

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 001 case report forms. For questions about this section or about general data collection policies, procedures, or materials, please contact Karen Patterson (karen@scharp.org or karenp@scharp.org).

For this study, the SDMC (Statistical and Data Management Center) is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, WA, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN001 team members, along with their job roles and e-mail addresses, are listed below.

Role on MTN 001	Name	E-mail address
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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 re-faxed pages are received, SCHARP staff review the corrected pages and resolve the QCs.

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

13.2 DataFax Form Completion

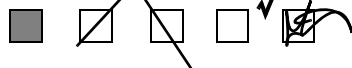
13.2.1 Guidelines

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

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

13.2.2 How to Mark Response Boxes

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

Correct:**Incorrect:**

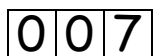
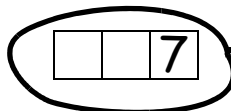
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

13.2.3 How to Record Numbers

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

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

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

Correct:**Incorrect:**

→ This example would result in a QC note.

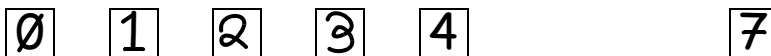
- Write the number(s) as large as possible while staying within the boundaries of the box; try not to stray outside the boundaries of the box.

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

Correct:**Incorrect:**

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

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

Easily Identified:**Difficult to Identify:**

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, 2008 is recorded as:

0	6	J	U	N	0	8
<i>dd</i>		<i>MMM</i>			<i>yy</i>	

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, 2008 would be recorded as follows:

O	C	T	0	8
<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
7:00 a.m.	07:00	7:00 p.m.	19:00
8:00 a.m.	08:00	8:00 p.m.	20:00
9:00 a.m.	09:00	9:00 p.m.	21:00
10:00 a.m.	10:00	10:00 p.m.	22:00
11:00 a.m.	11:00	11:00 p.m.	23:00

13.2.6 Data Corrections and Additions

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

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

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

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

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

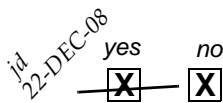
- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it unreadable with multiple cross-outs),
- place the correct or clarified answer near the box, and

- initial and date the correction as shown below:



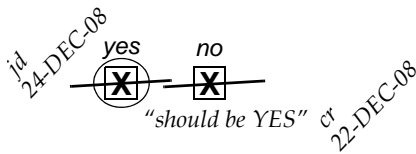
If an **X** is marked in the wrong response box, correct it by doing the following:

- 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:

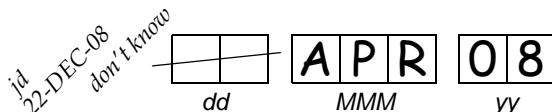


The standards above must **always** be followed whenever a CRF is changed, clarified, or amended, even if the change is made **before** the CRF is faxed to SCHARP for the first time.

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 MTN 001 Study-Specific Data Collection Information

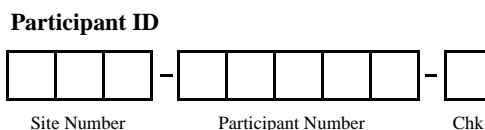
13.3.1 Participant ID numbers (PTIDs)

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

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

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

The PTIDs used for this study are nine digits and formatted as “XXX-YYYYY-Z.” The PTID consists of three parts: the 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 001.



13.3.2 Study Visit Timing

Screening and Enrollment

Screening visit procedures may take place over more than one day, when needed. 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 30 days of the initial screening visit.

For MTN 001, a participant is considered enrolled once the participant has been assigned a MTN 001 Randomization Envelope (or MTN 001 Replacement Randomization Document, if a replacement participant). Assignment of MTN 001 randomization envelopes will be documented using the MTN 001 Randomization Envelope Tracking Record provided to each site by SCHARP.

Multiple Screening Attempts (Re-screens)

If a participant's first screening attempt is unsuccessful, she may re-screen for the study if she chooses. If she does re-screen, ALL screening procedures (except PTID assignment), evaluations, and forms must be repeated, including provision of written informed consent. Once a PTID is assigned to a participant, that PTID is used for that participant for all re-screens and enrollment into the study. If a participant re-screens, only case report forms from the successful screening and enrollment visits are faxed to SCHARP.

Follow-Up Visits

There are 9 required follow-up visits for this study. For each of the nine visits, the visit type, visit code, target visit day, and visit windows (allowable and target) are listed in table 13-1.

Table 13-1: List of MTN 001 Required Visits, Target Visit Dates, and Visit Windows

All windows are listed in days, with Enrollment = Day0						
Visit Type	Visit Code	Allowable Window Opens	Target Window Opens	Target Day	Target Window Closes	Allowable Window Closes
Week 3	3.0	1	18	21	24	31
Week 6	4.0	32	39	42	45	45
Week 7	5.0	46	46	49	52	59
Week 10	6.0	60	67	70	73	80
Week 13	7.0	81	88	91	94	94
Week 14	8.0	95	95	98	101	108
Week 17	9.0	109	116	119	122	129
Week 20	10.0	130	137	140	143	143
Week 21	11.0	144	144	147	150	150

Target Days and Visit Windows

Whenever possible, visits should be completed within the target window. Ideally, visits will be completed on the target day for the visit. Visits completed within the target window will appear on the MTN 001 Retention Report as being completed “on-time”. It is not always possible to complete the visit on the target day, or within the target window. In these cases, every effort should be made to complete the visit within the allowable window for the visit. The allowable window is, in most cases, larger than the target window. Visits completed within the allowable window will count with regard to participant retention (that is, the participant will be considered retained for the visit). However, visits completed within the allowable window will appear on the MTN 001 Retention Report as being completed “early” or “late” depending on when the visit was completed. For example, a Week 17 visit completed 124 days after Enrollment will be listed as being completed “late”.

SCHARP will provide sites with an Excel spreadsheet tool that may be used to generate individual participant follow-up visit calendars. The spreadsheet requires that the participant’s Enrollment date be entered. Once the enrollment date is entered, the target day and visit windows for each of the 9 required follow-up visits will appear in the spreadsheet, which can then be printed and added to the participant’s study notebook.

Split Visits

In cases where a participant is not able to complete all required visit evaluations on the same day, the participant may come back and complete the remaining evaluations on another day, as long as the evaluations are completed within the allowable visit window. For example, a participant comes in on her Week 3 target day and completes all required evaluations except for the pelvic exam (she is on menses).

She comes back 5 days later (once she is off menses) and completes the pelvic exam and associated procedures.

Note that end-of-study period PK procedures cannot be split across days; the end-of-period PK procedures must all be completed on the same day (see the Participant Follow-up section of this manual for more information on PK procedures). Also note that the Study Product Adherence and Behavior Assessment must be completed on the same day as the end-of-period PK procedures.

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 allowable 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 32 days after enrollment. Per table 13-1, the Week 3 allowable window closes on Day 31. In this case, since the allowable visit window has “closed”, the Week 3 visit is considered missed, and is documented by completion of a Missed Visit case report form.

Interim Visits

A clinic visit is considered an Interim Visit when a participant presents at the site for additional clinical/laboratory/pharmacy assessments and/or procedures *outside* of the required evaluations for a scheduled study visit. A clinic visit is also considered an Interim Visit when the participant presents to the clinic early on in the allowable visit window and the site decides not to complete the required visit at that time (and instead wait until the participant is closer to her target visit day). The following are examples of interim visits for MTN 001:

1. A participant completes all required evaluations for a scheduled study visit within the visit window (target or allowable). She then returns to the site clinic within the same visit window (target or allowable) to request replacement study product for lost study product.
2. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the clinic within the same visit window (target or allowable) to request a pregnancy test.
3. A participant completes all required evaluations for the Week 3 visit within the target window. At the Week 3 visit, superficial epithelial disruption is noted during her pelvic exam. She then returns to the clinic 2 days later (still within the Week 3 allowable visit window) for clinical follow-up (another pelvic exam) of the superficial epithelial disruption.
4. A participant enrolls on 04-NOV-08. She returns to the site clinic three days later (07-NOV-08) to request replacement study product for lost study product. Since it is so early in her Week 3 window, and the participant has been shown to be reliable, the site does not want to conduct the Week 3 visit on 07-NOV-08. Instead, the site conducts an Interim Visit to resupply the participant with study product. The site then schedules the participant to come back to the clinic on her Week 3 target day to complete her Week 3 visit.

Phone contact with a participant is also considered an Interim Visit if the phone contact results in reporting of a new Adverse Experience (AE). Phone contact is also considered an Interim Visit if, during the phone contact, the participant is instructed by site staff to resume product use (after a product hold has been initiated). The following are examples of phone contacts that would need to be documented as Interim Visits on MTN 001:

1. A participant completes her Week 6 visit on the target day. The next day (still within the Week 6 window), she calls the clinic to report a new symptom, which results in the reporting of a new adverse experience. Although she is still within the Week 6 allowable window, she has already completed all

required Week 6 visit evaluations. Thus, the phone contact is considered an interim visit, and is assigned an interim visit code.

2. A participant completes her Week 3 visit on the target day. At the Week 3 visit, she is diagnosed with grade 2 sexually-transmitted infection (STI). She is given treatment to take for the STI, and per protocol, is put on study product hold. Three days later you call her to confirm she has completed the STI treatment and that she has no STI symptoms. Once confirmed, you instruct her to begin using study product. In this case, the phone contact is considered an interim visit, and is assigned an interim visit code.

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

For questions about phone contacts and assignment of visit codes to such contacts, please contact the SCHARP MTN 001 Project Managers.

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.

MTN 001 has four scheduled study visits. When visit code boxes are provided, site staff are responsible for entering the visit code in the boxes provided in the upper right corner of each page.

The following table lists the visit codes assigned to each required study visit.

Table 13-2: Visit Code Assignments for Required Study Visits

Visit Type	Visit Code
Screening	01.0
Enrollment	02.0
Week 3	03.0
Week 6	04.0
Week 7	05.0
Week 10	06.0
Week 13	07.0
Week 14	08.0
Week 17	09.0
Week 20	10.0
Week 21	11.0

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 (even though some forms and evaluations will have different visit dates). For example, a participant comes in on her Week 3 target day of 23-AUG-08 and completes all required evaluations except for the pelvic exam (she is on menses). She comes back on 28-AUG-08 and completes the pelvic exam and associated procedures. All case report forms completed on 23 and 28 August are assigned a visit code of 03.0 (since all evaluations are Week 3 evaluations).

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 unscheduled/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: A participant returns to the site clinic two days after Enrollment in order to replace study product that she lost. Since she is early on in her Week 3 window, the site decides to wait until closer to the Week 3 target day to complete the Week 3 visit. At this time, she is only given study product, and the visit is considered an interim visit and is assigned the following interim visit code:

Visit Code for this Interim Visit:

Visit Code .

Page numbers

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

Page

Assign page numbers in sequential order, starting with 01 (or 001, for Adverse Experience Log 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 case report forms for this study include DataFax forms (forms that are completed and faxed to SCHARP DataFax) and non-DataFax forms (forms that are completed but **not** faxed to SCHARP DataFax).

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. The following table (Table 13-3) lists the DataFax and non-DataFax forms that are **required** to be completed at each study visit.

Table 13-3: Case Report Form Completion Schedule

SCREENING (DAY -30)	
Form Acronym	Form Name
SC	Screening Consent
DEM	Demographics
SPE	Screening and Enrollment Pelvic Exam
PLR	Pelvic Laboratory Results
SL	Safety Laboratory Results
SSL	Screening and Enrollment STI Laboratory Results
CM	Concomitant Medications
nonDataFax	MTN 001 Baseline Medical and Menstrual History
nonDataFax	Physical Exam
nonDataFax	Pelvic Exam Diagrams
nonDataFax	Screening Eligibility
nonDataFax	Clinical Eligibility
nonDataFax	Screening Summary
ENROLLMENT (DAY 0)	
Form Acronym	Form Name
FPM	Family Planning Methods
BGS	Baseline Genital Symptoms
SPE	Screening and Enrollment Pelvic Exam
PLR	Pelvic Laboratory Results
SL	Safety Laboratory Results
PRE	Pre-existing Conditions
ENR	Enrollment
EBA	Enrollment Behavior Assessment
nonDataFax	Enrollment Eligibility
nonDataFax	Physical Exam
nonDataFax	Pelvic Exam Diagrams
nonDataFax	Clinical Eligibility
nonDataFax	LDMS Specimen Tracking Sheet – US or Africa version as applicable
Mid-study Period Visits (Weeks 3, 10, and 17)	
Form Acronym	Form Name
FV	Follow-up Visit
FPM	Family Planning Methods
FGS	Follow-up Genital Symptoms
FPE	Follow-up Pelvic Exam

SL	Safety Laboratory Results
SPA	Study Product Adherence and Behavior Assessment
PKI	Pharmacokinetics-Intensive <i>US sites only</i>
PKN	Pharmacokinetics-Non-intensive <i>Africa sites only</i>
nonDataFax	Physical Exam
nonDataFax	Pelvic Exam Diagrams
nonDataFax	LDMS Specimen Tracking Sheet – US or Africa version as applicable
Week 7 and 14 Visits	
Form Acronym	Form Name
FV	Follow-up Visit
FPM	Family Planning Methods
FGS	Follow-up Genital Symptoms
FPE	Follow-up Pelvic Exam
SL	Safety Laboratory Results
SLR	STI Laboratory Results
nonDataFax	Physical Exam
nonDataFax	Pelvic Exam Diagrams
End-of Study Period Visits (Weeks 6, 13, and 20)	
Form Acronym	Form Name
FV	Follow-up Visit
FPM	Family Planning Methods
FGS	Follow-up Genital Symptoms
FPE	Follow-up Pelvic Exam
PLR	Pelvic Laboratory Results
SL	Safety Laboratory Results
SPA	Study Product Adherence and Behavior Assessment
PSA	Product Sharing Assessment
AA	Acceptability Assessment <i>Weeks 6 and 13 only</i>
FAA-	Final Acceptability Assessment <i>Week 20 only</i>
PKI	Pharmacokinetics-Intensive <i>US sites only</i>
PKN	Pharmacokinetics-Non-intensive <i>Africa sites only</i>
FC	Flow Cytometry
nonDataFax	Physical Exam
nonDataFax	Pelvic Exam Diagrams
nonDataFax	LDMS Specimen Tracking Sheet – US or Africa version as applicable
Week 21/Study Exit	
Form Acronym	Form Name
FV	Follow-up Visit
FPM	Family Planning Methods
FGS	Follow-up Genital Symptoms
SL	Safety Laboratory Results
SLR	STI Laboratory Results
TM	Termination

ESI	End of Study Inventory
nonDataFax	LDMS Specimen Tracking Sheet – US or Africa version as applicable

13.3.6 Site Review of DataFax Forms

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

- Other than the participant ID number (PTID), there is no information on the form that could identify the participant (e.g., name, phone number, national identification number, or any other personal identifiers).
- A response has been recorded for each item, unless the item was skipped as instructed by a skip pattern or the item was marked as missing or unknown as described in 13.2.7.
- All text responses are clearly recorded.
- There are no marks on or above the DataFax barcode at the top of each DataFax page.
- There are no:
 - missing dates,
 - missing visit codes,
 - incorrect PTIDs,
 - incorrect visit codes,
 - missing data for items beginning a series of skip patterns, and/or
 - inconsistent or discrepant data.

While CRFs are being reviewed, it is important that they are stored and tracked systematically. It is also necessary to have a system to identify whether a CRF has been faxed to SCHARP DataFax. Such a system may include using a stamp to date the back of the CRF, or utilizing the SCHARP CRF Tracking System (see SSP Section 13.3.7 for more information).

Important: If a date stamp is used to document when the form is faxed, 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 001 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 001 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 001 sites will receive non-DataFax forms from SCHARP. These forms will be easily identifiable because there will not be a DataFax barcode along the top of the CRF. In place of the barcode, the following text will appear: “NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.”

These forms should **not** be faxed to SCHARP DataFax. Instead, they should be kept in the participant’s file as a record of the activities recorded on the form. The form completion guidelines described in sections 13.3.1 through 13.3.4 should be applied when completing non-DataFax CRFs.

13.4 Form Supply and Storage

13.4.1 Form and Specimen Label Supply

All case report forms needed for the study will be provided by SCHARP. Forms will be supplied using form visit packets, where the packet contains all of the required CRFs for the visit. For example, the Screening Visit packet will include all of the CRFs listed for this visit in the Case Report Form Completion Schedule table (table 13-3). In addition for form packets for each visit listed in Table 13-3, bulk supplies of “as needed” CRFs will be provided to the site (for example, Pregnancy Report and History, Pregnancy Outcome, Genital Bleeding Assessment, etc.).

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

13.4.2 Form Storage

Specifications for form storage will be detailed in the site’s MTN 001 Data Management SOP. It is recommended that for each participant, study CRFs be stored in a hard-cover notebook. SCHARP can provide a template for use in creating notebook cover labels and spine labels. SCHARP can also provide a template that can be used to create tab dividers.

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

13.5 How to Complete Interviewer-administered Forms

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

Interviewing Techniques

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

Welcoming the Participant

- When a new participant arrives at the clinic, everything about the study is new. Help make the participant feel comfortable.
- Perhaps offer the participant a glass of water or other beverage.
- Introduce yourself, and try to create rapport (connection) between yourself and the participant to help her feel comfortable during the interview.
- Some DataFax forms include introduction statements before certain items to help prepare the participant for sensitive questions. Read each of these introductions as they appear on the forms.

Asking Sensitive Questions

This study is about a very sensitive subject: HIV. Gaining an understanding of sexual behavior patterns can affect the transmission of HIV and the development of prevention methods.

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

Recording Participants' Responses Verbatim

Often, interviewer-administered questions will have a list of response categories provided to capture the participant's response. Almost always, an "other, specify" box is included as one of the response categories in order to capture participant responses that do not fit into one of the categories already listed. When a participant's response does not match or fit into one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.

Pacing the Interview

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

Reading Items Aloud

Read all items to the participant **word-for-word**, and speak clearly. Avoid re-phrasing items because this can change the meaning of the item, making it inconsistent with another participant's interview. Provide explanation or interpretation if necessary only after reading the item word-for-word. Avoid tangential—though related—counseling and educational discussions during data collection. When applicable, acknowledge

questions and concerns raised by the participant during the interview, and state that the subject can be discussed after the end of the interview.

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

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

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

Probing

One of the major goals of the study's interviews is to obtain accurate information on many HIV related behaviors. These interviews ask participants to recall many aspects of personal behaviors. However, participants may not remember or know the answer to every question. The technique for helping a participant remember an answer, clarify a response, decide between two similar but different answers, or report something more precisely is called “probing.”

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

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

- **Repeat Probe:** The repeat probe is used by repeating the item or response categories (if the response categories are part of the question). Although the participant might hear you the first time you ask a question, she may need to hear the question more than once to provide an answer. Instead of rephrasing a question if you notice the participant is confused, always first repeat the item as it is written. Sometimes hearing the question a second time is all that is needed.
- **Echo Probe:** The echo probe involves repeating the participant's exact response. Sometimes hearing the answer with a different voice will help her be more precise. The echo should always be repeated in a neutral, non-judgmental style.
- **Silent Probe:** The silent probe is used by pausing briefly after a participant gives what seems to be an uncertain answer. Although silence can feel awkward, sometimes it is helpful when a participant is trying to determine the most accurate answer to a question. Use a silent probe when the participant sounds unsure of her answer and may need some extra time to think more carefully about the question.
- **Non-verbal Probe:** The non-verbal probe is used by giving hand or facial gestures that may help the participant to come up with an answer. Remember that all such gestures must be neutral and non-judgmental.
- **Specification Probe:** The specification probe is used by asking the participant to give a more precise answer. Although a participant may give an answer that he or she considers accurate, it may not be specific enough. For example, if an item asks how many times the participant did something and she answers with a range (“5 to 10”). Ranges are not acceptable for this type of interviewing. In this case, the probe, “Can you be more specific?” is often enough to help the participant choose the most accurate response.
- **Historical Probe:** The historical probe is used by asking whether the event in question occurred anytime around major holidays or personal events such as a birthday or other life event. Some items require the participant to recall dates, and initially she may be unable to recall a date. Referencing a calendar can also help the participant remember dates.

Watching for Non-verbal Cues

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

Checking Your Work

During the interview it is important to use the forms instructions (those on the front and back of each page) to guide the interview. Also, make sure the participant is understanding and responding to you, and record all reported information on the forms. **After the interview and while the participant is still there**, review the forms for accuracy and completeness so you can complete an item that might have accidentally been missed. **Once the participant has left, any items identified as missed must remain as is and will be considered “missing data”**. Because all interviewer-administered CRFs are source documents (with the participant being the source of the data), missing items cannot be completed once the participant has left the clinic. For items identified as “missed”, please line through the item and write “item missed in error” in the white space next to the item, and initial and date.

13.6 Form Completion Instructions

Detailed form completion instructions for each form are provided on the back of each form page. These instructions include the purpose of each form as well as how each form should be completed. Some items on forms are straightforward and do not require specific instructions. Therefore, you will not see all form items listed in the form-specific completion instructions, but rather, only those items needing detailed explanation.

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

Pre-existing Conditions and Concomitant Medication Log

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

Adverse Experience Log (AE Log)

- For the Adverse Experience Log form, do **not** wait until the AE resolves before faxing the form page to SCHARP. In most cases, when you first report the AE on an AE Log form, the AE will have a “continuing” status (form item 6). Once the AE has an outcome (the AE resolves, the AE is grade 5 - death, or the AE increases in severity/frequency), update item 6 and 6a of the **original** AE Log form page. Initial and date all additions, and any other changes made to the form page, and refax the page to SCHARP.
- Always make changes, corrections, and updates to the **originally-completed** Adverse Experience Log form page. Once an AE Log form page has been started and faxed to SCHARP, the data from that page should **never** be transcribed onto another AE Log form page. All updates and corrections should be made to the originally-completed form page (regardless of how messy or crowded the form page becomes).
- For item 1, note that planned procedures or surgeries are **not** AEs. For example, a tonsillectomy is not an AE and should not be reported as an AE. Any adverse experiences associated with the planned procedure or surgery are AEs and should be reported on an AE Log form. For example, a throat infection that resulted from the tonsillectomy is a reportable AE.

- Note that for **item 3**, the Female Genital Grading Table for Use in Microbicide Studies (Female Genital Tox Table) is used to assign severity grades to AEs (in addition to the DAIDS “Tox Table”). The Female Genital Tox Table is in Section Appendix 11-1 of this SSP Manual.
- For **item 4**, note that if “not related” is marked, you need to record the reason the AE is determined to be “not related” in the Comments section of the form. For example, for an AE of headache that is judged “not related”, the Comments entry may be something like “#4 - not related in time to this AE onset”.
- For **item 5**, mark “no change” if the AE does not result in a product hold or discontinuation. This includes AEs that are reported during the washout weeks (Weeks 6, 13, and 20).
- For **item 7**, note that if the AE results in a new or prolonged hospitalization, the AE meets the criteria for “serious” and item 8 of the AE Log form should be marked “yes”.
- There may be a situation where an AE reported on an Adverse Experience Log form needs to be deleted (for example, in the case where the AE is later found to actually be a pre-existing condition). To indicate an AE Log page should be deleted, draw a diagonal line across the entire form page, write “delete due to _____” (include the reason the AE is being deleted), and initial and date. Refax the form to SCHARP. Do **not** reassign the page number assigned to the deleted AE to another AE, and do not renumber the other AE Log pages present for the participant. Do not renumber AE Log pages after faxing unless specifically instructed to do so by SCHARP.
- For **item 10**, note that the Visit Code recorded in item 10 is the visit code assigned to the visit date in the “Date Reported to Site” field
- For AEs of gradable laboratory results (e.g., “Increased ALT”), the date the laboratory report is received should be recorded as the “Date Reported to Site” on the AE Log. The date of specimen collection should be recorded as **item 2** “Onset Date”. The **item 6a** “Status/Outcome Date” should be the collection date of the follow-up specimen that yields a result within normal range (non-gradable), or a result of increased severity (thus requiring completion of a new AE Log).

13.7 Case Report Forms

This section contains each MTN 001 case report form developed for the study. Detailed form completion instructions for each form are provided on the back of each form page.

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

CRF Table of Contents

Demographics	13-21	
Screening Consent.....	13-25	
Pre-existing Conditions	13-27	
Baseline Genital Symptoms	13-29	
Screening and Enrollment		
Pelvic Exam	13-31	
Screening and Enrollment STI		
Laboratory Results	13-33	
Pharmacokinetics–Non-intensive	13-37	
Pharmacokinetics–Intensive	13-39	
Flow Cytometry	13-41	
Enrollment	13-43	
Enrollment Behavior Assessment	13-45	
Family Planning Methods	13-51	
Follow-up Visit	13-53	
Follow-up Genital Symptoms	13-55	
STI Laboratory Results	13-57	
Pelvic Laboratory Results	13-59	
Follow-up Pelvic Exam	13-61	
Safety Laboratory Results	13-63	
Study Product Adherence and		
Behavior Assessment	13-67	
Product Sharing Assessment	13-87	
Acceptability Assessment	13-93	
Interim Visit	13-97	
HIV Test Results.....	13-99	
Final Acceptability Assessment.....	13-101	
Product Hold/Discontinuation Log....	13-107	
		Adverse Experience Log..... 13-109
		Concomitant Medications Log
		13-111
		Pregnancy Report and History.....
		13-113
		Pregnancy Outcome
		13-115
		Missed Visit.....
		13-117
		Participant Transfer.....
		13-119
		Participant Receipt.....
		13-121
		End of Study Inventory.....
		13-123
		Termination
		13-125
		 NON-DATAFAX
		MTN001 Baseline Medical and
		Menstrual History Form
		13-127
		Screening Eligibility.....
		13-135
		Screening Summary
		13-143
		Enrollment Eligibility.....
		13-147
		Clinical Eligibility
		13-151
		Physical Exam
		13-155
		Pelvic Exam Diagrams.....
		13-157
		Follow-up Medical History Log.....
		13-159
		Genital Bleeding Assessment.....
		13-161
		Africa Sites–LDMS Specimen
		Tracking Sheet.....
		13-167
		US Sites–LDMS Specimen
		Tracking Sheet.....
		13-169

SAMPLE. Do NOT FAX
TO DATAFAX



MTN 001 (146)

DEM-1 (001)

Participant ID

- -
Site Number Participant Number Chk

Demographics

Visit Date

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

2. What is your sex? male female

NOT APPLICABLE FOR THIS PROTOCOL.

3. Are you currently married? yes no → If yes, go to item 5.

4. Do you currently have a male sex partner? By sex partner, I mean someone with whom you have vaginal or anal sex. yes no

5. 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.

6. What is your race or ethnic group? *Read aloud. Mark all that apply.*

U.S.

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

SOUTH AFRICA

- Zulu
- Xhosa
- Indian
- Colored
- White
- other, specify: _____

UGANDA

- Bantu
- Nilotics
- other, specify: _____

→ **Go to item 8 on page 2.**

7. **U.S. only:** Do you consider yourself to be Latina or Hispanic? yes no

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. Refer to the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.*

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "refused" or "don't know," and initial and date the note in the white space next to the item.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. **Note:** *Participant must be between the ages of 18 and 45 years at the time of screening, as verified per site standard operating procedures (SOP), to be eligible for study participation.*
- **Item 5:** 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	0	2	1	4	5
---	---	---	---	---	---	---	---

If the household's average monthly income is greater than 99,999,999 write "99999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 6:** This item must be self-identified by the participant. 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.

SAMPLE. Do NOT FAX
TO DATAFAX



MTN 001 (146)

DEM-2 (002)

Participant ID

Site Number			Participant Number						Chk		

Demographics

8. 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

Demographics (DEM-2)

No instructions necessary.

SAMPLE. DO NOT FAX
TO DATAFAX



MTN 001 (146)

SC-1 (005)

Page 1 of 1

Participant ID

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

Screening Consent

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"/>
dd		MMM			yy		

1. Is the participant between the ages of 18 and 45 years old? *yes* *no* → **If no, participant is ineligible. End of form.**

2. Was the participant able and willing to provide written informed consent for screening per local regulations and guidelines? *yes* *no* → **If no, participant is ineligible. End of form.**

2a. Date the informed consent form for screening was marked or signed:

dd MMM yy

Comments: _____

Screening Consent (SC-1)

This form is used to document that a participant provided written informed consent for screening for this study. This form must be completed for each participant who is assigned an MTN 001 Participant ID (PTID).

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 Screening Consent form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Item 1:** Per protocol, a participant must be between the ages of 18 and 45 years-old at the time of screening (inclusive), as verified per site standard operating procedures (SOPs) in order to be eligible for the study. Participants who are under 18 years or over 45 years of age should not be screened for the study.

SAMPLE *Do NOT FAX*
TO DATAFAX



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

Page

MTN 001 (146)

PRE-1 (012)

Participant ID

- -

Site Number Participant Number Chk

Pre-existing Conditions

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

1.	Description 	<i>MMM</i> <i>yy</i> Date of Diagnosis/ Surgery <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Comments 	<i>yes</i> <i>no</i> Is condition ongoing? <input type="checkbox"/> <input type="checkbox"/>	 Staff Initials / Date
2.	Description 	<i>MMM</i> <i>yy</i> Date of Diagnosis/ Surgery <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Comments 	<i>yes</i> <i>no</i> Is condition ongoing? <input type="checkbox"/> <input type="checkbox"/>	 Staff Initials / Date
3.	Description 	<i>MMM</i> <i>yy</i> Date of Diagnosis/ Surgery <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Comments 	<i>yes</i> <i>no</i> Is condition ongoing? <input type="checkbox"/> <input type="checkbox"/>	 Staff Initials / Date
4.	Description 	<i>MMM</i> <i>yy</i> Date of Diagnosis/ Surgery <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Comments 	<i>yes</i> <i>no</i> Is condition ongoing? <input type="checkbox"/> <input type="checkbox"/>	 Staff Initials / Date
5.	Description 	<i>MMM</i> <i>yy</i> Date of Diagnosis/ Surgery <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Comments 	<i>yes</i> <i>no</i> Is condition ongoing? <input type="checkbox"/> <input type="checkbox"/>	 Staff Initials / Date
6.	Description 	<i>MMM</i> <i>yy</i> Date of Diagnosis/ Surgery <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Comments 	<i>yes</i> <i>no</i> Is condition ongoing? <input type="checkbox"/> <input type="checkbox"/>	 Staff Initials / Date

Pre-existing Conditions (PRE-1)

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

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

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after faxing, unless instructed by SCHARP.
- **Description:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
- **Date of Diagnosis/Surgery:** If the participant is unable to recall the date, obtain participant's best estimate. At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.
- **Comments:** This field is optional. Use it to record any additional relevant information about the condition.
- **Is condition ongoing?:** Mark "yes" if condition is ongoing at enrollment.
- **Pre-existing Conditions Revisions and Updates:**
 - If a participant recalls a pre-existing condition at a later date, update the form at that time. Refax updated page(s).

SAMPLE: Do NOT FAX TO DATAFAX



MTN 001 (146)

BGS-1 (030)

Participant ID

Site Number - Participant Number - Chk

Baseline Genital Symptoms

Visit Date

dd MMM yy

1. Since your last study visit, have you experienced any of the following symptoms:

If yes: Are you currently experiencing this symptom?

1a. genital sores? 1b. genital/vaginal itching? 1c. genital/vaginal burning? 1d. genital/vaginal pain (other than during sex)? 1e. pain during sex? 1f. difficulty when urinating? 1g. burning when urinating? 1h. abnormal or unusual genital/vaginal discharge? 1i. unusual genital/vaginal odor? 1j. menstrual symptoms worse than your usual menstrual symptoms? 1k. lower abdominal pain? 1l. other genital symptoms? 111. If yes, specify below.

Local Language: _____

English: _____

1m. vaginal bleeding or spotting between your usual menstrual periods? 1n. blood-tinged discharge?

Comments: _____

Baseline Genital Symptoms (BGS-1)

This form is interviewer-administered and is used to document genital symptoms reported by the participant at the Enrollment Visit.

Note: *If a participant is being re-screened, a new Baseline Genital Symptoms form must be completed as part of the subsequent screening attempt. Refer to the Study-Specific Procedures (SSP) Manual for more instructions regarding re-screening form completion and transmission procedures.*

Interview tips:

Refer to the Study-Specific Procedures (SSP) Manual for detailed interviewing techniques.

- It is important for you to review this form for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Note: *Responses to all of the items on this form are based on participant recall at the time of the Enrollment Visit. When administering this form, do **not** refer back to previous documentation completed at screening. Any clarifications and/or updates to this form should be made during the Enrollment Visit only, unless requested otherwise by SCHARP. Once the participant has completed the Enrollment Visit, do **not** make any further updates or changes to the responses recorded on this form. Record symptoms that are ongoing at the time of enrollment on the Pre-existing Conditions form.*

Item-specific Instructions:

Note: *There is no visit code field on this form since this form is only administered during enrollment.*

- **Item 1:** This item refers to any genitourinary symptoms the participant may have experienced since her last Screening Visit. This may include symptoms that were reported as ongoing at the last Screening Visit. Read each item 1a–1n aloud. For each item marked “yes,” complete the adjacent item, “If yes: Are you currently experiencing this symptom?” For items marked “no,” leave the adjacent item “If yes: Are you currently experiencing this symptom?” blank. For any item 1a–1l marked “yes,” evaluate the participant for a UTI or STIs/RTIs per the protocol and SSP. If the participant is diagnosed with a UTI/STI/RTI that is exclusionary per protocol, do **not** enroll the participant. Provide treatment as necessary (per WHO guidelines).
 - **If yes: Are you currently experiencing this symptom?:** For any item 1a–1n marked “yes” (meaning the condition is ongoing), record the symptom on the Pre-existing Conditions form.
 - **Item 1j:** This item is intended to capture dysmenorrhea reported at baseline.
 - **Item 1l:** If “yes” is marked, record the participant’s verbatim response on the “Local Language” line. If the response is given in a language other than English, provide the English translation on the “English” line.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “refused” or “don’t know” in the white space next to the response boxes, and initial and date.

SAMPLE. Do NOT FAX
TO DATAFAX

Visit Code

. 0

1

MTN 001 (146)

SPE-1 (041)

Participant ID

- -

Site Number

Participant Number

Chk

Screening and Enrollment Pelvic Exam

Exam Date

/ /

dd

MMM

yy

1. Naked eye, speculum, and bimanual exam assessments:

If no abnormal findings, go to item 3.

no abnormal findings

abnormal findings

If abnormal findings are noted, consult protocol to determine participant eligibility.

1a. Abnormal 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

- grossly white finding
- mass
- warts—on and/or interior to labia minora
- warts—exterior to labia minora
- adnexal tenderness
- cervical motion tenderness
- uterine tenderness
- other abnormal findings, specify: _____

If finding is present at Enrollment, record on Pre-existing Conditions form.

2. Do any of these exam findings involve Grade 2 or above genital lesions, erythema, and/or edema?

yes no

If yes, participant is ineligible at this time.

3. Cervical Ectopy: Percentage of cervical surface area.

0% 1-25% 26-50% 51-75% > 75%

not required stored not stored Reason:

4. Cervicovaginal lavage (CVL) fluid:

→ _____

Comments: _____

Screening and Enrollment Pelvic Exam (SPE-1)

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

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 screens more than once for the study (i.e., has multiple screening attempts), and eventually enrolls in the study, only the Screening and Enrollment Pelvic Exam form from the successful screening attempt that led to enrollment should be faxed to SCHARP. For each enrolled participant, only one Screening and Enrollment Pelvic Exam form for the Screening Visit (assigned visit code 01.0), and one Screening and Enrollment Pelvic Exam form for the Enrollment Visit (assigned visit code 02.0) should be faxed to SCHARP DataFax.*

Item-specific Instructions:

- **Item 1:** Document abnormal findings observed during the naked eye, speculum, and/or bimanual examinations. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 1a blank and go to item 3. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 1a.
- **Item 1a:** Abnormal findings: Mark the box to the left of **each** abnormal finding observed via naked eye, speculum, and/or bimanual examination. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.
- **Item 4:** CVL collection and storage is required at the Enrollment visit.

SAMPLE. Do NOT FAX
TO DATAFAX

MTN 001 (146)

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

SSL-1 (045)

Participant ID

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

Initial Specimen Collection Date

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

Screening and Enrollment STI Laboratory Results

Alternate Collection Date

Not done/ Not collected dd MMM yy
 [][] [][][][] [][]
 [][] [][][][] [][]

1. HIV TEST RESULTS

1a. Rapid test 1 kit negative positive
1b. Rapid test 2 kit negative positive

If both are positive, participant is ineligible.

Not done/ Not collected dd MMM yy
 [][] [][][][] [][]

1c. HIV ELISA negative positive

If positive, participant is ineligible.

Not done/ Not collected dd MMM yy
 [][] [][][][] [][]

1d. HIV Western Blot negative positive indeterminate

If negative, consult MTN Network Lab.

If positive, participant is ineligible.

If indeterminate, consult MTN Network Lab.

Alternate Collection Date

Not done/ Not collected dd MMM yy
 [][] [][][][] [][]

2. STI SEROLOGY

2a. Syphilis RPR test non-reactive reactive

If non-reactive, go to item 3 on page 2.

2a1. Syphilis titer 1: [][][][]

2b. Syphilis Treponomal test negative positive

If positive, participant must complete treatment and be asymptomatic to enroll.

Screening and Enrollment STI Laboratory Results (SSL-1)

This form is used to document local laboratory results of blood and urine specimens collected at the Screening and Enrollment Visit. Record specimen test results on this form as they become available.

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 screens more than once for the study (i.e., has multiple screening attempts), and eventually enrolls in the study, only the Screening STI Laboratory Results form from the successful screening attempt that led to enrollment should be faxed to SCHARP DataFax.*

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See 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* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. A complete date is required.
- **Not done/Not collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter a test result.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation in the Comments section (page 2).
- **Items 1a and 1b:** Record the assigned two-digit rapid test kit code. As of March, 2008, the rapid test kit codes are as follows. **Note:** *More test kit codes may be added to the list below as the study proceeds.*

Rapid Test	Kit Code
Abbott Determine	01
OraSure OraQuick	02
Uni-Gold Recombigen	03

- If the two HIV rapid test results are discordant, conduct Western Blot testing and record the associated test result in item 1d.
Note: *A participant must be confirmed HIV uninfected in order to be eligible for study participation.*
- **Item 2a:** If the syphilis (RPR) screening test is reactive, items 2a1 and 2b must be completed.
- **Item 2a1:** Remember to use leading zeros when recording a syphilis titer level. For example, a titer level of 1:20 would be recorded on the form as “1:0020.”

SAMPLE *Do NOT FAX TO DATAFAX*

MTN 001 (146)



SSL-2 (046)

Visit Code 0

1

Participant ID

- -
 Site Number Participant Number Chk

Screening and Enrollment STI Laboratory Results

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

3. OTHER STI TESTS

negative *positive*
 3a. *N. gonorrhoea*.....
 3b. *C. trachomatis*.....

If positive, participant must complete treatment and be asymptomatic to enroll.

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

3c. Hepatitis B Surface Antigen *non-reactive* *reactive*

If reactive, participant is ineligible.

Comments: _____

Screening and Enrollment STI Laboratory Results (SSL-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of the form for a given participant and visit.
- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. A complete date is required.
- **Not done/Not collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter a test result.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code . 0

1

MTN 001 (146)

PKN-1 (061)

Participant ID

- -
Site Number Participant Number Chk

**Pharmacokinetics—
Non-intensive**

Specimen Collection Date

dd MMM yy

1. Participant weight: kg

MID-STUDY PERIOD

Not done/
Not collected

2. PK blood draw: : **Time (24-hr clock)**
hr min **End of form.**

END OF STUDY PERIOD

Not done/
Not collected

- 3. Pre-dose blood draw: : **Time (24-hr clock)**
hr min
- 4. Observed dose of oral tenofovir:..... : **Time (24-hr clock)**
hr min
- 5. Observed dose of vaginal tenofovir gel: : **Time (24-hr clock)**
hr min
- 6. 1–3 hour post-dose blood draw: : **Time (24-hr clock)**
hr min
- 7. 3–5 hour post-dose blood draw: : **Time (24-hr clock)**
hr min
- 8. 5–7 hour post-dose blood draw: : **Time (24-hr clock)**
hr min

GENITAL SPECIMENS FOR STORAGE

Not done/
Not collected

9. Cervicovaginal Lavage (CVL) fluid: : **Time (24-hr clock)**
hr min **End of form.**

10. Was menstrual blood present at the time of genital specimen collection?
yes no

Comments: _____

Pharmacokinetics—Non-intensive (PKN-1)

This form is used to document collection of pharmacokinetic (PK) laboratory specimens for non-intensive PK participants at the Mid-study period and End-of-study period visits. A separate form should be used for the Mid-study period and End-of-study period visits.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Not done/Not collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter the time of specimen collection.
- **Item 2:** This item applies to the Mid-study period visits only. For End-of-study period visits, mark the “Not done/Not collected” box and proceed to item 3.
- **Items 3–10:** Complete at End-of-study period visits only. For Mid-study period visits, leave these items blank.
- **Item 3:** Per protocol, the pre-dose blood draw is required for all non-intensive PK participants and should occur 15–30 minutes prior to the observed dose(s) of study product(s).
- **Items 4–5:** Record the time (using a 24-hour clock) that the participant administered the observed dose of study product(s) at the site clinic. If the participant is in the oral period, record the time of the observed oral tenofovir dose in item 4 and mark the “Not done/Not collected” box for item 5. If the participant is in the vaginal use period, record the time of the observed vaginal tenofovir gel dose in item 5 and mark the “Not done/Not collected” box for item 4. If the participant is in the dual use period, record the times of each respective observed dose of study product (oral and vaginal) in items 4 and 5.
- **Items 6–8:** Choose the item that corresponds to the participant’s randomized post-dose sampling time (1–3 hours, 3–5 hours, or 5–7 hours post-dose), and record the time of blood draw (using a 24-hour clock). Mark the “Not done/Not collected” box for the remaining items. If no post-dose blood specimen was collected or stored, mark the “Not done/Not collected” box for each item and record the reason in the Comments section at the bottom of the form.
- **Item 9:** Record the time (using a 24-hour clock) that the CVL specimen was collected. If CVL was not collected or stored, mark the “Not done/Not collected” box and record the reason in the Comments section at the bottom of the form.

***Note:** Per protocol, the post-dose blood and CVL collections should occur with 15–30 minutes of each other (either sample may be collected first). For each of the three study periods, the same sampling time point (within 15 minutes) should be used. For example, if a participant is randomized to specimen collections 1–3 hours post-dose, and the Week 6 Visit post-dose blood and CVL are collected 2 hours post-dose, then the Week 13 and Week 20 post-dose blood and CVL collections should also occur 2 hours post-dose (plus or minus 15 minutes).*

SAMPLE: Do NOT FAX TO DATAFAX



Visit Code [][] . [0]

[1]

MTN 001 (146)

PKI-1 (062)

Participant ID

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

Pharmacokinetics—Intensive

Specimen Collection Date

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

1. Participant weight: [][][] kg

MID-STUDY PERIOD

Not done/ Not collected

2. PK blood draw:

Time (24-hr clock) hr [][] min [][]

End of form.

END OF STUDY PERIOD

Not done/ Not collected

3. Pre-dose blood draw:

Time (24-hr clock) hr [][] min [][]

4. Observed dose of oral tenofovir:.....

Time (24-hr clock) hr [][] min [][]

5. Observed dose of vaginal tenofovir gel:

Time (24-hr clock) hr [][] min [][]

6. 1-hour post-dose blood draw:

Time (24-hr clock) hr [][] min [][]

7. 2-hour post-dose blood draw:

Time (24-hr clock) hr [][] min [][]

8. 4-hour post-dose blood draw:

Time (24-hr clock) hr [][] min [][]

9. 6-hour post-dose blood draw:

Time (24-hr clock) hr [][] min [][]

10. 8-hour post-dose blood draw:

Time (24-hr clock) hr [][] min [][]

GENITAL SPECIMENS FOR STORAGE

Not done/ Not collected

11. Cervicovaginal Lavage (CVL) fluid:

Time (24-hr clock) hr [][] min [][]

12. Cervical cytology brush:

Time (24-hr clock) hr [][] min [][]

13. Vaginal tissue biopsy:

Time (24-hr clock) hr [][] min [][]

End of form.

14. Was menstrual blood present at the time of genital specimen collection?

yes [] no []

Comments: _____

Pharmacokinetics—Intensive (PKI-1)

This form is used to document collection of pharmacokinetic (PK) laboratory specimens for intensive PK participants at the Mid-study period and End-of-study period visits. A separate form should be used for the Mid-study period and End-of-study period visits.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Not done/Not collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter the time of specimen collection.
- **Item 2:** This item applies to the Mid-study period visits only. For End-of-study period visits, mark the “Not done/Not collected” box and proceed to item 3.
- **Items 3–14:** Complete at End-of-study period visits only. For Mid-study period visits, leave these items blank.
- **Item 3:** Per protocol, the pre-dose blood draw is required for all intensive PK participants and should occur 15–30 minutes prior to the observed dose(s) of study product(s).
- **Items 4–5:** Record the time (using a 24-hour clock) that the participant administered the observed dose of study product(s) at the site clinic. If the participant is in the oral period, record the time of the observed oral tenofovir dose in item 4 and mark the “Not done/Not collected” box for item 5. If the participant is in the vaginal use period, record the time of the observed vaginal tenofovir gel dose in item 5 and mark the “Not done/Not collected” box for item 4. If the participant is in the dual use period, record the times of each respective observed dose of study product (oral and vaginal) in items 4 and 5.
- **Items 6–10:** Record the time of blood draw (using a 24-hour clock) for each of the required post-dose blood sampling times (1, 2, 4, 6, and 8 hours post-dose). If a post-dose blood specimen was not collected or stored, mark the “Not done/Not collected” box and record the reason in the Comments section at the bottom of the form.
- **Items 11–13:** Record the time (using a 24-hour clock) that each of the genital specimens (CVL, cervical cytology brush and vaginal tissue biopsy) was collected. If a genital specimen was not collected or stored, mark the “Not done/Not collected” box and record the reason in the Comments section at the bottom of the form.

***Note:** Per protocol, the blood and genital specimen collections should occur within 15–30 minutes of the assigned sampling time, and within 15–30 minutes of each other (either blood or genital specimens may be collected first.) For each of the 3 study periods, the same sampling time point (within 15 minutes) should be used. For example, if a participant is randomized to the 2-hour post-dose genital specimen collections, the genital specimens should be collected between 1 hour 30 minutes and 2 hours 30 minutes post-dose. If, at the Week 6 Visit, the samples are collected 2 hours 15 minutes post-dose, site staff should attempt to collect the same samples 2 hours 15 minutes post-dose (plus or minus 15 minutes) at the Week 13 and Week 20 Visits.*

SAMPLE *DO NOT FAX*
TO DATAFAX

MTN 001 (146)



FC-1 (064)

Visit Code

1

Participant ID

- -
Site Number Participant Number Chk

Flow Cytometry

Specimen Collection Date

dd MMM yy

Not done/
Not collected

1. FLOW CYTOMETRY

1a. Lymphocyte Absolute Count *cells/mm³*

1b. CD3 (CD3/CD4) % AND Absolute Count *cells/mm³*

1c. CD4 (CD3/CD4) % AND Absolute Count *cells/mm³*

1d. CD38 (CD3/CD4/CD38) % AND Absolute Count *cells/mm³* AND MFI

1e. HLA-DR (CD3/CD4/HLA-DR) % AND Absolute Count *cells/mm³* AND MFI

1f. Dual Positive Absolute Count *cells/mm³*
(CD3/CD4/CD38/HLA-DR).....

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

Comments: _____

Flow Cytometry (FC-1)

Purpose: To document flow cytometry laboratory results.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Data Collection section of the Study Specific Procedures (SSP) for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Not done/Not collected:** Mark this box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Explain in the Comments section at the bottom of the form why the result is not available.

SAMPLE. Do NOT FAX
TO DATAFAX



MTN 001 (146)

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

Visit Date

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

1. Date the informed consent form for enrollment was marked or signed:

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

2. Was the participant willing and able to provide written informed consent for specimen storage and future research?

yes no

 → **If no, go to item 3.**

2a. Date the informed consent form for specimen storage and future research was marked or signed:

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

3. Randomization envelope number:

OR N/A

4. Date assigned:

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

5. Time assigned:

: 24-hour clock

hr min

6. Study regimen sequence:

→ **If not a US participant, go to item 8.**

7. Intensive PK sampling time point:

pre-dose 2 hours 4 hours 6 hours

8. Was the participant randomized to a Week 21 In-depth interview?

yes no

 → **If not a replacement participant, go to item 10.**

9. Participant ID of participant being replaced:

<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"/>
----------------------	----------------------	----------------------	---	----------------------	----------------------	----------------------	----------------------	----------------------	---	----------------------

10. Date study product(s) dispensed:

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

11. How many **cartons** of tenofovir gel were dispensed?

of **cartons** dispensed

12. How many **bottles** of oral tenofovir were dispensed?

of **bottles** dispensed

13. Participant height:

cm

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 or a Replacement Participant Randomization for replacement participants), and only after completion of the Enrollment Visit.

Item-specific Instructions:

- **Item 3:** Consent for specimen storage and future research is optional and does not affect a participant's study eligibility.
- **Item 2a:** If the participant re-screened for the study and signed another enrollment informed consent as part of the re-screening process, record the most recent date she signed the enrollment informed consent prior to study randomization. If a participant reconsents to study participation or specimen storage and future research during her study follow-up (i.e., due to an updated IRB/EC-approved informed consent form) do not update the response to item 2a.
- **Item 3:** Record the three-digit envelope number present on the randomization envelope assigned to this participant. If this is a replacement participant, mark the "N/A" box.
- **Item 4:** Record the date the randomization envelope or Replacement Participant Randomization was assigned to the participant. If the participant was assigned a randomization envelope, this date should match the "date assigned" recorded for this participant on the appropriate Envelope Tracking Record. If the participant is a replacement participant, this date should match the "date assigned" recorded for this participant on the appropriate Replacement Participant Randomization Tracking Record.
- **Item 5:** Record the time (using a 24-hour clock) when the envelope or Replacement Participant Randomization was assigned to the participant. This time should match the "time assigned" recorded on the Envelope Tracking Record or Replacement Participant Randomization Tracking Record for a given participant.
- **Item 6:** Record the study regimen letter code present on the study randomization contained inside the randomization envelope, (or on the Replacement Participant Randomization, if a replacement participant).
- **Item 7:** This item is for participants at US sites only. Mark the box that corresponds to the intensive PK sampling time point (for collection of genital samples) present on the study randomization document (or on the Replacement Participant Randomization, if a replacement participant.)
- **Item 8:** Mark the box that corresponds to the Week 21 in-depth interview randomization on the study randomization document (or on the Replacement Participant Randomization, if a replacement participant.)
- **Item 9:** This item is for replacement participants only. Record the Participant ID (PTID) present on the study randomization of the participant who is being replaced.
- **Item 10:** Record the exact day, month, and year study product(s) (tenofovir gel and/or tenofovir (TDF) tablets) were first dispensed to this participant.
- **Item 11:** Record the number of vaginal tenofovir gel cartons dispensed to the participant. *NOTE: A standard number of two cartons should be dispensed at the Enrollment Visit.*
- **Item 12:** Record the number of oral tenofovir (TDF) bottles dispensed to the participant. *NOTE: A standard number of one bottle should be dispensed at the Enrollment Visit.*

SAMPLE. Do NOT FAX
TO DATAFAX



MTN 001 (146)

EBA-1 (072)

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 Behavior Assessment

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 your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. Your honest answers will be very helpful to us. There is no right or wrong answer to these questions. Remember, we do not have your name on these papers, and all of your answers will be kept confidential.

There are many different ways people have sex. Some of the questions are about vaginal sex, and some are about anal sex. Vaginal sex means when a man puts his penis inside your vagina. Anal sex means when a man puts his penis inside your anus.

1. In the **past 3 months**, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex. # of partners
- If 0, participant is ineligible. Go to statement above item 9 on page 3.**
- 1a. Were any of these sex partners casual partners? By casual partner, I mean someone whom you do not consider to be your main partner.
- | | | |
|--------------------------|--------------------------|---|
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | |
| yes | no | |
| <input type="checkbox"/> | <input type="checkbox"/> | → If no, go to statement above item 5 on page 2. |
2. In the **past 3 weeks**, did you have vaginal sex?
- 2a. In the **past 3 weeks**, how often did you have vaginal sex?
Showcard #2.
- | | | | | |
|----------------------------------|-----------------------------|-----------------------------|--------------------------|---------------------------------|
| <i>less than
once a week</i> | <i>1-3 times
a week</i> | <i>4-6 times
a week</i> | <i>once
a day</i> | <i>more than
once a day</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

I know that you have been counseled to use male condoms for each act of vaginal sex, but I also know that it is sometimes difficult to use condoms all the time. We are interested in your actual experiences using male condoms with vaginal sex, so your honest and accurate answers are very important to us.

- 2b. In the **past 3 weeks**, how often did your partner(s) use a male condom during vaginal sex?
Showcard #3.
- | | | | | |
|--------------------------|--------------------------|--------------------------|-----------------------------|--------------------------|
| <i>never</i> | <i>rarely</i> | <i>sometimes</i> | <i>most of
the time</i> | <i>always</i> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Enrollment Behavior Assessment (EBA-1)

This form is used to collect baseline information about the participant's sexual behaviors. This is an interviewer-administered form, and it is administered only once to each enrolled participant as part of her Enrollment visit.

Interview tips:

See Study-Specific Procedures (SSP) Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

***Note:** Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made during the Enrollment Visit interview only, unless requested otherwise by SCHARP. Once the participant has completed the Enrollment Visit interview in which this form is administered, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write "don't know" or "refused," and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX TO DATAFAX



MTN 001 (146)

EBA-2 (073)

Participant ID

Participant ID form with Site Number, Participant Number, and Chk boxes

Enrollment Behavior Assessment

No data recorded on this page checkbox

3. In the past 7 days, how many times did you have vaginal sex? ... # of times [] [] -> If 0, go to item 4.

3a. In the past 7 days, how many times did your partner(s) use a male condom during vaginal sex? ... # of times [] []

4. The last time you had vaginal sex, did your partner use a male condom? ... yes [] no []

I am now going to ask you some questions about a different way that people have sex. This way is anal sex. I am asking you these questions because understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

5. Have you ever had anal sex? ... yes [] no [] -> If no, go to statement above item 9 on page 3.

6. In the past 3 weeks, did you have anal sex? ... yes [] no [] -> If no, go to statement above item 9 on page 3.

6a. In the past 3 weeks, how often did you have anal sex? Showcard #2

Frequency options for anal sex: less than once a week, 1-3 times a week, 4-6 times a week, once a day, more than once a day

I know that you have been counseled to use male condoms for each act of anal sex, but I also know that it is sometimes difficult to use condoms all the time. We are interested in your actual experiences using male condoms with anal sex, so your honest and accurate answers are very important to us.

6b. In the past 3 weeks, how often did your partner(s) use a male condom during anal sex? Showcard #3

Frequency options for partner condom use: never, rarely, sometimes, most of the time, always

Enrollment Behavior Assessment (EBA-2)

Item-specific Instructions:

- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE *Do NOT FAX TO DATAFAX*



MTN 001 (146)

EBA-3 (074)

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 Behavior Assessment

7. In the **past 7 days**, how many times did you have anal sex?.....

of times

→ **If 0, go to item 8.**

7a. In the **past 7 days**, how many times did your partner(s) use a male condom during anal sex?

of times

8. The **last time** you had anal sex, did your partner use a male condom?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

I am now going to ask you some different types of personal and sensitive questions. Some of the questions may not apply to you, but we ask the same questions of all study participants.

9. For the next question, I am going to ask you about items that women sometimes insert inside their vaginas. For each item, please tell me if you inserted it inside your vagina in the **past month**. It is possible to answer "yes" more than once.

9a. water?

yes	no	# of times in past week
<input type="checkbox"/>	<input type="checkbox"/>	→ <input type="text"/> <input type="text"/>

9b. water with vinegar? **Note for U.S. sites:** This includes all commercial douching products.

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

9c. water with soap?

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

9d. paper, cloth, cotton, or cotton wool?

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

9e. tampons?

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

9f. fingers without anything else?

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

9g. anything else? Specify below.

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

Local Language: _____

English: _____

Enrollment Behavior Assessment (EBA-3)

Item-specific Instructions:

- **Item 9:** Read each item 9a–9g aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many times in the **past week** (the last 7 days) she has used that particular item. Record the response in the “# of times in **past week**” boxes. If “yes” is marked for item 9g, record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

Family Planning Methods (FPM-1)

This form is completed by a site staff member to collect information about the family planning methods that the participant is currently using. It is completed at the Enrollment Visit and at each regularly scheduled follow-up visit.

Item-specific Instruction:

- **Item 1:** Transcribe the family planning methods as documented during the baseline or follow-up Medical History Assessments.

SAMPLE. Do NOT FAX TO DATAFAX

MTN 001 (146)



FV-1 (121)

Visit Code

. 0

1

Participant ID

- -
Site Number Participant Number Chk

Follow-up Visit

Visit Date

dd MMM yy

1. hCG for pregnancy: *not done* *negative* *positive*
1a. Specify reason(s): ← → **If positive, complete Pregnancy Report and History form and Product Hold/Discontinuation form.**

- 2. Were any new adverse experiences reported at this visit? *yes* *no* → **If no, go to item 3.**
- 2a. How many **new** AE Log pages were completed for this visit? # of pages
- 3. At this visit, how many **unused applicators** of tenofovir gel did the participant return? # of **unused applicators** returned
- 4. At this visit, how many **unused tablets** of oral tenofovir did the participant return? # of **unused tablets** returned
- 5. At this visit, how many **applicators** of tenofovir gel were dispensed? # of **applicators** dispensed
- 6. At this visit, how many **tablets** of oral tenofovir were dispensed? # of **tablets** dispensed

Comments: _____

Follow-up Visit (FV-1)

This form is used to document the required (regularly scheduled) follow-up visits. It is completed at each regularly scheduled follow-up visit, regardless of whether the visit is conducted within the protocol-specified window or made up outside the visit window.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Item 1:** Record the hCG urine pregnancy test result. If a urine pregnancy test result is not available (specimen not collected and/or test not done), mark the “not done” box and complete item 1a. *Note: A Pregnancy Report and History form must be completed for each pregnancy.* Once a participant tests positive for hCG urine pregnancy and a Pregnancy Report and History form (PR-1) has been completed for this pregnancy, subsequent positive pregnancy test results should not be recorded on a new PR-1 unless they represent a new pregnancy.
- **Item 2:** Mark the “yes” box if a new (previously unreported) AE is reported or observed at this visit. If the box is marked “yes,” record in item 2a 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 the number of **unused** vaginal tenofovir gel applicators the participant returned at this visit only, as determined by site clinic staff.
- **Item 4:** Record the number of **unused** oral tenofovir tablets the participant returned at this visit only, as determined by site clinic staff.
- **Item 5:** Record the number of **applicators** of vaginal tenofovir gel given to the participant at this visit. This will be the same amount documented on the **Study Product Request Slip**, unless documentation from the pharmacy staff states otherwise. For End-of-study period visits (6-Week, 13-Week, and 20-Week visits), include applicators dispensed for the in-clinic observed doses for PK.
- **Item 6:** Record the number of **tablets** of oral tenofovir given to the participant at this visit. This will be the same amount documented on the **Study Product Request Slip**, unless documentation from the pharmacy staff states otherwise. For End-of-study period visits (the 6-Week, 13-Week, and 20-Week visits), include tablets dispensed for the in-clinic observed doses for PK.

SAMPLE *DO NOT FAX*
TO DATAFAX



Visit Code

MTN 001 (146)

FGS-1 (130)

Participant ID

- -

Site Number Participant Number Chk

Follow-up Genital Symptoms

Visit Date

dd MMM yy

1. Since your last study visit, have you experienced any of the following symptoms:

If yes: When did you first experience this symptom?

Continuing from previous visit

	yes	no	dd	MMM	yy	OR	<input type="checkbox"/>
1a. genital sores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1b. genital/vaginal itching?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1c. genital/vaginal burning?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1d. genital/vaginal pain (other than during sex)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1e. pain during sex?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1f. difficulty when urinating?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1g. burning when urinating?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1h. abnormal or unusual genital/vaginal discharge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1i. unusual genital/vaginal odor?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1j. menstrual symptoms worse than your usual menstrual symptoms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1k. lower abdominal pain?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1l. other genital symptoms?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>

111. If yes, specify below.

If no, go to item 1m.

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

Local Language: _____

English: _____

	yes	no	dd	MMM	yy	OR	<input type="checkbox"/>
1m. vaginal bleeding or spotting between your usual menstrual periods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>
1n. blood-tinged discharge?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	OR	<input type="checkbox"/>

Continuing from previous visit

If yes to any, complete Genital Bleeding Assessment form if indicated. Conduct pelvic exam if indicated. Update or complete Adverse Experience Log when applicable.

Comments: _____

21-APR-08

Language

Staff Initials / Date

Follow-up Genital Symptoms (FGS-1)

This form is interviewer-administered, and is used to document genital symptoms reported by the participant during study follow-up. It is completed at each regularly scheduled follow-up visit.

Interview tips:

Refer to the Study-Specific Procedures (SSP) Manual for detailed interviewing techniques.

- It is important for you to review this form for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

***Note:** Responses to all of the items on this form are based on participant recall at the time the form is being administered. When administering this form, **do not** refer back to previously completed Genital Symptoms forms (Baseline and Follow-up). Any clarifications and/or updates to this form should be made only during the visit in which this form is completed, unless requested otherwise by SCHARP. Once the participant has completed the visit, do not make any further updates or changes to the responses recorded on this form. If, at a subsequent study visit, the participant reports additional symptoms she experienced at baseline or at a time point covered by a previous Follow-up Genital Symptoms form, do **not** update any of the previously completed forms. Instead, record the new information on the current Follow-up Genital Symptoms form and explain the discrepancy in both the Comments section and/or in the participant's chart notes. If the participant reports additional symptoms that were ongoing at enrollment, record these on the Pre-existing Conditions form.*

***Once the interview is complete,** review the completed Genital Symptoms form (Baseline or Follow-up) from the previous visit and identify any symptoms that were a) reported as ongoing, and b) documented on an AE Log. If the same symptoms are reported as not present at the current visit (response on current visit's Follow-up Genital Symptoms form is "no"), query the participant for an outcome date and record this in item 6a of the associated AE Log.*

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the SSP for more specific information on assigning visit codes.
- **Item 1:** Read each item 1a–1n aloud. For any item marked “yes,” conduct a pelvic exam if clinically indicated (and not already required for the visit). For each item marked “yes,” complete an Adverse Experience (AE) Log if the symptom is new or has increased in severity. If the symptom was first reported on the participant's Baseline Genital Symptoms and Pre-existing Conditions forms and it has not increased in severity or frequency, **do not** complete an AE Log—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.
- **Item 1j:** This item is intended to capture dysmenorrhea reported during follow-up visits. If the participant reports dysmenorrhea and/or any other symptom(s) related to menstruation, probe for further information (i.e., type and severity of symptoms), then compare to participant's usual baseline menstrual symptoms (as documented on the Local Baseline Medical History Assessment and the Baseline Genital Symptoms form) to determine whether an AE should be reported.
- **Item 1l:** If “yes” is marked, record the participant's verbatim response on the “Local Language” line. If the response is given in a language other than English, provide the English translation on the “English” line.
- **If yes: When did you first experience this symptom?:** For each item marked “yes,” record the day, month, and year the participant first began experiencing symptoms; if necessary, use a calendar to probe. If the participant provides a date that is prior to the date of the previous visit, mark “continuing from previous visit” and leave the day, month, and year boxes blank. If the participant states that a symptom began on the exact date of the previous visit, clarify whether or not the symptom was present at the time the visit occurred. If she states that the symptom was present during the previous visit, mark “Continuing from previous visit” and leave the day, month, and year boxes blank. If the participant states that the symptom occurred on the same day as the previous visit, but after she had completed the visit, record the day, month, and year of the previous visit and leave the “continuing from previous visit” box blank.
- **Continuing from previous visit:** Mark this box for symptoms reported as continuing since the time of the previous visit. If this box is marked, leave the “If yes: When did you first experience symptoms?” boxes blank. If a date is recorded, leave the corresponding “continuing from previous visit” box blank.
- **Items 1m–1n:** If the participant reports vaginal bleeding or spotting between usual menstrual periods, or any blood-tinged genital/vaginal discharge, refer to the SSP.

SAMPLE *Do NOT FAX TO DATAFAX*



Visit Code

MTN 001 (146)

SLR-1 (131)

Participant ID

- -
Site Number Participant Number Chk

STI Laboratory Results

Initial Specimen Collection Date

dd MMM yy

Alternate Collection Date

Not done/ Not collected dd MMM yy

dd MMM yy

Not done/ Not collected dd MMM yy

1. HIV TEST RESULTS

1a. Rapid test 1
1b. Rapid test 2
1c. HIV ELISA.....

If positive for any, complete HIV Test Results and Product Hold/Discontinuation forms.

2. STI SEROLOGY

2a. Syphilis RPR test
2a1. Syphilis titer..... 1:
2b. Syphilis Treponomal test
If non-reactive, go to item 3.
If negative, go to item 3.
If positive, complete Adverse Experience Log when applicable.

3. OTHER STI TESTS

3a. *N. gonorrhoea*
3b. *C. trachomatis*
3c. Hepatitis B Surface Antigen
If either is positive, complete Adverse Experience Log when applicable.
If reactive, complete Adverse Experience Log when applicable.

Comments: _____

STI Laboratory Results (SLR-1)

This form is used to document local laboratory results of blood and urine specimens collected during study follow-up. Record specimen test results on this form as they become available. Fax this form to SCHARP DataFax once results for all collected specimens are recorded on this form.

If a test result(s) recorded on this form indicates that the participant has a new laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on the Adverse Experience Log form.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See 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* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. A complete date is required.
- **Not done/Not collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter a test result.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation in the Comments section.
- **Item 1:** If items 1a, 1b, or 1c are positive, conduct Western Blot testing and record the associated test results on the HIV Test Results form and hold study product(s) until the participant’s HIV status is confirmed.
- **Items 1a and 1b:** Record the assigned two-digit rapid test kit code. As of March, 2008, the rapid test kit codes are as follows. *Note: More test kit codes may be added to the list below as the study proceeds.*

Rapid Test	Kit Code
Abbott Determine	01
OraSure OraQuick	02
Uni-Gold Recombigen	03

- **Item 2:** If the syphilis screening test is reactive, items 2a1 and 2b must be completed.
- **Item 2a1:** Remember to use leading zeros when recording a syphilis titer level. For example, a titer level of 1:20 would be recorded on the form as “1:0020.”
- **Items 2b–3c:** If a result is positive at any time during the study, provide treatment according to WHO guidelines. If a result is positive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log form and hold study product(s). Complete an MTN 001 Study Product Hold/Resume Slip and mark “hold.” Complete items 1–3 of the Product Hold/Discontinuation form and fax it to SCHARP DataFax.

SAMPLE: Do NOT FAX TO DATAFAX

Visit Code

Form boxes for Visit Code

Form box for page number 1

MTN 001 (146)

PLR-1 (143)

Participant ID

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

Initial Specimen Collection Date

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

Pelvic Laboratory Results

Alternate Collection Date form boxes: Not done/Not collected, dd, MMM, yy

1. VAGINAL WET PREP STUDIES

Not done

Form box for Not done

- 1a. Homogeneous vaginal discharge
1b. pH
1c. Whiff test
1d. Clue cells > 20%
1e. Trichomonas vaginalis
1f. Buds and/or hyphae (yeast)

Wet Prep:

Staff Initials/Date

Not done/Not collected

Form box for Not done/Not collected

- 2. HSV Culture

HSV Culture:

Staff Initials/Date

Alternate Collection Date form boxes: Not done/Not collected, dd, MMM, yy

3. PAP SMEAR

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

Pap Smear:

Staff Initials/Date

Comments:

Form boxes and date 21-APR-08

Pelvic Laboratory Results (PLR-1)

This form is used to document results of specimens collected during the Screening, Enrollment, and follow-up pelvic exams. Record test results on this form as they become available. Fax this form to SCHARP DataFax once results for all collected specimens are recorded on this form.

If a test result(s) recorded on this form indicates that the participant has a laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as either a pre-existing condition on the Pre-existing Conditions form (for Enrollment test result(s) only), or an adverse experience on the Adverse Experience (AE) Log (for follow-up visit test result(s) only). Per protocol, otherwise eligible participants diagnosed at screening or enrollment with a UTI/STI/RTI requiring treatment (per WHO guidelines) are not eligible to enroll in the study until treatment is complete and symptoms have resolved.

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* (NOT the date results were reported or recorded on the form) for this visit. A complete date is required.
- **Alternate Collection Date:** This date is to be completed **ONLY** if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form. A complete date is required.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
- **Item 1:** A vaginal wet prep is required at the Screening, Enrollment, 6-Week, 13-Week, and 20-Week Visits, and when clinically indicated. If a vaginal wet prep was not performed, mark the “Not done/Not collected” box. If a vaginal wet prep was performed but not all assays were completed, mark the “Not done” box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason in the Comments section.
- **Item 1a:** Mark the “positive” box if homogeneous vaginal discharge was observed. If homogeneous discharge was observed and is considered to be abnormal, mark “abnormal vaginal discharge” in item 1a of the Screening and Enrollment Pelvic Exam form, or the Follow-up Pelvic Exam form completed for this pelvic exam.
- **Item 3:** If done, record the Pap Smear result. Mark only one box. *Note: A Pap Smear result is required at the Screening Visit only, and only for those participants who do not have documentation of a normal Pap test result in the 12 calendar months prior to Screening. Per protocol, only participants with a negative Pap Smear result will be eligible to enroll in the study. Refer to the SSP Manual for further information.*
 - **negative for intraepithelial lesion or cancer (malignancy):** Includes all normal findings and any findings of infection (trichomonas, candida, etc.), reactive changes/inflammation, glandular changes due to hysterectomy, or atrophic changes.
 - **ASC-US:** Mark this box when abnormal/atypical squamous cells of undetermined significance are reported.
 - **ASC-H:** Mark this box when abnormal/atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesion (HSIL) are reported.
 - **SIL-low grade (LSIL):** Mark this box when low-grade squamous interepithelial lesions are reported. This category includes presence of human papillomavirus (HPV) infection, mild dysplasia, and cervical interepithelial neoplasia (CIN 1).
 - **SIL-high grade (HSIL):** Mark this box when high-grade squamous interepithelial lesions are reported. This category includes the presence of moderate to severe dysplasia, carcinoma in situ (CIS), CIN 2, and CIN 3, or changes suspicious for invasive cancer.
 - **AGC:** Mark this box when atypical/abnormal glandular cells are reported. This category includes endocervical (from cervical canal) atypical cells; endometrial atypical cells; glandular atypical cells.
 - **AGC-favor neoplastic:** Mark this box when atypical/abnormal glandular cells that favor cell growth (neoplastic changes) are reported. This category includes endocervical cells and glandular cells.
 - **cancer:** Mark this box when cancer or adenocarcinoma is reported. This includes endocervical, endometrial, extrauterine, and other (not specified) cancers/adenocarcinomas.

SAMPLE. Do NOT FAX
TO DATAFAX

Visit Code

MTN 001 (146)

FPE-1 (145)

Participant ID

- -

Site Number Participant Number Chk

Follow-up Pelvic Exam

Exam Date

dd MMM yy

1. Naked eye, speculum, and bimanual exam assessments: *not done*

If not done, specify reason in Comments. End of form.

no abnormal findings

abnormal findings

If no abnormal findings, go to item 3.

1a. Abnormal 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

- grossly white finding
- mass
- warts—on and/or interior to labia minora
- warts—exterior to labia minora
- adnexal tenderness
- cervical motion tenderness
- uterine tenderness
- other abnormal findings, specify:

Complete or update Adverse Experience Log when applicable.

2. Do any pelvic exam findings from this visit warrant a product hold? *yes* *no*

If yes, complete Product Hold/Discontinuation form.

3. Cervical Ectopy: Percentage of cervical surface area.

0% 1–25% 26–50% 51–75% > 75%

Comments: _____

Follow-up Pelvic Exam (FPE-1)

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

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Item 1:** Document 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 in the Comments section at the bottom of the page. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 2 blank and go to item 3. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed via naked eye, speculum, and bimanual examination. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.

SAMPLE *Do NOT FAX*
TO DATAFAX



Visit Code

□□□□.□□

1

MTN 001 (146)

SL-1 (151)

Participant ID

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

Safety Laboratory Results

Initial Specimen Collection Date

□□ □□□□ □□
dd MMM yy

Alternate Collection Date
Not done/ Not collected dd MMM yy
 □□ □□□□ □□

1. URINE TESTS

Not done		<i>negative or trace</i>	1+	2+	3+	4+	Severity Grade <i>If applicable</i>	AE Log Page #	Not reportable as an AE
<input type="checkbox"/>	1a. Protein	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	□□□□	OR <input type="checkbox"/>
<input type="checkbox"/>	1b. Leukocyte esterase (LE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	} If positive for LE or nitrites, perform culture if standard of care.	} Complete Adverse Experience Log when applicable.	
<input type="checkbox"/>	1c. Nitrites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				
<input type="checkbox"/>	1d. Culture.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>				

Alternate Collection Date
Not done/ Not collected dd MMM yy
 □□ □□□□ □□

2. HEMOGRAM

Not reported			Severity Grade <i>If applicable</i>	AE Log Page #	Not reportable as an AE
<input type="checkbox"/>	2a. WBC	□□□□.□□ $\times 10^3/mm^3$	<input type="checkbox"/>	□□□□	OR <input type="checkbox"/>
<input type="checkbox"/>	2b. Hemoglobin	□□.□□ g/dL	<input type="checkbox"/>	□□□□	OR <input type="checkbox"/>
<input type="checkbox"/>	2c. Hematocrit	□□.□□ %			
<input type="checkbox"/>	2d. Platelets	□□□□□□.□□ $\times 10^3/mm^3$	<input type="checkbox"/>	□□□□	OR <input type="checkbox"/>

Safety Laboratory Results (SL-1)

This form is used to document local safety laboratory results of specimens collected during screening, enrollment, and study follow-up. 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** collected specimens are recorded on the form.

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

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 was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
- **Not done/Not collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter a test result.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation in the Comments section on page 2.
 - 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) Manual for conversion instructions.
 - 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.
 - If the result reported by the lab has less digits than on the form, fill in “0” for each missing digit. For example a hematocrit value of “42%” would be recorded as “42.0%.”
- **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. Assign severity grades according to the *Female Genital Grading Table for Use in Microbicide Studies* and the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.
 - 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 *Female Genital Grading Table for Use in Microbicide Studies* or the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the appropriate *DAIDS Table*.
- **AE Log Page #:** If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.
- **Not Reportable as an AE:** Mark if the lab value is gradable per the *Female Genital Grading Table for Use in Microbicide Studies* or the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code .

1

MTN 001 (146)

SL-2 (152)

Participant ID

- -
Site Number Participant Number Chk

Safety Laboratory Results

Not done/
Not collected Alternate Collection Date
dd MMM yy

3. CHEMISTRIES

U/L

Severity Grade
If applicable

AE Log
Page #

Not reportable
as an AE

3a. AST (SGOT)

OR

3b. ALT (SGPT)

OR

mg/dL

3c. Creatinine

.

OR

3c1. Calculated creatinine
clearance

mL/min

Not done/
Not collected Alternate Collection Date
dd MMM yy

3d. Phosphorus
(Phosphate)

mg/dL

Severity Grade
If applicable

AE Log
Page #

Not reportable
as an AE

.

OR

Alternate Collection Date
dd MMM yy

4. Plasma *not required* *stored* *not stored* Reason: _____

Comments: _____

Safety Laboratory Results (SL-2)

Item-specific Instructions:

- **Alternate Collection Date:** This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
- **Not done/Not collected:** For every test, mark *either* the “Not done/Not collected” box *or* enter a test result.
- **Results Reporting**
 - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation in the Comments section.
 - 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) Manual for conversion instructions.
 - 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.
 - If the result reported by the lab has fewer digits than on the form, fill in “0” for each missing digit. For example a hematocrit value of “42%” would be recorded as “42.0%.”
- **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. Assign severity grades according to the *Female Genital Grading Table for Use in Microbicide Studies* and the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.
 - 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 *Female Genital Grading Table for Use in Microbicide Studies* or the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*. Per the protocol-specific AE reporting requirements, report this as an AE, as appropriate, and grade it according to the appropriate *DAIDS Table*.
- **AE Log Page #:** If the lab value is reportable as an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.
- **Not Reportable as an AE:** Mark if the lab value is gradable per the *Female Genital Grading Table for Use in Microbicide Studies* or the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, but is not reportable as an AE. This includes Pre-existing Conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements.
- **Item 4:** Plasma archive is required at the Enrollment, 6-Week, 13-Week, 20-Week, and 21-Week Visits. If a plasma specimen was required but not collected, mark the “not stored” box and record the reason.

SAMPLE. Do NOT FAX TO DATAFAX

MTN 001 (146)



SPA-1 (180)

Visit Code [][] . []

1

Participant ID

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

Study Product Adherence and Behavior Assessment

Visit Date

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

Instructions: Complete items 1-3c before the interview. Also, prior to the interview, circle the correct study product (tenofovir gel, tenofovir tablets, tenofovir gel and tablets together) in the statement above item 4 to read aloud.

- 1. Participant's current study regimen period: [] vaginal tenofovir [] oral tenofovir [] dual use (vaginal and oral tenofovir)
If oral tenofovir, go to item 3.

- 2. Date and time of last three applications of vaginal tenofovir gel prior to this visit starting with the most recent:

Not done/ Not collected dd MMM yy hr min
2a. [][] [][][] [][] [][] : [][]
2b. [][] [][][] [][] [][] : [][]
2c. [][] [][][] [][] [][] : [][]

If participant is in the vaginal study period, go to statement above item 4.

- 3. Date and time of last three doses of oral tenofovir tablets prior to this visit starting with the most recent:

Not done/ Not collected dd MMM yy hr min
3a. [][] [][][] [][] [][] : [][]
3b. [][] [][][] [][] [][] : [][]
3c. [][] [][][] [][] [][] : [][]

I would like to ask you some questions about the way you have been using the study product during this study period. By study product, I mean [tenofovir gel tenofovir tablets tenofovir gel and tablets together]. We need to understand what people really are doing and why, so please report your experience as it happened. Do not worry if you did not use your study product every day. It is common for people to miss some days, and while some people use their study product every day, others may not be able to do so. We would like to know what is really happening for you.

- 4. In the past 3 weeks, how often did you use the study product? Showcard #4.

never less than once a week 1-3 times a week 4-6 times a week once a day
[] [] [] [] []

Study Product Adherence and Behavior Assessment (SPA-1)

This form is used to collect information about the participant's study product use (both vaginal and oral) and sexual behavior during her study follow-up. This is an interviewer-administered form (with the exception of items 1–3c), and is administered at the Week 3, 6, 10, 13, 17, and 20 Visits.

***Note:** Responses to all of the items on this form are based on participant recall at the time the form is being administered. Any clarifications and/or updates to this form should be made only during the interview in which this form is completed, unless requested otherwise by SCHARP. Once the interview is finished, do not make any further updates or changes to the responses recorded on this form.*

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Item 4:** Read each response category aloud, using the appropriate showcard to help the participant respond.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don't know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX

MTN 001 (146)



SPA-2 (181)

Visit Code

Participant ID

- -

Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

5. In the **past 3 weeks**, what was the longest number of days in a row that you missed using the study product? This does not include doses that you missed, but were able to make up prior to your next scheduled dose.

of days

→ **If 00, go to item 8 on page 3.**

6. For the days you did not use the study product, what were the reasons?
Mark all that apply.

- 6a. away from home
- 6b. feeling sick because of using study product
- 6c. had other health problems not related to study product
- 6d. instructed by study staff to stop using study product
- 6e. tired of using study product daily
- 6f. busy/interfered with daily activities
- 6g. forgot
- 6h. gave study products(s) away
- 6i. sold study product
- 6j. someone took study product
- 6k. menses
- 6l. lack of privacy
- 6m. participant thought it interfered with sex
- 6n. partner thought it interfered with sex
- 6o. partner did not approve
- 6p. lost study product
- 6q. ran out of study product
- 6r. other, specify:

Local Language: _____

English: _____

Study Product Adherence and Behavior Assessment (SPA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 6: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reason reported by the participant. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX
TO DATAFAX

MTN 001 (146)



SPA-3 (182)

Visit Code

Participant ID

- -
Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

7. In the **past 3 weeks**, how many days did you not use the study product? This does not include doses that you missed but were able to make up prior to your next scheduled dose.

of days
 → **If 00, go to item 8.**

7a. In the **past 7 days**, how many days did you not use the study product? This does not include doses that you missed but were able to make up prior to your next scheduled dose.

of days

8. In the **past 3 weeks**, did you ever insert study gel into your anus?.....

yes no
 → **If no, go to statement above item 9.**

8a. In the **past 3 weeks**, how many times did you insert study gel into your anus?

of times

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. Your honest answers will be very helpful to us. There are no right or wrong answers to these questions. Remember, we do not have your name on these papers, and all of your answers will be kept confidential.

There are many different ways people have sex. Some of the questions are about vaginal sex, and some are about anal sex. Vaginal sex means when a man puts his penis inside your vagina. Anal sex means when a man puts his penis inside your anus.

9. In the **past 3 weeks**, have you had a new sex partner? By sex partner, I mean someone with whom you have had vaginal or anal sex.

yes no

Now I am going to ask you some questions about vaginal sex only.

10. In the **past 3 weeks**, did you have vaginal sex?

yes no
 → **If no, go to statement above item 14 on page 6.**

10a. In the **past 3 weeks**, how often did you have vaginal sex?
Showcard #2.

less than once a week 1-3 times a week 4-6 times a week once a day more than once a day

Study Product Adherence and Behavior Assessment (SPA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX TO DATAFAX

MTN 001 (146)



SPA-4 (183)

Visit Code [][] . []

1

Participant ID

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

Study Product Adherence and Behavior Assessment

No data recorded on this page

I know that you have been counseled to use male condoms for each act of vaginal sex, but I also know that it is sometimes difficult to use condoms all the time. We are interested in your actual experiences using male condoms with vaginal sex, so your honest and accurate answers are very important to us.

10b. In the **past 3 weeks**, how often did your partner(s) use a male condom during vaginal sex?
Showcard #3.

never rarely sometimes most of the time always

11. In the **past 7 days**, how many times did you have vaginal sex? # of times [][] **If 00, go to item 12.**

11a. In the **past 7 days**, how many times did your partner(s) use a male condom during vaginal sex? # of times [][]

12. The **last time** you had vaginal sex:

12a. did your partner use a male condom? yes no **If participant is in the oral tenofovir period, go to item 12f on page 5.**

12b. did you use the tenofovir gel that same day? yes no

If no, and participant is in the vaginal tenofovir period, go to statement above item 14 on page 6.
If no and participant is in the dual use period, go to item 12f on page 5.

12c. did you use the tenofovir gel **before** sex? yes no **If no, go to item 12d.**

12c1. How long before? # [][][] minutes hours
Mark only one measurement of time (e.g., minutes or hours).

12d. did you use the tenofovir gel **after** sex? yes no **If no, go to item 12e on page 5.**

12d1. How long after? # [][][] minutes hours
Mark only one measurement of time (e.g., minutes or hours).

Study Product Adherence and Behavior Assessment (SPA-4)

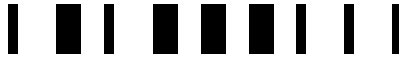
Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX TO DATAFAX

MTN 001 (146)



SPA-5 (184)

Visit Code [][] . []

1

Participant ID

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

Study Product Adherence and Behavior Assessment

No data recorded on this page

12e. did you use the tenofovir gel at a different time than usual because you had sex?

yes [] no []

If participant is in the vaginal tenofovir period, go to statement above item 14 on page 6.

12f. did you use the tenofovir tablets that same day?

yes [] no []

If no, go to statement above item 14 on page 6.

12g. did you use the tenofovir tablets before sex?

yes [] no []

If no, go to item 12h.

12g1. How long before? Mark only one measurement of time (e.g., minutes or hours).

[][] minutes [] hours []

12h. did you use the tenofovir tablets after sex?

yes [] no []

If no, go to item 12i.

12h1. How long after? Mark only one measurement of time (e.g., minutes or hours).

[][] minutes [] hours []

12i. did you use the tenofovir tablets at a different time than usual because you had sex?

yes [] no []

13. Did you have vaginal sex today or yesterday?

yes [] no []

If no, go to statement above item 14 on page 6.

13a. Thinking about when you had vaginal sex today and yesterday, did you have any vaginal sex without using a male condom?

yes [] no []

If yes, go to statement above item 14 on page 6.

Study Product Adherence and Behavior Assessment (SPA-5)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX TO DATAFAX



Visit Code [][] . []

1

MTN 001 (146)

SPA-6 (185)

Participant ID

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

Study Product Adherence and Behavior Assessment

13b. When you had vaginal sex today and yesterday, did you and your partner experience any of the following:

- 13b1. the male condom burst, broke or had a tear during sex or during removal of the penis from your vagina? yes no [] []
13b2. the male condom slipped off completely during sex or during removal of the penis from your vagina? yes no [] []
13b3. semen or fluid spilled from the male condom into your vagina? yes no [] []

13c. When you had vaginal sex today and yesterday, did your partner ever:

- 13c1. insert his penis inside your vagina before putting a male condom on? yes no [] []
13c2. remove the male condom and continue having vaginal sex? yes no [] []

I am now going to ask you some questions about another way that people have sex. This way is anal sex, which is when a man puts his penis inside his partner's anus. I am asking you these questions because understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

14. In the past 3 weeks, did you have anal sex? yes no [] [] If no, go to instructions above item 18 on page 10.

14a. In the past 3 weeks, how often did you have anal sex? Showcard #2.

less than once a week 1-3 times a week 4-6 times a week once a day more than once a day [] [] [] [] []

Study Product Adherence and Behavior Assessment (SPA-6)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX TO DATAFAX

MTN 001 (146)



SPA-7 (186)

Visit Code [][] . []

1

Participant ID

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

Study Product Adherence and Behavior Assessment

No data recorded on this page

I know that you have been counseled to use male condoms for each act of anal sex, but I also know that it is sometimes difficult to use condoms all the time. We are interested in your actual experiences using male condoms with anal sex, so your honest and accurate answers are very important to us.

14b. In the **past 3 weeks**, how often did your partner(s) use a male condom during anal sex?

Showcard #3.

never rarely sometimes most of the time always

15. In the **past 7 days**, how many times did you have anal sex?.....

of times [][] → If 00, go to item 16.

15a. In the **past 7 days**, how many times did your partner(s) use a male condom during anal sex?

of times [][]

16. The **last time** you had anal sex:

16a. did your partner use a male condom?

yes no
 → If participant is in the oral tenofovir period, go to item 16f on page 8.

16b. did you insert the tenofovir gel into your vagina that same day?

yes no

If no, and participant is in the vaginal tenofovir period, go to statement above item 18 on page 10.

If no and participant is in the dual use period, go to item 16f on page 8.

16c. did you use the tenofovir gel **before** sex?

yes no
 → If no, go to item 16d.

16c1. How long before?
Mark only one measurement of time (e.g., minutes or hours).

[][][] minutes
 hours

16d. did you use the tenofovir gel **after** sex?

yes no
 → If no, go to item 16e on page 8.

16d1. How long after?
Mark only one measurement of time (e.g., minutes or hours).

[][][] minutes
 hours

Study Product Adherence and Behavior Assessment (SPA-7)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX
TO DATAFAX

MTN 001 (146)



SPA-8 (187)

Visit Code

1

Participant ID

- -
Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

No data recorded on this page

16e. did you use the tenofovir gel at a different time than usual because you had sex?

yes no

If participant is in the vaginal tenofovir period, go to statement above item 18 on page 10.

16f. did you use the tenofovir tablets that same day?

yes no

If no, go to statement above item 18 on page 10.

16g. did you use the tenofovir tablets **before** sex?

yes no

If no, go to item 16h.

16g1. How long before?
Mark only one measurement of time (e.g., minutes or hours).

 minutes
 hours

16h. did you use the tenofovir tablets **after** sex?

yes no

If no, go to item 16i.

16h1. How long after?
Mark only one measurement of time (e.g., minutes or hours).

 minutes
 hours

16i. did you use the tenofovir tablets at a different time than usual because you had sex?

yes no

17. Did you have anal sex today or yesterday?

yes no

If no, go to statement above item 18 on page 10.

17a. Thinking about when you had anal sex today and yesterday, did you have any anal sex **without** using a male condom?

yes no

If yes, go to statement above item 18 on page 10.

Study Product Adherence and Behavior Assessment (SPA-8)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX

MTN 001 (146)



SPA-9 (188)

Visit Code .

1

Participant ID

- -
Site Number Participant Number Chk

Study Product Adherence and Behavior Assessment

No data recorded on this page

17b. When you had anal sex today and yesterday, did you and your partner experience any of the following:

17b1. the male condom burst, broke or had a tear during sex or during removal of the penis from your anus? *yes* *no*

17b2. the male condom slipped off completely during sex or during removal of the penis from your anus? *yes* *no*

17b3. semen or fluid spilled from the male condom into your anus? *yes* *no*

17c. When you had anal sex today and yesterday, did your partner ever:

17c1. insert his penis inside your anus before putting a male condom on? *yes* *no*

17c2. remove the male condom and continue having anal sex? *yes* *no*

Study Product Adherence and Behavior Assessment (SPA-9)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **No data recorded on this page:** Mark this box if no data is recorded on this page other than the Participant ID and the Staff Initials/Date.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE *DO NOT FAX*
TO DATAFAX

MTN 001 (146)

██████████ Visit Code

□□□.□□

1

SPA-10 (189)

Participant ID

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

Study Product Adherence and Behavior Assessment

I am now going to ask you some different types of personal and sensitive questions. Some of the questions may not apply to you, but we ask the same questions of all study participants.

18. For the next question, I am going to ask you about items that women sometimes insert inside their vaginas. For each item, please tell me if you inserted it inside your vagina in the **past month**. It is possible to answer "yes" more than once.

	yes	no	# of times in past week
18a. water?	<input type="checkbox"/>	<input type="checkbox"/>	→ □□
18b. water with vinegar? Note for U.S. sites: <i>This includes all commercial douching products.</i>	<input type="checkbox"/>	<input type="checkbox"/>	→ □□
18c. water with soap?	<input type="checkbox"/>	<input type="checkbox"/>	→ □□
18d. paper, cloth, cotton, or cotton wool?	<input type="checkbox"/>	<input type="checkbox"/>	→ □□
18e. tampons?	<input type="checkbox"/>	<input type="checkbox"/>	→ □□
18f. fingers without anything else?	<input type="checkbox"/>	<input type="checkbox"/>	→ □□
18g. anything else? Specify below:	<input type="checkbox"/>	<input type="checkbox"/>	→ □□
Local Language: _____			
English: _____			

Study Product Adherence and Behavior Assessment (SPA-10)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 18:** Read each item 18a–18g aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many times in the **past week** (the last 7 days) she has used that particular item. Record the response in the “# of times in **past week**” boxes. If “yes” is marked for item 18g, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

MTN 001 (146)

PSA-1 (201)

Participant ID

- -

Site Number Participant Number Chk

Product Sharing Assessment

Visit Date

dd MMM yy

Instructions: Before the interview, circle the correct study product (tenofovir gel, tenofovir tablets, tenofovir gel and tablets together) in the statement above item 1 to read aloud. Complete items 1-3h at the end-of-study period visits (Weeks 6, 13, and 20) only.

I am now going to ask you some questions about sharing of study product during this study period. By study product, I mean [tenofovir gel tenofovir tablets tenofovir gel and tablets together]. I know that you are counseled to **not** share your study product with other people, but I also know that this is not always possible.

1. Since you started using the study product, has anyone asked you for your study product?..... yes no **→ If no, go to item 2 on page 2.**

Who asked you for your study product:

	yes	no	n/a	# of tablets shared	# of applicators shared
1a. husband or primary male sex partner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
1b. other sex partner(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
1c. your children?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
1d. other relative(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
1e. friend(s) who you do not have sex with?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
1f. neighbor(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
1g. other study participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
1h. other, specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Local Language: _____

English: _____

Product Sharing Assessment (PSA-1)

Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Items 1a–1h:** Read each item aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many study tablets and applicators were shared. Record the responses in the “#of tablets shared” and “# of applicators shared” boxes. For each “yes,” response, both the “# of tablets shared” and the “# of applicators shared” boxes should be completed. Use leading zeros when needed so that all boxes are filled. If “yes” is marked for “other, specify,” record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

.

MTN 001 (146)

PSA-2 (202)

Participant ID

- -

Site Number Participant Number Chk

Product Sharing Assessment

2. Since you started using the study product, have you ever sold, traded, or given away your study product? *yes* *no*

If no, go to item 3 on page 3.

Who did you sell, trade, or give your study product to:

	<i>yes</i>	<i>no</i>	<i>n/a</i>	<i># of tablets sold/traded/given</i>	<i># of applicators sold/traded/given</i>
2a. husband or primary male sex partner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
2b. other sex partner(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
2c. your children?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
2d. other relative(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
2e. friend(s) who you do not have sex with?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
2f. neighbor(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
2g. other study participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
2h. other, specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Local Language: _____

English: _____

Product Sharing Assessment (PSA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 2a–2h:** Read each item aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many study tablets and applicators were sold/traded/given. Record the responses in the “#of tablets sold/traded/given” and “# of applicators sold/traded/given” boxes. For each “yes,” response, both the “# of tablets sold/traded/given” and the “# of applicators sold/traded/given” boxes should be completed. Use leading zeros when needed so that all boxes are filled. If “yes” is marked for “other, specify,” record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

MTN 001 (146)

PSA-3 (203)

Participant ID

- -

Site Number Participant Number Chk

Product Sharing Assessment

3. Since you started using the study product, has anyone taken your study product without your permission? *yes* *no* → **If no, end of form.**

Who do you think took your study product:

	<i>yes</i>	<i>no</i>	<i>n/a</i>	<i># of tablets taken</i>	<i># of applicators taken</i>
3a. husband or primary male sex partner?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
3b. other sex partner(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
3c. your children?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
3d. other relative(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
3e. friend(s) who you do not have sex with?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
3f. neighbor(s)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
3g. other study participants?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
3h. other, specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

Local Language: _____

English: _____

Product Sharing Assessment (PSA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 3a–3h:** Read each item aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many study tablets and applicators were taken. Record the responses in the “#of tablets taken” and “# of applicators taken” boxes. For each “yes,” response, both the “# of tablets taken” and the “# of applicators taken” boxes should be completed. Use leading zeros when needed so that all boxes are filled. If “yes” is marked for “other, specify,” record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

If the participant refuses or is unable to give a response to any item(s), draw a line through the response boxes, write “don’t know” or “refused,” and initial and date the note in the white space next to the item.

SAMPLE. DO NOT FAX
TO DATAFAX

MTN 001 (146)



AA-1 (272)

Visit Code .

1

Participant ID

- -
Site Number Participant Number Chk

Acceptability Assessment

Visit Date

dd MMM yy

Instructions: Complete item 1 before the interview.

1. Which study regimen period is the participant in?

- vaginal tenofovir —————> **If vaginal tenofovir, go to item 2.**
- oral tenofovir —————> **If oral tenofovir, go to item 3.**
- dual use (both vaginal and oral tenofovir) —————> **If dual use, go to item 4.**

2. One goal of this study is to understand how acceptable daily use of the vaginal tenofovir gel is to women and their partners. I would like to ask you about your experience using the tenofovir gel. Your honest answer will be very helpful to us. If daily use of tenofovir gel is found to protect people from HIV, how likely would you be to use it? **Showcard #1**

very likely likely unlikely very unlikely

} —————> **Go to item 5.**

3. One goal of this study is to understand how acceptable daily use of oral tenofovir tablets is to women and their partners. I would like to ask you about your experience using oral tenofovir. Your honest answer will be very helpful to us. If daily use of oral tenofovir is found to protect people from HIV, how likely would you be to use it? **Showcard #1**

very likely likely unlikely very unlikely

} —————> **Go to item 5.**

4. One goal of this study is to understand how acceptable daily use of vaginal tenofovir gel and oral tenofovir tablets is to women and their partners. I would like to ask you about your experience using vaginal and oral tenofovir. Your honest answer will be very helpful to us. If daily use of vaginal tenofovir gel and oral tenofovir is found to protect people from HIV, how likely would you be to use them? **Showcard #1**

very likely likely unlikely very unlikely

5. How worried are you that you will become HIV-positive in the next year? **Showcard #5**

very worried somewhat worried not very worried not at all worried

Acceptability Assessment (AA-1)

This form is used to collect study product acceptability information from study participants. This is an interviewer-administered form except for item 1, which should be completed by study staff before starting the interview. This form is administered at each 6-Week and 13-Week visit.

Item-specific Instructions:

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

SAMPLE. Do NOT FAX
TO DATAFAX

MTN 001 (146)



AA-2 (273)

Visit Code .

Participant ID

- -
Site Number Participant Number Chk

Acceptability Assessment

6. Are you currently married?

yes no

If yes, go to item 8.

7. Do you currently have a primary male sex partner? By primary partner, I mean someone you have sex with on a regular basis, and who you consider to be your main partner.

yes no

If no, end of form.

8. Is he HIV-positive?

yes no don't know

If yes, go to item 10.

9. How worried are you that he will become HIV-positive in the next year?
Showcard # 5

very worried *somewhat worried* *not very worried* *not at all worried*

10. Did he accompany you here to the clinic during this study period?

yes no

11. Did he know that you were using the study product?

yes no don't know

If no or don't know, end of form.

12. What was his reaction to your use of the study product? *Mark all that apply.*

- 12a. he liked it
- 12b. he did not like it
- 12c. he thought it improved sex
- 12d. he thought it worsened sex
- 12e. he thought it interfered with sex
- 12f. he had no reaction
- 12g. don't know
- 12h. other, specify:

Local Language: _____

English: _____

Acceptability Assessment (AA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.

SAMPLE *Do NOT FAX TO DATAFAX*

MTN 001 (146)



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 an AE → **Update Adverse Experience Log if indicated.**
- 1d. participant needs study product
- 1e. participant is returning unused study product
- 1f. other, specify: _____

2. hCG for pregnancy: *not done* *negative* *positive* → **If positive, complete Pregnancy Report and History form and Product Hold/Discontinuation form.**

2a. Specify reason(s): ← _____

3. Besides this form, what other DataFax forms with the same visit code as this form were completed for this visit? *Mark "none" or all that apply.*

- 3a. none
- 3b. Follow-up Pelvic Exam
- 3c. Pelvic Laboratory Results
- 3d. STI Laboratory Results
- 3e. Adverse Experience Log (new)
 - 3e1. How many **new** AE Log pages were completed for this visit? # of pages
- 3f. Product Hold/Discontinuation
- 3g. Safety Laboratory Results
- 3h. Follow-up Genital Symptoms
- 3i. other, specify: _____

4. At this visit, how many **unused applicators** of tenofovir gel did the participant return? # of **unused applicators** returned

5. At this visit, how many **unused tablets** of oral tenofovir did the participant return? # of **unused tablets** returned

6. At this visit, how many **applicators** of tenofovir gel were dispensed to the participant? # of **applicators** dispensed

7. At this visit, how many **tablets** of oral tenofovir were dispensed to the participant? # of **tablets** dispensed

Comments: _____

Interim Visit (IV-1)

This form is used to document interim visits during follow-up. Refer to the Study-Specific Procedures (SSP) Manual for a definition and examples of interim visits that require an Interim Visit form to be completed. Note that all DataFax forms completed for an Interim Visit must have the same interim Visit Code as the Interim Visit form.

Item-specific Instructions:

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:
 - Record the two-digit whole number visit code for the most recent scheduled regular visit.
 - Record the number that corresponds to the Interim Visit in the third box (the box to the right of the decimal point):
 - XX.1 = First Interim Visit after the most recent scheduled regular visit.
 - XX.2 = Second Interim Visit after the most recent scheduled regular visit.
- **Item 1:** Mark the box to the left of each reason(s) this Interim Visit was conducted. Mark all that apply.
- **Item 2:** A urine pregnancy test is required at each interim visit. Record the hCG urine pregnancy test result. If a required urine pregnancy test result is not available (specimen not collected and/or test not done), mark the “not done” box and complete item 2a.

*Note: A **Pregnancy Report and History** form must be completed for each pregnancy. Once a participant tests positive for hCG urine pregnancy and a **Pregnancy Report and History** form (PR-1) has been completed for this pregnancy, subsequent positive pregnancy test results should not be recorded on a new PR-1 (unless they represent a new pregnancy).*
- **Item 3:** For each DataFax form completed for this visit, mark the box to the left of the form name. Mark all boxes that apply. Note that marking a box indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.
 - **none:** Mark this box if the Interim Visit form is the **only** DataFax form completed for this visit.
 - **Adverse Experience Log (new):** 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 in item 3e1 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.
 - **other, specify:** Mark this box if a DataFax form(s) other than the ones listed was completed for this visit. Specify the form name(s) on the line provided.
- **Item 4:** Record the number of **unused** tenofovir gel applicators the participant returned at this visit only, as determined by site clinic staff.
- **Item 5:** Record the number of **unused** oral tenofovir tablets the participant returned at this visit only, as determined by site clinic staff.
- **Item 6:** Record the number of tenofovir gel applicators given to the participant at this visit.
- **Item 7:** Record the number of oral tenofovir tablets given to the participant at this visit.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

1

MTN 001 (146)

HTR-1 (351)

Participant ID

- -
Site Number Participant Number Chk

HIV Test Results

Sample 1

1. HIV Western Blot
Not done/ Not collected Specimen Collection Date
dd MMM yy
negative positive indeterminate
If negative, go to item 5, and contact MTN Network Lab.

Sample 2

2. HIV Western Blot
Not done/ Not collected Specimen Collection Date
dd MMM yy
negative positive indeterminate
If positive, go to item 5. If negative or indeterminate, contact MTN Network Lab.

Sample 3

3. HIV Western Blot
Not done/ Not collected Specimen Collection Date
dd MMM yy
negative positive indeterminate

Sample 4

4. HIV Western Blot
Not done/ Not collected Specimen Collection Date
dd MMM yy
negative positive indeterminate

FINAL HIV STATUS

5. Final status: negative positive other, specify: _____
If positive, permanently discontinue all study products.

Comments: _____

HIV Test Results (HTR-1)

This form documents confirmatory HIV test results and final HIV status. This form is completed each time a participant has a positive HIV rapid test or HIV ELISA test result during follow-up.

*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 5 has been completed.*

Item-specific Instructions:

- **Visit Code:** The visit code recorded on this form should be the same visit code recorded on the STI Laboratory Results form documenting a positive HIV ELISA or rapid 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 positive HIV rapid or ELISA specimen.
- **Not done/Not collected:** Mark this box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Explain in the Comments section at the bottom of the form why the result is not available.
- **Item 5:** Once a participant's HIV status has been determined, record the final HIV status. If the final HIV status is not clearly negative or clearly positive, mark the "other, specify" box and specify reason(s) on the line provided. If the participant's final HIV status is determined to be positive (according to the protocol testing algorithm), report the HIV infection as an AE on an AE Log form.

SAMPLE. DO NOT FAX
TO DATAFAX

MTN 001 (146)



FAA-1 (372)

Visit Code .

1

Participant ID

- -
Site Number Participant Number Chk

Final Acceptability Assessment

Visit Date

dd MMM yy

Instructions: Complete item 1 before the interview.

1. Which study regimen period is the participant in?

- vaginal tenofovir —————> **If vaginal tenofovir, go to item 2.**
- oral tenofovir —————> **If oral tenofovir, go to item 3.**
- dual use (both vaginal and oral tenofovir) —————> **If dual use, go to item 4.**

2. One goal of this study is to understand how acceptable daily use of the vaginal tenofovir gel is to women and their partners. I would like to ask you about your experience using the tenofovir gel. Your honest answer will be very helpful to us. If daily use of tenofovir gel is found to protect people from HIV, how likely would you be to use it? **Showcard #1**

very likely
 likely
 unlikely
 very unlikely

} —————> **Go to item 5.**

3. One goal of this study is to understand how acceptable daily use of oral tenofovir tablets is to women and their partners. I would like to ask you about your experience using oral tenofovir. Your honest answer will be very helpful to us. If daily use of oral tenofovir is found to protect people from HIV, how likely would you be to use it? **Showcard #1**

very likely
 likely
 unlikely
 very unlikely

} —————> **Go to item 5.**

4. One goal of this study is to understand how acceptable daily use of vaginal tenofovir gel and oral tenofovir tablets is to women and their partners. I would like to ask you about your experience using vaginal and oral tenofovir. Your honest answer will be very helpful to us. If daily use of vaginal tenofovir gel and oral tenofovir is found to protect people from HIV, how likely would you be to use them? **Showcard #1**

very likely
 likely
 unlikely
 very unlikely

5. How worried are you that you will become HIV-positive in the next year? **Showcard #5**

very worried
 somewhat worried
 not very worried
 not at all worried

Final Acceptability Assessment (FAA-1)

This form is used to collect study product acceptability information from study participants. This is an interviewer-administered form except for item 1, which should be completed by study staff before starting the interview. This form is administered at the 20-Week visit.

Item-specific Instructions:

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

SAMPLE: Do NOT FAX TO DATAFAX



Visit Code [][] . []

1

MTN 001 (146)

FAA-2 (373)

Participant ID

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

Final Acceptability Assessment

6. Are you currently married?

yes [] no []

If yes, go to item 8.

7. Do you currently have a primary male sex partner? By primary partner, I mean someone you have sex with on a regular basis, and who you consider to be your main partner.

yes [] no []

If no, go to item 16 on page 3.

8. Is he HIV-positive?

yes [] no [] don't know []

If yes, go to item 10.

9. How worried are you that he will become HIV-positive in the next year? Showcard #5

very worried [] somewhat worried [] not very worried [] not at all worried []

10. Did he accompany you here to the clinic during this study period?

yes [] no []

11. Did he know that you were using the study product?

yes [] no [] don't know []

If no or don't know, go to item 16 on page 3.

12. What was his reaction to your use of the study product? Mark all that apply.

- 12a. he liked it []
12b. he did not like it []
12c. he thought it improved sex []
12d. he thought it worsened sex []
12e. he thought it interfered with sex []
12f. he had no reaction []
12g. don't know []
12h. other, specify: []

Local Language: _____

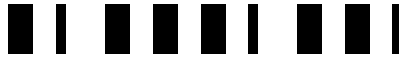
English: _____

Final Acceptability Assessment (FAA-2)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code .

1

MTN 001 (146)

FAA-3 (374)

Participant ID

- -
Site Number Participant Number Chk

Final Acceptability Assessment

13. Since you joined the study, how supportive was he about your use of the study gel?
Showcard #6

very supportive *somewhat supportive* *not very supportive* *not at all supportive*

14. Since you joined the study, how supportive was he about your use of the study tablets?
Showcard #6

very supportive *somewhat supportive* *not very supportive* *not at all supportive*

15. What did he prefer that you use—using the study gel or the study tablets?

- study gel
- study tablets
- neither—disliked both study products
- both—liked both study products equally

16. What did you prefer—using the study gel or taking the study tablets?

- study gel
- study tablets
- neither—disliked both study products
- both—liked both study products equally

Comments: _____

Final Acceptability Assessment (FAA-3)

Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.

SAMPLE TO DATAFAX



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

Page [][]

MTN 001 (146)

PH-1 (410)

Participant ID

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

Product Hold/Discontinuation

1. Date product hold was initiated this study period: [][] [][][] [][] Visit Code [][] . []

2. Product being held this study period: oral tenofovir [] vaginal tenofovir gel [] oral and vaginal tenofovir []

3. Why is product being held? Mark only one.

- 3a. pregnant or breastfeeding
3b. Grade >= 3 hypophosphatemia
3c. Grade >= 2 STI/RTI requiring treatment
3d. HIV infection
3e. Hepatitis B infection
3f. Grade >= 3 nausea and/or vomiting
3g. Grade >= 3 diarrhea
3h. Grade >= 3 AST/ALT elevation
3i. creatinine clearance < 50 mL/min
3j. other adverse experience
3k. use of prohibited medication(s)
3l. participant non-compliant with study product use procedures
3m. other, specify: _____

AE Log page #(s) [][][] [][][] [][][]

4. Date last tablet was taken this study period: [][] [][][] [][] OR []

5. Date last applicator was used this study period: [][] [][][] [][] OR []

6. Was the participant instructed to resume product use this study period? yes [] no (discontinued) [] (hold continuing for another reason) [] In item 6a, record the date and visit code on which product would have been resumed if not being held for another reason.

6a. Date participant instructed to resume product use this study period: [][] [][][] [][] Visit Code [][] . []

Comments: _____

Product Hold/Discontinuation (PH-1)

This form is used to document unexpected temporary holds and discontinuations of study product use within a given study period. Do not complete a new Product Hold/Discontinuation (PH-1) form at the End-of-study period visits, as discontinuation of product use for a given study period is expected at these visits.

This form is completed each time a participant is instructed to temporarily stop (hold) or discontinue study product use at an unscheduled timpani within a given study period. Only complete this form if product use in the current study period is held or discontinued. For example, if the participant has an adverse experience that warrants hold of oral study product, only complete the PH-1 form if she is in the oral or dual use period.

If more than one reason contributes to a product hold or discontinuation, complete one Product Hold/Discontinuation form for each reason listed in item 3. For example, if a participant is in the oral tenofovir period and has Grade 3 nausea and diarrhea at the 3-Week Visit, complete one PH-1 form with item 3f marked and one PH-1 form with item 3g marked. Assign page # “001” to one PH-1 form and page # “002” to the other PH-1 form. Record visit code 03.0 in item 1 on each form. If a participant has an ongoing product hold and another reason for a product hold/discontinuation occurs during that time, complete a new PH-1 form for the new reason. For example, a participant has product held at her 3-Week Visit for a Grade 2 STI. The site completes a PH-1 form and records visit code 03.0. The participant returns at 4 weeks for an interim visit and tests positive for pregnancy. Complete a new PH-1 form for the pregnancy, assign the next sequential page number, and record the appropriate interim visit code in item 1 on the form.

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 5 have been completed. Refax the form once item 6 has been completed.

Item-specific Instructions:

- **Item 1:** Record the date and visit code at which the participant was instructed by a study staff member to hold or discontinue study product use in the current study period. If study product is being held or discontinued as a result of an adverse experience, the visit code recorded in item 1 on this form should match the visit code recorded in item 10 of the AE Log documenting the product hold/discontinuation.
- **Item 2:** Mark the product that corresponds to the participant's current study period. For example, if the participant is in the oral tenofovir period, mark the 'oral tenofovir' box. If the participant is in the vaginal tenofovir period, mark the 'vaginal tenofovir gel' box. If the participant is in the dual use period, mark the 'oral and vaginal tenofovir' box.
- **Item 3:** Mark the box to the left of the reason why the participant is being instructed to hold or discontinue study product use in the current study period. If study product is being held or discontinued due to an adverse experience, record the page number(s) of the AE Log documenting the study product hold or discontinuation. If the study product hold/discontinuation is due to a reason other than the ones listed, mark “other, specify” and record the reason for the hold/discontinuation on the line provided.
- **Item 4:** Record the date of the participant’s last dose of oral tenofovir during the current study period. Use a best estimate if the actual date cannot be determined. Mark “N/A” if the participant is in the vaginal period or if the participant did not use oral tenofovir during the current study period.
- **Item 5:** Record the date of the participant’s last dose of vaginal tenofovir gel during the current study period. Use a best estimate if the actual date cannot be determined. Mark “N/A” if the participant is in the oral period, or if the participant did not use vaginal tenofovir gel during the current study period.
- **Item 6:** Complete this item once study staff have determined that the participant can resume study product use during the current study period based on resolution of the reason marked in item 3, or have determined that she is discontinued from study product use for the current study period. Mark this item “yes” if study staff instructed the participant that she can resume use of study product during the current study period. If the participant was discontinued from study product use for the current study period, mark the “no (discontinued)” box and end the form—leave item 6a blank. If the participant is eligible to resume study product use during the current study period based on resolution of the reason marked in item 3, but is continuing on study product hold for a reason recorded on another (separate) Product Hold/Discontinuation form, mark the “no (hold continuing for another reason)” response box. If a reason for product hold remains ongoing from one study period to the next, complete item 6 at the end of the first study period. Complete a new PH-1 form at the start of the next study period if the reason requires a product hold during the next study period. Record on the new form the same reason and AE Log page #, if applicable, that are recorded in item 3 of the original PH-1 form.
- **Item 6a:** Record the date and visit code on which the participant was told by a study staff member that she could resume study product use during the current study period. If “no (hold continuing for another reason)” is marked for item 6, in item 6a record the date the participant would have been instructed to resume study product use based on resolution of the reason marked in item 3 of the form.

SAMPLE. Do NOT FAX TO DATAFAX



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

Page [][][]

MTN 001 (146)

AE-1 (420)

Participant ID

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

Adverse Experience Log

Date Reported to Site

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

1. Adverse Experience (AE)

2. Onset Date

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

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

3. Severity

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

4. Relationship to Study Product

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

Record reason why AE is "not related" in Comments below.

5. Study Product Administration

- No change
- Held
- Permanently discontinued
- N/A
- Change in administration
Comment below.

6. Status/Outcome

- Continuing
- Resolved
- Death
- Severity/frequency increased
Report as 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

11. Was this AE a worsening of a pre-existing condition?

yes no

9. Has/will this AE be reported as an EAE?

10. This AE was first reported at visit:.....
Visit code required (regular or interim)

[][] [][]

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 *Female Genital Grading Table for Use in Microbicide Studies* (as appropriate).
- **Item 4:** When judging causal association (relationship) between an AE and the study agent consult the terms used in DAIDS-sponsored studies as documented in the *Manual for Expedited Reporting of Adverse Events to DAIDS*.
 - **NOTE: IN CASES OF DEATH**, when relationship of study product is under investigation, write "Pending" in the adjacent white space until relationship has been determined. Update accordingly.
- **Item 5:**
 - **No change:** Mark if the AE does NOT result in a study product hold, permanent discontinuation, or change in administration.
 - **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 occurred after the participant had completed all administration of the study product, or the study product is held or permanently discontinued for a different AE or other reason, or the AE is Grade 5-death.
- **Item 6:**
 - **Continuing:** AE is continuing at the time it is reported.
 - **Resolved:** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
 - **Death:** Mark only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation."
 - **Severity/frequency increased:** If an AE increases in severity or frequency after it has been reported on the AE Log, line through the "Continuing" box previously marked and mark "Severity/frequency increased." Record the date of increase in the "Status/Outcome Date." Report the increase in severity or frequency as a new AE. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. 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*.

SAMPLE *Do NOT FAX TO DATAFAX*



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

Page

MTN 001 (146)

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.

Medication (generic name)									
Indication								Staff Initials/Log Entry Date	
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			OR <input type="checkbox"/> Continuing at end of study		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no	
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"/> <input type="checkbox"/> _____							
Frequency Mark only one.		<input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> qxh: every <input type="text"/> <input type="text"/> hrs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____							
						Record AE Log page(s):		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
								<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Medication (generic name)									
Indication								Staff Initials/Log Entry Date	
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			OR <input type="checkbox"/> Continuing at end of study		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no	
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"/> <input type="checkbox"/> _____							
Frequency Mark only one.		<input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> qxh: every <input type="text"/> <input type="text"/> hrs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____							
						Record AE Log page(s):		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
								<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Medication (generic name)									
Indication								Staff Initials/Log Entry Date	
Date Started <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			Date Stopped <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>			OR <input type="checkbox"/> Continuing at end of study		Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no	
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"/> <input type="checkbox"/> _____							
Frequency Mark only one.		<input type="checkbox"/> prn <input type="checkbox"/> qd <input type="checkbox"/> tid <input type="checkbox"/> qhs <input type="checkbox"/> qxh: every <input type="text"/> <input type="text"/> hrs <input type="checkbox"/> once <input type="checkbox"/> bid <input type="checkbox"/> qid <input type="checkbox"/> other, specify: _____							
						Record AE Log page(s):		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
								<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	

Concomitant Medications Log (CM-1)

All medication(s) that are used by the participant during the study, 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.

- When to fax this form:
 - when pages have been updated or additional Log pages have been completed (only fax updated or new pages);
 - when the participant has completed study participation; and/or
 - when instructed by SCHARP.
- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after faxing, unless instructed by SCHARP.
- **No medications taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant at the time of the Screening or Enrollment visit. Record “Staff Initials/Date.”
- **No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. Record “Staff Initials/Date.”
- **Medication:** Record the generic name for all medications. For combination medications, record the generic names of 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 is required.
- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response boxes 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).
- **Route and Frequency:** Below is a list of common route and frequency abbreviations.

Route Abbreviations:

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

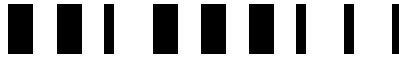
Frequency Abbreviations:

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

- **Taken for a reported AE?:** If the medication was not taken for a reported AE, mark the “no” box and leave the AE Log page boxes blank

SAMPLE *DO NOT FAX*
TO DATAFAX

MTN 001 (146)



PR-1 (440)

Visit Code

1

Participant ID

- -
Site Number Participant Number Chk

Pregnancy Report and History

PREGNANCY REPORT

1. Date of onset of last menstrual period: ^{dd} ^{MMM} ^{yy}
2. Estimated date of delivery: ^{dd} ^{MMM} ^{yy}

PREGNANCY HISTORY

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

4. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before study enrollment? ^{yes} ^{no} → **If yes, document in participant's records.**

Comments: _____

Pregnancy Report and History (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:** Complete date required. Record best estimate if date not known.
- **Item 2:** Complete date required.

SAMPLE. Do NOT FAX
TO DATAFAX



Visit Code

1

MTN 001 (146)

PO-1 (441)

Participant ID

- -
Site Number Participant Number Chk

Pregnancy Outcome

Outcome unknown at end of study. _____
Staff Initials/Date
▶ **End of form. Fax to SCHARP DataFax.**

1. How many pregnancy outcomes resulted from the reported pregnancy?

2. OUTCOME #1

dd MMM yy

2a. Outcome Date

2b. Specify Outcome: Mark only one.

full term live birth (≥ 37 weeks) }
 premature live birth (< 37 weeks) }
 spontaneous fetal death and/or still birth (≥ 20 weeks) }
 spontaneous abortion (< 20 weeks) }
 ectopic pregnancy }
 therapeutic/elective abortion }
2b1. Method: C-section vaginal
Complete AE Log and EAE Reporting form.

2c. Were any fetal/infant congenital anomalies identified? yes no not assessed

If only one outcome, end of form.

▶ **If yes, complete EAE Reporting form.**

3. OUTCOME #2

dd MMM yy

3a. Outcome Date

3b. Specify Outcome: Mark only one.

full term live birth (≥ 37 weeks) }
 premature live birth (< 37 weeks) }
 spontaneous fetal death and/or still birth (≥ 20 weeks) }
 spontaneous abortion (< 20 weeks) }
 ectopic pregnancy }
 therapeutic/elective abortion }
3b1. Method: C-section vaginal
Complete AE Log and EAE Reporting form.

3c. Were any fetal/infant congenital anomalies identified? yes no not assessed

▶ **If yes, complete EAE Reporting form.**

Comments: _____

21-APR-08

0 1
Language

13-115
Staff Initials / Date

Pregnancy Outcome (PO-1)

This form is used to report the pregnancy outcome(s) of a pregnancy reported post enrollment through termination. A **Pregnancy Outcome** form is required for each **Pregnancy Report and History** form completed for a participant. This form is completed when information about a pregnancy outcome becomes available to study staff. If an outcome is unknown at study end, mark the “Outcome unknown at end of study” box at the top of the page and fax to DataFax. When the outcome is known, draw a line through this box, record the outcome, and refax. A pregnancy outcome can be an infant or a fetus. The conception of twins should result in reporting of two outcomes. If a pregnancy results in more than two outcomes, contact SCHARP for guidance on how to complete this form.

- **Visit Code:** Record the visit code of the participant’s corresponding **Pregnancy Report and History** form.
- **Specify Outcome:** If the outcome is therapeutic/elective abortion, note that while the abortion itself is not an Adverse Experience (AE), if the abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an **Adverse Experience Log**, with “procedure/surgery” marked under “Treatment.”

Congenital anomalies: This item should be updated if information becomes available during the mother’s (the study participant’s) study follow-up period regarding a congenital anomaly. If a woman on study has a baby with a congenital anomaly and the infant does not have his/her own participant ID, report the event as an AE and record in item 1 “Congenital Anomaly in Offspring.” Record the PTID of the woman on study (mother) on the form, just as you would for any other AE reported for the participant.

SAMPLE. DO NOT FAX
TO DATAFAX



Visit Code

□ □ . 0

□ 1

MTN 001 (146)

MV-1 (463)

Page 1 of 1

Participant ID

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

Missed Visit

Form Completion Date

□ □ □ □ □ □ □ □ □
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 relocated
- 2e. participant incarcerated
- 2f. participant admitted to a health care facility
- 2g. participant withdrew from the study —————> **Complete a Termination form.**
- 2h. participant deceased —————> **Complete a Termination form. Complete an Adverse Experience Log if applicable. Complete EAE Reporting form.**
- 2i. other, specify:

Comments: _____

Missed Visit (MV-1)

Purpose: Complete this form whenever an enrolled participant misses a required visit according to the visit window.

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).

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



MTN 001 (146)

PT-1 (465)

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	

Participant Transfer

Form Completion Date

<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. Name of transferring study site: _____

2. Name of receiving study site: _____

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

4. Date participant records were sent to receiving study site:
dd MMM yy

Comments: _____

Participant Transfer (PT-1)

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

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

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

Item-specific instructions:

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

SAMPLE. Do NOT FAX
TO DATAFAX



MTN 001 (146)

PRC-1 (466)

Page 1 of 1

Participant ID

- -

Site Number Participant Number Chk

Participant Receipt

Form Completion Date

dd MMM yy

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

1. Name of receiving study site: _____

2. Name of transferring study site: _____

3. Date informed consent signed at receiving study site:

dd MMM yy

yes

no

4. Did participant provide informed consent for specimen storage at receiving study site?

→ If no, end of form.

4a. Date informed consent for specimen storage signed:

dd MMM yy

Comments: _____

Participant Receipt (PRC-1)

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

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

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

Item-specific instructions:

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

SAMPLE *DO NOT FAX*
TO DATAFAX



MTN 001 (146)

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"/>	<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 (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 2:** Record the total number of Interim Visit DataFax forms submitted for this participant. If no Interim Visit forms were submitted for the participant, record "000" in the boxes.

SAMPLE. Do NOT FAX TO DATAFAX



MTN 001 (146)

TM-1 (490)

Participant ID

Site Number - Participant Number - Chk

Termination

1. Termination Date: dd MMM yy Date the site determined that the participant was no longer in the study.

2. Reason for termination. Mark only one.

2a. scheduled exit visit/end of study -> End of form.

2b. death, indicate date and cause if known

2b1. date of death dd MMM yy OR date unknown
2b2. cause of death OR cause unknown

Complete or update Adverse Experience Log. Complete EAE Reporting form as applicable.

2c. participant refused further participation, specify:

2d. NOT APPLICABLE FOR THIS PROTOCOL.

2e. participant relocated, no follow-up planned

2f. investigator decision, specify:

2g. NOT APPLICABLE FOR THIS PROTOCOL.

2h. NOT APPLICABLE FOR THIS PROTOCOL.

2i. inappropriate enrollment -> End of form.

2j. invalid ID due to duplicate screening/enrollment -> End of form.

2k. other, specify:

2l. early study closure -> End of form.

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

3a. Record AE Log page:

Comments:

Termination (TM-1)

Purpose: Complete this form 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: A complete date is required, unless termination is due to death. If a participant is terminated prior to completing all study product administration, complete a Product Hold/Discontinuation form.

Item-specific Instructions:

- **Item 1:** Complete date 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.

PTID: _____

Screening Visit Date: _____
dd-MMM-yy

B. Reproductive History

Has the participant ever been pregnant? Yes No **If No, skip to Section C. Family Planning.**

Number of pregnancies: _____

Number of full term live births (greater than or equal to 37 weeks): _____

If number of pregnancies and number of full term live births are the same, skip to section C.

Number of premature live births (less than 37 weeks): _____

Number of spontaneous fetal deaths and/or still births (greater than or equal to 20 weeks): _____

Number of spontaneous abortions (less than 20 weeks): _____

Number of therapeutic/elective abortions: _____

Number of ectopic pregnancies: _____

Record information on any gynecologic and obstetrical procedures or surgeries here:

Record information on any fetal/infant congenital anomalies here:

PTID: _____

Screening Visit Date: _____

dd-MMM-yy

D. Medical History

Since becoming sexually active, have you ever had or do you currently have.....	YES	NO
a)...any problems with your scalp, like infection or hair loss?		
b)...any problems with your eyes, like infection, cataracts, or needing glasses?		
c)...any problems with your ears, like infection, pain, or difficulty hearing?		
d)...any problems with your nose, like chronic congestion or nosebleeds?		
e)...any problems with your teeth, mouth or throat, like an abscess or difficulty swallowing or thrush?		
f)...any problems with swollen glands or swollen feet?		
g)...any problems with your heart or blood vessels, like chest pain, palpitations or high blood pressure?		
h)...any problems with your lungs, like difficulty breathing, cough, TB, pneumonia or asthma?		
i)...any problems with your liver, like jaundice?		
j)...any problems with your kidneys or bladder, like blood in urine or urinary incontinence?		
k)...any problems with your stomach, spleen, pancreas or intestines, like nausea, vomiting, diarrhea, bloody stools or heartburn?		
l)...any problems with your muscles or bones, like chronic pain, swelling, arthritis, numbness, tingling, or broken bones?		
m)...any problems with headaches, fainting spells, muscle weakness, seizures, memory loss, dizziness, or paralysis?		
n)...any problems with your skin, like a rash, dry skin, swelling, shingles or infection?		
o)...any problems with diabetes, thyroid, or goiter?		
p)...any problems with your blood, like anemia, sickle cell, or easy bruising/bleeding?		
q)...any cancer?		
r)...any problems with fatigue, unintentional weight loss, immune deficiency or unexplained fever?		
s)...any problems related to your vaginal area, such as genital sores, vaginal itching, vaginal soreness, burning when urinating, genital bleeding not related to your menses?		
t)...any other obstetric or gynecologic procedures or problems, like hysterectomy, tubes tied, vaginal prolapse, rectal-vaginal fistula, etc?		
u) ...any sexually transmitted infections or diseases (herpes, warts, syphilis, etc)?		
v)...any history of sexual abuse, trauma or rape?		
w)...any problems with alcohol abuse or drug use? (<u>note</u> : record usual alcohol intake on the line below; also record any drug use on Concomitant Meds Log form)		
x)...any allergic or anaphylactic reaction (tightening in your chest, difficulty breathing or hives) to medications, vaccines, latex, or had any other allergies?		
y) ...any mental illness, depression, suicidal ideation/attempt, or psychosis?		
z)...any hospitalizations or emergency medical visits?		
aa)...any other problems or infections that we haven't already discussed?		

PTID: _____

Screening Visit Date: _____

dd-*MMM*-yy

E. Detailed Problem Descriptions of Participant-Reported Medical Conditions/Events

For each item marked "YES" in the table above (Section D), provide a detailed description of the medication condition(s)/event(s) referred to by that item (table row).

At the Enrollment Visit, review each condition/event marked as "ongoing" and confirm whether the condition/event is still ongoing at Enrollment. Update the entry as needed. All conditions/events marked as "ongoing" as of the Enrollment Visit need to be recorded on the Pre-Existing Conditions form.

_____	<input type="text"/> <input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed		symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

_____	<input type="text"/> <input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed		symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

_____	<input type="text"/> <input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed		symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX

PTID: _____

Screening Visit Date: _____
dd-MMM-yy

_____	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed	symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

_____	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed	symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

_____	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed	symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

_____	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed	symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX

PTID: _____

Screening Visit Date: _____
dd-MMM-yy

_____	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed	symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

_____	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed	symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

_____	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed	symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

_____	<input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
organ system	month and year diagnosed	symptom or diagnosis	ongoing problem	resolved problem

If ongoing, determine GRADE: _____
If ongoing, describe frequency and severity: _____

The information in Section E was reviewed and updated at the Enrollment Visit by:

Staff Initials: _____ **Date:** _____

If more pages are needed, add additional pages to the end of the form.

PTID: _____

Screening Visit Date: _____
dd-MMM-yy

F. Partner STI-RTI Symptoms

Does the participant's partner have any symptoms of a sexually-transmitted infection? Symptoms to ask about include penile discharge, genital rash, genital pain, and genital itching.

YES NO

If YES, describe the symptoms as well as the plans for follow-up:

Form Completion/Review Checklist

At the Enrollment Visit, review this form along with the Pre-existing Conditions, Concomitant Medications Log, and Family Planning Methods case report forms to make sure all of the below have been completed.

- 1. At Screening and Enrollment, I have asked the participant about current complaints and recorded all complaints in Sections D and E of this form.

Staff Initials: _____ Date: _____
dd/MMM/yy

- 2. At Enrollment, Sections D and E of this form were reviewed and updated, and all ongoing conditions were recorded on the **Pre-existing Conditions** form.

Staff Initials: _____ Date: _____

- 3. At Screening and Enrollment, Section C was reviewed and any **current or "as needed" medications** were recorded on the **Concomitant Medications Log** form.

Staff Initials: _____ Date: _____

- 4. At Enrollment, all of the participant's **current family planning/contraceptive** methods have been recorded on the **Family Planning Methods** form.

Staff Initials: _____ Date: _____

SAMPLE. Do NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

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 Eligibility

Form Completion Date

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

Complete items 1–4 before the interview.

- | | | | |
|---|--------------------------|--------------------------|---|
| 1. Was the participant willing and able to provide a written informed consent for screening?..... | yes | no | |
| | <input type="checkbox"/> | <input type="checkbox"/> | → If no to either, participant is ineligible. End of form. |
| 2. Was the participant willing and able to provide adequate locator information?..... | yes | no | |
| | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3. Was the participant previously enrolled in this study? | yes | no | |
| | <input type="checkbox"/> | <input type="checkbox"/> | → If yes, participant is ineligible. End of form. |
| 4. Is documentation of a normal Pap test result in the last 12 calendar months available?..... | yes | no | |
| | <input type="checkbox"/> | <input type="checkbox"/> | → If no, perform Pap test as necessary. |

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

- | | | | |
|--|--------------------------|--------------------------|--|
| 5. Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)? | yes | no | |
| | <input type="checkbox"/> | <input type="checkbox"/> | → If yes to any, participant is ineligible. |
| 6. Do you have any current male sex partner(s) who have had an adverse or bad reaction to latex (such as latex condoms or gloves)? | <input type="checkbox"/> | <input type="checkbox"/> | |
| 7. Have you ever had an adverse or bad reaction to either of the study products (Tenofovir (Viread) oral tablet or Tenofovir 1% vaginal gel and/or applicator)? | <input type="checkbox"/> | <input type="checkbox"/> | |
| 8. Have you ever been diagnosed with a pathologic bone fracture not related to trauma?..... | <input type="checkbox"/> | <input type="checkbox"/> | |
| 9. Are you breastfeeding?..... | <input type="checkbox"/> | <input type="checkbox"/> | |
| 10. Do you plan to become pregnant during the 21 weeks of study participation?..... | <input type="checkbox"/> | <input type="checkbox"/> | |
| 11. Do you plan to use a diaphragm, vaginal ring, and/or spermicide for birth control at any time during your study participation?..... | <input type="checkbox"/> | <input type="checkbox"/> | |
| 12. Do you plan to use acyclovir, valacyclovir, post-exposure prophylaxis for HIV exposure, Truvada, or non-study vaginal products (other than tampons) at any time during your study participation? | <input type="checkbox"/> | <input type="checkbox"/> | |
| 13. Have you had more than three male sex partners in the past month (30 days)? | <input type="checkbox"/> | <input type="checkbox"/> | |

Screening Eligibility – Page 1 of 4 (nonDF)

This form is used to document the participant's eligibility for the study at screening. This is a mixed form—some of the items are interviewer-administered (items 5–25), while other items are not (items 1–4 and 26–27). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

***Note:** If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 25. Do not inform her that she is ineligible for the study until the form has been administered. Also, avoid letting the participant know the reason why she is ineligible, to prevent socially desirable reporting.*

Item-specific Instructions:

- **Items 1–4:** These items are NOT interviewer-administered and should not be read aloud to the participant.
- **Item 2:** Adequate locator information is defined in site standard operating procedures (SOP).
- **Item 3:** Review the Screening and Enrollment Log to verify that the participant has not previously enrolled in the study.
- **Item 4:** Per protocol, a participant must have either a normal Pap test result at screening or documentation of a normal Pap test result in the 12 calendar months prior to screening in order to be eligible to enroll in the study. If the participant does not provide documentation of a normal Pap test result in the 12 calendar months prior to screening, conduct a Pap Smear test for this participant as part of the Screening Visit pelvic exam.

SAMPLE. Do NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

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 Eligibility

14. In the past 4 weeks, how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.....

<input type="text"/>	<input type="text"/>	→ If < 4, participant is ineligible. Go to item 16.
----------------------	----------------------	---

15. Do you anticipate having vaginal sex at least once per week during your study participation?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible.

16. Do you have a regular menstrual cycle that is 21 days or longer?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	
		→ If yes, go to item 17.

16a. Is it because of the birth control you are using, such as Depo-Provera or Norplant?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible.

17. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, go to item 18.

17a. When did you last give birth, have a miscarriage or abortion?

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

If date is within the last 60 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last pregnancy outcome.

18. In the past 3 months (90 days), have you had any gynecological surgery? This would include such procedures as: dilation and curettage (D&C), surgery of the uterus, ovaries, or fallopian tubes (including tubal ligation), biopsy, or cryotherapy (freezing) of the cervix?

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, go to item 19.

18a. When did you last have gynecological surgery?

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

If date is within the last 60 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last gynecological surgery.

Screening Eligibility – Page 2 of 4 (nonDF)

No additional instructions needed.

SAMPLE. *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

Participant ID

Site Number			Participant Number						Chk	

Screening Eligibility

19. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If yes, participant is ineligible.

20. In the past month (30 days), have you participated in any other research study that involves drugs, medical devices, or vaginal products?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If no, go to item 21.

20a. When did you last participate in one of these studies?

dd		MMM			yy		

If participant is currently participating in another investigational drug, device, or vaginal product research study, participant is ineligible. Otherwise, schedule enrollment when participant is no longer within 30 days of other study participation.

Screening Eligibility – Page 3 of 4 (nonDF)

No additional instructions needed.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

Participant ID

Site Number			Participant Number					Chk		

Screening Eligibility

- 21. Do you agree to not participate in any other research study that involves drugs, medical devices, or vaginal products?
- 22. From the day of your study enrollment, through one month after you finish your study participation, do you agree to use one of the following types of birth control: Depo-Provera ("the shot"), hormonal contraceptives ("the pill"), Ortho-Evra ("the patch"), an intrauterine device (IUD - inserted at least 30 days prior to enrollment), female sterilization, or have vaginal sex with a male partner who has had a vasectomy?
- 23. Are you willing to use the study products, which are tenofovir oral tablets and tenofovir 1% vaginal gel, once a day as directed by study staff?
- 24. Are you willing to attend all scheduled study visits?
- 25. Are you willing to undergo all study evaluations, including a pelvic exam, urine testing, and blood draws?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>

If no to any, participant is ineligible.

Complete item 26 when Screening urine hCG result is available.

- 26. Is the participant pregnant?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If yes, participant is ineligible.

- 27. Does the participant have any other condition that, in the opinion of the site investigator, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study objectives, or otherwise interfere with achieving study objectives?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If yes, participant is ineligible.

Screening Eligibility – Page 4 of 4 (nonDF)

Item-specific Instructions:

- **Item 22:** If the participant's chosen effective method of contraception is sterilization (of participant or her sexual partner(s)), participant self-report is acceptable and sufficient documentation in order to enroll the participant.
- **Item 26:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Screening Visit urine hCG result here.
- **Item 27:** This item is NOT interviewer-administered and should not be read aloud to the participant. This item should be completed by the site investigator or his/her designee once the Screening Visit has been completed. If, for some reason other than those listed on any of the screening forms, the investigator or designee feels the participant is **not** a good candidate for the study, mark the "yes" box, record the reason in the participant's chart notes, and do not enroll the participant in the study.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

Page 1 of 2

Participant ID

Site Number			Participant Number						Chk	

Screening Summary

Form Completion Date

dd		MMM			yy		

1. Is the participant eligible based on review of all screening data? ^{yes} ^{no}

→ **If yes, end of form.**

2. The participant is ineligible because she: *Mark all that apply.*
 - 2a. is not between the ages of 18 and 45 at screening
 - 2b. is not able and willing to provide written informed consent to be screened for and/or to take part in the study
 - 2c. is not in general good health, as determined by the site investigator of record or designee
 - 2d. is HIV-infected
 - 2e. has an abnormal Pap test result
 - 2f. is not sexually active (has not had vaginal intercourse at least four times in the four weeks prior to screening)
 - 2g. is unwilling to use an effective method of contraception (as defined in the protocol) from enrollment through one month after study exit
 - 2h. has had an IUD inserted in the 29 days prior to enrollment
 - 2i. is unwilling to undergo all study-related assessments (clinical and laboratory)
 - 2j. is unwilling to adhere to follow-up visit schedule
 - 2k. is unwilling to use tenofovir oral tablets and/or tenofovir 1% vaginal gel as directed by study staff
 - 2l. does not agree to refrain from participation in another study that involves drugs, medical devices, or vaginal products during study participation
 - 2m. has had more than three male sex partners in the month prior to screening
 - 2n. is using or plans to use acyclovir, valacyclovir, post-exposure prophylaxis for HIV exposure, Truvada, or non-study vaginal products (other than tampons) during study participation
 - 2o. does not have a predictable menstrual cycle
 - 2p. is not willing or able to provide adequate locator information
 - 2q. has a history of adverse reaction to latex
 - 2r. has a male sex partner with a history of adverse reaction to latex
 - 2s. is using or plans to use a diaphragm, vaginal ring, and/or spermicide for contraception during study participation

Screening Summary – Page 1 of 2 (nonDF)

This form is used to document the participant's eligibility for the study based on the entire screening process. This form is completed once all Screening Visit evaluations and forms/documentation have been completed and reviewed. If a participant is found to be ineligible at the Screening or Enrollment Visit (prior to randomization), use this form to document the reason(s) the participant was not eligible for study participation. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

- **Item 2:** If the participant is NOT eligible for enrollment in the study, *mark all* of the listed reasons that apply:
 - **Item 2a:** Review **Screening Consent and Demographics** forms.
 - **Item 2b:** Review **Screening Consent and Enrollment** forms.
 - **Item 2c:** Review **Clinical Eligibility** form from the Screening and Enrollment Visits.
 - **Item 2d:** Review **Screening and Enrollment STI Laboratory Results** form from the Screening Visit, OR if an **HIV Test Results** form is completed at the Screening Visit, review the **HIV Test Results** form.
 - **Item 2e:** Review **Pelvic Laboratory Results** form from the Screening Visit.
 - **Item 2f:** Review **Screening Eligibility** form.
 - **Item 2g–2l:** Review **Screening Eligibility, and Enrollment Eligibility** forms.
 - **Item 2m:** Review **Screening Eligibility** form.
 - **Item 2n:** Review **Screening Eligibility, and Enrollment Eligibility** forms.
 - **Item 2o–2r:** Review **Screening Eligibility** form.
 - **Item 2s:** Review **Screening Eligibility, and Enrollment Eligibility** forms.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

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 Summary

- 2t. has a history of pathologic bone fracture, not related to trauma
- 2u. has a history of adverse reaction to either study product (tenofovir oral tablets, tenofovir 1% vaginal gel and/or applicator)
- 2v. has a history of prior participation in the study
- 2w. has a laboratory value or abnormality at screening that is exclusionary per protocol
- 2x. had a gynecological surgical procedure within 90 days of enrollment
- 2y. is pregnant or plans to become pregnant during the study period
- 2z. is within 90 days of last pregnancy outcome at enrollment
- 2aa. has an abnormal physical or pelvic exam finding that is exclusionary, per investigator or designee
- 2ab. is diagnosed with a current UTI, or an STI and/or other RTI requiring treatment according to WHO guidelines
- 2ac. has a significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory immunologic disorder or infectious disease, including active TB, or any other medical condition that is exclusionary, per site investigator
- 2ad. has a history of non-therapeutic injection drug use in the 12 months prior to screening
- 2ae. has participated in another study that involves drugs, medical devices or vaginal products in the 30 days prior to enrollment
- 2af. does not intend to have vaginal intercourse at least once per week during study participation
- 2ag. is breastfeeding
- 2ah. exceeded the 30-day screening window
- 2ai. has any other condition that, in the opinion of the Investigator, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives

Screening Summary – Page 2 of 2 (nonDF)

Item-specific Instructions:

- **Item 2t–2v:** Review **Screening Eligibility** form.
- **Item 2w:** Review **Safety Laboratory Results** form from the Screening Visit.
- **Item 2x–2z:** Review **Screening Eligibility and Enrollment Eligibility** forms.
- **Item 2aa:** Review **Screening and Enrollment Pelvic Exam** forms from both the Screening and Enrollment Visits; **and** the **Physical Exam** form; **and** the **Clinical Eligibility** form from both the Screening and Enrollment Visits.
- **Item 2ab–2ac:** Review **Clinical Eligibility** forms from both the Screening and Enrollment Visits.
- **Item 2ad:** Review **Screening Eligibility** form.
- **Item 2ae–2ag:** Review **Screening Eligibility and Enrollment Eligibility** forms.
- **Item 2ah:** Review **Screening Consent** form *and* date of enrollment as recorded on the **Enrollment** form.
- **Item 2ai:** Review **Screening Eligibility and Enrollment Eligibility** forms.

SAMPLE. Do NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

Participant ID

Site Number			Participant Number						Chk	

Enrollment Eligibility

Visit Date

dd		MMM		yy	

Complete item 1 before the interview.

1. Was the participant willing and able to provide a written informed consent for enrollment? **yes** **no** → *If no, participant is ineligible. End of form.*

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

2. In the past month (30 days), have you participated in any other research study that involves drugs, medical devices, or vaginal products? **yes** **no**

3. Are you breastfeeding? **yes** **no**

4. Do you plan to become pregnant during the 21 weeks of study participation? **yes** **no**

5. In the past 3 months (90 days), have you had any gynecological surgery? This would include such procedures as: dilation and curettage (D&C), surgery of the uterus, ovaries, or fallopian tubes (including tubal ligation), biopsy, or cryotherapy (freezing) of the cervix? **yes** **no**

6. Are you currently using, or do you plan to use a diaphragm, vaginal ring, and/or spermicide for birth control at any time during your study participation? **yes** **no**

7. Are you currently using, or do you plan to use acyclovir, valacyclovir, post-exposure prophylaxis for HIV exposure, Truvada, or non-study vaginal products (other than tampons) at any time during your study participation? **yes** **no**

8. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion? **yes** **no**

9. Have you had an intrauterine device (IUD) inserted in the past 29 days? **yes** **no** → *If yes to any, participant is ineligible.*

Enrollment Eligibility – Page 1 of 2 (nonDF)

This form is used to document the participant's eligibility for the study at enrollment. This is a mixed form—some of the items are interviewer-administered (items 2–15), while other items are not (items 1, 16–17). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

General Interviewer Tips:

Refer to the Study-Specific Procedures (SSP) Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.

It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

Item-specific Instructions:

- **Items 2–15:** These items were also asked during the Screening Visit. They must be asked again in order to confirm the participant's eligibility for the study per the inclusion/exclusion criteria stated in the protocol. If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 15. Do not inform her that she is ineligible for the study until the form has been administered. Also, refrain from indicating to the participant the reason why she is ineligible, to prevent socially desirable reporting.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

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 Eligibility

Visit Date

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

- 10. Do you agree to not participate in any other research study that involves drugs, medical devices, or vaginal products while participating in this study? *yes* *no*
- 11. Do you anticipate having vaginal sex at least once per week during your study participation? *yes* *no*
- 12. From today through one month after you finish your study participation, do you agree to use one of the following types of birth control: Depo-Provera ("the shot"), hormonal contraceptives ("the pill"), Ortho-Evra ("the patch"), an intrauterine device (IUD - inserted at least 30 days prior to enrollment), female sterilization, or have vaginal sex with a male partner who has had a vasectomy? *yes* *no*
- 13. Are you willing to use the study products, which are tenofovir oral tablets and tenofovir 1% vaginal gel, once a day as directed by study staff? *yes* *no*
- 14. Are you willing to attend all scheduled study visits? *yes* *no*
- 15. Are you willing to undergo all study evaluations, including a pelvic exam, urine testing, and blood draws? *yes* *no*

If no to any, participant is ineligible.

Complete item 16 when Enrollment urine hCG result is available.

- 16. Is the participant pregnant?..... *yes* *no*

If yes, participant is ineligible.

Complete item 17 after reviewing all Screening and Enrollment forms.

- 17. Does the participant have any other condition that, in the opinion of the site investigator, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study objectives, or otherwise interfere with achieving study objectives? *yes* *no*

If yes, participant is ineligible.

Enrollment Eligibility – Page 2 of 2 (nonDF)

Item-specific Instructions:

- **Item 12:** If the participant's chosen effective method of contraception is female sterilization or sexual activity with a vasectomized partner, participant self-report is sufficient documentation, per protocol, that this eligibility criterion has been met.
- **Item 16:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Enrollment Visit urine hCG result here.
- **Item 17:** This item is NOT interviewer-administered and should not be read aloud to the participant. This item should be completed by the site investigator or his/her designee once the Enrollment Visit procedures have been completed, but prior to study randomization. If, for some reason other than those listed on any of the screening forms, the investigator or designee feels the participant is **not** a good candidate for the study, mark the "yes" box, record the reason in the participant's chart notes, and do not enroll the participant in the study.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

Participant ID

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Site Number Participant Number Chk

Clinical Eligibility

Visit Date

--	--	--	--	--	--

dd *MMM* *yy*

1. At this visit, was the participant diagnosed by study staff with any of the following sexually transmitted infections (STIs) or reproductive tract infections (RTIs) requiring treatment per WHO guidelines:

- | | <i>yes</i> | <i>no</i> |
|---|--------------------------|--------------------------|
| 1a. chlamydia? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1b. gonorrhea? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1c. syphilis? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1d. symptomatic BV? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1e. symptomatic vaginal candidiasis (yeast)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1f. trichomoniasis? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1g. chancroid? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1h. genital HSV-1 or HSV-2 (active lesions)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1i. genital warts of the labia minora, vagina, or cervix, any other symptomatic genital warts, or genital warts exterior to the labia minora requiring treatment? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1j. cervicitis? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1k. other vaginitis? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1l. pelvic inflammatory disease (PID)? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1m. genital sores or ulcers? | <input type="checkbox"/> | <input type="checkbox"/> |
| 1n. any other STI or RTI requiring treatment? Specify:
_____ | <input type="checkbox"/> | <input type="checkbox"/> |

If yes to any, treat per protocol and SSP. Do not enroll participant until treatment is complete and all symptoms have resolved.

Clinical Eligibility – Page 1 of 2 (nonDF)

This form is completed at the Screening and Enrollment Visits only, and is used to document the participant's clinical eligibility for the study. It is completed once at the Screening Visit, and again at the Enrollment Visit. For the Screening Visit, this form is completed once the screening pelvic exam and wet mount have been conducted. For the Enrollment Visit, this form is completed once the enrollment pelvic exam and wet mount have been conducted. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: *Because a participant is not eligible for enrollment if she is currently diagnosed with any of the UTIs/STIs/RTIs on this form, and because the Pre-existing Conditions form only documents ongoing conditions at the time of enrollment, none of the UTIs/STIs/RTIs recorded on this form should be documented on the Pre-existing Conditions form.*

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Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

Participant ID

Site Number			Participant Number						Chk	

Clinical Eligibility

2. At this visit, was the participant diagnosed with a urinary tract infection (UTI)?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If yes, treat per protocol and SSP. Do not enroll participant until treatment is complete and all symptoms have resolved.

3. At this visit, does the participant have a clinically apparent pelvic exam finding (observed by study staff) involving Grade 2 or higher genital lesions, erythema, and/or edema?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

4. At this visit, does the participant have any other abnormal physical or pelvic exam finding that, in the opinion of the investigator or designee, would exclude her from the study?

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

5. At this visit, does the participant have any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease, including active tuberculosis, or any other medical condition that, in the opinion of the site investigator, could make participation unsafe for the participant?

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

If yes to any, participant is ineligible at this time. End of form.

6. Is the participant in general good health, as determined by the site Investigator of Record or designee?

yes	no
<input type="checkbox"/>	<input type="checkbox"/>

If no, participant is ineligible. End of form.

Comments: _____

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	21-APR-08
--------------------------	--------------------------	--------------------------	-------------------------------------	-----------

0	1
Language	

13-153
Staff Initials / Date

Clinical Eligibility – Page 2 of 2 (nonDF)

No additional instructions needed.

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Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

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	

Physical Exam

Exam Date

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

VITAL SIGNS

1. Were vital signs done?..... *yes* *no* → **If no, specify reason in Comments.**

Weight kg BP / mmHg

Height cm Pulse per minute

Oral Temp . °C Respirations per minute

Vital Signs: _____ Staff Initials / Date

FINDINGS

not evaluated *normal* *abnormal* **Items 2 and 3 are required. If not evaluated or abnormal, please specify.**

2. General appearance _____

3. Abdomen _____

Items 4-15 are optional. If abnormal, please specify.

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: _____

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

Findings: _____ Staff Initials / Date

Comments: _____

Physical Exam (nonDF)

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 in the space provided.
- **Findings:** The staff member who completes these items should initial and date in the space provided.
- **Items 2 and 3:** These items are required when a physical exam is performed.
- **Items 4–15:** These items are optional.
- **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 001 (146)

Participant ID

- -

Site Number Participant Number Chk

Pelvic Exam Diagrams

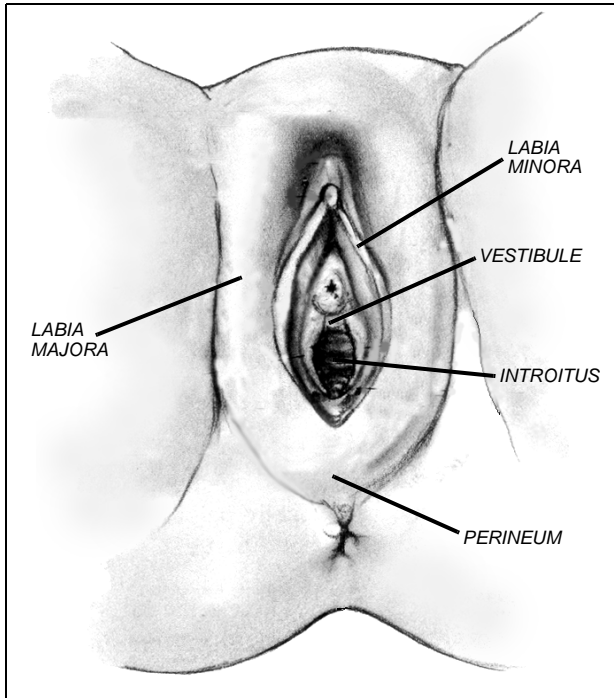
no normal variants or abnormal findings observed

Exam Date

/ /

dd MMM yy

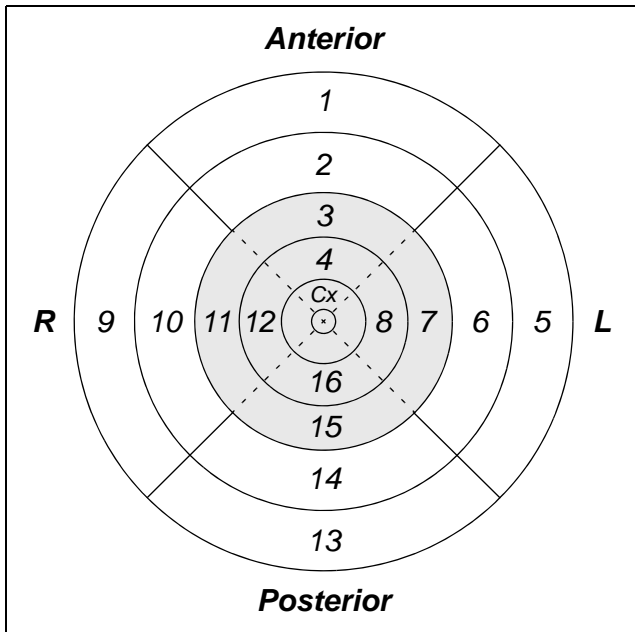
External Genitalia



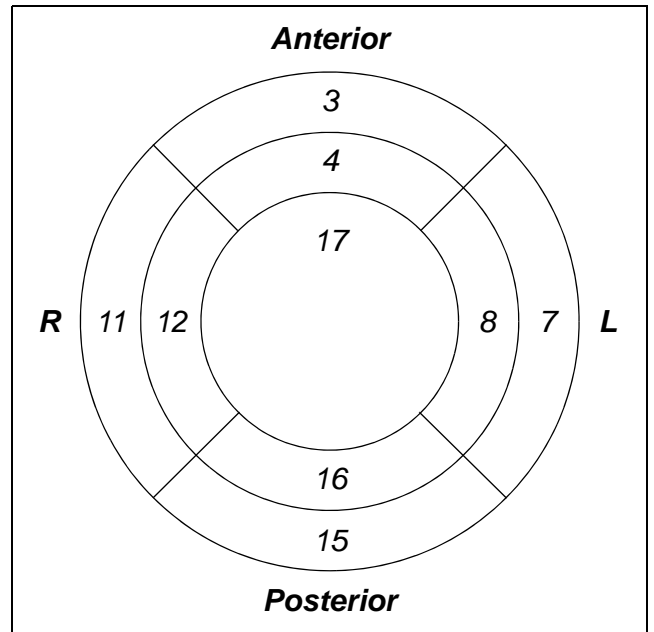
Legend for Vagina/Cervix

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



Pelvic Exam Diagrams – Page 1 of 1 (nonDF)

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 exam is performed unless the site is using another document as source for the pelvic exam. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Item-specific Instructions:

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

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

Participant ID

Site Number			Participant Number					Chk			

Follow-up Medical History Log

Page

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Medical Condition	Onset Date (dd- MMM -yy)	Staff Initials/Log Entry Date	Is this condition reportable as an AE? yes no <input type="checkbox"/> <input type="checkbox"/>		
	Outcome Date (dd- MMM -yy)	Severity Grade	AE Log Page # <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td></tr></table>		
Comments					

Medical Condition	Onset Date (dd- MMM -yy)	Staff Initials/Log Entry Date	Is this condition reportable as an AE? yes no <input type="checkbox"/> <input type="checkbox"/>		
	Outcome Date (dd- MMM -yy)	Severity Grade	AE Log Page # <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td></tr></table>		
Comments					

Medical Condition	Onset Date (dd- MMM -yy)	Staff Initials/Log Entry Date	Is this condition reportable as an AE? yes no <input type="checkbox"/> <input type="checkbox"/>		
	Outcome Date (dd- MMM -yy)	Severity Grade	AE Log Page # <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td></tr></table>		
Comments					

Medical Condition	Onset Date (dd- MMM -yy)	Staff Initials/Log Entry Date	Is this condition reportable as an AE? yes no <input type="checkbox"/> <input type="checkbox"/>		
	Outcome Date (dd- MMM -yy)	Severity Grade	AE Log Page # <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td><td style="width: 30px; height: 20px;"></td></tr></table>		
Comments					

Follow-up Medical History Log (non-DataFax)

This form is used to track symptoms reported by the participant during a study follow-up. This form is also used to track symptoms ongoing at Enrollment.

Review this log at every visit. If a condition has no outcome date listed, assess the status of that condition at the current visit and update the entry as needed.

Once the participant's Enrollment Visit is completed, record any ongoing symptoms (ongoing at the time of Enrollment) onto this form. Review each of these symptoms at the participant's first follow-up visit and update the entries as needed.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers.
- **Medical Condition:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms.
- **Onset Date:** At a minimum, month and year are required.
- **Outcome Date:** At a minimum, month and year are required. Record one of the following, as appropriate:
 - the date on which the participant no longer experiences the medical condition,
 - the date of the study visit or specimen collection at which the change in status/outcome is first noted, or
 - if condition is continuing at end of study, record "CES" in the space provided.
- **Severity:** To determine the severity, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences*. If a symptom increases in severity, record the date the severity increased as the "Outcome date", and record a new entry for the symptom with the increased grade.
- **Is this condition reportable as an AE:**
 - Refer to the protocol for AE reporting criteria.

SAMPLE *DO NOT FAX TO DATAFAX*

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

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	

Genital Bleeding Assessment

Visit Date

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

This form should not be completed for pregnant participants. This form is completed whenever an episode of unexpected genital bleeding is self-reported by the participant and/or clinically observed with no identifiable source. Completion of this form is not required for episodes of expected genital bleeding.

1. First day of participant's last menstrual period: **OR** *amenorrheic*

Obtain from Follow-up Medical History form.

If amenorrheic, go to item 4.
2. Last day of participant's last menstrual period:

Obtain from Follow-up Medical History form.
3. Length in days of participant's last menstrual period (based on dates recorded in items 1 and 2): days
4. First day of genital bleeding episode:

Per participant report or clinical exam.
5. Last day of genital bleeding episode: **OR** *ongoing*
6. Total number of days of genital bleeding: days **OR** *ongoing*
7. According to the participant, was the amount of genital blood a normal amount, lighter amount, or heavier amount when compared to the heaviest flow day of her regular menses?

<i>normal</i>	<i>lighter</i>	<i>heavier</i>	<i>unknown</i>	<i>N/A</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. According to the participant or the clinician, what color was the genital blood? *Mark "unknown," or all that apply.*

<i>bright red</i>	<i>brown</i>	<i>unknown</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. According to the participant, did she continue to use study gel during this genital bleeding episode?

<i>yes</i>	<i>no</i>	<i>N/A</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If yes or N/A, go to item 11 on page 2.

Genital Bleeding Assessment – Page 1 of 3 (nonDF)

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 review the Baseline Medical History form and refer to the Study-Specific Procedures (SSP) Manual 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 genital bleeding episode occurred during the oral study period or during one of the one-week washout periods (between Weeks 6 and 7, Weeks 13 and 14, and Weeks 20–21). Also mark “NA” if the participant is in the vaginal or dual use study periods, but her vaginal tenofovir gel use was already held or discontinued due to another reason.

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Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

Participant ID

Site Number			Participant Number						Chk	

Genital Bleeding Assessment

10. Number of days between last application of study gel 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. application of the study gel?	<input type="checkbox"/>	<input type="checkbox"/>	N/A
11d. painful or uncomfortable application of the study gel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11e. painful or uncomfortable insertion or removal of any other vaginal product/preparation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11f. 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.

11g. 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? **Go to item 14 on page 2.**

13. Is the participant currently using (non-injectable) hormonal contraceptives? *Review Concomitant Medications Log.* yes no **If no, go to item 14 on page 2.**

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 on page 2.**

Genital Bleeding Assessment – Page 2 of 3 (nonDF)

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.
- **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.

SAMPLE. DO NOT FAX TO DATAFAX

Not a DataFax form. Do not fax to DataFax.

MTN 001 (146)

Participant ID

Site Number			Participant Number						Chk	

Genital Bleeding Assessment

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.**

14b. Record Adverse Experience Log page: AE Log Page #

Comments: _____

Genital Bleeding Assessment – Page 3 of 3 (nonDF)

Item-specific Instructions:

- **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 Assessment form and refer to the Study-Specific Procedures (SSP) Manual 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 (as documented on the Baseline Medical History form). Refer to the 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 SSP for further information.
- **Item 14b:** Record the AE Log page number of the AE reported for this unexpected genital bleeding episode. When determining the relationship to study product, carefully review the information recorded in items 11–13c of this form. Record information relevant to the product relatedness determination in the Comments section of the AE Log.

MTN 001 Africa Sites - LDMS Specimen Tracking Sheet

For login of MTN 001 stored specimens into LDMS

MTN 001 – Africa Sites - LDMS Specimen Tracking Sheet (non-DataFax)

Purpose: This non-DataFax form is used to document collection and entry of MTN 001 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 LDMS specimens were collected.
- **Specimen Type:** For the post-dose blood and CVL specimens, circle the collection timepoint used for these specimens.
- **NUMBER OF TUBES or SPECIMENS COLLECTED:** In the box to the left of each primary additive type, record the total number of tubes or specimens collected. If no LDMS specimens of the primary specimen type were collected, record "0".
- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials - Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date - LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

Participant ID			Visit Code	Specimen Collection Date		
[][] - [][][][] - []			[][] . []	[][]	[][][]	[][]
Site Number	Participant Number	Chk		<i>dd</i>	<i>MMM</i>	<i>yy</i>

SPECIMEN TYPE/VISIT	PRIMARY SPECIMEN TYPE	TIME COLLECTED hh:mm 24-hr clock	NUMBER of TUBES or SPECIMENS COLLECTED (Primary additive)	INSTRUCTIONS FOR PROCESSING LAB
Enrollment	Cervicovaginal Lavage (CVL)	<i>Not applicable</i>	<input type="checkbox"/> NSL (saline)	Keep on ice or refrigerate until specimen is frozen long term. Centrifuge and Freeze supernatant within 8 hours of collection. Store with derivative CVL.
Plasma for storage	Blood (BLD)	<i>Not applicable</i>	<input type="checkbox"/> EDT (Purple top)	Store as plasma with derivative PL 1/2.

PK Specimens

Mid-period Visit	Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
Pre-dose	Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
1 Hour	Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.
2 Hour	Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.
	Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.

Initials: _____ LDMS Data Entry Date: [][] / [][][] / [][] _____
 Sending Staff Receiving Staff *dd* *MMM* *yy* LDMS Staff

Purpose: This non-DataFax form is used to document collection and entry of MTN 001 specimens (US sites only) 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 LDMS specimens were collected.
- **NUMBER OF TUBES or SPECIMENS COLLECTED:** In the box to the left of each primary additive type, record the total number of tubes or specimens collected. If no LDMS specimens of the primary specimen type were collected, record "0."
- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials - Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date - LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.

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"/> <small>Site Number Participant Number Chk</small>		Visit Code <input type="text"/> <input type="text"/> . <input type="text"/>		Specimen Collection Date <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <small>dd MMM yy</small>		
SPECIMEN TYPE/VISIT	PRIMARY SPECIMEN TYPE	TIME COLLECTED hh:mm 24-hr clock	NUMBER of TUBES or SPECIMENS COLLECTED (Primary additive)	INSTRUCTIONS FOR PROCESSING LAB		
4 Hour	Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.		
	Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.		
6 Hour	Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.		
	Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.		
8 Hour	Blood (BLD) Tenofovir Level		<input type="checkbox"/> Non (red top)	Transport to lab and process within eight hours. Freeze immediately after centrifugation. Store with derivative SER.		
	Blood (BLD) PBMC		<input type="checkbox"/> CPS (CPT Tube)	The time from blood draw to centrifugation and lysis should be eight hours or less. Store with derivative CEL.		
<i>Circle correct time point:</i>	Cervicovaginal Lavage (CVL)		<input type="checkbox"/> NSL (saline)	Keep on ice or refrigerate until specimen is frozen long term. Centrifuge and Freeze supernatant within 8 hours of collection. Store with derivative CVL.		
Pre-dose						
___ Hour	Cervical cytology brush (CER)		<input type="checkbox"/> PBS	Keep on ice or refrigerate until processing for storage. Freeze within 8 hours of collection. Store with derivative CTB.		
	Vaginal tissue (VGL)		<input type="checkbox"/> NON	Keep on ice or refrigerate until specimen is frozen long term. Freeze within 8 hours of collection. Store with derivative TIS. Enter location of biopsies in specimen comments.		

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

Item-specific Instructions:

- **Visit Code:** Check to make sure the Visit Code recorded on page 1 and page 2 match.
- **Specimen Type:** For the three PK genital specimens listed at the bottom of the table, record the time point of collection of these specimens. For example, 2, 4, or 6-Hour. For genital specimens collected pre-dose, circle “Pre-dose”.
- **NUMBER OF TUBES or SPECIMENS COLLECTED:** In the box to the left of each primary additive type, record the total number of tubes or specimens collected. If no LDMS specimens of the primary specimen type were collected, record “0.”
- **Initials – Sending Staff:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab, records his/her initials here.
- **Initials - Receiving Staff:** The laboratory staff person who received this form (and the LDMS specimens accompanying the form), records his/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS specimens listed on this form were entered into LDMS.
- **LDMS Data Entry Date - LDMS Staff:** The LDMS laboratory staff person who entered the specimens into LDMS, records his/her initials here.