

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-013/IPM-026 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact the SCHARP Project Manager for the study as listed below.

The SDMC (Statistical and Data Management Center) for this study is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN-013/IPM-026 team members, along with their job role and e-mail address, are listed below.

MTN-013/IPM-026 Statistical and Data Management Center (SDMC) Staff

Job Role	Name	Email Address
Protocol Statistician	Barbara Richardson	barbrar@u.washington.edu
Project Manager	Missy Cianciola	missy@scharp.org
Project Coordinator	Jen Berthiaume	jberthia@scharp.org
Statistical Research Associate	Marla Husnik	marla@scharp.org
Statistical Research Associate	Jason Pan	zpan@scharp.org
Protocol Programmer	Iraj Moheballan	iraj@scharp.org
Data Coordinator	Craig Silva	csilva@scharp.org
Document Specialist	Lori Filipcic	lorif@scharp.org
Lab Operations	Jeff Peterson	pjeterse@scharp.org
CASI Programmer	Lynda McVarish	lmcv@scharp.org
Clinical Affairs Safety Associate	Maija Anderson	maanders@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.
- Next, each CRF is 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 refaxed 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 refaxed 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 General 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.

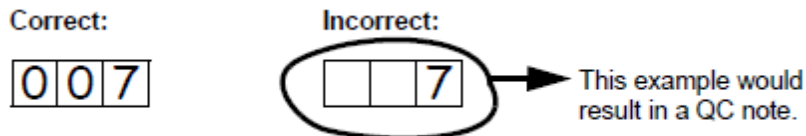


Mark only one response box for each item unless the “Mark all that apply” instruction is present.

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:

- 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:



- 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:

Ø 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, 2012 is recorded as:

06 JUN 12
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:

<i>MMM</i>			<i>yy</i>	

A diagnosis date of October, 2011 would be recorded as follows:

O	C	T	1	1
<i>MMM</i>			<i>yy</i>	

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
<i>hr</i>			<i>min</i>	

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

12-hour clock (a.m.)	24-hour clock	12-hour clock (p.m.)	24-hour clock
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.

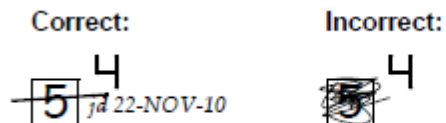
It is important to make these changes to the original CRF—**never** copy data onto a new form. After making the change, the CRF *must* be re-faxed to SCHARP DataFax.

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

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:

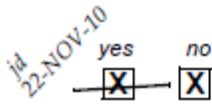
- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),
- place the correct or clarified answer near the box, and
- initial and date the correction as shown below:



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

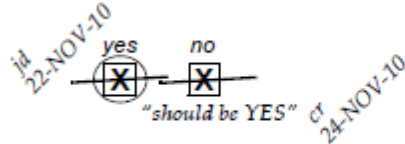
- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and

- 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:

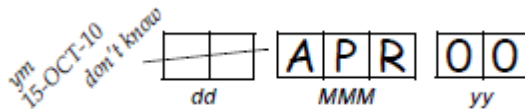


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

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.

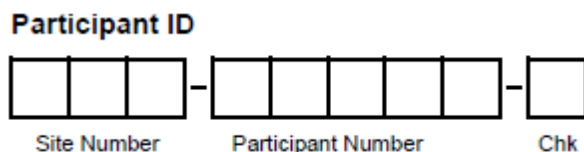
13.3 Study-Specific Data Collection Information

13.3.1 Participant ID numbers (PTIDs)

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. Prior to study start, SCHARP provides each site with a list of PTIDs to be used for the study in the form of a study-specific MTN PTID Name-Linkage Log. The site assigns one PTID to each participant screened for the study. The PTIDs are assigned in sequential order as participants present for the screening visit. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, that same PTID is maintained throughout the entire study.

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

The PTIDs used for this study are nine digits and formatted as “XXX-YYYYY-Z.” The PTID consists of three parts: the DataFax site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The check digit (Z) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. Below is an example of the PTID structure used in MTN-013/IPM-026.



13.3.2 Study Visit Timing

Screening and Enrollment

The initial screening visit is defined as the day the participant provided written informed consent to be screened for the study. The enrollment visit will be scheduled to take place within 45 days of the initial screening visit. The Enrollment Visit is considered Day 0.

Multiple Screening Attempts (Re-screens)

If a participant’s first screening attempt is unsuccessful, she may re-screen a maximum of one time for the study if she chooses. If she does re-screen, all screening procedures (except PTID assignment) and forms must be repeated, including provision of written informed consent. Once a PTID is assigned to a participant, that PTID is used for the re-screen procedures and forms completed for that participant (do not assign a new PTID). If a participant re-screens and enrolls in the study, only case report forms from the successful screening and enrollment visit are faxed to SCHARP.

Follow-Up Visits

There are 14 required follow-up visits. For each of these visits, the visit type, visit code, target visit day, and visit window are listed in the table below. Target days and windows are listed in days, with the day of Enrollment equal to Day 0.

Table 13-1: Required follow-up Visit Timing Requirements

Visit Type	Visit Code	Target Day	Window Opens	Window Closes
Day 1	03.0	1	no window for this visit	
Day 2	04.0	2	no window for this visit	
Day 3	05.0	3	no window for this visit	
Day 5	06.0	5	5	6
Day 7	07.0	7	7	8
Day 14	08.0	14	13	15
Day 21	09.0	21	20	22

Day 28	10.0	28	no window for this visit	
Day 29	11.0	29	no window for this visit	
Day 30	12.0	30	no window for this visit	
Day 31	13.0	31	31	32
Day 35	14.0	35	34	36
Day 42	15.0	42	41	43
Day 52/ Termination	16.0	52	51	53

Target Days and Visit Windows

Whenever possible, visits should be completed on the target day. If not possible to complete the visit on the target day, the visit should be completed within the visit window. Visits completed within the window will appear on the MTN-013/IPM-026 Retention Report as being completed “on-time”.

SCHARP will provide sites with a spreadsheet tool that may be used to generate individual participant follow-up visit calendars. The spreadsheet requires that the participant’s Enrollment date be entered. Once the enrollment date is entered, the target day and visit window for each required follow-up visit will appear. The calendar can then be printed and added to the participant’s study notebook.

Split Visits

In those 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 example, a participant comes in on her Day 35 target day and completes most of the required evaluations. She comes back the next day (Day 36) and completes the remaining required Day 35 visit procedures. This is allowed, as Day 36 is within the Day 35 visit window. Note that for split visits, only 1 Follow-up Visit form is completed, and the “Visit Date” should be the date of the first part of the split visit. 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 visit window, the visit is considered “missed”. For example, an enrolled participant does not report to the clinic for her first follow-up visit until 2 days after enrollment. Per table 13-1, the Day 1 visit has been missed (note that the Day 1 visit has no window – it must be completed on the target day, Day 1). The missed visit is documented in the study database by completion of a Missed Visit case report form that is faxed to SCHARP.

Interim Visits

A phone contact or clinic visit is considered an Interim Visit if the visit occurs on a day that is not within a visit window. An Interim Visit also occurs when a participant completes all required visit

procedures, but presents for additional evaluations before her next required visit. The following are examples of interim visits:

1. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the site clinic to request a replacement ring, and she is not within her next scheduled visit window.
2. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the clinic on a day that is not within any visit window to request a pregnancy test.
3. A participant completes all required evaluations for the Day 7 visit on the target day. At this visit, deep epithelial disruption is noted during her pelvic exam. She then returns to the clinic 2 days later for a clinically-indicated follow-up pelvic exam.
4. A participant completes her Day 14 visit on the target day. The next day, she calls the clinic to report a new symptom, which results in the reporting of a new adverse experience. The phone contact is assigned an interim visit code.

Phone contact with a participant is also considered an Interim Visit if the phone contact results in reporting of a new Adverse Experience (AE) or the participant withdraws consent for the study (termination). Phone contact is also considered an Interim Visit if, during the phone contact, the participant is instructed by site staff to hold, permanently discontinue, or resume product use. The following is an example of a phone contact that would be documented as an interim visit.

Note that if an interim phone contact or clinic visit results in completion of a new DataFax CRF (for example, an Interim Visit or new AE Log CRF is completed), you will need to assign a visit code to the interim contact/visit. Assignment of visit codes to interim visits/contacts is outlined below (section 13.3.3). For questions about assignment of visit codes to interim contacts and visits, please contact the SCHARP Project Manager.

13.3.3 Visit Codes and Page Numbers

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

When visit code boxes are provided on a CRF, site staff are responsible for recording the visit code. The table below lists the visit codes assigned to each required study visit.

Table 13-2: Visit Code Assignments for Required Visits

Visit Type	Visit Code
Screening	01.0
Enrollment	02.0
Day 1	03.0
Day 2	04.0

Day 3	05.0
Day 5	06.0
Day 7	07.0
Day 14	08.0
Day 21	09.0
Day 28	10.0
Day 29	11.0
Day 30	12.0
Day 31	13.0
Day 35	14.0
Day 42	15.0
Day 52/Termination	16.0

Visit Codes for Split Visits

See Section 13.3.2 for a definition of split visits. When split visits occur, 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, a participant comes in on her Day 14 target day of 23-AUG-11 and completes most of the required evaluations. She comes back on 24-AUG-11 (Day 15) and completes the remaining required Day 14 visit procedures. Since 24-AUG-11 is within the Day 14 visit window, this is a “split visit”. All case report forms completed on 23 and 24 August are assigned a visit code of 08.0.

Visit codes for interim visits

In addition to the scheduled, protocol-required visits listed in Table 13-1, interim visits may occur once the participant is enrolled (see Section 13.3.2 for a definition and examples of interim visits). Interim visit codes are assigned using the following guidelines:

- In the boxes to the left of the decimal point, record the two-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 #1: A participant completes her Day 21 visit (Visit Code = 09.0) on Day 20. She returns to the site one day later to report a new symptom. Since has completed all Day 21 evaluations but is still within the Day 21 window, this is an Interim Visit, assigned an interim visit code of 09.1:

Visit Code for this Interim Visit

Visit Code

0	9	.	1
---	---	---	---

Page numbers

Other CRFs, such as log forms (e.g., Adverse Experience Log or Concomitant Medications Log), may include boxes in the upper right corner for page numbers, as shown below:

Page

--	--

Assign page numbers in sequential order, starting with 01 (or 001, for Adverse Experience Log CRFs). 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.

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 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 table (Table 13-2) lists the DataFax and non-DataFax forms that are required to be completed at each study visit.

Table 13.3: Schedule of Forms – CRFs Required to be Completed at Each Visit

Screening Visit	Form Acronym
Demographics	DEM-1,DEM-2, DEM-3
Concomitant Medications Log	CM-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) Screening Behavioral Eligibility	n/a
Enrollment Visit	Form Acronym
Pelvic Exam	PE-1
Cervical Ectopy	CE-1
Pharmacokinetics Specimens	PKS-1
Tear Test Strip Weights	TTW-1
Laboratory Results	LR-1 and LR-2
Pre-existing Conditions	PRE-1
Eligibility Criteria	ECI-1
Enrollment	ENR-1
Specimen Storage	SS-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) Enrollment Behavioral Eligibility	n/a
(non DataFax) LDMS Specimen Tracking Sheet	n/a
(non-DataFax) Enrollment and Day 28 Blood PK LDMS Specimen Tracking Sheet	n/a

Day 1, 2, 3, & 5 Visits	Form Acronym
Follow-up Visit	FV-1
Pelvic Exam Ring Assessment	PER-1
Pelvic Exam	PE-1
Pharmacokinetics Specimens	PKS-1
Tear Test Strip Weights	TTW-1
**Specimen Storage (required on Day 3 only)	SS-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a
Day 7, 14, & 21 Visits	Form Acronym
Follow-up Visit	FV-1
Pelvic Exam Ring Assessment	PER-1
Ring Adherence	RA-1
Pelvic Exam	PE-1
Pharmacokinetics Specimens	PKS-1
Tear Test Strip Weights	TTW-1
Follow-up CASI Tracking	FCT-1
**Specimen Storage (required at Day 7 only)	SS-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a

(non-DataFax) LDMS Specimen Tracking Sheet	n/a
Day 28	Form Acronym
Follow-up Visit	FV-1
Pelvic Exam Ring Assessment	PER-1
Ring Adherence	RA-1
Pelvic Exam	PE-1
Pharmacokinetics Specimens	PKS-1
Tear Test Strip Weights	TTW-1
Cervical Biopsy Weights	CBW-1
Specimen Storage	SS-1
Laboratory Results	LR-1 and LR-2
Follow-up CASI Tracking	FCT-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a
(non-DataFax) Enrollment and Day 28 Blood PK LDMS Specimen Tracking Sheet	n/a
Day 29 & 30	Form Acronym
Follow-up Visit	FV-1
Pharmacokinetics Specimens	PKS-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a

Day 31, 35 & 42	Form Acronym
Follow-up Visit	FV-1
Pharmacokinetics Specimens	PKS-1
Specimen Storage (required at Day 31 only)	SS-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a

<u>**Required on randomly assigned tear test strip/cervical PK Visit</u>	
**Pelvic Exam	<i>PE-1</i>
**Tear Test Strip Weights	<i>TTW-1</i>
**Cervical Biopsy Weights	<i>CBW-1</i>
**Follow-up CASI Tracking	<i>FCT-1</i>
**<i>(non-DataFax) Pelvic Exam Diagrams</i>	<i>n/a</i>
Day 52/Termination	Form Acronym
Follow-up Visit	FV-1
Pelvic Exam	PE-1
Pharmacokinetics Specimens	PKS-1
Tear Test Strip Weights	TTW-1
Specimen Storage	SS-1
Laboratory Results	LR-1 and LR-2
Termination	TM-1
End of Study Inventory	ESI-1

Follow-up CASI Tracking	FCT-1
(non-DataFax) Physical Exam	n/a
(non-DataFax) Pelvic Exam Diagrams	n/a
(non-DataFax) LDMS Specimen Tracking Sheet	n/a
“As Needed” CRFs – To be complete as needed during the study	Form Acronym
Concomitant Medications Log	CM-1
Pre-existing Condition	PRE-1
Product-Hold/Discontinuation Log	PH-1
Pregnancy Report	PR-1
Pregnancy Outcome	PO-1, PO-2
Adverse Experience Log	AE-1
Interim Visit	IV-1
Missed Visit	MV-1
HIV Test Results	HIV-1
Follow-up CASI Tracking	FCT-1
(non-DataFax) Genital Bleeding Assessment	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 Section 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, stamp only the back of the CRF, never the front. Be sure to date stamp the back of the CRF each time it is faxed, including refaxes.

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-013/IPM-026 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-013/IPM-026 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-013/IPM-026 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. When applicable, the guidelines described above for DataFax CRFs should also be applied when completing non-DataFax CRFs.

13.4 Form Supply and Storage

13.4.1 Form Supply

Prior to study start, each site will receive an initial shipment of case report forms from SCHARP. This initial shipment will include both CRF visit packets (containing the required CRFs for a particular visit) as well as bulk (individual) CRFs that are used on an “as needed” basis. Non-CRF documents developed for the study (the Medical History Log, for example) will be available for printing by the site on the MTN-013/IPM 026 Study Implementation Materials webpage (<http://www.mtnstopshiv.org/node/3594>).

13.4.2 Form Storage

Specifications for form storage will be detailed in the site’s MTN-013/IPM-026 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 log forms, i.e. Concomitant Medications Log, Adverse Experience Log, Follow-up Medical History Log, and Product Hold/Discontinuation Log, 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 Completing 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.

13.6 Form Completion Instructions

Detailed form completion instructions for each form are provided on the back of each form page. 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 some of the CRFs used in this study (these instructions do not appear on the back of the form page).

Laboratory Results (LR-1, LR-2)

- For those lab results that require severity grading (indicated by the presence of the “Severity Grade” box), determine what severity grade the value is. If the value is severity grade 1 or higher, record the grade in the box provided and complete either the “AE Log Page #” field or the “Not Reportable as an AE” box. For Grade 1 or higher lab values obtained at the Screening or Enrollment Visit, the “Not Reportable as an AE” box should always be marked for these values.

Pre-existing Conditions (PRE-1) and Concomitant Medication Log (CM-1)

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

Adverse Experience Log (AE-1)

- Do not wait until the AE resolves before faxing the form page to SCHARP.
- Always make changes, corrections, and updates are made to the originally-completed form page (do not complete a new form). Once an AE Log form page has been started and faxed to SCHARP, the data from that page should never be transcribed onto another AE Log form page.
- Note that AE Log page numbers do not need to be assigned in any special order with regard to AE onset date or date reported to site. For example, if it is discovered that for a participant, page 001 and 003 were assigned, but not 002, simply assign page # 002 to the next AE Log form you complete. It does not matter if the AE's onset date or date reported to site on page 002 is later than these dates reported on AE Log page 003 (a QC will not be generated).
- If an AE is marked as "related", please avoid putting additional detail regarding relatedness in the "Comments" section. Rather, provide as much relevant information as possible in item 1 (the text description of the AE). This will help avoid MedDRA coding queries during the study.
- For item 1, note that planned procedures or surgeries are not AEs. For example, a tonsillectomy is not an AE; rather, it is a treatment that will be collected in item 7. Any adverse experiences associated with the planned procedure or surgery, are AEs.

13.7 Case Report Forms

This section contains each MTN-013/IPM 026 case report form developed for the study (in alphabetical order by form title), DataFax forms first followed by non-DataFax forms.

SAMPLE. DO NOT FAX TO DATAFAX



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

Page [][][]

MTN-013/IPM 026 (150)

AE-1 (460)

Participant ID

[][][] - [][][][][] - []
Site Number Participant Number Chk

Adverse Experience Log

Date Reported to Site

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

1. Adverse Experience (AE)

Record diagnosis if available. Include anatomical location, if applicable.

2. Onset Date

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

3. Severity

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

4. Relationship to Study Product

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

5. Study Product Administration

- No change
- Held
- Permanently discontinued
- N/A

6. Status/Outcome

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

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

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

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

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

8. Is this an SAE according to ICH guidelines? yes no

9. Has/will this AE be reported as an EAE? yes no

10. At which visit was this AE first reported? [][] [][]
Visit code required (regular or interim).

11. Was this AE a worsening of a pre-existing condition? yes no

Comments: _____

Adverse Experience Log (AE-1)

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

General Information/Instructions: Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency. If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE page #" (specify page number of diagnosis AE).

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.
- **Item 1:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
- **Item 2:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected.
- **Item 3:** To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the Addendum 1 (*Female Genital Grading Table for Use in Microbicide Studies*).
- **Item 4:** Mark the assessment of the relationship between the AE and the study agent. Mark "Related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "Not related" if there is not a reasonable possibility that the AE is related to the study agent. If "Not related," record an alternative etiology, diagnosis, or explanation in the "Comments" field. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
- **Item 5:** Provide the action taken by study staff with regard to study product.
 - **No change:** Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation.
 - **Held:** Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark "Held" for the AE(s) that contributed to the product hold.
 - **Permanently discontinued:** Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark "Permanently discontinued" for the AE(s) that contributed to the permanent discontinuation.
 - **N/A (not applicable):** Mark if the AE is being reported after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is Grade 5-death.
- **Item 6:**
 - **Continuing:** AE is continuing at the time it is reported.
 - **Resolved:** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
 - **Death:** Mark only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation."
 - **Severity/frequency increased:** If an AE increases in severity or frequency after it has been reported on the AE Log, line through the "Continuing" box previously marked and mark "Severity/frequency increased." Record the date of increase in the "Status/Outcome Date." Report the increase in severity or frequency as a new AE. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. Update EAE form if applicable. Note that decreases in severity should not be recorded as new AEs.
 - **Continuing at end of study participation:** Mark this box whenever an AE is continuing at the time of participant study termination.
- **Item 6a:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant no longer experienced the AE; or the date of the study visit or specimen collection at which the change in status/outcome is first noted.
- **Item 7:** Indicate if treatment was clinically indicated for the AE, regardless of whether the treatment was actually used. Also mark this item if the participant self-treated.
- **Items 8 and 9:** For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.

Version 1.0, 01-AUG-11

N:\hivnet\forms\MTN_013\forms\m013_std_AE_14may10.fm

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code

MTN-013/IPM 026 (150)

CBW-1 (174)

Participant ID

- -
Site Number Participant Number Chk

Cervical Biopsy Weights

Visit Date

dd MMM yy

PRE-COLLECTION

Note: Weights include empty cryovial and screw lid.

Not done

Weight

- 1. Cervical biopsy for PK#1: Pre-collection mg
- 2. Cervical biopsy for PK#2: Pre-collection mg
- 3. Cervical biopsy for PD: Pre-collection mg

POST-COLLECTION

Note: Weights include cryovial, tissue biopsy and screw lid.

Not done

Weight

- 4. Cervical biopsy for PK#1: Post-collection mg
- 5. Cervical biopsy for PK#2: Post-collection mg
- 6. Cervical biopsy for PD: Post-collection mg

Comments: _____

Cervical Biopsy Weights (CBW-1)

Purpose: This form is used to document pre- and post-collection weights of cervical tissue (biopsy) pharmacokinetic (PK) and pharmacodynamics (PD) specimens. Completion of this form is required at Day 28 and at Day 31, 35 or 42 based on randomization assignment.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Visit Date:** Record the date of the visit at which the specimens were collected. A complete date is required.
- **Not done:** Mark this box if the listed item was not done, either because it was missed or it was not required. If the item was required at the visit but was missed in error, record brief details in the “Comments” section at the bottom of the form.
- **Items 1–3, Pre-collection Weights:** Record the pre-collection weights in milligrams. Be sure to include all items listed in the “Note” section above these items when obtaining the weights.
- **Items 4–6, Post-collection Weights:** Record the post-collection weights in milligrams. Be sure to include all items listed in the “Note” section above these items when obtaining the weights.

SAMPLE *DO NOT FAX*
TO DATAFAX

MTN-013/IPM 026 (150)



CE-1 (069)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number							Chk

Cervical Ectopy

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>dd</i>		<i>MMM</i>			<i>yy</i>		

1. Cervical Ectopy: Percentage of cervical surface area.

0%	25%	26-50%	51-75%	>75%
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: _____

Cervical Ectopy (CE-1)

Purpose: This form is used to document the percentage of cervical surface area detected through a naked eye exam.

General Information/Instructions: Completion of this form is required during pelvic exams at Enrollment.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Visit Date:** Record the date of the cervical ectopy assessment.

SAMPLE *Do NOT FAX TO DATAFAX*



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

Page

MTN-013/IPM 026 (150)

CM-1 (423)

Participant ID

- -
 Site Number Participant Number Chk

Concomitant Medications Log

No medications taken at Screening/Enrollment. Staff Initials/Date _____
 ➔ Fax to SCHARP DataFax.

No medications taken throughout study. Staff Initials/Date _____
 ➔ End of form. Fax to SCHARP DataFax.

1. Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date Started	Date Stopped	
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i> OR <input type="checkbox"/> Continuing at end of study	
Frequency Mark only one. <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____		
Dose/Units	Route PO IM IV TOP IHL VAG REC other, specify: Mark only one. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	

2. Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date Started	Date Stopped	
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i> OR <input type="checkbox"/> Continuing at end of study	
Frequency Mark only one. <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____		
Dose/Units	Route PO IM IV TOP IHL VAG REC other, specify: Mark only one. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	

3. Medication (generic name)		Staff Initials/Log Entry Date
Indication		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no ➔ Record AE Log page(s): <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Date Started	Date Stopped	
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i> OR <input type="checkbox"/> Continuing at end of study	
Frequency Mark only one. <input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____		
Dose/Units	Route PO IM IV TOP IHL VAG REC other, specify: Mark only one. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> _____	

Concomitant Medications Log (CM-1)

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

General Information/Instructions: When to fax this form:

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

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
- **No medications taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01.
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study.
- **Medication:** For combination medications, record the first three main active ingredients.
- **Indication:** For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). For recreational drugs, record “recreation.”
- **Date Started:** If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.
- **Date Stopped:** At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year are required.
- **Frequency:** Below is a list of common frequency abbreviations:

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

- Use “other, specify” for alternate dosing schedules.

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

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

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

SAMPLE *Do NOT FAX TO DATAFAX*



MTN-013/IPM 026 (150)

DEM-1 (001)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number				Chk	

Demographics

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

I will start by asking you some general questions about yourself.

1. What is your date of birth? → If unknown, record age:

dd MMM yy years

NOT APPLICABLE FOR THIS PROTOCOL.

2. What is your gender? male female

3. Are you currently married? yes no

If yes, go to item 4a.

4. Do you currently have a regular male sex partner? yes no

If no, go to item 5 on page 2.

4a. How old is he? years don't know

4b. Are you currently living with him? yes no

4c. Does he have more than one sex partner? yes no don't know

4d. Does he provide you with financial and/or material support? yes no

4e. What is his average monthly income? don't know no income

4f. What is his highest level of education?

<input type="checkbox"/> no schooling	<input type="checkbox"/> secondary, not complete
<input type="checkbox"/> primary school, not complete	<input type="checkbox"/> secondary, complete
<input type="checkbox"/> primary school, complete	<input type="checkbox"/> attended college or university
	<input type="checkbox"/> don't know

Demographics (DEM-1)

This interviewer-administered form is used to collect participants' demographic and socioeconomic information.

This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment visit.

Note: If a participant is being re-screened, a new Demographics form must be completed as part of the subsequent screening attempt. See the Study-specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.

Item-specific Instructions:

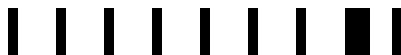
- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers.
- **Item 4a:** If the participant does not know her husband's or regular male sex partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 4d:** Record whether or not the participant's husband or regular male sex partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 4e:** Record the husband's or regular male sex partner's **average** monthly income. The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

- **Item 4f:** If the participant does not know her primary partner's highest level of education, record her best estimate.

SAMPLE. Do NOT FAX
TO DATAFAX



MTN-013/IPM 026 (150)

DEM-2 (002)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number							Chk

Demographics

5. Do you earn an income of your own? *yes* *no* → **If no, go to item 6.**

5a. What is your average monthly income? *don't know*

5b. How do you earn your income? *Mark all that apply.*

formal employment *self-employed* *other, specify*

Specify: _____

6. What is your highest level of education?

- no schooling
- primary school, not complete
- primary school, complete
- secondary, not complete
- secondary, complete
- attended college or university

7. Which of the following best describes where you live?

- own a house/apartment/condo
- rent a house, apartment, or condo
- staying with relatives/family
- staying with friends
- other, specify: _____

8. How many people, including children, live in your household?

8a. How many are children?.....

9. What is your household's average monthly income? This includes income from all sources, even income from people who may not live in the household. *don't know* *no income*

Demographics (DEM-2)

Item-specific Instructions:

- **Item 5a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

- **Item 5b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment. If "other, specify below" box is marked, record the participant's verbatim (word-for-word) response on the "Specify" line.

- **Item 9:** Record the **average** monthly income for the household (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

For example, if the income is 2,145 record:

0	0	0	2	1	4	5
---	---	---	---	---	---	---

SAMPLE. Do NOT FAX
TO DATAFAX



MTN-013/IPM 026 (150)

DEM-3 (003)

Participant ID

			-						-		
Site Number				Participant Number							Chk

Demographics

10. Do you consider yourself to be Latina or of Hispanic origin?..... yes no

11. What is your race? *Read categories aloud. Mark all that apply.*

- American Indian or Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- other, specify: _____

Demographics (DEM-3)

Item-specific Instructions:

- **Item 10:** Per NIH policy, Latina or Hispanic is considered an ethnic category and not a race. It includes a person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.
- **Item 11:** This item asks about race. Read each category aloud and mark the response(s) that apply based on the participant's response. If the participant feels that an appropriate choice is not listed mark the "Other, specify" box and record her response on the line provided. If the participant states that she is "Latina", record this in item 4 only. Per NIH policy, "Latina" is an ethnic group and should not be recorded as a race category in item 5. For example, a participant originally from the Dominican Republic could have a response of "yes" to item 4, and "Black or African American" to item 5.

SAMPLE. Do NOT FAX TO DATAFAX



MTN-013/IPM 026 (150)

ECI-1 (023)

Participant ID

			-						-		
Site Number				Participant Number							Chk

Eligibility Criteria

Form Completion Date

dd		MMM			yy

1. Does this participant meet all eligibility criteria? *yes* *no*

**If no, participant is not eligible.
Do not fax to SCHARP DataFax.
Do not enroll participant.**

1a. Obtain signature: _____

Signature of Principal Investigator (or designee)

Date

1b. Obtain signature: _____

Signature of second staff member verifying eligibility

Date

2. Does the participant agree to long-term storage of specimens for future testing for the following?

- | | <i>yes</i> | <i>no</i> |
|---|--------------------------|--------------------------|
| 2a. blood | <input type="checkbox"/> | <input type="checkbox"/> |
| 2b. vaginal and/or cervical fluid | <input type="checkbox"/> | <input type="checkbox"/> |
| 2c. cervical tissue | <input type="checkbox"/> | <input type="checkbox"/> |

Comments: _____

Eligibility Criteria (ECI-1)

General Information/Instructions: Submit this form to SCHARP DataFax only if participant is enrolled.

Item-specific Instructions:

- **Items 1a and 1b:** Local site SOPs must specify staff members designated to affirm eligibility.
- **Item 2:** Complete this item based on the signed informed consent for long-term specimen storage. Update as needed if the participant changes her consent during the study.

SAMPLE *DO NOT FAX*
TO DATAFAX



MTN-013/IPM 026 (150)

ESI-1 (489)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number						Chk	

End of Study Inventory

Form Completion Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<i>dd</i>		<i>MMM</i>			<i>yy</i>		

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

visit code

<input type="text"/>	<input type="text"/>	.	<input type="text"/>
----------------------	----------------------	---	----------------------

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

of interim visits

<input type="text"/>	<input type="text"/>
----------------------	----------------------

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

3a. Adverse Experience Log (AE-1) *page #* **OR** *no pages submitted*

3b. Concomitant Medications Log (CM-1) *page #*

3c. Pre-existing Conditions (PRE-1) *page #*

3d. Product Hold/Discontinuation Log (PH-1) *page #* **OR** *no pages submitted*

Comments: _____

End of Study Inventory (ESI-1)

This form is used to confirm that SCHARP has received all study data for a given participant. Complete this form once for each enrolled participant after participant has terminated from the study (as documented by a Termination form).

- **Form Completion Date:** Complete date required.
- **Item 1:** Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.
- **Item 3a:** Record the highest page number of the Adverse Experience Log submitted for this participant, even if that page was marked for deletion.
- **Item 3d:** Record the highest page number of the Product Hold/Discontinuation Log submitted for this participant, even if that page was marked for deletion.

SAMPLE *Do NOT FAX*
TO DATAFAX

MTN-013/IPM 026 (150)



ENR-1 (070)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>
Site Number				Participant Number						Chk

Enrollment

- Date the informed consent form for screening was marked or signed:

dd *MMM* *yy*
- Date the informed consent form for enrollment was marked or signed:

dd *MMM* *yy*
- Randomization envelope number assigned:
- Date envelope assigned:

dd *MMM* *yy*
- Time envelope assigned: : *24-hour clock*

hr *min*
- Post product tear test strip/cervical tissue PK collection assignment: *Day 31* *Day 35* *Day 42*
- Did the participant complete the Baseline CASI questionnaire? *yes* *no*
- Was plasma archived? *yes* *no*

Comments: _____

Enrollment (ENR-1)

This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants determined to be eligible for the study. This form is faxed to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a randomization envelope), and only after completion of the Enrollment Visit.

Item-specific Instructions:

- **Item 4:** This date should match the "date assigned" recorded for this envelope on the MTN-013 Randomization Envelope Tracking Record and the date on the study prescription or randomization document inside the envelope.
- **Item 5:** This time should match the "time assigned" recorded for this envelope on the MTN-013 Randomization Envelope Tracking Record.
- **Item 6:** This assignment is found on the MTN-013 Prescription.

SAMPLE. Do NOT FAX TO DATAFAX

MTN-013/IPM 026 (150)



FCT-1 (128)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Follow-up CASI Tracking

Visit Date

dd MMM yy

- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| | <i>not required</i> | <i>completed</i> | <i>not completed</i> |
| 1. Ring Adherence questionnaire: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | ↓ |
| | <i>not required</i> | <i>completed</i> | <i>not completed</i> |
| 2. Protocol Adherence questionnaire: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | ↓ |
| | <i>not required</i> | <i>completed</i> | <i>not completed</i> |
| 3. Acceptability questionnaire: | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |



If "not completed" to any, record reason in Comments.

Comments: _____

Follow-up CASI Tracking (FCT-1)

Purpose: This form is used to document participant completion of the Computer-Assisted Self-Interview (CASI) web-based questionnaires during the study follow-up visits.

General Information/Instructions: Complete this form each time a participant completes one (or more) of the CASI questionnaires listed.

Item-specific instructions:

- **Items 1–3:** Mark the “not required” box if the questionnaire was not required at the visit. Mark “completed” for both fully-completed and partially-completed questionnaires. Mark “not completed” if the questionnaire was required but not completed.
- **Comments:** Use this space to record any unusual events regarding the administration of the CASI questionnaires during Follow-up.

SAMPLE. DO NOT FAX
TO DATAFAX

MTN-013/IPM 026 (150)



FV-1 (121)

Visit Code . 0

1

Participant ID

- -
Site Number Participant Number Chk

Follow-up Visit

Visit Date

dd MMM yy

not required negative positive

1. hCG for pregnancy: →

If newly positive, complete Pregnancy Report form and Product Hold/Discontinuation Log.

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

3. How many **new** Product Hold/Discontinuation Log pages were completed for this visit?
of pages

4. Was a **used** vaginal ring collected at this visit?
yes no

5. Was a new vaginal ring inserted at this visit? → **If no, end of form.**
yes no

5a. Date new vaginal ring was inserted:
dd MMM yy

Comments: _____

Follow-up Visit (FV-1)

Item-specific Instructions:

- **Item 2:** Record in item 2 how many **new** AE Log pages were completed for this visit. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
- **Item 3:** Record how many **new** Product Hold/Discontinuation Log pages were completed for this visit. For example, if two new product holds/discontinuations were reported, record “02.” Note that the Visit Code recorded in item 1 of the Product Hold/Discontinuation Log pages should be the same as the Visit Code recorded on this form.
- **Item 5:** A complete date is required.

SAMPLE *DO NOT FAX*
TO DATAFAX



Visit Code

1

MTN-013/IPM 026 (150)

HTR-1 (351)

Participant ID

- -
Site Number Participant Number Chk

HIV Test Results

Sample 1

1. HIV Western Blot or IFA

Not done/
Not collected

Specimen Collection Date

dd MMM yy

negative

positive

indeterminate

If negative or indeterminate, contact MTN Network Lab.

Sample 2

2. HIV EIA

Not done/
Not collected

Specimen Collection Date

dd MMM yy

negative

positive

indeterminate

If negative, contact MTN Network Lab.

3. HIV Western Blot or IFA

Not done/
Not collected

Specimen Collection Date

dd MMM yy

negative

positive

indeterminate

If negative or indeterminate, contact MTN Network Lab.

FINAL HIV STATUS

negative

positive

other, specify: _____

4. Final HIV status:

Comments: _____

01-AUG-11

0 1

Language

Staff Initials / Date

HIV Test Results (HTR-1)

Purpose: This form documents confirmatory HIV test results and final HIV status during follow-up. This form is completed each time a participant has a positive HIV EIA test result 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:** The visit code recorded on this form should be the same visit code recorded on the Local Laboratory Results form documenting the positive HIV EIA test result.
- **Specimen Collection Date:** Record the date the specimen was collected (NOT the date results were reported or recorded on the form). For Sample 1, the Specimen Collection Date should be the same date as the collection date of the HIV EIA positive specimen.
- **Not done/Not collected:** Mark the “Not done/Not collected” box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Record the reason why the result is not available on the Comments lines at the bottom of the form.

Item-specific Instructions:

- **Item 4:** Once a participant’s HIV status has been determined, record the final HIV status. If, per the appropriate algorithm, the final HIV status is not clear, mark the “other, specify” box and provide a reason(s) on the line provided.
- **Comments:** Document any problems or reasons why expected results are not available (for example, if the sample was lost or damaged), on the lines provided.

SAMPLE. DO NOT FAX
TO DATAFAX

MTN-013/IPM 026 (150)



IV-1 (350)

Visit Code .

1

Participant ID

- -
Site Number Participant Number Chk

Interim Visit

Visit Date

dd MMM yy

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

- 1a. in-person visit to report new symptoms → **Complete Adverse Experience Log.**
- 1b. phone call from participant to report new symptoms → **Complete Adverse Experience Log.**
- 1c. follow-up of symptoms and/or AE(s)
- 1d. for help with reinsertion or insertion of a new vaginal ring
- 1e. participant is returning a used vaginal ring
- 1f. other, specify: _____

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

- 2a. none
- 2b. Pelvic Exam
- 2c. Specimen Storage
- 2d. Laboratory Results
- 2e. Follow-up CASI Tracking
- 2f. Adverse Experience Log (new)
 - 2f1. How many **new** AE Log pages were completed for this visit? *# of pages*
- 2g. Product Hold/Discontinuation Log (new)
 - 2g1. How many **new** PH Log pages were completed for this visit? *# of pages*
- 2h. other, specify: _____

3. hCG for pregnancy: *not required* *negative* *positive* → **If newly positive, complete Pregnancy Report form and Product Hold/Discontinuation Log.**

4. Was a **used** vaginal ring collected at this visit? *yes* *no*

5. Was a new vaginal ring inserted at this visit? *yes* *no*

Interim Visit (IV-1)

Purpose: Complete this form when an interim visit occurs during study follow-up. See the Study-specific Procedures Manual for a definition and examples of interim visits that require an Interim Visit form to be completed.

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

Item-specific 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 Week 4 (Visit Code = 3.0), record “3” to the left of the decimal point in the visit code field.
 - Record the number that corresponds to the Interim Visit in the third 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.
- **Item 2:** Note that marking a box indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.
 - **Item 2a:** Mark the “none” box if the Interim Visit form is the **only** DataFax form completed for this visit.
 - **Item 2f:** Mark this box if a new (previously unreported) AE is reported or observed at this visit. If the box to the left of “Adverse Experience Log (new)” is marked, record how many **new** AE Log pages were completed for this visit in item 2f1. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
 - **Item 2g:** Mark this box if a new (previously unreported) product hold or discontinuation is reported at this visit. If the box to the left of “Product Hold/Discontinuation Log (new)” is marked, record how many **new** PH Log pages were completed for this visit in item 2g1. For example, if two new product holds were reported, record “02.” Note that the Visit Code recorded in item 1 of these two PH Log pages should be the same as the Visit Code recorded on this form.

SAMPLE *Do NOT FAX TO DATAFAX*

Visit Code

□□□□.□□

1

MTN-013/IPM 026 (150)

LR-1 (135)

Participant ID

□□□□-□□□□□□-□
Site Number Participant Number Chk

Laboratory Results

Initial Specimen Collection Date

□□ □□□□ □□
dd MMM yy

Not done/
Not collected

Alternate Collection Date

dd MMM yy
□□ □□□□ □□

1. HEMOGRAM

- Not reported
- 1a. Hemoglobin □□□□.□□ g/dL
- 1b. Hematocrit □□□□.□□ %
- 1c. MCV □□□□.□□ fL
- 1d. Platelets □□□□□□.□□ x10³/mm³
- 1e. WBC □□□□□□.□□ x10³/mm³

Severity Grade If applicable □

AE Log Page # □□□□

Not reportable as an AE OR

Severity Grade If applicable □

AE Log Page # □□□□

Not reportable as an AE OR

Not done

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

- Not reported
- 1f. Neutrophils Absolute Count cells/mm³ □□□□□□
- 1g. Lymphocytes □□□□□□
- 1h. Monocytes □□□□□□
- 1i. Eosinophils □□□□□□
- 1j. Basophils □□□□□□

Severity Grade If applicable □

AE Log Page # □□□□

Not reportable as an AE OR

Comments: _____

Laboratory Results (LR-1)

Item-specific Instructions:

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

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

Results Reporting

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

Severity Grade:

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

AE Log Page #: If a severity grade is present, record the page number of the AE Log form which is most closely associated with the abnormal lab value or mark the box as applicable.

Not reportable as an AE: Only mark this box if a severity grade is present, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

SAMPLE *DO NOT FAX*
TO DATAFAX

MTN-013/IPM 026 (150)



LR-2 (136)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Laboratory Results

Not done/ Not collected	Alternate Collection Date			2. CHEMISTRIES	Severity Grade If applicable	AE Log Page #	Not reportable as an AE
	dd	MMM	yy				
<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	2a. AST (SGOT) <i>U/L</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	2b. ALT (SGPT) <i>U/L</i>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>
<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	2c. Creatinine <i>mg/dL</i>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	OR <input type="checkbox"/>

Not done/ Not collected	Alternate Collection Date			3. HIV TEST RESULTS	negative/ non-reactive	positive/ reactive	indeterminate/ equivocal
	dd	MMM	yy				
<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	HIV EIA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

↓

If positive or indeterminate during follow-up, complete HIV Test Results form and Product Hold/Discontinuation Log if applicable.

Comments: _____

Laboratory Results (LR-2)

Item-specific Instructions:

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

Results Reporting

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

Severity Grade:

- If any abnormal laboratory values meet the criteria for severity grade 1 or greater, record the grade in the appropriate box next to the results. If a severity grade is recorded, complete the remaining items on that row (i.e., “AE Log Page #” or “Not reportable as an AE.”)
- Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value).
- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.
 - Treat all missing digits in the lab value as zeros.
 - If the lab value falls between two calculated severity grade ranges, assign it the higher grade.
- There may be situations in which a lab value falls within a site’s lab normal ranges and also within a gradable range per the toxicity table. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the toxicity table.

AE Log Page #: If a severity grade is present, record the page number of the AE Log form which is most closely associated with the abnormal lab value or mark the box as applicable.

Not reportable as an AE: Only mark this box if a severity grade is present, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

SAMPLE. Do NOT FAX
TO DATAFAX

MTN-013/IPM 026 (150)



MV-1 (463)

Visit Code

. 0

1

Participant ID

- -

Site Number

Participant Number

Chk

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(s) within allowable 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.**
Complete an Adverse Experience Log if applicable.
- 2h. other, specify:

Comments: _____

Missed Visit (MV-1)

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

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

Item-specific Instructions:

- **Item 1:** Record the target date of the visit. A complete date is required.
- **Item 2:** Record the reason the participant missed the visit.

SAMPLE: Do NOT FAX TO DATAFAX



Visit Code [][] . []

1

MTN-013/IPM 026 (150)

PE-1 (166)

Participant ID

[][][] - [][][][][] - []
Site Number Participant Number Chk

Pelvic Exam

Exam Date

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

1. Naked eye, speculum, and bimanual exam assessments:
not done abnormal findings no abnormal findings
If not done, specify reason in Comments. End of form. If no abnormal findings, go to item 6.

1a. Abnormal non-colposcopic findings: Mark all that apply.

- Enlarged/tender inguinal lymph nodes, Abnormal vaginal discharge, Abnormal cervical discharge, Blood-tinged discharge, Blood in vagina—no identified source, Blood from cervical os, Bleeding from site of epithelial disruption, Erythema, Ulceration, Laceration, Abrasion, Peeling, Petechia, Ecchymosis, Vesicles, Edema, Abnormal cysts, Mass, Warts, Adnexal tenderness, Cervical motion tenderness, Uterine tenderness, Other abnormal findings, specify:

Complete or update Pre-existing Conditions, Medical History Log, and/or Adverse Experience Log as applicable.

2. Do any of these exam findings involve generalized erythema or severe edema with an affected area of more than 50% of the vulvar surface or combined vaginal and cervical surface? yes no
3. Do any of these exam findings suggest cervicitis? yes no
4. Do any of these exam findings involve deep epithelial disruption? yes no

If yes to any during vaginal ring use, remove study vaginal ring and complete Product Hold/Discontinuation Log.

5. Do any of these exam findings involve unexpected genital bleeding? yes no

If yes and no identified source, complete Genital Bleeding Assessment form if indicated.

6. Vaginal pH: OR not done

Comments: _____

Pelvic Exam (PE-1)

This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document pelvic exams conducted during the study.

Item-specific Instructions:

- **Item 1:** Document only those abnormal findings observed during naked eye, speculum, and bimanual examination. If a pelvic exam was required but not done, mark the “not done” box and record the reason the required pelvic exam was not done on the Comments lines.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed via naked eye, speculum, and bimanual examination **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding on the line provided.
- **Item 5:** If unexpected genital bleeding was observed with no identifiable source, complete a Genital Bleeding Assessment form if applicable (unless one has already been completed for this visit).

SAMPLE. Do NOT FAX
TO DATAFAX

MTN-013/IPM 026 (150)



PER-1 (168)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Pelvic Exam Ring Assessment

Exam Date

dd MMM yy

1. Was the vaginal ring present in the vagina at the start of the exam? yes no → **If no, go to item 3.**
2. Was the vaginal ring removed during the exam? yes no → **If no, end of form.**
3. Was the vaginal ring rinsed prior to reinsertion? yes no not reinserted → **If yes or no, end of form.**

3a. Specify reason vaginal ring not reinserted:

Pelvic Exam Ring Assessment (PER-1)

Purpose: The purpose of this form is to document presence/absence of the vaginal ring during pelvic exams.

General Information/Instructions: This form is completed for pelvic exams performed during the vaginal ring use period (post enrollment up through Day 28 Visit).

SAMPLE *DO NOT FAX*
TO DATAFAX



Visit Code

1

MTN-013/IPM 026 (150)

PKS-1 (162)

Participant ID

- -
Site Number Participant Number Chk

Pharmacokinetics Specimens

Visit Date

dd MMM yy

Not done/
Not collected

1. Participant weight: kg

Collection Time
(24-hour clock)

hr min

Not done/
Not collected

2. Single time-point blood draw: :

3. Vaginal tear test strips: :

4. Cervical biopsies for PK: :

5. Cervical biopsy for PD: :

If Enrollment or Day 28 Visit, go to item 6 (complete items 6–12).

If Day 52 Visit, go to item 12.

At all other visits, end of form.

Not done/
Not collected

6. Vaginal ring insertion (Enrollment Visit) or removal (Day 28 Visit) time: :

Collection Time
(24-hour clock)

hr min

7. 0-hour blood draw: :

8. 1-hour blood draw: :

9. 2-hour blood draw: :

10. 4-hour blood draw: :

11. 6-hour blood draw: :

12. Last menstrual period:

Start Date

dd MMM yy

Stop Date

dd MMM yy

none

OR

Comments: _____

01-AUG-11

01

Language

Staff Initials / Date

Pharmacokinetics Specimens (PKS-1)

Purpose: This form is used to document collection and timing of collection of pharmacokinetic (PK) laboratory specimens.

Item-specific Instructions:

- **Item 6:** At the Enrollment (Day 0) visit, record the time the study vaginal ring was inserted. At the Day 28 visit, record the time the study vaginal ring was removed. Mark the "Not done/Not Collected" box at the Day 28 visit if the ring had already been removed (due to a permanent product discontinuation, for example).
- **Items 6–11:** Complete these items at the Enrollment (Day 0) and Day 28 visits only. At all other visits, leave these items blank.
- **Item 12:** Complete item 12 at the Enrollment, Day 28, and Day 52 visits. If the participant has not had a menstrual period since this item was last completed, mark "none." If, at Enrollment, the participant has not had a period within the last 30 days, mark "none." If one of the dates is not available (for example, participant is still on menses at her Day 28 Visit), line through the applicable date boxes, write "ongoing" or other description, and initial and date.
 - **Timing:** See below for a summary of which items get completed when:
 - All required (scheduled) visits: Complete items 1–5. If the item is not required at the visit, mark "Not done/Not collected."
 - Enrollment, Day 28: Complete all items (items 1–12).
 - Day 52: Complete items 1–5 and item 12. Leave items 6–11 blank.

SAMPLE *DO NOT FAX*
TO DATAFAX



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

MTN-013/IPM 026 (150)

PRE-1 (012)

Participant ID

- -
Site Number Participant Number Chk

Pre-existing Conditions

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

1.	Ongoing Condition	Onset Date	MMM yy	Comments	Severity Grade	Staff Initials / Date
		<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>		<input type="checkbox"/> <input type="checkbox"/> <i>not gradable</i>	
2.	Ongoing Condition	Onset Date	MMM yy	Comments	Severity Grade	Staff Initials / Date
		<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>		<input type="checkbox"/> <input type="checkbox"/> <i>not gradable</i>	
3.	Ongoing Condition	Onset Date	MMM yy	Comments	Severity Grade	Staff Initials / Date
		<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>		<input type="checkbox"/> <input type="checkbox"/> <i>not gradable</i>	
4.	Ongoing Condition	Onset Date	MMM yy	Comments	Severity Grade	Staff Initials / Date
		<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>		<input type="checkbox"/> <input type="checkbox"/> <i>not gradable</i>	
5.	Ongoing Condition	Onset Date	MMM yy	Comments	Severity Grade	Staff Initials / Date
		<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>		<input type="checkbox"/> <input type="checkbox"/> <i>not gradable</i>	
6.	Ongoing Condition	Onset Date	MMM yy	Comments	Severity Grade	Staff Initials / Date
		<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>		<input type="checkbox"/> <input type="checkbox"/> <i>not gradable</i>	

Pre-existing Conditions (PRE-1)

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

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

- **Pre-existing Conditions Revisions and Updates:** If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s) to SCHARP DataFax.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
- **Ongoing Condition:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
- **Onset Date:** If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.
- **Comments:** This field is optional. Use it to record any additional relevant information about the condition.
- **Severity Grade:** For each condition, grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences* and the *DAIDS Female Genital Grading Table for Use in Microbicide Studies* (as appropriate). If a condition is not gradable, mark the "not gradable" box.

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 form that is completed for a participant.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the participant's corresponding Pregnancy Report form.
- **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 pregnancies resulting in one pregnancy outcome, record "1" here. For pregnancies 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 (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and fax both pages of this form to SCHARP DataFax.
- **Item 1:** If a pregnancy results in two outcomes, complete two Pregnancy Outcome forms (one for each outcome). Both Outcome forms will have the same visit code but different outcome numbers (for example, one Outcome form will have an outcome number =1 and the second form will have an outcome number = 2).
- **Item 4:** If the outcome is spontaneous fetal death, still birth, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an Adverse Experience. If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under item 7, "Treatment." If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-Specific Procedures (SSP) Manual, and *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2* for guidance on AE and expedited AE reporting requirements.
- **Item 5:** 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-013/IPM 026 (150)



PO-2 (443)

Visit Code

Outcome Number

Participant ID

- -
Site Number Participant Number Chk

Pregnancy Outcome

No data recorded on this page.

yes no unknown

6. Were any fetal/infant congenital anomalies identified?

If no or unknown, go to statement below item 6b.

6a. Congenital anomalies identified. *Mark all that apply. Complete AE Log and EAE Reporting form.*

- Central nervous system, cranio-facial
- Central nervous system, spinal
- Cardiovascular
- Renal
- Gastrointestinal
- Pulmonary
- Musculoskeletal/extremities
- Physical defect
- Skin
- Genitourinary
- Chromosomal
- Cranio-facial (structural)
- Hematologic
- Infectious
- Endocrine/metabolic
- Other

6b. Describe the congenital anomaly/defect: _____

Complete items 7–10 for live births only. Otherwise, end of form.

7. Infant gender: male female

8. Infant birth weight: kg OR unavailable

9. Infant gestational age by examination: weeks days OR unavailable **If unavailable, go to item 10.**

9a. Method used to determine gestational age: Ballard Dubowitz other, specify: _____

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

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

Pregnancy Outcome (PO-2)

Item-specific Instructions:

- **Visit Code:** Record the visit code that is present on page 1 of this form.
- **No data recorded on this page:** This box must only be marked if all items on the page are left blank.
- **Outcome Number:** Record the outcome number that is present on page 1 of this form.
- **Item 6a:** If a woman on study has a baby with a congenital anomaly, report the event on an Adverse Experience (AE) Log, if prior to termination. On the AE Log, record “Congenital Anomaly in Offspring” on Item 1, record the Outcome Date as the Onset Date, and record the specific anomaly on the Comments line. Also submit an Expedited Adverse Event (EAE) Reporting form.
- **Item 8:** Record the infant’s birth weight as documented in medical records. If no medical record documentation of infant birth weight is available, complete this item based on participant report. Mark the “unavailable” box if no medical record documentation is available and the participant does not know the infant’s birth weight.
- **Item 9:** Record the infant’s gestational age at birth. If the infant’s gestational age is determined using the Ballard method, please record “0” in the “days” box. Mark the “unavailable” box if no medical record documentation of the infant’s gestational age is available.

SAMPLE. *DO NOT FAX*
TO DATAFAX

MTN-013/IPM 026 (150)



PR-1 (440)

Visit Code .

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number						Chk	

Pregnancy Report

1. Date of onset of last menstrual period: *dd* *MMM* *yy*

2. Estimated date of delivery: *dd* *MMM* *yy*

Comments: _____

Pregnancy Report (PR-1)

Purpose: Complete this form when reporting a pregnancy of a study participant post enrollment through termination.

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

Item-specific instructions:

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

Product Hold/Discontinuation Log (PH-1)

This form is used to document temporary holds and permanent discontinuations of study vaginal ring use as instructed by study site staff. This form is completed each time a participant is instructed by study staff to temporarily stop (hold) or permanently discontinue vaginal ring use. If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete a Product Hold/Discontinuation Log page for each reason. The same visit code should be used on each Log page.

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

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers.
- **Item 3:** Record the date the participant last used a vaginal ring (the last date the vaginal ring was present in the vagina). Use a best estimate if the actual date cannot be determined.
- **Item 4:** If the reason for the product hold, as recorded in item 2, has resolved but there is another reason (e.g., pregnancy) for continuing the product hold, mark “no (hold continuing for another reason).”
- **Item 4a:** Record the date and visit code on which the participant was told by study staff that she could resume vaginal ring use or the date it was determined vaginal ring use must be permanently discontinued. If “no (hold continuing for another reason)” is marked for item 4, in item 4a record the date and visit code that the participant would have been instructed to resume vaginal ring use based on resolution of the reason marked in item 2.

Ring Adherence (RA-1)

Purpose: This form is used to collect participant-reported information on ring use (adherence). This includes all instances where the participant reports the ring has not been used, regardless of reason for non-use.

General Information/Instructions: Complete this form at the Day 7, 14, 21, and 28 visits only. This form is required at each of these visits, even if the participant has been on product hold. Do not complete this form at Interim Visits.

Item-specific Instructions:

- **Item 1:** Record the date of enrollment and visit code "02.0" the first time this form is completed for each participant.
- **Item 2:** Per participant report, if the ring has been out (not inserted) for any amount of time since the last time the form was completed for the participant, mark "yes" and continue with the form. If the participant reports the study vaginal ring has been in continuously since the last time this form was completed, mark "no" and end the form.
- **Item 2a:** Record how many separate times the participant reports the ring has been out since the last time the form was completed.
- **Items 3a–3e:** Complete one row for each separate time the participant reports the ring has been out. For example, if the participant reported that the ring has been out for two separate times since the last time this form was completed, complete rows 3a and 3b. In this case, item 2a of the form should be "02". When possible, complete items 3a–3e in ascending order by date, with item 3a being the earliest date the ring was out and item 3e the most recent date the ring was out.
 - **Removal/Expulsion Code:** Select from the codes below and record the code that best describes why the vaginal ring was taken out or came out on its own.

Removal/Expulsion Codes

Codes if the ring came out on its own
01 urinating
02 having a bowel movement
03 having sex or just finished having sex
04 physical activity or just finished physical activity
05 had or was expecting menses
06 other

Codes if the ring was taken out
10 ring caused discomfort
11 didn't feel it was correctly placed
12 had or was expecting menses
13 didn't want husband/male sex partner to know about ring
14 husband/male sex partner did not like ring and/or wanted her to remove ring
15 worried ring would be expelled during sex
16 didn't want to have vaginal sex with ring in vagina
17 site staff told her to remove ring
18 family member (other than husband/male sex partner) told her to remove ring
19 religious reasons
20 other

SAMPLE. Do NOT FAX TO DATAFAX

MTN-013/IPM 026 (150)



SS-1 (164)

Visit Code

Form boxes for Visit Code

Form box for page number 1

Participant ID

Participant ID form boxes: Site Number, Participant Number, Chk

Specimen Storage

Initial Specimen Collection Date

Initial Specimen Collection Date form boxes: dd, MMM, yy

Alternate Collection Date

dd MMM yy

Alternate Collection Date form boxes for item 1

1. Vaginal smear for gram stain: not required stored not stored Reason:

Alternate Collection Date

dd MMM yy

Alternate Collection Date form boxes for item 2

2. Vaginal swab for culture: not required stored not stored Reason:

2a. Was blood visible on the swab? yes no N/A

Alternate Collection Date

dd MMM yy

Alternate Collection Date form boxes for item 3

3. Vaginal swab for PD and biomarkers: not required stored not stored Reason:

3a. Was blood visible on the swab? yes no N/A

Alternate Collection Date

dd MMM yy

Alternate Collection Date form boxes for item 4

4. Used vaginal ring for PK residual assessment: not required stored not stored Reason:

Alternate Collection Date

dd MMM yy

Alternate Collection Date form boxes for item 5

5. Used vaginal ring for biofilm, FISH, and SEM: not required stored not stored Reason:

Alternate Collection Date

dd MMM yy

Alternate Collection Date form boxes for item 6

6. Vaginal swab for PK validation: not required stored not stored Reason:

6a. Was blood visible on the swab? yes no N/A

Comments: _____

Specimen Storage (SS-1)

Purpose: This form is used to document collection and storage of non-PK specimens by the local site laboratory.

General Information/Instructions: Check the information on this form against the LDMS Specimen Tracking Sheet completed for this visit to make sure the information is the same.

- **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.
- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the Initial Collection Date. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

Item-specific Instructions:

- **Items 1–6:** If the specimen is not required to be collected and stored at this visit, mark the “not required” box. If the specimen is required to be stored, but for some reason it is not stored at this visit, mark the “not stored” box and record the reason why on the line provided.

SAMPLE. DO NOT FAX
TO DATAFAX

MTN-013/IPM 026 (150)



TTW-1 (172)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Tear Test Strip Weights

Visit Date

dd MMM yy

PRE-COLLECTION

Note: Weights for pre-collection tear test strips include glass tube, screw lid, and unused tear test strip.

Not done

Weight

1. Tear Test Strip **#1 (Introitus)**: Pre-collection mg

2.. Tear Test Strip **#2 (Cervix)**: Pre-collection mg

POST-COLLECTION

Note: Weights for post-collection tear test strips include glass tube, screw lid, and used (absorbed) tear test strip.
Record the length of the moistened strip after absorption is completed. (the length of absorbed fluid)

Not done

Weight

Length

3. Tear Test Strip **#1 (Introitus)**: Post-collection mg mm

4. Tear Test Strip **#2 (Cervix)**: Post-collection mg mm

Comments: _____

Tear Test Strip Weights (TTW-1)

Purpose: This form is used to document pre- and post-collection weights of vaginal tear test strip specimens. Completion of this form is required at the following visits: Enrollment, Day 1, 2, 3, 5, 7, 14, 21, 28, 52 and at Day 31, 35 or 42 based on randomization assignment.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Visit Date:** Record the date of the visit at which the specimens were collected. A complete date is required.
- **Not done:** Mark this box if the listed item was not done and record the reason in the “Comments” section at the bottom of the form.
- **Items 1–2, Pre-collection Weights:** Record the pre-collection weights in milligrams. Be sure to include all items listed in the “Note” section above these items when obtaining the weights.
- **Items 3–4, Post-collection Weights and Collection Location:** Record the post-collection weights in milligrams. Be sure to include all items listed in the “Note” section above these items when obtaining the weights.

Termination (TM-1)

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

General Information/Instructions: If a participant is terminated prior to completing study product administration, complete a Product Hold/Discontinuation Log.

Item-specific Instructions:

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

SAMPLE. Do NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN-013/IPM 026 (150)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	
Site Number				Participant Number						Chk	

Enrollment Behavioral Eligibility

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

To confirm your eligibility for the study, I need to ask you a few more questions.

- In the past 60 days, have you participated in any research study involving drugs, medical devices, or vaginal products? *yes* *no*
- In the past 5 days, have you inserted, or do you plan to insert, any non-study vaginal products or objects into the vagina, including but not limited to spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), douches, lubricants, sex toys (vibrators, dildos, etc.), or tampons while participating in this study? *yes* *no*

If any items 1–2 are marked “yes,” participant is ineligible. ←

- In the past 14 days, have you abstained from receptive sexual activity (including oral, vaginal and anal intercourse), and do you plan to abstain from these activities for the duration of your study participation? *yes* *no*
- Are you willing to abstain from receptive sexual activity (including oral, vaginal and anal intercourse) for the duration of your study participation? *yes* *no*
- Do you plan to continue using your current birth control method for the duration of your study participation? *yes* *no*
- Are you willing to not participate in other research studies involving drugs, medical devices, or vaginal products for the duration of your study participation? *yes* *no*

If any items 3–6 are marked “no,” participant is ineligible. ←

Enrollment Behavioral Eligibility (Non-DataFax)

Purpose: This interviewer-administered form is used to document/confirm the participant's behavioral eligibility for the study at the Enrollment Visit, prior to enrollment/randomization. Read all introductory statements and items aloud as they appear on the form. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

General Information/Instructions: If the participant provides a response indicating that she is ineligible for the study, continue to administer this form so that all items are completed. Refrain from indicating to the participant the reason why she is not eligible.

Genital Bleeding Assessment (non-DataFax) – Page 1

This form is completed by the study clinician, and used to guide study clinicians' assessment of genital bleeding events that occur during follow-up. This form is completed each time an episode of unexpected genital bleeding is self-reported by a study participant and is either not observed during pelvic examination, or is clinically-observed with no identifiable source. Specifically, this form guides clinicians to collect and consider information on the many factors that may contribute to the unexpected genital bleeding event. Study clinicians should refer to the Study-specific Procedures Manual (SSP) to determine whether or not an episode of genital bleeding is unexpected.

Item-specific Instructions:

- **Item 1:** Mark “amenorrheic” if the participant has been without menses for at least the past three cycle intervals, or the past 6 months, whichever is shorter.
- **Item 5:** If the participant experienced intermittent bleeding as part of the same episode of genital bleeding, record the last date in which she experienced bleeding for that episode.
- **Item 6:** Record the total number of days in which the participant experienced bleeding during this genital bleeding episode. For example, if the participant experienced bleeding over 7 consecutive days and bled each of the 7 days, record “07.” If the participant experienced genital bleeding over a 6-day period, but only bled on days 1, 2, 4, and 7, record “04.”
- **Item 7:** Mark “unknown” in cases where the information is not known by the participant. Mark “N/A” if the genital bleeding was not reported by the participant, but was observed during the pelvic examination only.
- **Item 8:** Mark “unknown” in cases where the information is not known by the participant or the clinician.
- **Item 9:** Mark “NA” if the participant’s study VR use was held or permanently discontinued prior to this genital bleeding episode.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN-013/IPM 026 (150)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number			Participant Number				Chk

Genital Bleeding Assessment

10. Number of days between last use of study VR and first day of genital bleeding episode: days

11. According to the participant, did the genital bleeding occur within 2 days after

- | | yes | no |
|--|--------------------------|--------------------------|
| 11a. vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11b. painful vaginal sex? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11c. painful or uncomfortable insertion or removal of the study VR? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11d. painful or uncomfortable insertion or removal of any other vaginal product/preparation? | <input type="checkbox"/> | <input type="checkbox"/> |
| 11e. a pelvic or colpo exam? | <input type="checkbox"/> | <input type="checkbox"/> |

If "yes" to any, record related details in Comments on page 3.

If yes, record date of last pelvic/colpo exam in Comments on page 3.

11f. condom use? yes no

12. Is the participant currently using injectable contraceptives? *Review Concomitant Medications Log.* yes no **→ If no, go to item 13.**

12a. When was her last injection? *dd* *MMM* *yy*

12b. When is/was her next injection due? *dd* *MMM* *yy* **→ Go to item 14 on page 3.**

Genital Bleeding Assessment (non-DataFax) – Page 2

Item-specific Instructions:

- **Item 12:** If the participant reports currently using injectable contraceptives, make sure the injectable contraceptives are listed on the participant's Concomitant Medications Log.

SAMPLE. DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN-013/IPM 026 (150)

Participant ID

Site Number			Participant Number						Chk	

Genital Bleeding Assessment

13. Is the participant currently using (non-injectable) hormonal contraceptives? *Review Concomitant Medications Log.* yes no
 → **If no, go to item 14.**
- 13a. Has the participant missed one or more days of contraceptives in the week before the genital bleeding started? yes no
 → **If no, go to item 14.**
- 13b. Did the participant miss two or more days of contraceptives? yes no
 → **If yes, go to item 14.**
- 13c. **For participants using oral contraceptives only:** Did the participant make up the missed dose of oral contraceptives? yes no
14. Based on all information available, is this bleeding unexpected? yes no
 → **If no, end of form. DO NOT complete AE Log.**
- 14a. Is this unexpected bleeding menstrual or non-menstrual?

menstrual

↓

**Complete AE Log.
Report as "menorrhagia" or "menometrorrhagia." Grade per "menorrhagia" row of the Female Genital Toxicity Table.**

non-menstrual

↓

**Complete AE Log.
Report as "metrorrhagia" or "postcoital bleeding." Grade per "metrorrhagia" or "postcoital bleeding" row of the Female Genital Toxicity Table.**

Comments: _____

Genital Bleeding Assessment (non-DataFax) – Page 3

Item-specific Instructions:

- **Item 13:** Non-injectable hormonal contraceptives include oral contraceptives (“the pill”), Ortho-Evra (“the patch”), and vaginal rings. If the participant reports currently using non-injectable hormonal contraceptives, make sure these are listed on the participant’s Concomitant Medications Log.
- **Item 13c:** This item applies only to those participants using oral contraceptives. For participants who do not use oral contraceptives, leave item 13c blank and go to item 14.
- **Item 14:** Review the Baseline Medical History form and refer to the Study-specific Procedures Manual (SSP) to determine whether or not the genital bleeding is unexpected.
- **Item 14a:** If the unexpected genital bleeding is:
 - **menstrual** - grade the AE of menorrhagia [defined as prolonged (more than 7 days) or excessive (>80 mL) uterine bleeding] or menometrorrhagia (defined as prolonged uterine bleeding occurring at irregular intervals) using the “menorrhagia” row of the *Female Genital Grading Table for Use in Microbicide Studies* (protocol Appendix IV).

Note: unexpected menstrual bleeding is defined as menstrual bleeding that is heavier in volume or longer in duration than the participant’s usual menses. Refer to the Study-specific Procedures Manual (SSP) for further information.

- **non-menstrual** - grade an AE of metrorrhagia (intermenstrual bleeding) using the “metrorrhagia” row of the *Female Genital Grading Table for Use in Microbicide Studies* (protocol Appendix IV). Grade an AE of postcoital bleeding using the “postcoital bleeding” row of the *Female Genital Grading Table for Use in Microbicide Studies*.

Note: unexpected non-menstrual genital bleeding—regardless of severity—that is associated with an observed pelvic exam finding should be reported as an AE, with the AE description = “bleeding source and location” (e.g., ulceration-vaginal). Unexpected non-menstrual bleeding—regardless of severity—that is associated with an underlying cause (e.g., fibroids, uterine laceration, trauma) should be reported as an AE, with the diagnosis as the AE description. Refer to the Study-specific Procedures Manual (SSP) for further information.

SAMPLE. Do NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN-013/IPM 026 (150)

Participant ID

- -

Site Number Participant Number Chk

Pelvic Exam Diagrams

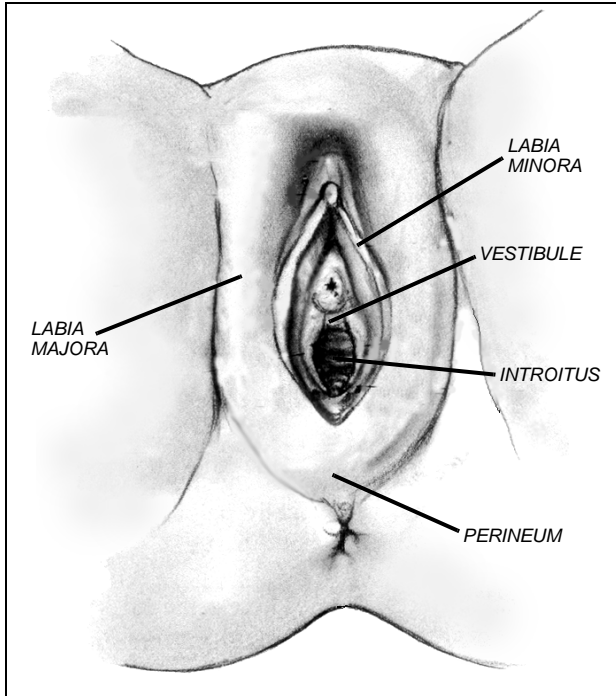
Exam Date

dd MMM yy

no normal variants or abnormal findings observed

Speculum Type (screening only)			Speculum Size (screening only)		
<i>Pederson</i>	<i>Graves</i>	<i>Cusco</i>	<i>small</i>	<i>medium</i>	<i>large</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

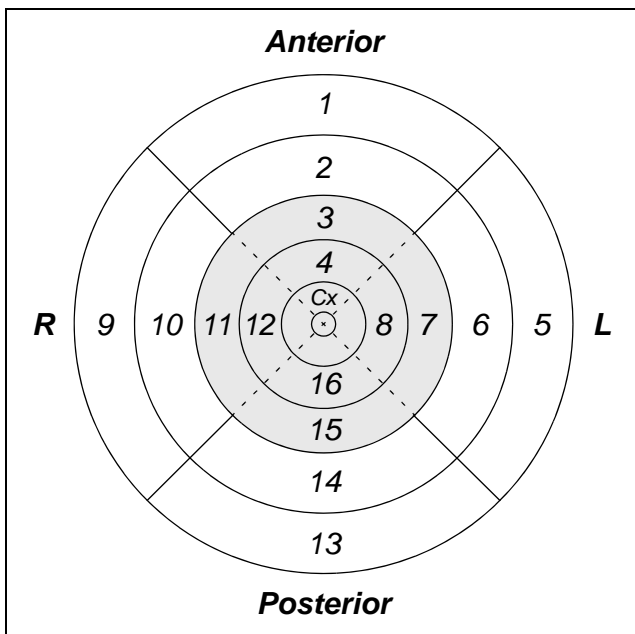
External Genitalia



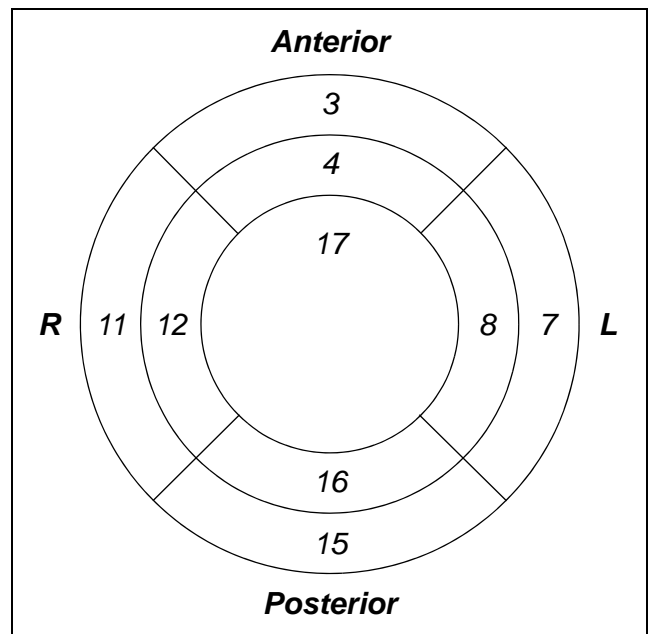
Legend for Vagina/Cervix

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

Vagina



Cervix



01-AUG-11

Language

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax)

This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through study exit). This form is completed each time a pelvic or pelvic/colposcopy exam is performed. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

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

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN-013/IPM 026 (150)

Participant ID

Site Number			Participant Number						Chk	

Physical Exam

Exam Date

dd		MMM		yy	

VITAL SIGNS

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

Weight kg

BP / mmHg

Height cm **OR** *N/A*

Pulse per minute

Oral Temp . °C

Respirations per minute

Vital Signs: Staff Initials / Date

FINDINGS

not evaluated *normal* *abnormal* *If abnormal, please specify.*

 2. General appearance _____

 3. Abdomen _____

 4. HEENT _____

 5. Neck _____

 6. Lymph Nodes _____

 7. Heart _____

 8. Lungs _____

 9. Extremities _____

 10. Neurological _____

 11. Skin _____

 12. Breast Exam _____

 13. Other, specify: _____

 14. Other, specify: _____

 15. Other, specify: _____

Physical Exam (non-DataFax)

This form is used to document the participant's vital signs and physical exam findings. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

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

SAMPLE *Do NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN-013/IPM 026 (150)

Participant ID

<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	-	<input type="text"/>
Site Number				Participant Number						Chk

Screening Behavioral Eligibility

Visit Date

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	

I am now going to ask you some questions about yourself. Some of these questions are personal and sensitive, but remember that we do not have your name on these papers. All of your answers will be kept confidential.

- | | | |
|--|--------------------------|--------------------------|
| 1. Have you ever had an adverse reaction to silicone, titanium dioxide, or to any of the components of the study products? | yes | no |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Have you used, or do you plan to use during the period of your study participation, CYP3A inducer(s) and/or inhibitor(s)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Have you used non-therapeutic injection drugs in the past 12 months? | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Have you used post-exposure prophylaxis for HIV exposure within the past 6 months? | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Are you currently breastfeeding? | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Do you plan to become pregnant within the next 4 months? | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Do you plan to move away from the area in the next 4 months? | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Are you currently participating in any research study involving drugs, medical devices, or vaginal products? | <input type="checkbox"/> | <input type="checkbox"/> |

If any items 1–8 are marked “yes,” participant is ineligible. ←

- | | | |
|---|--------------------------|--------------------------|
| 9. Are you willing to abstain from receptive sexual activity (including oral, vaginal and anal intercourse) for the 14 days prior to enrollment and continuing for the duration of your study participation? | yes | no |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Starting before your enrollment visit and continuing through the duration of your study participation, are you willing to use one of the following types of birth control: hormonal contraceptives (except contraceptive vaginal rings), an intrauterine device (IUD)–inserted at least 28 days prior to enrollment, being a woman who identifies as a woman who has sex with women exclusively, sterilization, and/or sexually abstinent for the past 90 days? | yes | no |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Are you willing to refrain from inserting any non-study vaginal products or objects into the vagina, including but not limited to, spermicides, female condoms, diaphragms, contraceptive vaginal rings, vaginal medications, menstrual cups, cervical caps (or any other vaginal barrier method), douches, lubricants, sex toys (vibrators, dildos, etc.), and tampons for the 5 days prior to enrollment throughout the duration of your study participation? | yes | no |
| | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Are you willing to not participate in other research studies involving drugs, medical devices, or vaginal products for the duration of your study participation? | yes | no |
| | <input type="checkbox"/> | <input type="checkbox"/> |

If any items 9–12 are marked “no,” participant is ineligible. ←

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	01-AUG-11
--------------------------	--------------------------	--------------------------	-------------------------------------	-----------

0	1
---	---

Language

Staff Initials / Date

Screening Behavioral Eligibility (non-DataFax)

Purpose: This interviewer-administered form is used to document the participant's behavioral eligibility for the study at the Screening Visit. Read all introductory statements and items aloud as they appear on the form. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

General Information/Instructions: If the participant provides a response indicating that she is ineligible for the study, continue to administer this form so that all items are completed. Refrain from indicating to the participant the reason why she is not eligible.

Item-specific Instructions:

- **Items 1–4:** The interviewer should provide examples as needed in order for the participant to be able to provide an accurate response. Refer to the Study-specific Procedures Manual (SSP) for relevant examples.

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

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

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the specimens were collected.
- **TUBES or SPECIMENS COLLECTED:** In the box provided, record the total number of tubes or specimens collected for that primary specimen type. If no LDMS specimens of the primary specimen type were collected, record "0".
- **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

BLD: Whole Blood	NON: No Additive	TFM: Tissue Freezing Medium (90% FBS + 10% DMSO)
BTM: Biopsy Transport Medium	PBS: Phosphate buffered saline	TFS: Tear Flow Strip (same as Tear Test Strip)
CVB Cervical Biopsy	PL1/2: Single or double spun plasma	TIS: Tissue
EDT: EDTA	SLD: Slide	VAG: Vagina
GRS: Gram Stain	SWB: Swab	VSC: Vaginal Secretions
IVR: Intravaginal ring	TIS: Tissue	

- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials – Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
 - **LDMS Data Entry Date – LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

Participant ID			Visit Code		Specimen Collection Date		
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Site Number	Participant Number	Chk			dd	MMM	yy

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADD/DER	INSTRUCTIONS FOR PROCESSING LAB
<input type="checkbox"/>	Cervical Biopsies for PK (CVB) Collection time: ____:____ hour : min	NON	TIS	N/A	Place tissue in a cool pre-weighed cryovial and store at ≤-70°C locally.
<input type="checkbox"/>	Fenway & UAB only Cervical Biopsy for PD (ex vivo challenge) (CVB) Collection time: ____:____ hour : min	TFM	TIS	N/A	Place biopsy for ex vivo challenge into a 2ml cryovial containing 1ml of sterile freezing mix (90% FBS + 10% DMSO), Freeze in a slow rate freezing container for 24 hrs, and store at ≤-70°C . Send to MTN NL at end of study.
<input type="checkbox"/>	Fenway & UAB only Used vaginal ring for PK residual assessment (IVR) Collection time – Day 28: ____:____ hour : min	NON	IVR	N/A	Autoclave used ring in autoclavable bag and store at room temp.
<input type="checkbox"/>	Pittsburgh only Cervical Biopsy for PD (ex vivo challenge) (CVB) Collection time: ____:____ hour : min	BTM	TIS	N/A	Place biopsy into a 50 ml conical tube containing 10 ml of chilled biopsy transport medium, take to MTN NL immediately for processing.
<input type="checkbox"/>	Pittsburgh only Used vaginal ring for Biofilm, FISH and SEM (IVR) Collection time – Day 28: ____:____ hour : min	NON	IVR	N/A	Immediately place ring into a sterile container and transport to MTN NL for processing.

Comments: _____

Initials: _____
Sending Staff Receiving Staff

LDMS Data Entry Date: / / _____
dd MMM yy LDMS Staff

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

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

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the specimens were collected.
- **TUBES or SPECIMENS COLLECTED:** In the box provided, record the total number of tubes or specimens collected for that primary specimen type. If no LDMS specimens of the primary specimen type were collected, record “0.”
- **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

BLD: Whole Blood	NON: No Additive	TFM: Tissue Freezing Medium (90% FBS + 10% DMSO)
BTM: Biopsy Transport Medium	PBS: Phosphate buffered saline	TFS: Tear Flow Strip (same as Tear Test Strip)
CVB Cervical Biopsy	PL1/2: Single or double spun plasma	TIS: Tissue
EDT: EDTA	SLD: Slide	VAG: Vagina
GRS: Gram Stain	SWB: Swab	VSC: Vaginal Secretions
IVR: Intravaginal ring	TIS: Tissue	

- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials – Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
 - **LDMS Data Entry Date – LDMS Staff:** The LDMS laboratory staff person who entered the specimens into DMS, records his/her initials here.

MTN-013/IPM 026

LDMS Specimen Tracking Sheet

Enrollment and Day 28 Blood PK

For login of stored specimens into LDMS

Participant ID	Visit Code	Specimen Collection Date
<input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
<small>Site Number Participant Number Chk</small>		<small>dd MMM yy</small>

# of TUBES or SPECIMENS	PRIMARY SPECIMEN	PRIMARY ADDITIVE	ALIQUOT DERIVATIVE	ALIQUOT SUB ADD/DER	INSTRUCTIONS FOR PROCESSING LAB
<input type="checkbox"/>	Blood PK – 0 Hour (BLD) Collection Time ____ : ____ hour : min	EDT (purple top)	PL1/2	N/A	Transport to lab ASAP. Centrifuge, split, and label two or more cryovials with a minimum of 1.5mL of plasma. Freeze within 2 hrs of blood collection.
<input type="checkbox"/>	Blood PK – Hour 1 (BLD) Collection Time ____ : ____ hour : min	EDT (purple top)	PL1/2	N/A	Transport to lab ASAP. Centrifuge, split, and label two or more cryovials with a minimum of 1.5mL of plasma. Freeze within 2 hrs of blood collection.
<input type="checkbox"/>	Blood PK – Hour 2 (BLD) Collection Time ____ : ____ hour : min	EDT (purple top)	PL1/2	N/A	Transport to lab ASAP. Centrifuge, split, and label two or more cryovials with a minimum of 1.5mL of plasma. Freeze within 2 hrs of blood collection.
<input type="checkbox"/>	Blood PK – Hour 4 (BLD) Collection Time ____ : ____ hour : min	EDT (purple top)	PL1/2	N/A	Transport to lab ASAP. Centrifuge, split, and label two or more cryovials with a minimum of 1.5mL of plasma. Freeze within 2 hrs of blood collection.
<input type="checkbox"/>	Blood PK – Hour 6 (BLD) Collection Time ____ : ____ hour : min	EDT (purple top)	PL1/2	N/A	Transport to lab ASAP. Centrifuge, split, and label two or more cryovials with a minimum of 1.5mL of plasma. Freeze within 2 hrs of blood collection.

Comments: _____

Initials: _____
Sending Staff Receiving Staff

LDMS Data Entry Date: / /
dd MMM yy LDMS Staff

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

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

Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the specimens were collected.
- **TUBES or SPECIMENS COLLECTED:** In the box provided, record the total number of tubes or specimens collected for that primary specimen type. If no LDMS specimens of the primary specimen type were collected, record “0.”
- **Primary Specimen, Primary Additive, and Aliquot Derivative Codes:** See table below for a listing of the codes.

BLD: Whole Blood	NON: No Additive	TFM: Tissue Freezing Medium (90% FBS + 10% DMSO)
BTM: Biopsy Transport Medium	PBS: Phosphate buffered saline	TFS: Tear Flow Strip (same as Tear Test Strip)
CVB Cervical Biopsy	PL1/2: Single or double spun plasma	TIS: Tissue
EDT: EDTA	SLD: Slide	VAG: Vagina
GRS: Gram Stain	SWB: Swab	VSC: Vaginal Secretions
IVR: Intravaginal ring	TIS: Tissue	

- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials – Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
 - **LDMS Data Entry Date – LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.