

  dd *MMM* *yy*

3. Date of birth: ....

  ☐☐ ☐☐☐ ☐☐

  dd *MMM* *yy*

  If equal to or greater than one year ago, participant is ineligible. End of form. Do not fax to SCHARP DataFax.

4. Gestational age based on pediatric assessment (using Ballard):

  weeks ☐☐ **OR** *not assessed* ☐

Comments**:** _____

☐ ☐ ☐ ☒ 08-JUL-09

0 1

Language

Staff Initials / Date

Infant Enrollment (IEN-1)

Purpose: This form is used to document an infant participant's study enrollment. This form is completed when the infant is 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, the infant is eligible and the guardian has provided informed consent).

- **Participant ID:** complete the Participant ID as follows:
    - the first 8 digits are identical to the mother's PITD

    - the last digit, the cohort, is completed as follows:
      - for the first infant born **and** enrolled in MTN 016, cohort = 1
      - for the second infant born **and** enrolled in MTN 016, cohort = 2
      - for the third infant born **and** enrolled in MTN 016, cohort = 3
      - for the fourth infant born **and** enrolled in MTN 016, cohort = 4; etc.

      Refer to the Study-Specific Procedures (SSP) Manual for more specific information on Participant IDs for MTN 016.

Note: There is no visit code field on this form since this form is only completed once for each infant participant.

Item-specific Instructions:

- **Item 1:** If the response to this item is "no" (the participant does not meet all eligibility criteria), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.

- **Items 2 and 2b:** If the guardian marks the informed consent using his/her thumbprint, record the date the thumbprint was made.

- **Item 3:** A complete date is required. If the date of birth is greater than one year ago, the participant is ineligible, end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.

SAMPLE: *DO NOT FAX TO DATAFAX*

| | | | | | | | | |

MTN 016 (168)   IFV-1   (125)

Visit Code ☐.☐   1

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ☐   **Infant Visit**

Site Number   Participant Number   Chk   Cohort

Visit Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

1. Weight: .... ☐☐.☐ *kg* **AND** ☐☐.☐ % *local percentile* **OR** ☐ *not assessed* → **If not assessed, record reason in Comments.**

2. Length: .... ☐☐.☐ *cm* **AND** ☐☐.☐ % *local percentile* **OR** ☐ *not assessed* → **If not assessed, record reason in Comments.**

3. Head circumference: ☐☐.☐ *cm* **OR** ☐ *not assessed* → **If not assessed, record reason in Comments.**

4. Abdominal circumference (only for infants ≤ 1 month): .... ☐☐.☐ *cm* **OR** ☐ *not assessed*

5. Were photographs taken and submitted to document suspected or confirmed anomalies as clinically indicated? .... *yes* ☐ *no* ☐

Specimen Collection Date

dd	*MMM*	*yy*			*not required*	*stored*	*not stored*	*Reason:*
☐☐	☐☐☐	☐☐	6.	Plasma	☐	☐	☐ →	_____
☐☐	☐☐☐	☐☐	7.	Dried blood spot	☐	☐	☐ →	_____
☐☐	☐☐☐	☐☐	8.	Cell pellet	☐	☐	☐ →	_____

Comments: _____

_____

☐ ☐ ☐ ☒ 08-JUL-09

0 1
Language

_____
Staff Initials / Date

Infant Visit (IFV-1)

Purpose: This form is required at each completed scheduled follow-up visit, as well as at interim visits.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Participant ID:** Refer to the SSP Manual for specific information on Participant IDs for MTN 016.

Item-specific Instructions:

- **Items 1 and 2:** If these items are "not assessed," record reason on Comments lines.

- **Item 4:** Abdominal circumference is only recorded for infants less than or equal to one month of age. For all infants greater than a month old, mark the "not assessed" box.

- **Items 6–8:** 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. Complete date required. If the specimen is not required, mark the "not required" box and leave the Specimen Collection Date blank.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (168)   IPE-1   (130)

Visit Code ☐.☐☐   1

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ☐

Site Number   Participant Number   Chk   Cohort

Infant Physical Exam

Exam Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

VITAL SIGNS

yes   *no*

1. Were vital signs done?....... ☐ ☐ ➔ *If no, specify reason:* _____

   Heart rate ☐☐☐ *beats per minute*   Respirations ☐☐ *breaths per minute*

SYMPTOM-DIRECTED FINDINGS

		not done	*normal*	*abnormal*	*If abnormal, record description:*
2.	General appearance	☐	☐	☐	_____
3.	Skin	☐	☐	☐	_____
4.	Head	☐	☐	☐	_____
5.	Scalp	☐	☐	☐	_____
6.	Eyes	☐	☐	☐	_____
7.	Ears	☐	☐	☐	_____
8.	Nose	☐	☐	☐	_____
9.	Mouth & mandible	☐	☐	☐	_____
10.	Neck	☐	☐	☐	_____
11.	Chest	☐	☐	☐	_____
12.	Cardiovascular	☐	☐	☐	_____
13.	Lungs	☐	☐	☐	_____
14.	Abdomen	☐	☐	☐	_____
15.	Genitalia	☐	☐	☐	_____
16.	Anus	☐	☐	☐	_____
17.	Back	☐	☐	☐	_____
18.	Extremities	☐	☐	☐	_____
19.	Hands and feet	☐	☐	☐	_____
20.	Neurological	☐	☐	☐	_____

yes   *no*

21. Were any other abnormalities observed? .... ☐ ☐

➔ *If yes, specify:* _____

☐ ☐ ☐ ☒ 08-JUL-09

☐☐ — 0 1

Language   Staff Initials / Date

N:\hivnet\forms\MTN_016\forms\forms_infant\m016_inf_phy_exam.fm

Version 1.0   29 July 2009

Infant Physical Exam (IPE-1)

Purpose: This form is used to document the infant physical exam completed at each visit (that is, the Newborn/Initial visit, and the Months 1, 6, and 12 visits).

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Participant ID:** Refer to the SSP Manual for specific information on Participant IDs for MTN 016.

- **Exam Date:** This is the date the physical exam is completed.

Item-specific Instructions:

- **Items 2–20:** For each item marked "abnormal," record the description of the abnormality on the corresponding line provided.

- **Item 21:** If any other abnormality (not listed in items 2–20) is identified, mark the "yes" box and record the abnormality on the corresponding line.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

▌█▌█▌█▌█▌█▌█▌

MTN 016 (168)   IDS-1   (132)

Visit Code ☐.☐☐   1

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ☐   **Infant Developmental Screening**

Site Number   Participant Number   Chk   Cohort

Exam Date

☐☐ ☐☐☐ ☐☐
dd   *MMM*   *yy*

1. Adjusted age or chronological age at testing .... ☐☐ *months* ☐☐ *days*

2. Was the Denver II test administered? ....
   yes ☐   *no* ☐ ➞ ***If no, record reason in Comments. End of form.***

3. Test results:

	advanced	*normal*	*caution*	*delay*	*refused*	*no opportunity*
3a. Gross motor	☐	☐	☐	☐	☐	☐
3b. Fine motor-adaptive	☐	☐	☐	☐	☐	☐
3c. Language	☐	☐	☐	☐	☐	☐
3d. Personal-social	☐	☐	☐	☐	☐	☐

4. In your opinion, are the test results a valid indicator of this child's development?...
   yes ☐   *no* ☐ ➞ ***If yes, end of form.***

   4a. Reason test results are not valid:

   ☐ child not responsive to examiner or refuses to participate

   ☐ child asleep or very sleepy during exam

   ☐ other, specify: _____

Comments: _____

_____

☐ ☐ ☐ ☒ 08-JUL-09

☐☐ ☐ ☐ ☐ ☐ | 0 | 1 | _____

Language   Staff Initials / Date

Infant Developmental Screening (IDS-1)

Purpose: This form is used to document the results of the Denver II developmental screening exam.

General Information/Instructions: Complete this form at the Month 6 and Month 12 visits.

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Participant ID:** Refer to the SSP Manual for specific information on Participant IDs for MTN 016.

- **Exam Date:** This is the date the Denver II developmental screening exam is completed.

Item-specific instructions:

- **Item 1:** For infants who are less than 36 weeks old, the adjusted age must be used. Follow the steps on the visit checklist to calculate the infant's adjusted age at the time of testing, and record the complete adjusted age. For infants who are greater than or equal to 36 weeks old, the chronological age must be used.

- **Items 3a–3d:** For each item, mark the most appropriate response. Mark only one box for each item. Mark "refused" if the child refuses to attempt the item. Mark "no opportunity" if the child has not had the chance to perform the item, due to restrictions from the caregiver or other reasons.

- **Item 4:** Test results should be considered invalid if **none** of the four testing areas are assessed.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (168)   HTR-1   (135)

Visit Code [ ] . [ ]   [1]

Page 1 of 1

Participant ID

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

Site Number   Participant Number   Chk   Cohort

Infant HIV Test Results

Sample 1

1.   HIV DNA

Not done/ Not collected   **Specimen Collection Date**

dd   *MMM*   *yy*

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

1a.   HIV Qualitative DNA ....

negative   *positive*

[ ]   [ ]

➤ *If negative, go to item 4.*

2.   HIV RNA

Not done/ Not collected   **Alternate Collection Date**

dd   *MMM*   *yy*

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

2a.   HIV RNA PCR (plasma) .....

\> = <   *viral copies/mL*

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

2b.   RNA PCR kit lower limit of detection

50   *400*   *viral copies/mL*

[ ]   [ ]   **OR**   [ ][ ][ ]

Sample 2

3.   HIV RNA

Not done/ Not collected   **Specimen Collection Date**

dd   *MMM*   *yy*

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

3a.   HIV RNA PCR (plasma) .....

\> = <   *viral copies/mL*

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

3b.   RNA PCR kit lower limit of detection

50   *400*   *viral copies/mL*

[ ]   [ ]   **OR**   [ ][ ][ ]

Final HIV status   *negative*   *positive*   *other, specify:* _____

4.   Final HIV status: ....   [ ]   [ ]   [ ]

Comments: _____

[ ][ ][ ][x]   08-JUL-09

[0][1]
Language   Staff Initials / Date

Infant HIV Test Results (HTR-1)

Purpose: This form documents infant HIV test results and final HIV status during study follow-up. This form is completed each time an infant participant has HIV testing during study follow-up.

General Information/Instructions: Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for **all** required specimens are available and recorded, and item 4 has been completed.

- **Visit Code:** Record the visit code assigned to the visit. This should be the same as the visit code recorded on the corresponding Infant Visit form or Infant Interim Visit form at which Sample 1 was collected. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Participant ID:** Refer to the SSP Manual for specific information on Participant IDs for MTN 016.

- **Specimen Collection Date:** Record the date the specimen was collected (NOT the date results were reported or recorded on the form).

- **Alternate Collection Date:** This applies only to item 2a. The first HIV RNA PCR testing should be completed using Sample 1, the same sample used for DNA testing. If that is not possible, record the date the specimen for the first RNA PCR testing is collected. If the dates for items 1a and 2a are the same, leave the Alternate Collection Date blank.

- **Not Done/Not Collected:** For each test, mark *either* the "Not Done/Not Collected" box *or* enter a test result. If the "Not Done/Not Collected" box is marked, record the reason on the Comments lines.

Item-specific Instructions

- **Items 2 and 3:** Record the participant's HIV RNA PCR result exactly as it/they appear(s) on the lab report(s) source documentation, regardless of whether the result is more or less than the limit of detection for the assay. For example, if a participant is tested with an assay that has 400 viral copies/mL as the lower limit of detection, and the lab reports the result as "238 viral copies/mL," mark the "=" box and record "00000238" viral copies/mL for item 2a or 3a.

- **Item 4:** Once an infant participant's HIV status has been determined, record the final HIV status. If the final HIV status is not clearly negative or clearly positive, mark the "other, specify" box and specify reason(s) on the line provided.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

▮▮ ▮▮ ▮ ▮▮▮▮ ▮

MTN 016 (168)   IV-1   (350)

Visit Code ☐.☐☐   1

Page 1 of 1

Participant ID

☐☐☐-☐☐☐☐-☐-☐

Site Number   Participant Number   Chk   Cohort

Infant Interim Visit

Visit Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

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

    ☐ 1a. follow-up on previous abnormal findings

    ☐ 1b. follow-up on HIV-exposed or HIV-infected infant

    ☐ 1c. photographic documentation of suspected or confirmed anomalies

    ☐ 1d. other, specify: _____

2. At this visit, besides this Infant Interim Visit form and the Infant Visit form, what other DataFax forms were completed? *Mark "none" or all that apply.*

    ☐ 2a. none ————————▶ ***If none, end of form.***

    ☐ 2b. Infant Concomitant Medications

    ☐ 2c. Infant HIV Test Results

    ☐ 2d. Infant Physical Exam

    ☐ 2e. Infant Developmental Screening

    ☐ 2f. Infant Termination

    ☐ 2g. Infant End of Study Inventory

    ☐ 2h. other, specify: _____

☐ ☐ ☐ ☒ 08-JUL-09

☐☐ 0 1
Language

_____
Staff Initials / Date

Infant Interim Visit (IV-1)

Purpose: Complete this form when an interim visit occurs during the infant's study follow-up.

General Information/Instructions:

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:

  - Record the one-digit whole number visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was the first Quarterly visit (Visit Code = 2.0), record "2" 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):

    X.1 = First Interim Visit after the most recent scheduled regular visit.
    X.2 = Second Interim Visit after the most recent scheduled regular visit.

    Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

- **Participant ID:** Refer to the SSP Manual for specific information on Participant IDs for MTN 016.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

MTN 016 (168)   CM-1 (423)

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

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ☐☐

Site Number / Participant Number / Chk / Cohort

Infant 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

Date Started   ☐☐ ☐☐☐ ☐☐
dd / MMM / yy

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

Frequency *Mark only one.*
☐ prn ☐ qd ☐ tid ☐ qhs ☐ qxh: every ☐☐ hrs
☐ 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

Date Started   ☐☐ ☐☐☐ ☐☐
dd / MMM / yy

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

Frequency *Mark only one.*
☐ prn ☐ qd ☐ tid ☐ qhs ☐ qxh: every ☐☐ hrs
☐ 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

Date Started   ☐☐ ☐☐☐ ☐☐
dd / MMM / yy

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

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

Dose/Units

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

☐ ☐ ☐ ☒ 08-JUL-09

☐☐ **0 1**
Language

Infant Concomitant Medications Log (CM-1)

Purpose: This form is used to document all medication(s) used by the infant participant during the study including any time between birth and enrollment. This includes, but is not limited to, prescription medications, non-prescription (that is, 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.

• **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.

• **Participant ID:** Refer to the Study-Specific Procedures (SSP) Manual for specific information on Participant IDs for MTN 016.

• **No medications taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant from birth through Enrollment. 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.

Item-specific instructions:

• **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 | **qxh** every x hours |

• **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).

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

■ ■ ■ | | ■ ■ ■

Visit Code ☐ . | 0 | | 1 |

MTN 016 (168)   MV-1   (463)

Page 1 of 1

Participant ID

☐☐☐-☐☐☐☐-☐-☐   **Infant Missed Visit**

Site Number   Participant Number   Chk   Cohort

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

dd   *MMM*   *yy*

1. Target Visit Date: ☐☐ ☐☐☐ ☐☐

2. Comments: _____

_____

_____

_____

☐ ☐ ☐ ☒   08-JUL-09

| 0 | 1 | _____

Language   Staff Initials / Date

Infant Missed Visit (MV-1)

Purpose: Complete this form whenever an enrolled infant participant misses a required visit according to the visit window outlined in the Study-Specific Procedures (SSP) Manual.

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.

- **Visit Code:** Record the visit code of the visit that was missed. Refer to the SSP Manual for more specific information on assigning visit codes.

- **Participant ID:** Refer to the SSP Manual for specific information on Participant IDs for MTN 016.

- **Form Completion Date:** Record the date the form is completed. This will not necessarily be the date of the missed visit.

Item-specific Instructions:

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

- **Item 2:** The comments lines may be used to record the reason a visit is missed, or it may be left blank.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

■ ■ ■ ❙ ■ ❙ ❙ ❙ ■

MTN 016 (168)   PT-1   (465)

Page 1 of 1

Participant ID

☐☐☐ – ☐☐☐☐ – ☐ – ☐

Site Number   Participant Number   Chk   Cohort

Infant Participant Transfer

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd   *MMM*   *yy*

1. Name of transferring study site: _____

2. Name of receiving study site: _____

visit code

3. Visit Code of last completed contact with participant: ☐ . ☐   ☐ 1 ☐

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

dd   *MMM*   *yy*

Comments: _____

_____

☐ ☐ ☐ ☒ 08-JUL-09

☐0☐1☐

Language   Staff Initials / Date

Infant Participant Transfer (PT-1)

Purpose: Complete this form when an infant participant is transferring to another study clinic/site.

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 Study-Specific Procedures (SSP) Manual, and/or MTN Manual of Operations (MOP).

• **Participant ID:** Refer to the SSP Manual for specific information on Participant IDs for MTN 016.

Item-specific instructions:

• **Item 3:** Record the Visit Code corresponding to the last completed contact with the participant. Refer to the SSP Manual for more specific information on assigning visit codes.

   Note: Do not alter or make any changes to the last box filled with a "1" as this is required for DataFax.

• **Item 4:** Complete date required.

Version 1.0, 08-JUL-09

SAMPLE: DO NOT FAX TO DATAFAX

MTN 016 (168)   PRC-1   (466)

Page 1 of 1

Participant ID

☐☐☐–☐☐☐☐–☐–☐

Site Number   Participant Number   Chk   Cohort

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

Infant Participant Receipt

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd   MMM   yy

1. Name of receiving study site: _____

2. Name of transferring study site: _____

3. Date informed consent signed at receiving study site: ☐☐ ☐☐☐ ☐☐

dd   MMM   yy

Comments: _____

_____

☐ ☐ ☐ ☒   08-JUL-09

| 0 | 1 |

Language   Staff Initials / Date

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Version 1.0

29 July 2009

Infant Participant Receipt (PRC-1)

Purpose: Complete this form when a transferred infant participant has been consented at the receiving study clinic/site.

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 Study-Specific Procedures (SSP) Manual, and/or MTN Manual of Operations (MOP).

Participant ID: Refer to the SSP Manual for specific information on Participant IDs for MTN 016.

Item-specific instructions:

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

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

■■■■❙ ■❙❙ ■

MTN 016 (168)   ESI-1   (489)

Page 1 of 1

Participant ID

☐☐☐ - ☐☐☐☐ - ☐ - ☐

Site Number   Participant Number   Chk   Cohort

Infant 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

☐ . ☐   [1]

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

# of interim visits

0 ☐ ☐

3. Indicate the **highest** page number submitted for this participant for each of the following form(s):

page #

3a.   Infant Concomitant Medications Log ....   ☐☐

Comments: _____

☐ ☐ ☐ ☒   08-JUL-09

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Version 1.0

0 1

Language   Staff Initials / Date

29 July 2009

Infant End of Study Inventory (ESI-1)

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

- **Participant ID:** Refer to the Study-Specific Procedures (SSP) Manual for specific information on Participant IDs for MTN 016.

- **Form Completion Date:** A complete date is required.

Item-specific instructions:

- **Item 1:** Record the Visit Code corresponding to 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. Refer to the SSP Manual for more specific information on assigning visit codes.

  Note: Do not alter or make any changes to the last box filled with a "1" as this is required for DataFax.

- **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 "000" in the boxes.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX*

▮▮▮▮▮❙▮❙▮▮❙

MTN 016 (168)   TM-1   (490)

Page 1 of 1

Participant ID

☐☐☐☐ - ☐☐☐☐☐ - ☐ - ☐   **Infant Termination**

Site Number   Participant Number   Chk   Cohort

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

☐ 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

☐ 2c. participant refused further participation, specify: _____

   2d. participant **NOT APPLICABLE FOR THIS PROTOCOL.** ~~unable to adhere to visit schedule~~

☐ 2e. participant relocated, no follow-up planned

☐ 2f. investigator decision, specify: _____

☐ 2g. unable to contact participant

   2h. HIV ~~infected~~ **NOT APPLICABLE FOR THIS PROTOCOL.**

☐ 2i. inappropriate enrollment

☐ 2j. invalid ID due to duplicate screening/enrollment

☐ 2k. other, specify: _____

☐ 2l. early study closure

☐ 2m. mother terminated from MTN 016

Comments: _____

☐ ☐ ☐ ☒ 08-JUL-09

☐0☐1
Language

_____
Staff Initials / Date

Infant Termination (TM-1)

Purpose: Complete this form **once** for each enrolled infant participant when the participant is no longer participating in the study.

General Information/Instructions:

• **Participant ID:** Refer to the Study-Specific Procedures (SSP) Manual for specific information on Participant IDs for MTN 016.

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.

Version 1.0, 08-JUL-09

SAMPLE: *DO NOT FAX TO DATAFAX* **Not a DataFax form. Do not fax to DataFax.**

MTN 016 (168)

Participant ID

			–					–		–	

Site Number   Participant Number   Chk   Cohort

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		

			X	08-JUL-09

0	1

Language

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Version 1.0   29 July 2009

Infant Medical History Log (non-DataFax)

Purpose: This form is used to document and track all medical conditions experienced by the infant participant 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.

- **Participant ID:** Refer to the Study-Specific Procedures (SSP) Manual for specific information on Participant IDs for MTN 016.

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.

Version 1.0, 08-JUL-09