Section 14. Data Collection

This section provides information needed to successfully complete and submit MTN-003 case report forms (CRFs). It is important for sites to collect and record data carefully on CRFs; by doing so, the Statistical and Data Management Center (SDMC) can be confident that the data they are analyzing are accurate and complete. For questions about this section or about general data collection policies, procedures, or materials, please contact Karen Patterson (karen@scharp.org).

For this study, the SDMC is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, WA, USA, and is in the US Pacific Time (PT) time zone. The SCHARP MTN-003 team members, along with their job roles and e-mail addresses, are listed below.

Role on MTN-003	Name	E-mail Address
Protocol Statisticians	Benôit Mâsse	bmasse@scharp.org
	Barbra Richardson	barbra@scharp.org
Project Manager	Karen Patterson	karen@scharp.org
Statistical Research Associates	Cliff Kelly	cwkelly@scharp.org
	Sharavi Gandham	sharavi@scharp.org
	Joleen Borgerding	jborgerd@scharp.org
Clinical Affairs Safety Associate	Molly Swenson	molly@scharp.org
Protocol Programmers	Jami Moksness	jami@scharp.org
	Hongli Li	hongli@scharp.org
	Martha Doyle	mdoyle@scharp.org
ACASI Programmer	Lynda McVarish	lmcv@scharp.org
Reports Programmer	Drew Edwards	drew@scharp.org
Laboratory Programmer	Della Wilson	della@scharp.org
Data Coordinators	Jennifer Schille	jens@scharp.org
	Craig Silva	csilva@scharp.org
Document Specialist	Stacie Kentop	stacie@scharp.org

14.1 DataFax Overview

DataFax is the data management system used by SCHARP to receive and manage data collected at study sites. The site faxes an electronic image of each case report form (CRF) to SCHARP DataFax, and the original hard copy 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 sites 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 a site has technical questions or problems with their fax equipment or transmitting data to SCHARP.

Data Entry/Quality Control

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

- DataFax identifies the study to which each CRF belongs using the barcode at the top of the form. It reads and enters the data into the study database and stores each CRF on a computer disk.
- Each CRF is then reviewed by at least two members of SCHARP's Data Operations Group. Problems such as missing or potentially incorrect data are identified and marked with Quality Control notes (QCs).
- QCs are compiled into QC reports that are sent via e-mail to the study site on a regular basis. Sites are asked to correct or clarify any problems identified on the QC reports and refax the corrected CRFs to SCHARP DataFax.
- When the re-faxed pages are received, SCHARP staff review the corrected pages and resolve the QCs as appropriate.

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

14.2 DataFax Form Completion

14.2.1 General Guidelines

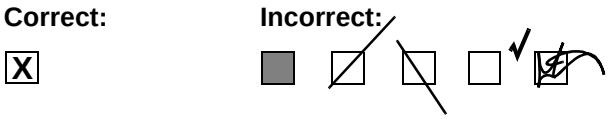
Based on the use of fax technology and Good Clinical Practices (GCPs), follow the guidelines below when completing DataFax CRFs:

- Read carefully and follow all form instructions, which are printed on the back of each form
- 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 margins at the top, bottom, or sides of the CRF.
- Record written text responses on the lines provided. If additional space is needed, continue writing the response 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 the 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.
- Review completed CRFs, per local site SOP(s), for completeness and accuracy prior to faxing to SCHARP DataFax
- Fax CRFs 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. **Adverse Experience (AE) Log and Product Hold/Discontinuation (PH) Log CRFs are priority, as they are used for purposes of study safety monitoring; they should be faxed to SCHARP, ideally, within one working day of site awareness of the event/hold/discontinuation.**

14.2.2 How to Mark Response Boxes

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



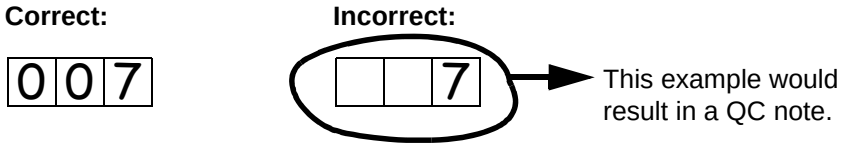
Mark only one response box for each item unless the “Mark all that apply” instruction is present.

14.2.3 How to Record Numbers

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

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

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



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

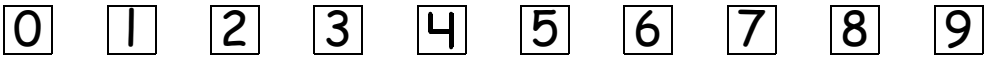
In the following example, the 4 could be misinterpreted as a 7 or a 1 because DataFax can only read what is *inside* the box:

Correct: **Incorrect:**

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

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

  Easily Identified:



  Difficult to Identify:

14.2.4 How to Record Dates

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

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

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

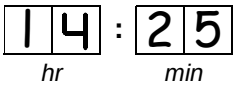
For example, September 8, 2009 is recorded as:

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

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

14.2.5 How to Record Time

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



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

The following chart shows equivalencies between the 12- and 24-hour clocks. Please note that 12:00am is often referred to as “midnight” and 12:00pm is often referred to as “noon”.

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

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

14.2.6 Data Corrections and Additions

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

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

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

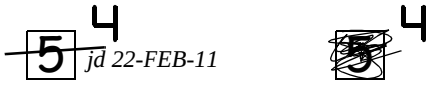
Note: Never write over an entry once it is recorded. Use the standards outlined in the following paragraphs when changing, clarifying, or amending data.

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

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),

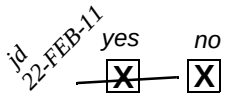
- place the correct or clarified answer near the box, and initial and date the correction as shown below:

Correct: **Incorrect:**



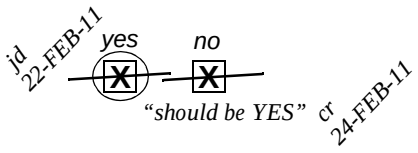
If an **X** is marked in the wrong response box, correct it by doing the following:

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



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

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

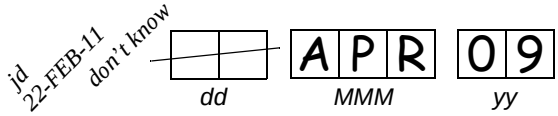


For regulatory purposes, the standards above must ***always*** be followed whenever a CRF is changed, clarified, or amended, even if the change is made ***before*** the CRF is faxed to SCHARP for the first time.

14.2.7 How to Handle Missing and Unknown Data

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

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



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

14.3 MTN-003 Study-Specific Data Collection Information

14.3.1 Participant ID numbers (PTIDs)

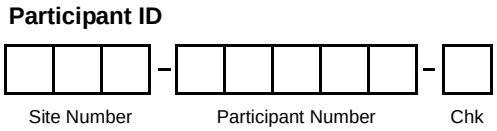
DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. SCHARP provided each site with a list of PTIDs, prior to study start-up, in the form of a PTID-Name Link Log. The site should assign one PTID to each participant screened for the study. Ideally, the PTIDs are assigned in sequential order as participants present for the Screening Part 1 Visit. The site should ensure that each PTID is assigned only once. Once a participant has received a PTID, she will maintain that same PTID throughout the entire study.

Note for sites participating in MTN-003B: The PTID that is assigned to a participant in MTN-003 will be the same PTID that is used for MTN-003B (see Section 18 for more information).

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

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

The PTIDs used for this study are nine digits long and are formatted as "XXX-YYYYY-Z." The three parts of the PTID are: the site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The check digit (Z) is a number generated by SCHARP using a mathematical algorithm based on the participant number, and helps ensure that the correct PTID is recorded. Below is an example of the PTID structure used in MTN-003.



14.3.2 Study Visit Timing

Screening and Enrollment

There are two Screening visits required prior to Enrollment into MTN-003. Screening Part 1 may take place up to 56 days prior to Enrollment. Multiple visits may be conducted to complete all required screening procedures if necessary. If more than one visit is needed to complete all required procedures, procedures not completed at the Screening Part 1 visit may be performed on the same day as Screening Part 2. Multiple visits may also be conducted to complete all required procedures for Screening Part 2, if necessary. The initial screening visit is defined as the day the participant provides written informed consent to be screened for the study. The Enrollment Visit must take place no later than 56 days after the initial screening visit.

For MTN-003, a participant is considered enrolled once the participant has been assigned a MTN-003 Clinic Randomization Envelope. Assignment of MTN-003 randomization envelopes will be documented using the MTN-003 Clinic 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 be invited to re-screen for the study, per discretion of the Investigator of Record or designee. 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, the same 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 should be faxed to SCHARP.

Follow-Up Visits

Participants in MTN-003 will have monthly, quarterly, semiannual, and annual follow-up visits while they are in the study. Follow-up visits are targeted to take place every 28 days based on the date of enrollment. The number of follow-up visits will vary by participant. Each participant is expected to have a minimum of 12 months and a maximum of 36 months of study product use. In addition, each participant will have approximately 8 weeks off study product followed by one final follow-up visit, the Study Exit/ Termination Visit.

For a maximum of 36 months of study product use, the visit type, visit code, target visit day, and visit windows are listed in Table 14-1 below.

Product Use End Visit and Study Exit/Termination Visit

The last two scheduled visits for each participant are referred to as the Product Use End Visit (PUEV) and the Study Exit/Termination Visit. The PUEV will serve as the participant's last routine monthly follow-up visit. The study month when the PUEV is completed will vary for each participant, based on when a participant *terminates* from the study (and not necessarily when a participant permanently discontinues her use of study product).

- For participants who remain in study follow-up through their expected study product use end date, the Product Use End Visit (PUEV) is conducted when the participant is *expected* to permanently discontinue study product use. For example, a participant is expected to remain on study product for the maximum time allowed per protocol (36 months). If the participant remains in study follow-up through Month 36, she completes her PUEV at Month 36. This is true regardless of whether or not the participant permanently discontinued study product use prior to Month 36.

- For participants who terminate early from the study, prior to their expected product use end date, the final study visit is considered the PUEV. For example, a participant is expected to remain on study product for the minimum amount of time allowed per protocol (12 months). The participant presents to the site clinic for her Month 3 Visit and informs study staff that she no longer wants to participate in the study. If the participant is willing, study staff conduct at this time one final study visit, which counts as the participant's PUEV (Month 3). All protocol-specified PUEV procedures should be conducted at this visit. Regardless of whether or not the participant permanently discontinued study product use prior to Month 3, the Month 3 Visit counts as her PUEV. Participants who choose to terminate early from the study will not complete the protocol-specified Study Exit/Termination visit.

SCHARP will monitor study endpoints closely throughout the study. When the study begins to near the desired number of HIV endpoints, the Protocol Team will inform site staff when the study will be completed (study end date), and therefore, when the PUEV should be conducted for the remaining participants in study follow-up.

For each participant who remains in follow-up for the expected duration, the scheduled Study Exit/ Termination visit will take place approximately 8 weeks after the target date of her PUEV.

Table 14-1: List of MTN-003 Visits, Visit Codes, Target Visit Dates, and Visit Windows

All visit windows are listed in days.

Visit	Visit Code	Visit Window Opens	Target Day	Visit Window Closes
Screening Part 1	1.0	Up to day -56	Not applicable	Not applicable
Screening Part 2	2.0	Not applicable	Not applicable	Day -1
Enrollment	3.0	Not applicable	**0**	56 days after screening consent date
Month 1	4.0	14	**28**	41
Month 2	5.0	42	**56**	69
Month 3	6.0	70	**84**	97
Month 4	7.0	98	**112**	125
Month 5	8.0	126	**140**	153
Month 6	9.0	154	**168**	181
Month 7	10.0	182	**196**	209
Month 8	11.0	210	**224**	237
Month 9	12.0	238	**252**	265
Month 10	13.0	266	**280**	293
Month 11	14.0	294	**308**	321
Month 12	15.0	322	**336**	349
Month 13	16.0	350	**364**	377
Month 14	17.0	378	**392**	405
Month 15	18.0	406	**420**	433
Month 16	19.0	434	**448**	461
Month 17	20.0	462	**476**	489
Month 18	21.0	490	**504**	517
Month 19	22.0	518	**532**	545
Month 20	23.0	546	**560**	573
Month 21	24.0	574	**588**	601
Month 22	25.0	602	**616**	629
Month 23	26.0	630	**644**	657
Month 24	27.0	658	**672**	685
Month 25	28.0	686	**700**	713
Month 26	29.0	714	**728**	741
Month 27	30.0	742	**756**	769
Month 28	31.0	770	**784**	797
Month 29	32.0	798	**812**	825

Visit	Visit Code	Visit Window Opens	Target Day	Visit Window Closes
Month 30	33.0	826	**840**	853
Month 31	34.0	854	**868**	881
Month 32	35.0	882	**896**	909
Month 33	36.0	910	**924**	937
Month 34	37.0	938	**952**	965
Month 35	38.0	966	**980**	993
Month 36	39.0	994	**1008**	1021
Product Use End Visit (PUEV)*	will vary	PUEV target day-14 days	will vary	PUEV target day +13 days
Scheduled Study Exit/Termination**	89.0	Termination target day -14 days	PUEV target day +56 days	Study end date

** If a participant chooses to terminate early from the study, her final study visit is considered her PUEV.*

*** Use the visit code, target day, and visit windows of the follow-up month (as listed in the table above) in which the scheduled Study Exit/Termination Visit occurs.*

Target Days and Visit Windows

Ideally, visits will be completed on the target day for the visit. Follow-up visits in MTN-003 are targeted to occur every 28 days following the participants enrollment date into the study (Enrollment = Day 0). Target dates are set based on the enrollment date and do not change if subsequent actual visits take place before or after the target date. Since the visit windows in MTN-003 are contiguous, visits may only be completed within the visit window. Completed visits will appear on the MTN-003 Retention Report as being completed "on-time".

It is not always possible to complete a study visit on the target day. Therefore, follow-up visits may be completed within an approximate 4-week window around the target date (-14 days and +13 days from the target date). For example, if a participant enrolls into MTN-003 on 14 February 2011, her month 1 target date is 28 days later, on 14 March 2011. However, she can complete her Month 1 visit any time during the 4-week window, which opens between 28 February 2011 and closes 27 March 2011. For participants who do not complete scheduled visits within the visit window, the visit will be considered "missed" and relevant CRFs will be completed to document the missed visit.

SCHARP has provided sites with an Excel spreadsheet tool that may be used to generate individual participant follow-up visit calendars. Once the enrollment date is entered into the spreadsheet, the target day and visit windows for the participant's follow-up visits will appear and can then be printed and added to the participant's study notebook. The calendar tool provides target dates for each of the monthly follow-up visits, up to the maximum 36 months of study product use. The calendar tool also calculates the target date and visit windows for the scheduled Study Exit/Termination Visit, based on entry of the expected PUEV date.

There is no specific "Day Target Window Closes" for the Study Exit/Termination Visit. Study staff should make every effort to complete a participant's Study Exit/Termination Visit 8 weeks (56 days) after her PUEV. However, if this is not possible, a woman can still return to the site clinic to complete her Study Exit/Termination Visit even though more than 8 weeks have passed since her PUEV. Sites should continue to make reasonable efforts to contact participants and complete the Study Exit/Termination Visit up until the study end date, as determined by SCHARP.

Split Visits

Split visits are allowed for all visits except the Enrollment Visit. All Enrollment Visit procedures must be conducted on the same day, with two exceptions: informed consent for enrollment may take place at a prior date within the 56-day screening window, and informed consent for specimen storage may occur as late as the Month 3 visit.

In cases where a participant is not able to complete all required screening or follow-up visit evaluations on the same day, the participant may return and complete the remaining evaluations on another day - as long as the evaluations are completed within the visit window. For example, if a participant comes in on her Month 6 target day and completes all required evaluations except for the pelvic exam (she is on menses), she can return up to 13 days later (once she is off menses) to complete the pelvic exam and have the pelvic exam be considered part of the same Month 6 Visit.

Certain visit procedures, such as ACASI and behavioral CRFs, must be completed on one date, and cannot be split across multiple dates. For example, if a participant starts an ACASI survey then is unable to complete it, and plans to return the next day to complete the visit (hence, a split visit), the next day (or whenever the participant is able to return within the visit window) the ACASI survey must be restarted and completed in its entirety. In addition, it is strongly preferred that other study procedures or evaluations, such as pharmacy procedures (product returns/re-supplies/re-issues) are completed on the same day.

See section 14.3.3 for information on assigning visit codes to split visits.

Missed Visits

In cases where a participant is not able to complete *any* part of a required visit within the visit window, the visit is considered missed. For example, if a participant who enrolls in MTN-003 on 14 February 2011 shows up for her Month 1 Visit on 30 March 2011, her Month 1 Visit is considered missed, as she is now in the visit window for her Month 2 Visit. The site documents the missed Month 1 Visit by completing a Missed Visit case report form.

Interim Visits

A clinic visit is considered an Interim Visit when a participant presents at the site for reasons *other* than to complete regularly scheduled study visit procedures. Interim visits may be performed at any time during the study for reasons that may be administrative (a participant has study-related questions for the staff), product-related (a participant needs additional study product), lab-related (a participant needs a safety lab test repeated for confirmation), or clinical in nature (a participant needs management and/or follow-up of an AE), etc.

NOTE: *not all interim visits are assigned interim visit codes. An interim visit should be assigned an interim visit code only if 1) data collected at the visit warrants completion of a new DataFax form, such as an AE Log or Product Hold/Discontinuation (PH) Log form, or 2) product use was previously held and is now being resumed, resulting in an update to the PH Log form (items 4-4a). An Interim Visit form must be completed for each and every visit that is assigned an interim visit code. See section 14.3.3. below for instructions on how to assign interim visit codes.*

Below are examples of interim visits in MTN-003.

1. A participant completes all required evaluations for her Month 1 Visit. She then returns to the site clinic, within the Month 1 visit window, requesting additional study product to replace the study product she lost. An Interim Visit, Product Re-supply and Re-issues, and Product Returns CRF are completed and assigned interim visit code 04.1.

2. A participant completes all required evaluations for her Month 2 Visit within the visit window. She then returns to the clinic within the same Month 2 visit window to request a pregnancy test. An Interim

Visit CRF is completed, the pregnancy test result is recorded on the form, and interim visit code 05.1 is assigned.

3. A participant completes her Month 3 Visit on the target day. Her lab test results indicate that she has an abnormal serum creatinine level. Seven days later, she returns to the clinic for an interim visit to repeat the creatinine test. An Interim Visit and Safety Laboratory Results CRF are completed and assigned interim visit code 06.1.

4. A participant enrolls on 02-MAR-11. She returns to the site clinic two days later (04-MAR-11) requesting additional study product to replace lost study product. Since the participant's Month 1 visit window has not yet opened, the site conducts an interim visit to re-supply the participant with study product. An Interim Visit, Product Re-supply and Re-issues, and Product Returns CRF are completed and assigned interim visit code 03.1. The site then schedules the participant to return to the clinic on her Month 1 target date to complete her Month 1 Visit.

Phone contact with a participant is also considered an Interim Visit, and is assigned an interim visit code, if 1) the phone contact results in reporting of a new Adverse Event (AE), or 2) during the phone contact, the participant is instructed by site staff to hold, discontinue, or resume product use (after a product hold has been initiated). Below are examples of phone contacts that qualify as interim visits and are assigned interim visit codes.

1. A participant completes her Month 2 Visit on the target day. The next day (still within the Month 2 window), she calls the clinic to report a new symptom, which results in the reporting of a new adverse experience. The phone contact is considered an interim visit. The Interim Visit and AE Log CRF are completed and are assigned interim visit code 05.1.

2. A participant completes her Month 3 Visit within the visit window. The site clinic receives her lab report two days later, and it shows a lab value that warrants a study product hold. The site clinician calls the participant, instructs her to hold study product, and asks her to return to the site clinic as soon as possible for repeat testing and to return unused study product. Thus, the phone contact is considered an interim visit. The Interim Visit And Product Hold/Discontinuation Log CRF are completed and are assigned interim visit code 06.1.

For questions about interim visits, please contact the SCHARP MTN 003 Project Manager.

14.3.3 Visit Codes and Page Numbers

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

Site staff are responsible for entering the visit code in the boxes provided in the upper right corner of each page. For CRFs with multiple pages, site staff need to make sure that all the pages of the CRF are marked with the same visit code for a given participant and visit.

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

Table 14-2: Visit Code Assignments for Study Visits

Visit Type	Visit Code
Screening Part 1	01.0
Screening Part 2	02.0
Enrollment	03.0
Month 1	04.0
Month 2	05.0
Month 3 (Quarterly Visit)	06.0
Month 4	07.0
Month 5	08.0
Month 6 (Semiannual Visit)	09.0
Month 7	10.0
Month 8	11.0
Month 9 (Quarterly Visit)	12.0
Month 10	13.0
Month 11	14.0
Month 12 (Annual Visit)	15.0
Month 13	16.0
Month 14	17.0
Month 15 (Quarterly Visit)	18.0
Month 16	19.0
Month 17	20.0
Month 18 (Semiannual Visit)	21.0
Month 19	22.0
Month 20	23.0
Month 21 (Quarterly Visit)	24.0
Month 22	25.0
Month 23	26.0
Month 24 (Annual Visit)	27.0
Month 25	28.0

Table 14-2: Visit Code Assignments for Study Visits

Visit Type	Visit Code
Month 26	29.0
Month 27 (Quarterly Visit)	30.0
Month 28	31.0
Month 29	32.0
Month 30 (Semiannual Visit)	33.0
Month 31	34.0
Month 32	35.0
Month 33	36.0
Month 34	37.0
Month 35	38.0
Month 36	39.0
Product Use End Visit	Varies
Scheduled Termination Visit	89.0

Visit Code Assignments for the Product Use End Visit and Study Exit/Termination Visit

The Product Use End Visit (PUEV) is assigned the visit code of the study month in which it is completed. For example, if a participant completes her PUEV at Month 33, then the PUEV is assigned the Month 33 visit code (36.0). If a participant terminates early from the study and completes her PUEV at Month 7, then her PUEV is assigned the Month 7 visit code (10.0).

For DataFax purposes, the scheduled Study Exit/Termination Visit is always assigned visit code 89.0.

Visit Codes for Split Visits

When split visits occur, the case report forms completed for the visit are all assigned the same visit code (even though some forms and evaluations will have different visit dates). For example, a participant goes to the site clinic for her Month 3 Visit on the target date, 25-MAY-11, and completes all required evaluations except for the blood draw (she had a family emergency and needed to leave the visit early). She returns to the site clinic on 01-JUN-11 (still within the Month 3 visit window) to complete the blood draw. All case report forms completed on 25-MAY-11 and 01-JUN-11 are assigned visit code 06.0, since they were all completed to document Month 3 visit procedures.

Visit codes for Interim Visits

In addition to the scheduled, protocol-required visits listed in Table 14-1, interim visits may occur once a participant is enrolled in the study. Interim visit codes are assigned using the guidelines listed below.

- In the boxes to the left of the decimal point, record the two-digit visit code for the most recent scheduled visit whose visit window has closed (regardless of 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 weeks after her Month 3 Visit (done on the target date) for a repeat blood draw to follow-up on an abnormal lab result. Since it is early in her Month 4 visit window, study staff decide to wait until closer to the Month 4 target date to complete the Month 4 Visit. At this time, only a repeat blood draw is done. The visit is considered an interim visit and is assigned the interim visit code below.

Visit Code for this Interim Visit:

Visit Code 0 6 . 1

Page numbers

Other CRFs, such as log forms (e.g., Adverse Experience Log, Product Hold/Discontinuation 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). For example, the second Concomitant Medications Log page would be assigned page number 02, the third page would be assigned 03, and so on.

14.3.4 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 completing the form. This individual will complete the staff initials/date field. The individual not identified in the staff initials/date field writes his/her initials and date next to each data element for which he/she is responsible.

14.3.5 Case Report Form Completion Schedule

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

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. Table 14-3 lists the DataFax and non-DataFax forms that are **required** to be completed at each MTN-003 study visit.

Table 14-3: MTN-003 Case Report Form Completion Schedule

SCREENING PART 1 (DAY -56)	VISIT CODE: 01.0
Form Acronym	**Form Name**
REQUIRED	
DEM	Demographics
SC	Screening Consent
SEH	Screening and Enrollment HIV Test Results
SLR	STI Laboratory Results
SL	Safety Laboratory Results
Non-DataFax	Screening Part 1 Eligibility

SCREENING PART 2 (BETWEEN DAY -56 and DAY 0)	VISIT CODE: 02.0
Form Acronym	**Form Name**
REQUIRED	
SPE	Screening and Enrollment Pelvic Exam
VTR	Vaginal Test Results
SS	Specimen Storage/PK
CM	Concomitant Medications Log
CL	Contraceptives Log
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Baseline Medical and Menstrual History
Non-DataFax	Physical Exam
Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Screening Part 2 Medical Eligibility
Non-DataFax	Screening Part 2/Enrollment Behavioral Eligibility
AS NEEDED	
SL	Safety Laboratory Results
SLR	STI Laboratory Results
PTR	PAP Test Result

Enrollment (Day 0)	VISIT CODE: 03.0
Form Acronym	**Form Name**
REQUIRED	
PRE	Pre-existing Conditions
SEH	Screening and Enrollment HIV Test Results
FPB	Baseline Family Planning
BBA	Baseline Behavior Assessment
ENR	Enrollment
SS	Specimen Storage/PK
Non-DataFax	Screening Part 2/Enrollment Behavioral Eligibility
Non-DataFax	Enrollment Medical Eligibility
Non-DataFax	LDMS Specimen Tracking Sheet
AS NEEDED	
SPE	Screening and Enrollment Pelvic Exam
VTR	Vaginal Test Results
SL	Safety Laboratory Results
Non-DataFax	Pelvic Exam Diagrams

Monthly Visits - Months 1, 2, 4, 5, etc.	VISIT CODES: 04.0, 05.0, 07.0, 08.0, etc.
Form Acronym	**Form Name**
REQUIRED	
PRD	Product Re-supply and Re-issues
PRT	Product Returns

FV	Follow-up Visit
FHT	Follow-up HIV Rapid Test Results
SL	Safety Laboratory Results (required only at first monthly visit)
FPF	Follow-up Family Planning
MBA	Monthly Product Adherence and Behavior Assessment
MS	Monthly Symptoms
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam (required only at first monthly visit)
AS NEEDED	
ICC	Ongoing Informed Consent Comprehension
SLR	STI Laboratory Results
VTR	Vaginal Test Results
PTR	Pap Test Results
FPE	Follow-up Pelvic Exam
SCR	Seroconverter Laboratory Test Results
SS	Specimen Storage/PK
HTR	HIV Western Blot Test Results
PH	Product Hold/Discontinuation Log
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
MV	Missed Visit
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Genital Bleeding Assessment

Quarterly Visits - Months, 3, 9, 15, 21, 27 **VISIT CODES: 06.0, 12.0, 18.0, 24.0, 30.0**

Form Acronym	Form Name
REQUIRED	
PRD	Product Re-supply and Re-issues
PRT	Product Returns
FV	Follow-up Visit
FHT	Follow-up HIV Rapid Test Results
SL	Safety Laboratory Results
FPF	Follow-up Family Planning
SS	Specimen Storage/PK
OPA	Oral Product Adherence and Behavior Assessment (for participants in oral arm only)
VPA	Vaginal Product Adherence and Behavior Assessment (for participants in vaginal arm only)
MS	Monthly Symptoms
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
AS NEEDED	
SLR	STI Laboratory Results
VTR	Vaginal Test Results
PTR	Pap Test Results
FPE	Follow-up Pelvic Exam
SCR	Seroconverter Laboratory Test Results
HTR	HIV Western Blot Test Results
PH	Product Hold/Discontinuation Log
AE	Adverse Experience Log

PR	Pregnancy Report and History
PO	Pregnancy Outcome
MV	Missed Visit
Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Genital Bleeding Assessment

Semiannual Visits - Months 6, 18, 30, 33	**VISIT CODES: 09.0, 21.0, 33.0, 36.0**
Form Acronym	**Form Name**
REQUIRED	
PRD	Product Re-supply and Re-issues
PRT	Product Returns
FV	Follow-up Visit
FHT	Follow-up HIV Rapid Test Results
VTR	Vaginal Test Results
FPE	Follow-up Pelvic Exam
SL	Safety Laboratory Results
FPF	Follow-up Family Planning
SS	Specimen Storage/PK
OPA	Oral Product Adherence and Behavior Assessment (for participants in oral arm only)
VPA	Vaginal Product Adherence and Behavior Assessment (for participants in vaginal arm only)
MS	Monthly Symptoms
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
Non-DataFax	Pelvic Exam Diagrams
AS NEEDED	
SLR	STI Laboratory Results
PTR	Pap Test Results
SCR	Seroconverter Laboratory Test Results
HTR	HIV Western Blot Test Results
PH	Product Hold/Discontinuation Log
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
MV	Missed Visit
Non-DataFax	Genital Bleeding Assessment

Annual Visits - Months 12, 24	**VISIT CODES: 15.0, 27.0**
Form Acronym	**Form Name**
REQUIRED	
PRD	Product Re-supply and Re-issues
PRT	Product Returns
FV	Follow-up Visit
SLR	STI Laboratory Results
FHT	Follow-up HIV Rapid Test Results
VTR	Vaginal Test Results
FPE	Follow-up Pelvic Exam
SL	Safety Laboratory Results
FPF	Follow-up Family Planning
SS	Specimen Storage/PK
OPA	Oral Product Adherence and Behavior Assessment (for participants in oral arm only)

VPA	Vaginal Product Adherence and Behavior Assessment (for participants in vaginal arm only)
MPS	Menstrual Practices and Study Disclosure Assessment
MS	Monthly Symptoms
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
Non-DataFax	Pelvic Exam Diagrams
AS NEEDED	
PTR	Pap Test Results
SCR	Seroconverter Laboratory Test Results
HTR	HIV Western Blot Test Results
PH	Product Hold/Discontinuation Log
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
MV	Missed Visit
Non-DataFax	Genital Bleeding Assessment

Product Use End Visit (PUEV)

Form Acronym	Form Name
REQUIRED	
PRD	Product Re-supply and Re-issues
PRT	Product Returns
FV	Follow-up Visit
SLR	STI Laboratory Results
FHT	Follow-up HIV Rapid Test Results
VTR	Vaginal Test Results
PTR	Pap Test Results (for sites with capacity and/or where local standard of care)
FPE	Follow-up Pelvic Exam
SL	Safety Laboratory Results
FPF	Follow-up Family Planning
SS	Specimen Storage/PK
OPA	Oral Product Adherence and Behavior Assessment (for participants in oral arm only)
VPA	Vaginal Product Adherence and Behavior Assessment (for participants in vaginal arm only)
MPS	Menstrual Practices and Study Disclosure Assessment
PPA	Perceived Product Assessment
PEV	Product Use End Visit
MS	Monthly Symptoms
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
Non-DataFax	Pelvic Exam Diagrams
AS NEEDED	
SCR	Seroconverter Laboratory Test Results
HTR	HIV Western Blot Test Results
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
Non-DataFax	Genital Bleeding Assessment

	<u>Note</u>: If a participant terminates early from the study and does not complete PUEV procedures as part of a final study visit, complete only the PPA and PEV forms. Do not complete a Missed Visit form or any other CRFs for this visit.

Scheduled Termination/Study Exit

Form Acronym	Form Name
REQUIRED	
FHT	Follow-up HIV Rapid Test Results
FPF	Follow-up Family Planning
SS	Specimen Storage/PK
SEV	Study Exit Visit
MPS	Menstrual Practices and Study Disclosure Assessment
SBA	Study Exit Behavior Assessment
MS	Monthly Symptoms
ESI	End of Study Inventory
TM	Termination
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
AS NEEDED	
SLR	STI Laboratory Results
VTR	Vaginal Test Results
PTR	Pap Test Results
FPE	Follow-up Pelvic Exam
SCR	Seroconverter Laboratory Test Results
SL	Safety Laboratory Results
HTR	HIV Western Blot Test Results
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Genital Bleeding Assessment
	<u>Note</u>: If a participant terminates early from the study, the scheduled Study Exit/Termination Visit is *not* done. Complete only the SEV, TM, and ESI forms. Do not complete a Missed Visit form or any other CRFs for this visit.

Interim Visit

Form Acronym	Form Name
REQUIRED	
IV	Interim Visit
AS NEEDED	
PRD	Product Re-supply and Re-issues
PRT	Product Returns
SLR	STI Laboratory Results
FHT	Follow-up HIV Rapid Test Results
VTR	Vaginal Test Results

PTR	Pap Test Results (for sites with capacity and/or where local standard of care)
FPE	Follow-up Pelvic Exam
SCR	Seroconverter Laboratory Test Results
SL	Safety Laboratory Results
FPF	Follow-up Family Planning
SS	Specimen Storage/PK
MS	Monthly Symptoms
HTR	HIV Western Blot Test Results
PH	Product Hold/Discontinuation Log
AE	Adverse Experience Log
PR	Pregnancy Report and History
PO	Pregnancy Outcome
Non-DataFax	LDMS Specimen Tracking Sheet
Non-DataFax	Participant-reported Follow-up Medical and Menstrual History
Non-DataFax	Physical Exam
Non-DataFax	Pelvic Exam Diagrams
Non-DataFax	Genital Bleeding Assessment

14.3.6 Site Review of DataFax Forms

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

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

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

Important: If a date stamp is used to document when a form is faxed to SCHARP DataFax, 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 re-faxes.

14.3.7 Faxing DataFax Forms

To streamline the submission of DataFax forms, each site has designated in their Data Management SOP the staff members who are 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 003 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-mail listings: 1) a listing of the number of form pages received at SCHARP; and 2) a listing of the specific forms that were received at SCHARP for a given PTID and visit. All MTN003 sites have registered to use CTS. Please contact the MTN-003 Project Manager for questions or if you would like for more information.

14.3.8 Non-DataFax Forms

MTN-003 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 same form completion guidelines described in sections 14.3.1 through 14.3.4 apply when completing non-DataFax CRFs.

14.4 Form Supply and Storage

14.4.1 Form and Specimen Label Supply

The case report forms requiring completion at each visit are supplied to sites in form visit packets. One packet contains all of the required CRFs for a given visit. For example, the Enrollment Visit packet contains all of the CRFs listed as "required" for the Enrollment Visit in the Case Report Form Completion Schedule (Table 14-3). In addition to form visit packets, bulk supplies of "as needed" CRFs (for example, the Pregnancy Report and History form, Pregnancy Outcome form, and Genital Bleeding Assessment form, etc.) are provided to each site.

SCHARP also ensures that sites have access to primary specimen labels (either printed on-site or printed by SCHARP). It is strongly recommended that SCHARP-provided specimen labels be used for all primary specimen collection containers. Please refer to the Laboratory section of the SSP for more information on laboratory specimen collection and labeling.

14.4.2 Form Storage

Specifications for form storage are detailed in the site's MTN-003 Data Management SOP. It is recommended that study staff store each participant's CRFs in a hard-cover notebook designated as the participant's study notebook. SCHARP has provided a template for sites' optional use in creating

notebook cover labels and spine labels. At sites' request, SCHARP can also provide a template that sites can use to create tab dividers for the notebooks.

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

14.5 Completing Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize data quality, it is critical that site staff 1) complete interviewer-administered forms in a consistent manner from participant to participant 2) do not influence a participant's answer, and 3) help a participant feel comfortable enough to share personal information and opinions. By doing so, site staff help ensure that the data they collect is honest, accurate, and unbiased.

In MTN-003 there are ten total interviewer-administered forms. Two of these are non-DataFax forms: the Screening Part 1 Eligibility form and the Screening Part 2/Enrollment Behavioral Eligibility form. The rest are DataFax forms: the Baseline Behavior Assessment, Oral Product Adherence and Behavior Assessment, Vaginal Product Adherence and Behavior Assessment, Menstrual Practices and Study Disclosure Assessment, Study Exit Behavior Assessment, Perceived Product Assessment, Monthly Product Adherence and Behavior Assessment, and Monthly Symptoms form.

Note: *if a participant misses one or more regularly scheduled study visits, the missed behavioral CRF(s) should* ***not*** *be made up at her next study visit. When she presents for her next study visit, simply administer the behavioral CRF(s) required for that visit only.For example, a participant misses her Month 3 visit. When she comes in for her Month 4 visit, administer the Monthly Product Adherence and Behavior Assessment CRF only; do* ***not*** *administer the Oral/Vaginal Product Adherence and Behavior Assessment CRF that she missed at her Month 3 visit; the data is considered missing once the Month 3 visit window has closed.*

The DataFax interviewer-administered forms come with a Question by Question (Q x Q) guide, provided at the end of Section 14 of this SSP Manual, which provides specific guidelines on how to administer those forms. In addition to the guidance in the Q x Q, below are general interviewing tips and techniques that site staff can use to 1) obtain a participant's medical history, 2) encourage a participant to answer a question she might have trouble answering, and 3) probe a participant for additional information as needed.

Welcoming the Participant

- When a new participant arrives at the clinic, always make the participant feel comfortable.
- Introduce yourself, and try to create a rapport (connection) with her to help her feel comfortable during the interview.
- Let the participant know that you will be talking to her about personal and sensitive topics as part of the visit. Some DataFax forms include introduction statements before certain items to help prepare the participant for sensitive questions. Read each of these introductions aloud as they appear on the forms.

Asking Sensitive Questions

All microbicide studies involve asking sensitive questions (such as questions about sexual behaviors). Your level of comfort with asking sensitive questions will affect the participant's level of comfort with answering the questions. 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 are aware that you are asking her 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.

Pacing the Interview

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

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 other participants' interviews. 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.

For items with multiple sub-items, read all sub-items to the participant and record the appropriate response for each, based on participant report. Do not read response categories aloud unless the CRF specifically instructs to do so for the given item.

Vary your tone of voice so that you don't sound automated. Emphasize the important words in a given item, so that the participant understands the meaning of the question she is asked. When given the option, choose "clinical" versus "street" or "vernacular" language based on participant preferences/cues.

Probing

Participants may not remember or know the answer to every question they are asked. 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 to allow for adequate documentation.

- **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 respond more precisely. Always repeat the participant's response in a neutral, non-judgmental way.
- **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 she considers accurate, it may not be specific enough for purposes of form completion. For example, an item asks for the exact number of times the participant did something and she answers with a range ("5 to 10"). In this case, the probe, "Can you be more specific?" is often enough to help the participant give 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 specific 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. As needed, encourage the participant to respond by reminding her of the confidential nature of the interview and the importance of the information. In addition, remind her that there is no right or wrong answer to each question.

When to Skip Product Adherence Questions

Completion of a behavioral/adherence assessment CRF (MBA for monthly visits, and OPA/VPA for quarterly and PUEV visits) is required for all participants, including participants on product hold/discontinuation, per the schedule in Table 14-3. While the forms are required, the form questions on product adherence may be skipped in certain instances for participants who are on a site-initiated product hold/discontinuation, or who have chosen to stop using product and no longer receive product supplies. Specifically, if a participant did **not** have any unused study product in her possession, including any expired product, during the time frame in question (past 7 days for the MBA and past 4 weeks for the OPA/VPA), then the product adherence questions should be skipped per the form skip pattern. If a participant had unused product in her possession (including any expired product) during the time frame in question, then the product adherence questions should be administered; even if the participant did not use any study product or was not supposed to use any study product (due to a site-initiated product hold/discontinuation) during the time frame in question. For example, the Oral Product Adherence and Behavior Assessment (OPA) and Vaginal Product Adherence and Behavior Assessment (VPA) CRFs ask about product use in the past 4 weeks. If the participant had unused study product in her possession in the past 4 weeks, then sites should administer the product adherence questions. If the participant did not have study product in her possession in the past 4 weeks (for example, product was not dispensed to her at her last study visit because it was held by the site or because she refused it), then the adherence questions should be skipped; site staff should follow the skip pattern on the CRF and administer the remaining questions on the form.

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 as well as the Q x Q, if applicable. Make sure the participant understands what you are asking and responds accordingly. 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 the interview - *even if she is still at the site completing other visit procedures* - any missing responses will be considered missing data.** The

rationale is two-fold. First, all interviewer-administered CRFs are source documents (with the participant being the source of the data). Second, participant product adherence and risk-reduction counseling, which occurs after the interview, has the potential to bias participant responses by encouraging socially desirable reporting, Thus, missing items cannot be completed once the participant has left the interview. For items identified as "missing", please line through the response boxes, write "missing" in the white space next to the item, and initial and date.

14.6 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. Item-specific instructions are provided only for those items requiring additional clarification for purposes of form completion. Below is additional form-specific guidance to address some common data issues encountered in the study to date.

Pre-existing Conditions, Concomitant Medications Log, Contraceptives Log, Product Hold/ Discontinuation Log and **Adverse Experience Log** case report forms.

- Each time a new entry is added or an existing entry is modified, fax the form page to SCHARP DataFax - even if the page is not complete. Do **not** wait to complete all entries on a page before faxing it to SCHARP DataFax.
- When recording injections (e.g., Hepatitis B vaccine, Depo-Provera) on the Concomitant Medications Log or Contraceptives Log, record each injection as its own separate entry. The "Date Started" and "Date Stopped" dates should be the same date. Mark the "once" box for "Frequency" and the appropriate box for "Route" (e.g., "IM", or "Other" for subcutaneous injections).

Safety Laboratory Results (SL) form

- Depending on a site's normal reference ranges, it is possible that a participant can have a value that falls within the normal range, but is still gradable per the DAIDS Toxicity Table. Always refer to the DAIDS Toxicity Table when determining whether or not a lab value is gradable and should be reported as an AE.
- If a lab value is gradable per the DAIDS Toxicity Table, regardless of whether the specimen was collected at screening, enrollment, or during follow-up, record the severity grade in the "**Severity Grade**" box. Record the "**AE Log Page** #" if the gradable lab value is reportable as a stand-alone AE (e.g., "proteinuria"), or is part of a clinical AE (e.g., "urinary tract infection"). If a gradable lab value does not meet the criteria for AE reporting (i.e., the specimen was collected at screening or enrollment, or the severity grade represents an ongoing pre-existing condition), mark the "**Not Reportable as an AE**" box. If a severity grade is recorded in the "Severity Grade" box, either an "AE Log Page **#**" must be recorded, or the "Not reportable as an AE" box must be marked. The same "AE Log Page #" may be recorded for the same item on SL forms completed at different visits, for example, if a lab value AE persists at the same severity across study visits.

Adverse Experience Log (AE Log)

- Complete the AE Log form only for AEs that meet reporting requirements, per protocol section 8.2. **Fax AE Log pages** to SCHARP as soon as they are completed; **ideally, within one working day of site awareness of the event.** Do **not** wait until a given AE resolves before faxing the form page to SCHARP. In most cases, when you first report the AE the AE Log form will have a "continuing" status (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 items 6 and 6a of the **original** AE Log form page. Initial and date all additions, and any other changes made to the form page, then 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 appears).

- For item 1, note that planned procedures or surgeries are **not** AEs. The underlying condition that warranted the procedure or surgery constitutes the AE. In addition, any adverse consequence of the planned procedure or surgery is considered an AE and should be recorded on an AE Log form if reportable per protocol.
- For the "**Date Reported to Site"** field, record the date site clinic staff first become aware of the AE. If an AE is an abnormal exam finding, the "Date Reported to Site" is the exam date. If an AE is a participant-reported symptom, the "Date Reported to Site" is the date the participant first tells a site staff member about the given symptom. If the AE is an abnormal laboratory value, the "Date Reported to Site" is the date the result is received at the site clinic.
- For **item 3**, the Female Genital Grading Table for Use in Microbicide Studies (FGGT) is used to assign severity grades to AEs (in addition to the DAIDS "Tox. Table").
- For **item 4**, note that if "not related" is marked, you need to record a rationale or alternative etiology 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 7**, note that if the AE results in a new or prolonged hospitalization, the AE meets the criteria for a "serious" AE, and item 8 of the AE Log form should be marked "yes".
- There may be situations where an AE Log form needs to be deleted (for example, in the case where a condition is thought to be an AE and is later determined to have been pre-existing, or in the case where multiple AEs are later subsumed under a single diagnosis). To mark an AE Log form for deletion, draw a diagonal line across the entire AE Log 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 completed for the participant, if any. Do not renumber AE Log pages after faxing unless specifically instructed to do so by SCHARP.
- For **item 10,** record the Visit Code that is assigned to the date recorded in the "Date Reported to Site" field. AEs of gradable lab results are the one exception, as it is expected that site clinic staff may receive some lab results after the date of specimen collection (see the bullet below).
- For AEs of gradable lab results (e.g., "Increased ALT"), the date the lab report is received at the site clinic 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 next follow-up specimen that yields one of the following: 1) a non-gradable result, 2) a return to baseline severity, or 3) a result of increased severity (thus requiring completion of a new AE Log). For **item 10**, record the visit code that is assigned to the specimen collection date; this should be the same visit code that is assigned to the AE "Onset Date".

Product Returns (PRT) form

- This form is complete by transcribing source information from the Unused Product Returns Slip (version 2), which is completed by the site pharmacists. This form is required at each monthly visit through the PUEV, regardless of whether or not the participant returns unused product at the visit. In addition, this form is required at interim visits where product is returned due to a product hold/discontinuation, and at interim visits where product is re-supplied or re-issued (regardless of whether or not the participant returns unused product at the visit).

HIV Western Blot Test Results (HTR) form

- Typically, SCHARP instructs sites to wait until all test results are received and recorded on a lab results CRF before the CRF is faxed to SCHARP. However, since HIV infection is a primary endpoint in VOICE, fax

expectations differ for the HIV Western Blot Test Results form. If HIV Western Blot (WB) testing is required during study follow-up, complete item 1 on the HIV Western Blot Test Results form as soon as the Sample 1 WB result is received, and fax the completed form to SCHARP. Update the form and refax it to SCHARP each time a new test result is received, and when item 4 is completed. This process allows SCHARP to track a site's progress in following the HIV testing algorithm, and to identify cases where further site support or guidance is needed.

Data Expectations for Seroconverters

- Participants confirmed HIV-infected per the protocol testing algorithm are expected to have plasma storage, CD4 and HIV RNA PCR testing completed 1 month, 3 months, 6 months, and every 6 months thereafter (for the duration of follow-up) following the date of seroconversion (Sample 1 collection date). The 1-month post-seroconversion specimen collection and tests may be omitted if the window has elapsed before the site has confirmed the participant's HIV status per the algorithm.
- The 1-month post-seroconversion specimen collection is expected to occur within the window (-14/+13) of the next regularly scheduled monthly visit. For example, a participant has Sample 1 collected at Month 3 and has a positive rapid HIV test result. She is confirmed HIV-infected per the algorithm 2 weeks later. The site is expected to collect the 1-month post-seroconversion specimens within the Month 4 visit window. The windows for the specimen collections required 3 months, 6 months, and every 6 months thereafter following the date of seroconversion are based on the MTN015 visit windows. Sites are encouraged to use the MTN015 visit window calculator tool, posted on the MTN015 Study Implementation Materials web page (http://www.mtnstopshiv.org/node/468) to calculate these windows for participants who have seroconverted in VOICE. If a participant enrolls in MTN015, all post-seroconversion specimen collections will cease in the context of VOICE.
- Participants confirmed HIV-infected per the protocol testing algorithm are still expected to complete regularly scheduled monthly visits, with certain procedures omitted per protocol section 7.6.1. The post-seroconversion specimen collections and testing are additional requirements that are expected to be completed in the context of these visits, when appropriate.

Follow-up Family Planning (FPF) form

- Record dates for items 3-4 on the FPF form (first and last day of last menstrual period) *only* if the participant started a new menstrual cycle since her last completed visit (meaning, the first day of her last menstrual period is on or after the date of her last completed visit). Record the dates of the most recent menstrual cycle. If the participant is currently menstruating at the time of the visit, line through the item 4 date field, write "currently menstruating" underneath, and initial/date. If the participant did not **start** a new menstrual cycle since her last completed visit (meaning, the first day of her last menstrual period is prior to the date of the last completed visit), mark the "no menses since last visit" box and leave the item 3 and 4 date fields blank.

Product Hold/Discontinuation Log (PH) form

- Complete the PH Log CRF only for instances in which *site staff* initiate a new product hold or discontinuation at an unscheduled time point. Do not complete this CRF for participants who voluntarily choose to hold or discontinue study product use, as this represents participant non-adherence (and will be captured via ACASI, on the behavioral/adherence CRFs, and via the "Reason" code in item 2 on the Product Re-supply and Re-issues form if the participant refuses to receive further study product supplies). Also, do not complete the PH Log CRF at the Product Use End Visit (scheduled or early termination), as all participants are expected to permanently discontinue study product use at the PUEV.

Monthly Symptoms (MS) form

- When completing the MS form, consider only the period of time from the last visit in which the form was administered through the current visit date. For example, at her Month 6 visit a participant reports ongoing fatigue that she has experienced continually for the past two months. She reported the fatigue at her last visit

(Month 5) 28 days ago, when the Monthly Symptoms form was administered. At the current visit, record the “number of days” the participant experienced the fatigue as “28”.

14.7 Case Report Forms

This section contains each MTN-003 case report form developed for the study. The forms are organized in alphabetical order, with the DataFax forms appearing first, followed by the non-DataFax forms. 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 (in alphabetical order)

Non-DataFax Forms

SAMPLE: DO NOT FAX TO DATAFAX

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

MTN003 VOICE (160) AE-1 (460)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Adverse Experience Log

Date Reported to Site

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Adverse Experience (AE)

_____

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

2. Onset Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

3. Severity

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

4. Relationship to Study Product

- ☐ Related
- ☐ Not related

Record rationale or alternative etiology in Comments.

5. Study Product Administration

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

6. Status/Outcome

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

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

→ ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

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

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

		yes	*no*
8.	Is this an SAE according to ICH guidelines?	☐	☐
9.	Has/will this AE be reported as an EAE?	☐	☐
10.	At which visit was this AE first reported? ..... *Visit code required (regular or interim).*	☐☐.☐	
11.	Was this AE a worsening of a pre-existing condition?	☐	☐

Comments: _____

_____

_____

☐ ☐ ☐ ☒ 14-MAY-10

0 1
Language

Staff Initials / Date

Adverse Experience Log (AE-1)

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

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

Item-specific instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) BBA-1 (060)

Participant ID

Site Number – Participant Number – Chk

Baseline Behavior Assessment

Visit Date

dd MMM yy

Thank you for coming today for the study. As part of this research study, you will be asked questions about yourself, your sexual behaviors and reproductive health. We are all concerned about HIV/AIDS and how it is affecting women in our community. Your participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so please be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential, and none of your answers will affect your ability to participate in this research study.

1. Have you talked with any of the following people about your participation in this research study? You can answer "yes" to more than one item.

		yes	no	N/A
1a.	Your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
1b.	Other sex partners?	☐	☐	☐
1c.	Your mother or father?	☐	☐	☐
1d.	Your sister or brother?	☐	☐	☐
1e.	Other family member?	☐	☐	☐
1f.	A friend or neighbor?	☐	☐	☐
1g.	A nurse or clinician or doctor outside of the study?	☐	☐	☐
1h.	An elder or community leader?	☐	☐	☐
1i.	Anyone else? If yes, specify:	☐	☐	☐

Local Language: _____ *English:* _____

Baseline Behavior Assessment (BBA-1)

Purpose: This form is used to collect baseline information about the participant's sexual behaviors and vaginal hygiene practices. This is a mixed form; items 1–6e are interviewer-administered, and items 7–9a are not. This form is administered only once to each enrolled participant as part of her Enrollment visit.

Item-specific Instructions:

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

- **Item 1:** Read each item 1a–1i aloud and mark the participant's answer. If "yes" is marked for item 1i, record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) BBA-2 (061)

Participant ID

Site Number – Participant Number – Chk

Baseline Behavior Assessment

The next few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

2. In the **past 4 weeks** have you had vaginal sex? ..... *yes* ☐ *no* ☐ → ***If no, go to item 4.***

The next question is about vaginal sex in the **past 7 days**.

3. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... *# of acts* ☐☐ → ***If 00, go to item 4.***

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

3a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ***Use visual aid.*** *# of acts with condom* ☐☐ → ***If 00, go to statement above item 5.***

4. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** *yes* ☐ *no* ☐ → ***If no, go to statement above item 5.***

4a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... *male condom* ☐ *female condom* ☐

The next questions are about your menstrual period and items women sometimes insert inside their vagina for personal hygiene or other reasons.

5. In the **past 3 months**, have you had a menstrual period? ..... *yes* ☐ *no* ☐ → ***If no, end of interview. Go to statement above item 7 on page 3.***

Baseline Behavior Assessment (BBA-2)

Item-specific Instructions:

- **Item 3:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record “00” for this item.
- **Item 3a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record “00” for this item.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) BBA-3 (062)

Participant ID

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

Site Number Participant Number Chk

Baseline Behavior Assessment

6. In the **past 3 months**, what have you used during your menstrual period? You can answer "yes" to more than one item.

		yes	*no*
6a.	Paper or cloth or cotton wool—put inside the vagina?	☐	☐
6b.	Paper or cloth or cotton wool—placed in underwear?	☐	☐
6c.	Tampon?	☐	☐
6d.	Sanitary pad?	☐	☐
6e.	Anything else? If yes, specify:	☐	☐

Local Language: _____ *English:* _____

This is the end of this part of the interview. Thank you for taking the time to answer these questions.

***Interviewer**: Please complete items 7–9a below by transcribing data from the participant's Screening Part 1 Eligibility form (non-DataFax).*

7. *Screening Part 1 Eligibility form, item 6: .....* [ ][ ] *# of vaginal sex acts*

→ ***If 00, go to item 9.***

8. *Screening Part 1 Eligibility form, item 7: .....* [ ][ ] *# of vaginal sex acts with condom*

		yes	*no*
9.	*Screening Part 1 Eligibility form, item 8: .....*	☐	☐ → ***If no, end of form.***

		male condom	*female condom*
9a.	*Screening Part 1 Eligibility form, item 8a: .....*	☐	☐

Baseline Behavior Assessment (BBA-3)

Item-specific Instructions:

- **Item 6:** Read each item 6a–6e aloud and mark the participant's answer. If “yes” is marked for item 6e be sure to record the participant's verbatim response. Also provide the English translation in the space provided.
- **Items 7, 8, 9, and 9a:** These items are not interviewer-administered. These items must be completed by transcribing data from the participant’s Screening Part 1 Eligibility form (non-DataFax). For items 7 and 8, use leading zeros when needed so that all the boxes are filled.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) FPB-1 (055)

Participant ID ☐☐☐-☐☐☐☐☐-☐
Site Number Participant Number Chk

Baseline Family Planning

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1. What method(s) of contraception/family planning is the participant currently using? *Mark "none" or all that apply.*

- ☐ 1a. none → ***If none, participant is ineligible, end of form.***
- ☐ 1b. vaginal ring
- ☐ 1c. spermicide
- ☐ 1d. diaphragm
- ☐ 1e. sponge

→ ***Participant is ineligible.***

- ☐ 1f. intrauterine device (IUD)
- ☐ 1g. oral contraceptives/birth control pills
- ☐ 1h. injectable contraceptives (such as Depo-Provera)
- ☐ 1i. (Ortho Evra) The Patch
- ☐ 1j. implants

→ ***Record on Contraceptives Log.***

- ☐ 1k. female condoms
- ☐ 1l. natural methods such as the withdrawal or rhythm method
- ☐ 1m. male condoms

→ ***Must be combined with another effective method of contraception, per protocol, for participant to be eligible.***

- ☐ 1n. sterilization (tubal ligation/hysterectomy/laparoscopy /other surgical procedure that causes sterilization)
- ☐ 1o. sex with partner who had a vasectomy
- ☐ 1p. other, specify: _____

→ ***Record on Contraceptives Log, if applicable.***
If participant does not report use of at least one effective method of contraception, per protocol, or reports use of an exclusionary method, per protocol, participant is ineligible.

Comments: _____

☐☐☐☒ 17-MAR-09

01
Language

Staff Initials / Date

Baseline Family Planning (FPB-1)

Purpose: This form is used to document the methods of contraception/family planning used by the participant at the time of her Enrollment Visit.

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

Item-specific Instructions:

- **Item 1:** Complete this item based on source documentation recorded in the participant's Baseline Medical and Menstrual History.

SAMPLE: DO NOT FAX TO DATAFAX

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

MTN003 VOICE (160) CM-1 (423)

Participant ID

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

Concomitant Medications Log

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

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

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

Indication

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

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

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

Dose/Units

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

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

Indication

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

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

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

Dose/Units

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

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

Indication

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

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

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

Dose/Units

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

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Concomitant Medications Log (CM-1)

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

General Information/Instructions: When to fax this form:

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

Item-specific instructions:

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

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

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

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

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

SAMPLE: DO NOT FAX TO DATAFAX

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

MTN003 VOICE (160) CL-1 (430)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Contraceptives Log

☐ **No contraceptives taken at Screening/Enrollment.** Staff Initials/Date

→ ***Fax to SCHARP DataFax.***

☐ **No contraceptives taken throughout study.** Staff Initials/Date

→ ***End of form. Fax to SCHARP DataFax.***

1.

Contraceptive		**Staff Initials/Log Entry Date**
Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*	**Date Stopped** ☐☐ ☐☐☐ ☐☐ *dd MMM yy* **OR** ☐ Continuing at end of study	
Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *qxh: every* ☐☐ *hrs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____		
Dose/Units	**Route** *Mark only one.* *PO* ☐ *IM* ☐ *IU* ☐ *TOP* ☐ *VAG* ☐ *other, specify:* ☐ _____	

2.

Contraceptive		**Staff Initials/Log Entry Date**
Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*	**Date Stopped** ☐☐ ☐☐☐ ☐☐ *dd MMM yy* **OR** ☐ Continuing at end of study	
Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *qxh: every* ☐☐ *hrs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____		
Dose/Units	**Route** *Mark only one.* *PO* ☐ *IM* ☐ *IU* ☐ *TOP* ☐ *VAG* ☐ *other, specify:* ☐ _____	

3.

Contraceptive		**Staff Initials/Log Entry Date**
Date Started ☐☐ ☐☐☐ ☐☐ *dd MMM yy*	**Date Stopped** ☐☐ ☐☐☐ ☐☐ *dd MMM yy* **OR** ☐ Continuing at end of study	
Frequency *Mark only one.* ☐ *prn* ☐ *qd* ☐ *tid* ☐ *qhs* ☐ *qxh: every* ☐☐ *hrs* ☐ *once* ☐ *bid* ☐ *qid* ☐ *other, specify:* _____		
Dose/Units	**Route** *Mark only one.* *PO* ☐ *IM* ☐ *IU* ☐ *TOP* ☐ *VAG* ☐ *other, specify:* ☐ _____	

Contraceptives Log (CL-1)

Purpose: All contraceptives used by the participant during the study must be documented on this form. This includes, but is not limited to oral contraceptives, injectable contraceptives, intrauterine devices, implants (e.g., Norplant), Ortho Evra, spermicide, diaphragm, and emergency contraception. Do not record male or female condom use.

General Information/Instructions: When to fax this form:

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

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Contraceptives Log pages after faxing, unless instructed by SCHARP.
- **No contraceptives taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant from Screening through the Enrollment Visit. This box should only be marked on page 01.
- **No contraceptives taken throughout study:** Mark this box at the Termination visit if no contraceptive devices or medications were taken by the participant throughout the entire study.
- **Contraceptive:** If the contraceptive is an intrauterine device, record the brand name. For injectable contraceptives (e.g., Depo-Provera), record each injection as a separate entry.
- **Date Started:** If the participant is unable to recall the exact date, obtain participant's best estimate. At a minimum, the year is required.
- **Date Stopped:** At the participant's Termination visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked. At a minimum, the month and year are required.
- **Frequency:** Below is a list of common frequency abbreviations:

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

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

PO oral	**IM** intramuscular	**IU** intrauterine	**TOP** topical	**VAG** vaginal

- **Dose/Units:** If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) 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? ..... dd MMM yy → If unknown, record age: years

2. What is your gender? ..... male ☐ female ☒

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

4. Do you currently have a primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis or who you consider to be your main partner. ..... yes ☐ no ☐ → ***If no, go to item 12 on page 2.***

5. How old is your husband/primary sex partner? ..... ☐☐ years don't know ☐

6. Are you currently living with him? ..... yes ☐ no ☐

7. Does he have any sex partners other than you? ..... yes ☐ no ☐ don't know ☐

8. Does he provide you with financial and/or material support? ..... yes ☐ no ☐

9. What is his average monthly income? *Record in local currency.* ..... ☐☐☐☐☐☐☐☐☐ don't know ☐ no income ☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Demographics (DEM-1)

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

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

Note: There is no visit code field on this form, since this form is only completed at the Screening Part 1 Visit. If a participant is being re-screened, a new Demographics form must be completed as part of the subsequent screening attempt. See the Study-Specific Procedures Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.

Item-specific Instructions:

- **Item 1:** If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. ***NOTE:*** *participant must be between the ages of 18 and 40 years (inclusive) at the time of screening to be eligible for study participation.*
- **Item 4:** Record whether or not the participant **currently** has a primary sex partner.
- **Item 5:** Read aloud "husband" or "primary sex partner," depending on the participant's response to item 3 and item 4 (if not currently married). If the participant does not know her husband's or primary partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 8:** Record whether or not the participant's husband or primary partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 9:** Record the husband's or primary partner's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

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

0	*0*	*0*	*0*	*0*	*2*	*1*	*4*	*5*

  If the husband's or primary partner's average monthly income is greater than 999,999,999 write "999999999" in the boxes provided, and record the actual value in the white space near the item.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) DEM-2 (002)

Participant ID

___ ___ ___ – ___ ___ ___ ___ ___ – ___

Site Number Participant Number Chk

Demographics

10. What is his highest level of education?

- ☐ no schooling
- ☐ primary school, not complete
- ☐ primary school, complete
- ☐ secondary school, not complete
- ☐ secondary school, complete
- ☐ attended college or university
- ☐ don't know

11. Is he circumcised? By circumcised, I mean when the foreskin of the penis is removed. ..... ***Use visual aid.***

yes	*no*	*don't know*
☐	☐	☐

12. Do you earn an income of your own? .....

yes	*no*
☐	☐ → ***If no, go to item 13.***

12a. What is your average monthly income?
Record in local currency. .....

☐☐☐☐☐☐☐☐☐

12b. How do you earn your income?
Mark all that apply. .....

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

Local Language: _____ *English:* _____

13. What is your highest level of education?

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

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

_____
Staff Initials / Date

Demographics (DEM-2)

Item-specific Instructions:

- **Item 10:** If the participant does not know her husband or primary partner's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 11:** The intent of this item is to capture the circumcision status of the participant's husband/primary sex partner at the time this form is administered (Screening Part 1). If the participant's husband/primary sex partner (as reported in items 3–4) is circumcised after the Screening Part 1 Visit, do not update the response to item 11.
- **Item 12a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

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

0	*0*	*0*	*0*	*0*	*2*	*1*	*4*	*5*

  If the participant's average monthly income is greater than 999,999,999 write "999999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 12b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment. If "other, specify below" box is marked, record the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) DEM-3 (003)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Demographics

14. How many children have you given birth to who were alive at birth? [ ][ ] *# of children*

15. Do you, or does someone in your family, own the house you are currently living in? ..... *yes* [ ] *no* [ ]

16. How many rooms are in the house you are currently living in? ..... [ ][ ] *# of rooms*

17. What is your ethnic group or tribe? ..... [ ][ ] *ethnic/tribe code*
If other, specify:

Local Language: _____ *English:* _____

***Interviewer**: Complete item 18 after the interview.*

18. Where was the participant referred/recruited from?..... [ ][ ] *recruitment code*

Demographics (DEM-3)

Item-specific Instructions:

- **Item 14:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 15:** Record whether or not the participant (or someone in her extended family) owns the house she lives in.
- **Item 16:** Do not count bathrooms as rooms.
- **Item 17:** This item asks about ethnic group or tribe. Record the 2-digit country-specific code below that is associated with the participant's ethnic group or tribe. If the participant responds with "other," record, "99" and the participant's verbatim (word-for-word) response on the "Local Language" line. If the participant responds in a language other than English, provide the English translation of the response on the "English" line.

MALAWI	SOUTH AFRICA	UGANDA	ZAMBIA	ZIMBABWE
01 - Chichewa	07 - Zulu	11 - Black	12 - Bemba	16 - Shona
02 - Lombwe	08 - Xhosa	06 - White	13 - Chewa	17 - Ndebele
03 - Yao	09 - Indian	99 - Other	14 - Tonga	05 - Other African tribe
04 - Tumbuka	10 - Colored		15 - Lozi	06 - White
05 - Other African tribe	05 - Other African tribe		05 - Other African tribe	99 - Other
06 - White	06 - White		06 - White	
99 - Other	99 - Other		99 - Other	

- **Item 18:** This is not an interviewer-administered item. Record the 2-digit site-specific code associated with the location (or person) from where this participant was referred or recruited.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) ESI-1 (489)

Participant ID

Site Number – Participant Number – Chk

End of Study Inventory

Form Completion Date

dd MMM yy

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

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

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

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

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

End of Study Inventory (ESI-1)

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

General Information/Instructions: Complete this form once for each enrolled participant after the participant has terminated from the study (as documented by a Termination form).

Item-specific instructions:

- **Form Completion Date:** A complete date is required.
- **Item 1:** Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.
- **Item 2:** Record the total number of Interim Visit DataFax forms submitted for this participant. If no Interim Visit forms were submitted for the participant, record "000" in the boxes.
- **Item 3a:** Record the highest page number of the Adverse Experience Log submitted for this participant, even if that page was marked for deletion.
- **Item 3d:** Record the highest page number of the Product Hold/Discontinuation Log submitted for this participant, even if that page was marked for deletion.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) ENR-1 (070)

Participant ID

Site Number – Participant Number – Chk

Enrollment

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

   1a. When was the informed consent form for enrollment marked or signed? ..... ☐☐ dd ☐☐☐ MMM ☐☐ yy

2. Was the participant able and willing to provide written informed consent for specimen storage and future research? ..... yes ☐ no ☐ not yet consented ☐ → ***If no or not yet consented, go to item 3.***

   2a. When was the informed consent form for specimen storage and future research marked or signed? ..... ☐☐ dd ☐☐☐ MMM ☐☐ yy

3. Was a clinic randomization envelope assigned? ..... yes ☐ no ☐ → ***If no, specify reason in Comments. End of form.***

   3a. Clinic randomization envelope number: ..... ☐☐☐☐

   3b. Date assigned: ..... ☐☐ dd ☐☐☐ MMM ☐☐ yy

   3c. Time assigned: ..... ☐☐ : ☐☐ hr min *24-hour clock*

   3d. To which study group was the participant randomized? ..... *oral* ☐ *vaginal* ☐

4. Did the participant complete the ACASI Baseline Behavioral Questionnaire? ..... yes ☐ no ☐ ***If "no, vaccination not indicated" or "no, participant refused," end of form.***

5. Did the participant receive a Hepatitis B vaccination (initial or follow-up) at this visit? ..... yes ☐ no, vaccination not indicated ☐ no, participant refused ☐

   If yes, record the vaccination on the Concomitant Medications Log.

   5a. Which dose did she receive at this visit? ..... *0 (initial dose)* ☐ *1–2 months* ☐ *4–6 months* ☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Enrollment (ENR-1)

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

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

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

Item-specific Instructions:

- **Item 1:** If response to this item is "no" (the participant is not willing and able to provide written informed consent for enrollment), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.
- **Items 1a and 2a:** If the participant marks the informed consent using her thumbprint, record the date the thumbprint was made.
- **Item 2:** Mark "yes" only if the participant gave consent to have her lab specimens stored for future research testing. Mark the "not yet consented" box if the participant is not asked for informed consent for specimen storage at enrollment (rather, it is deferred to a later visit). When the participant is asked to provide informed consent for specimen storage, update the response to item 2 and initial, date, and refax the form to SCHARP.
- **Item 3:** If a clinic randomization envelope was not assigned, mark the "no" box and specify on the Comments line the reason an envelope was not assigned, then end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax if a clinic randomization envelope was not assigned.
- **Item 3a:** Record the 4-digit clinic randomization envelope number present on the clinic randomization envelope assigned to this participant.
- **Item 3b:** Record the date the clinic randomization envelope was assigned to the participant. This date should match the "date assigned" recorded for this envelope on the MTN 003 Clinic Randomization Envelope Tracking Record.
- **Item 3c:** Record the time (using a 24-hour clock) the clinic randomization envelope was assigned to the participant. This time should match the "time assigned" recorded for this envelope on the MTN 003 Clinic Randomization Envelope Tracking Record.
- **Item 3d:** Record the participant's randomization assignment present on the prescription contained in the participant's clinic randomization envelope.
- **Item 4:** Completion of the ACASI Baseline Behavioral Questionnaire is required for all participants at the Enrollment Visit. If the required questionnaire was not done, specify the reason on the Comments line.
- **Item 5:** If a Hepatitis B vaccination was indicated per protocol but not offered, line through the response boxes and initial and date. Record the reason on the Comments line. If the participant has already completed the series, or is between shots at this visit, mark the "no, vaccination not indicated" box.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) FPF-1 (155)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Follow-up Family Planning

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Has the participant's method of contraception/family planning changed since her last visit? ..... *yes* ☐ *no* ☐ → ***If no, go to item 3.***

2. What contraception/family planning method(s) has the participant used since her last visit? *Mark "none" or all that apply.*

- ☐ 2a. none
- ☐ 2b. vaginal ring
- ☐ 2c. spermicide
- ☐ 2d. diaphragm
- ☐ 2e. sponge

→ ***During counseling session, counsel participant regarding use of allowable methods of contraception, per protocol.***

- ☐ 2f. intrauterine device (IUD)
- ☐ 2g. oral contraceptives/birth control pills
- ☐ 2h. injectable contraceptives (such as Depo-Provera)
- ☐ 2i. (Ortho Evra) The Patch
- ☐ 2j. implants

→ ***Update Contraceptives Log.***

- ☐ 2k. female condoms
- ☐ 2l. natural methods such as the withdrawal or rhythm method
- ☐ 2m. male condoms

→ ***If not used in combination with another effective method of contraception, per protocol, provide appropriate counseling during counseling session.***

- ☐ 2n. sterilization (tubal ligation/hysterectomy/laparoscopy /other surgical procedure that causes sterilization)
- ☐ 2o. sex with partner who had a vasectomy
- ☐ 2p. other, specify: _____

→ ***Update Contraceptives Log, if applicable.***
If participant does not report use of at least one effective method of contraception, per protocol, or reports use of an exclusionary method, per protocol, provide appropriate counseling during counseling session.

	dd	*MMM*	*yy*	*no menses since last visit*
3. First day of last menstrual period:	☐☐	☐☐☐	☐☐	**OR** ☐ →
4. Last day of last menstrual period:	☐☐	☐☐☐	☐☐	

End of form.

☐☐☐☒ 17-MAR-09

01 Language

Staff Initials / Date

Follow-up Family Planning (FPF-1)

Purpose: This form is used to document the methods of contraception/family planning used by the participant during study follow-up. It is completed at each monthly follow-up visit through study exit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Items 1–4:** Complete these items based on source documentation recorded in the participant's Follow-up Medical and Menstrual History.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) FHT-1 (134)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Follow-up HIV Rapid Test Results

Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Not done/ Not collected ☐

1. HIV TEST RESULTS

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

Not done ☐

If positive for either, complete an HIV Western Blot Test Results form and Product Hold/ Discontinuation Log.

Comments: _____

☐☐☐☒ 17-MAR-09

01 Language

Staff Initials / Date

Follow-up HIV Rapid Test Results (FHT-1)

Purpose: This form is used to document local laboratory HIV Rapid test results of blood collected during the follow-up visits.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to 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. Record a complete date.
- **Not done/Not collected:** Mark *either* the "Not done/Not collected" box or enter a test result. If the "Not done/Not collected" box is marked, record reason on the Comments lines.
- **Not done:** Mark *either* the "Not done" box *or* enter a test result.

Item-specific Instructions:

- **Item 1:** 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

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) FPE-1 (145)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Follow-up Pelvic Exam

Exam Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

	abnormal findings	*no abnormal findings*	*not done*	
1. Pelvic exam assessments:	☐	☐	☐ →	***If not done, specify reason in Comments. End of form.***

If no abnormal findings, go to item 5.

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
- ☐ Cervical friability
- ☐ Edema
- ☐ Abnormal cysts
- ☐ Mass
- ☐ Warts
- ☐ Adnexal tenderness
- ☐ Cervical motion tenderness
- ☐ Uterine tenderness
- ☐ Other abnormal findings, specify: _____

Complete or update Adverse Experience Log when applicable.

	yes	*no*	
2. Do any of these exam findings involve deep epithelial disruption?	☐	☐ →	***If no, go to item 3.***
2a. Was the deep epithelial disruption observed in more than one distinct area?	☐	☐	
3. Do any of these exam findings involve unexpected genital bleeding?	☐	☐ →	***If no, go to item 4.***
3a. Was the genital bleeding observed with no identifiable source?	☐	☐	

If yes, complete Genital Bleeding Assessment form if indicated.

4. Do any of these exam findings warrant a product hold?	☐	☐

If yes, complete Product Hold/Discontinuation Log.

	0%	*1–25%*	*26–50%*	*51–75%*	*> 75%*	*N/A*
5. Cervical Ectopy: Percentage of cervical surface area.	☐	☐	☐	☐	☐	☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Follow-up Pelvic Exam (FPE-1)

Purpose: This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic exams conducted during study follow-up. A pelvic exam is required at each semi-annual and annual visit, the Product Use End Visit, and when clinically indicated.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 1:** If a pelvic exam was required but not done, mark the "not done" box and record the reason the required pelvic exam was not done on the Comments lines.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box and describe the abnormal finding on the line provided.
- **Item 3a:** If unexpected genital bleeding was observed with no identifiable source, complete a Genital Bleeding Assessment (non-DataFax) form if applicable (unless one has already been completed for this visit). Refer to the Clinical section of the Study-Specific Procedures (SSP) Manual for further information on how to manage and document genital bleeding.
- **Item 5:** Mark the "N/A" box if the participant does not have an intact cervix.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) FV-1 (121)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Follow-up Visit

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

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

   1a. Record the reason why the pregnancy test was not done:

   _____

   _____

   → ***If negative or positive, go to item 2. If newly positive, complete Pregnancy Report and History form and Product Hold/Discontinuation Log.***

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 **new AE Log** pages*

3. Was a **new** study product hold or discontinuation initiated at this visit? ..... *yes* ☐ *no* ☐ → ***If no, go to item 4.***

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

4. Did the participant complete the ACASI Follow-up Questionnaire at this visit? ..... *yes* ☐ *no* ☐ *not required* ☐ → ***If no or not required, go to item 5.***

   4a. Date ACASI Follow-up Questionnaire was completed: ..... ☐☐ ☐☐☐ ☐☐

   dd *MMM* *yy*

5. Did the participant receive a Hepatitis B vaccination (initial or follow-up) at this visit? ..... *yes* ☐ *no, vaccination not indicated* ☐ *no, participant refused* ☐ → ***If "no, vaccination not indicated" or "no, participant refused," end of form.***

   ← ***If yes, record the vaccination on the Concomitant Medications Log.***

   5a. Which dose did she receive at this visit? ..... *0 (initial dose)* ☐ *1–2 months* ☐ *4–6 months* ☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

_____ Staff Initials / Date

Follow-up Visit (FV-1)

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

General Information/Instructions:

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

Item-specific Instructions:

- **Item 1:** Pregnancy testing is required at every regularly scheduled study follow-up visit through the Termination Visit. 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 new 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** Adverse Experience 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:** Mark the "yes" box if a product hold or discontinuation is initiated at this visit. If the box is marked "yes," record, in item 3a, how many **new** Product Hold/Discontinuation Log pages were completed for this visit. For example, if two new product holds were reported, record "02." Note that the Visit Code recorded in item 1 of these two PH Log pages should be the same as the Visit Code recorded on this form.
- **Item 4:** Completion of the ACASI Follow-up Questionnaire is required at the quarterly, annual, Product Use End, and Termination Visits. If the questionnaire is required but not done, mark the "no" box and specify the reason on the Comments lines.
- **Item 5:** If a Hepatitis B vaccination was indicated per protocol but not offered, line through the response boxes and initial and date. Record the reason on the Comments lines. If the participant has already completed the series, or is between shots at this visit, mark the "no, vaccination not indicated" box.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) HTR-1 (351)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

HIV Western Blot Test Results

Sample 1

1. HIV Western Blot

Not done/ Not collected ☐ **Specimen Collection Date** ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

negative ☐ *positive* ☐ *indeterminate* ☐

If negative or indeterminate, consult MTN Network Lab and continue with algorithm.

If positive, go to item 2.

Not done ☐

If not done, go to item 2.

1a. HIV RNA PCR ..... > ☐ = ☐ < ☐ *viral copies/mL* ☐☐☐☐☐☐☐☐

1b. RNA PCR kit lower limit of detection *50* ☐ *400* ☐ **OR** *viral copies/mL* ☐☐☐

1c. HIV RNA PCR status ..... *negative* ☐ *positive* ☐

If negative, go to item 4.

Sample 2

2. HIV Western Blot

Not done/ Not collected ☐ **Specimen Collection Date** ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

negative ☐ *positive* ☐ *indeterminate* ☐

If positive, go to item 4.

If negative or indeterminate, contact MTN Network Lab for further testing and follow-up.

Sample 3

3. HIV Western Blot

Not done/ Not collected ☐ **Specimen Collection Date** ☐☐ ☐☐☐ ☐☐ (*dd* *MMM* *yy*)

negative ☐ *positive* ☐ *indeterminate* ☐

FINAL HIV STATUS

4. Final status: ..... *negative* ☐ *positive* ☐ *other, specify:* _____

Comments: _____

☐ ☐ ☒ ☐ 31-JAN-11

0 1 Language

Staff Initials / Date

HIV Western Blot Test Results (HTR-1)

Purpose: This form documents confirmatory HIV test results and final HIV status during study follow-up. This form is completed each time a participant has a positive HIV Rapid test result during study follow-up.

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

- **Visit Code:** The visit code recorded on this form should be the same visit code recorded on the Follow-up HIV Rapid Test Results form documenting the positive HIV Rapid test result. If this visit is the Study Exit Visit, record visit code 89.0.
- **Specimen Collection Date:** Record the date the specimen was *collected* (NOT the date results were reported or recorded on the form). For Sample 1, the Specimen Collection Date should be the same date as the collection date of the HIV Rapid test specimen that tested positive.
- **Not Done/Not Collected:** For every test, mark *either* the "Not Done/Not collected" box *or* enter a test result. If the "Not done/Not collected" box is marked, record reason on the Comments lines.
- **Not done:** Mark *either* the "Not done" box *or* enter a test result.

Item-specific Instructions:

- **Item 1a:** Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay. For example, if a participant is tested with an assay that has 400 viral copies/mL as the lower limit of detection, and the lab reports her result as "238 viral copies/mL," mark the "=" box and record "00000238" viral copies/mL for item 1a.
- **Item 1c:** Mark the "positive" box if the participant's HIV RNA PCR result is equal to or greater than the lower limit of detection as recorded in item 1b.
- **Item 4:** 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), update the Product Hold/Discontinuation Log.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) 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, if applicable.***

☐ 1b. phone call from participant to report new symptoms → ***Complete Adverse Experience Log, if applicable.***

☐ 1c. follow-up of symptoms and/or AE(s) → ***Update Adverse Experience Log, if applicable.***

☐ 1d. participant needs study product

☐ 1e. participant is returning unused study product

→ ***Complete Product Re-supply and Re-issues form and Product Returns form.***

☐ 1f. other, specify: _____

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

☐ 2a. none

☐ 2b. Follow-up Pelvic Exam

☐ 2c. Vaginal Test Results

☐ 2d. Safety Laboratory Results

☐ 2e. Product Re-supply and Re-issues form and Product Returns form

☐ 2f. Adverse Experience Log (new) → 2f1. How many **new** AE Log pages were completed for this visit? *# of pages* ☐☐

☐ 2g. Product Hold/Discontinuation Log (new) → 2g1. How many **new** PH Log pages were completed for this visit? ☐☐

☐ 2h. other, specify: _____

3. hCG for pregnancy: ..... *negative* ☐ *positive* ☐ *not done* ☐

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

4. Did the participant receive a Hepatitis B vaccination (initial or follow-up) at this visit? ..... *yes* ☐ *no, vaccination not indicated* ☐ *no, participant refused* ☐

If yes, record the vaccination on the Concomitant Medications Log.

If "no, vaccination not indicated" or "no, participant refused," end of form.

4a. Which dose did she receive at this visit? ..... *0 (initial dose)* ☐ *1–2 months* ☐ *4–6 months* ☐

Comments: _____

☐ ☐ ☒ ☐ 12-AUG-10

0 1 Language

Staff Initials / Date

Interim Visit (IV-1)

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

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

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:
  - Record the two-digit whole number visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was Month 1 (Visit Code = 04.0), record "04" to the left of the decimal point in the visit code field.
  - Record the number that corresponds to the Interim Visit in the third box (the box to the right of the decimal point):

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

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

Item-specific instructions:

- **Item 2:** Note that marking a box other than "none" indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.
  - **Item 2a:** Mark the "none" box if the Interim Visit form is the **only** DataFax form completed for this visit.
  - **Item 2f:** Mark this box if a new (previously unreported) AE is reported or observed at this visit. If the box to the left of "Adverse Experience Log (new)" is marked, record how many **new** AE Log pages were completed for this visit in item 2f1. For example, if two new AEs were reported, record "02." Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
  - **Item 2g:** Mark this box if a new (previously unreported) product hold or discontinuation is reported at this visit. If the box to the left of "Product Hold/Discontinuation Log (new)" is marked, record how many **new** PH Log pages were completed for this visit in item 2g1. For example, if two new product holds were reported, record "02." Note that the Visit Code recorded in item 1 of these two PH Log pages should be the same as the Visit Code recorded on this form.
- **Item 3:** *A Pregnancy Report and History form must be completed for each new 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 4:** If a Hepatitis B vaccination was indicated per protocol but not offered, line through the response boxes and initial and date. Record the reason on the Comments line. If the participant has already completed the series, or is between shots at this visit, mark the "no, vaccination not indicated" box.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) MPS-1 (240)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Menstrual Practices and Study Disclosure Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

The first questions ask about your menstrual period and items women sometimes insert inside their vagina for personal hygiene or other reasons.

		yes	*no*	
1.	In the **past 3 months**, have you had a menstrual period?	☐	☐ →	*If no, go to statement above item 3.*

2. In the **past 3 months**, what have you used during your menstrual period? You can answer "yes" to more than one item.

		yes	*no*
2a.	Paper or cloth or cotton wool—put inside the vagina?	☐	☐
2b.	Paper or cloth or cotton wool—placed in underwear?	☐	☐
2c.	Tampon?	☐	☐
2d.	Sanitary pad?	☐	☐
2e.	Anything else? If yes, specify:	☐	☐

Local Language: _____

English: _____

The next questions are about people you may have talked to about this study.

3. In the **past year**, have you talked with any of the following people about your participation in this study? You can answer "yes" to more than one item.

		yes	*no*	*N/A*
3a.	Your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
3b.	Other sex partners?	☐	☐	☐
3c.	Your mother or father?	☐	☐	☐
3d.	Your sister or brother?	☐	☐	☐
3e.	Other family member?	☐	☐	☐

Menstrual Practices and Study Disclosure Assessment (MPS-1)

Purpose: This form is used to collect information about the participant's menstrual practices and disclosure of study participation. This is an interviewer-administered form, and it is administered at each annual visit, the Product Use End Visit, and the Study Exit Visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.

Item-specific Instructions:

- **Item 2:** Read each item 2a–2e aloud and mark the participant's answer. If "yes" is marked for item 2e, record the participant's verbatim response. Also provide the English translation in the space provided.
- **Item 3:** Read each item 3a–3e aloud and mark the participant's answer.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) MPS-2 (241)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Menstrual Practices and Study Disclosure Assessment

		yes	no	N/A
3f.	A friend or neighbor?	☐	☐	☐
3g.	A nurse or clinician or doctor outside of the study?	☐	☐	☐
3h.	An elder or community leader?	☐	☐	☐
3i.	Anyone else? If yes, specify:	☐	☐	

Local Language: _____

English: _____

4. In the **past year**, have you talked with any of the following people about the tablets or gel you are using for this study? You can answer "yes" to more than one item.

		yes	no	N/A
4a.	Your primary sex partner?	☐	☐	☐
4b.	Other sex partners?	☐	☐	☐
4c.	Your mother or father?	☐	☐	☐
4d.	Your sister or brother?	☐	☐	☐
4e.	Other family member?	☐	☐	☐
4f.	A friend or neighbor?	☐	☐	☐
4g.	A nurse or clinician or doctor outside of the study?	☐	☐	☐
4h.	An elder or community leader?	☐	☐	☐
4i.	Anyone else? If yes, specify:	☐	☐	☐

Local Language: _____

English: _____

Menstrual Practices and Study Disclosure Assessment (MPS-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 3f–3i:** Read each item aloud and mark the participant's answer. If "yes" is marked for item 3i, record the participant's verbatim response. Also provide the English translation in the space provided.
- **Item 4:** Read each item 4a–4i aloud and mark the participant's answer. If "yes" is marked for item 4i, record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) MPS-3 (242)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Menstrual Practices and Study Disclosure Assessment

		yes	no	N/A
5.	In the **past year**, has your primary sex partner come to the study clinic for any reason?	☐	☐	☐
5a.	Did he attend a study meeting?	☐	☐	
5b.	Did he accompany you to a study visit?	☐	☐	
5c.	Did he receive counseling or other clinical services?	☐	☐	
5d.	Did he come to the study clinic for any other reason?	☐	☐	

If no or N/A, end of form.

If yes, specify:

Local Language: _____

English: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Menstrual Practices and Study Disclosure Assessment (MPS-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.
- **Item 5:** Read each item 5a–5d aloud and mark the participant's answer. If "yes" is marked for item 5d, record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code . 0 1

MTN003 VOICE (160) MV-1 (463)

Participant ID

Site Number – Participant Number – Chk

Missed Visit

Form Completion Date

dd MMM yy

1. Target Visit Date: dd MMM yy

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

- ☐ 2a. unable to contact participant
- ☐ 2b. unable to schedule appointment(s) within allowable window
- ☐ 2c. participant refused visit
- ☐ 2d. participant incarcerated
- ☐ 2e. participant admitted to a health care facility → ***Complete Adverse Experience Log, if applicable.***
- ☐ 2f. participant withdrew from the study → ***Complete Termination form.***
- ☐ 2g. participant deceased → ***Complete Termination form. Complete Adverse Experience Log and EAE Reporting form.***
- ☐ 2h. other, specify: _____
- ☐ 2i. participant relocated

Comments: _____

Missed Visit (MV-1)

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

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

Item-specific Instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) MBA-1 (275)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Monthly Product Adherence and Behavior Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first two questions are about vaginal sex.

		yes	*no*
1.	In the **past 4 weeks**, have you had vaginal sex?	☐	☐ →

If no, go to statement below item 2.

		yes	*no*
2.	Now I would like to ask you about your most recent vaginal sex act, that is the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.***	☐	☐

If the participant was not re-supplied/re-issued study product <u>and</u> did not having any remaining unused product (regardless of expiry) in her possession in the past 7 or more days, end of form.
If participant is in the vaginal group, go to statement above item 4.

Now I will ask about taking tablets in the **past 7 days** (not including today).

3. In the **past 7 days** (not including today),...

		# of days
3a.	on how many days did you take **no** tablets?	☐
3b.	on how many days did you take the **lighter** tablet and not the darker tablet?	☐
3c.	on how many days did you take the **darker** tablet and not the lighter tablet?	☐
3d.	on how many days did you take **both** tablets?	☐ →

End of form.

Now I will ask about inserting gel in the **past 7 days** (not including today).

4. In the **past 7 days** (not including today),...

		# of days
4a.	on how many days did you **not** insert gel?	☐
4b.	on how many days did you insert gel?	☐

☐☐☐☒ 17-DEC-10

01 Language

Staff Initials / Date

Monthly Product Adherence and Behavior Assessment (MBA-1)

Purpose: This form is used to collect information about the participant's product use while she is taking part in the study. This is an interviewer-administered form, and it is administered at each monthly visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- Per the instruction below item 2, items 3a–4b should be left blank for participants who were not exposed to study product in the past 7 or more days. This applies to product holds/discontinuations *initiated by site staff*. It also applies to cases where a participant chooses on her own to stop product use *and* has refused to receive product.

Item-specific Instructions:

- **Items 3–4:** If site permanently discontinued the participant's study product use 4 or more weeks ago, or has held the participant's study drug use for the past 4 weeks, leave items 3–4b blank.
- **Items 3a–3d:** If the participant reports "none" or "never" record "0." The sum of the responses to 3a–3d should equal "7."
- **Items 4a–4b:** If the participant reports "none" or "never" record "0." The sum of the responses to 4a–4b should equal "7."

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) MS-1 (310)

Visit Code ☐☐.☐ 1

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Monthly Symptoms

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Since your last visit, have you experienced any of the following:

		yes	no	don't know	a. If yes, for how many days? number of days	b. Ongoing? yes	b. Ongoing? no
1.	Fever?	☐	☐	☐	☐☐	☐	☐
2.	Fatigue?	☐	☐	☐	☐☐	☐	☐
3.	Sore throat?	☐	☐	☐	☐☐	☐	☐
4.	Rash?	☐	☐	☐	☐☐	☐	☐
5.	Headache?	☐	☐	☐	☐☐	☐	☐
6.	Shortness of breath?	☐	☐	☐	☐☐	☐	☐
7.	Abdominal pain?	☐	☐	☐	☐☐	☐	☐
8.	Nausea?	☐	☐	☐	☐☐	☐	☐
9.	Vomiting?	☐	☐	☐	☐☐	☐	☐
10.	Diarrhea?	☐	☐	☐	☐☐	☐	☐
11.	Excessive intestinal gas?	☐	☐	☐	☐☐	☐	☐
12.	Increased or decreased urinary output?	☐	☐	☐	☐☐	☐	☐
13.	Muscle weakness or pain?	☐	☐	☐	☐☐	☐	☐
14.	Swelling of the feet?	☐	☐	☐	☐☐	☐	☐
15.	Joint pain?	☐	☐	☐	☐☐	☐	☐
16.	Bone pain?	☐	☐	☐	☐☐	☐	☐
17.	Bone fracture?	☐	☐	☐	☐☐	☐	☐
18.	Numbness or tingling in your hands or feet?	☐	☐	☐	☐☐	☐	☐

Complete or update an Adverse Experience Log, if applicable.

☐☐☐☒ 02-DEC-09

0 1 Language

Staff Initials / Date

Monthly Symptoms (MS-1)

Purpose: This is an interviewer-administered form. Each question should be asked as it is written. All information on this form is based on participant self-report.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- The information reported on this form should cover the period from the last time the participant was questioned about these symptoms to the current visit.
- For every "yes" answer, indicate the number of days the symptoms have persisted and whether or not the symptoms are ongoing. Evaluate the participant for each reported symptom.
- If "yes" to any question, update or complete AE Log if applicable.

Item-specific Instructions:

- **For how many days:** If the participant does not recall the exact number of days of the symptoms, she should be asked to provide an approximation.
- **Ongoing:** Ongoing is defined as present during the current visit.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) OPA-1 (210)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the **past 3 months**, have you had vaginal sex? ..... *yes* ☐ *no* ☐ → *If no, go to statement below item 3a.*

The next question is about vaginal sex in the **past 7 days**.

2. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... *# of acts* ☐☐ → *If 00, go to item 3.*

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

2a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ***Use visual aid.*** *# of acts with condom* ☐☐ → *If 00, go to statement below item 3a.*

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** *yes* ☐ *no* ☐ → *If no, go to statement below item 3a.*

3a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... *male condom* ☐ *female condom* ☐

If the participant was not re-supplied/re-issued study product <u>and</u> did not having any remaining unused product (regardless of expiry) in her possession in the past 4 weeks or more, go to statement above item 18 on page 6.

Oral Product Adherence and Behavior Assessment (OPA-1)

Purpose: This form is used to collect information about the participant's oral product use and possible problems (emotional, physical, social, or other difficulties) experienced while she is taking part in the study. This is an interviewer-administered form, and it is administered at each quarterly visit and at the Product Use End Visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- Per the instruction below item 3a, items 4–17 should be left blank for participants who were not exposed to study product in the past 4 or more weeks. This applies to product holds/discontinuations *initiated by site staff*. It also applies to cases where a participant chooses on her own to stop product use *and* has refused to receive product.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

☐ No data recorded on this page.

I will now ask some questions about taking study tablets. We need to understand how women in the study are taking their tablets. We know that some women take their tablets every day, while others miss some days or stop taking the tablets for some time. Do not worry about telling me if there were times when you were not able to take your tablets every day. I would like to know what is really happening for you.

4. In the **past 4 weeks**, at what time of day did you typically take your tablets (the lighter tablet and the darker tablet)? ***Read response categories aloud. Use visual aid.***

   ☐ morning

   ☐ afternoon

   ☐ evening

   ☐ other, specify: *Local Language:* _____ *English:* _____

5. In the **past 4 weeks**, how often did you take your tablets at about the same time each day? ***Read response categories aloud. Showcard #1***

always	*sometimes*	*never*
☐	☐	☐

6. Different women have different ways of remembering to take their tablets. In the **past 4 weeks**, what has helped you remember to take your tablets? ***Do <u>not</u> read response categories aloud. Mark all that apply.***

   ☐ 6a. nothing → ***If nothing, go to item 7 on page 3.***

   ☐ 6b. calendar

   ☐ 6c. alarm/bell/cell phone ringer/pager

   ☐ 6d. pill box

   ☐ 6e. husband/primary sex partner

   ☐ 6f. family member or friend

   ☐ 6g. association with a daily activity

   ☐ 6h. association with having sex

   ☐ 6i. association with taking Oral Contraceptives

   ☐ 6j. association with taking other pills or medications

   ☐ 6k. other, specify: *Local Language:* _____ *English:* _____

Oral Product Adherence and Behavior Assessment (OPA-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.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Items 4–17:** If the site permanently discontinued the participant's study product use 4 or more weeks ago, or has held the participant's study product use for the past 4 weeks, leave items 4–17 blank. Mark the "No data recorded on this page" box in the upper-right corner of pages 2–5, then proceed to the statement above item 18 on page 6.
- **Item 4:** Read each response category aloud and mark the participant's answer. If the participant takes the lighter tablet at a different time of day than the darker tablet, mark the "other, specify" box and provide an explanation on the line provided. Also provide the English translation in the space provided. During the counseling session, counsel the participant on the importance of taking both the lighter and darker tablets together at the same time each day.
- **Item 5:** Read each response category aloud and mark the participant's answer.
- **Item 6:** Do not read responses 6a–6k aloud. If the participant reports a response other than those listed, mark item 6k and be record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) OPA-3 (212)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

☐ No data recorded on this page.

7. Different circumstances may prevent women from taking their tablets every day. Thinking about your experience in the **past 4 weeks**, please tell me **all** of the reasons that kept you from taking your tablets. ***Do not read response categories aloud. Mark all that apply.***

☐ 7a. not applicable—participant always took both tablets every day → ***Go to item 8 on page 4.***

☐ 7b. participant didn't have the tablets with her

☐ 7c. participant felt sick/was concerned about getting sick from the tablets

☐ 7d. participant ran out of or lost the tablets

☐ 7e. participant got tired of taking the tablets every day

☐ 7f. participant gave/sold/traded the tablets to someone else

☐ 7g. participant had a change in her daily routine

☐ 7h. participant forgot or was too busy

☐ 7i. participant was on menses

☐ 7j. participant did not have sex/was not intending to have sex

☐ 7k. participant had difficulty swallowing the tablets

☐ 7l. participant didn't like the tablets/taste of the tablets

☐ 7m. someone else took/stole some of participant's tablets

☐ 7n. participant's primary sex partner did not approve of her taking the tablets

☐ 7o. family member or friend did not approve of her taking the tablets

☐ 7p. other, specify: *Local Language:* _____ *English:* _____

Oral Product Adherence and Behavior Assessment (OPA-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.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 7:** Do not read responses 7a–7p aloud. If the participant reports a response other than those listed, mark item 7p and record the participant's verbatim response. Also provide the English translation in the space provided.
- **Item 7p:** If the participant missed taking some tablets due to a product hold/discontinuation, mark the "other, specify" box and record the reason in the space provided. Also provide the English translation in the space provided.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

☐ No data recorded on this page.

8. In the **past 4 weeks**, how often did you take both tablets (the lighter tablet and the darker tablet)? Was it...
Read response categories aloud. Showcard #2

- ☐ every day
- ☐ usually (most days)
- ☐ sometimes (some days)
- ☐ rarely (not many days)
- ☐ never → ***If never, go to item 10.***

9. In the **past 4 weeks**, what is the longest **number of days** in a row that you did **not** take **both** tablets? ..... *# of days* ☐☐

10. Different circumstances may lead women to take **more** than one of each tablet per day. Thinking about your experience taking tablets in the **past 4 weeks**, please tell me **all** of the reasons that led you to take **more than one of either tablet** on any single day. ***Do <u>not</u> read response categories aloud. Mark all that apply.***

- ☐ 10a. not applicable—never took more than 1 of each tablet per day → ***If not applicable, go to item 13 on page 5.***
- ☐ 10b. participant forgot she had taken her tablets already
- ☐ 10c. participant did not understand the instructions for taking her tablets
- ☐ 10d. participant wanted to have the correct number of tablets in her bottles at her next study visit
- ☐ 10e. participant had sex without a condom/had risky sex
- ☐ 10f. participant had a new partner
- ☐ 10g. participant wanted to make up for not taking tablets on earlier days
- ☐ 10h. participant thought it would protect her more
- ☐ 10i. participant's husband/primary sex partner asked her to take more tablets
- ☐ 10j. participant vomited after taking the tablet
- ☐ 10k. other, specify: *Local Language:* _____ *English:* _____

Oral Product Adherence and Behavior Assessment (OPA-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 all items on the page are left blank.
- **Item 8:** Read each response category aloud and mark the participant's answer.
- **Item 9:** Use leading zeros when needed so that all the boxes are filled. If the participant reports that she took both tablets every day, record "00" for this item.
- **Item 10:** Do not read responses 10a–10k aloud. If the participant reports a response other than those listed, mark item 10k and record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) OPA-5 (214)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

☐ No data recorded on this page.

# of days

11. In the **past 4 weeks**, on how many days did you take the **lighter** tablet **more** than once per day? ☐☐

# of days

12. In the **past 4 weeks**, on how many days did you take the **darker** tablet **more** than once per day? ☐☐

13. Please rate your ability, over the **past 4 weeks**, to take tablets exactly as you were instructed. ***Read response categories aloud. Showcard #3***

- ☐ very poor
- ☐ poor
- ☐ fair
- ☐ good
- ☐ very good
- ☐ excellent

Now I will ask about taking tablets in the **past 7 days** (not including today).

14. In the **past 7 days** (not including today),...

# of days

14a. on how many days did you take **no** tablets? ..... ☐

# of days

14b. on how many days did you take the **lighter** tablet and not the darker tablet? ..... ☐

# of days

14c. on how many days did you take the **darker** tablet and not the lighter tablet? ..... ☐

# of days

14d. on how many days did you take **both** tablets? ..... ☐

15. In the **past 7 days** (not including today),...

# of days

15a. on how many days did you take the **lighter** tablet **more** than once per day? ..... ☐

# of days

15b. on how many days did you take the **darker** tablet **more** than once per day? ..... ☐

Oral Product Adherence and Behavior Assessment (OPA-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 all items on the page are left blank.
- **Items 11 and 12:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she did not take either tablet more than once per day, record "00."
- **Item 13:** Read each response category aloud and mark the participant's answer.
- **Items 14a–14d:** If the participant reports "none" or "zero," record "0." The sum of the responses to 14a–14d should equal "7."
- **Items 15a–15b:** If the participant reports "none" or "zero," record "0."

Participant ID

Site Number – Participant Number – Chk

Oral Product Adherence and Behavior Assessment

The next questions are about the **last time** you took the tablets.

16. The **last time** you took the **darker** tablet, was it in the morning, afternoon, or evening?

- ☐ morning
- ☐ afternoon
- ☐ evening

17. The **last time** you took the **lighter** tablet, was it in the morning, afternoon, or evening?

- ☐ morning
- ☐ afternoon
- ☐ evening

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

18. In the **past 3 months**, have you had any problems with the following people as a result of being in this study:

		yes	*no*	*N/A*
18a.	your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
18b.	people at home/family?	☐	☐	☐
18c.	your friends/personal relationships?	☐	☐	☐
18d.	people at work?	☐	☐	☐
18e.	people at school?	☐	☐	☐
18f.	a nurse or clinician or doctor outside of the study?	☐	☐	☐
18g.	your landlord or property owner?	☐	☐	☐
18h.	anyone else? If yes, specify:	☐	☐	☐

*Local Language:*_____ *English:* _____

If no or N/A to all, end of form.

Oral Product Adherence and Behavior Assessment (OPA-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.
- **Item 18:** Read each item 18a–18h aloud and mark the participant's answer. If "yes" is marked for item 18h, record the participant's verbatim response. Also provide the English translation in the space provided. If items 18a through 18h are all "no" or "N/A," end the form. You must mark the "no data recorded on this page" box in the upper right corner of page 7. Also record the Visit Code, PTID, and staff initials and date on page 7 of this form. Leave all other items on page 7 blank. Fax all 7 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) OPA-7 (216)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Oral Product Adherence and Behavior Assessment

☐ No data recorded on this page.

19. Has this problem/have any of these problems resulted in:

		yes	no
19a.	emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem.	☐	☐
19b.	physical harm to you? For example, has anyone physically hurt you as a result of this problem?	☐	☐
19c.	economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income?	☐	☐
19d.	physical or other harm to your children?	☐	☐

20. Please describe the problem, including outcome, if any. ***Do not record the participant's verbatim response.***

Local Language: _____

_____

_____

_____

English: _____

_____

_____

_____

End of interview.

Interviewer: *Complete items 21–21a after the interview.*

21. *Did any of the problem(s) require reporting as an Adverse Event (AE)?* *yes* ☐ *no* ☐ → ***If no, end of form.***

21a. *Record AE Log page number(s):*

AE Log page # ☐☐☐ *AE Log page #* ☐☐☐ *AE Log page #* ☐☐☐

☐☐☐☒ 17-MAR-09

0 1 Language

_____ Staff Initials / Date

Oral Product Adherence and Behavior Assessment (OPA-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 all items on the page are left blank.
- **Item 20:** Do not record the participant's verbatim response. Instead, listen to the participant's response and probe as necessary. Describe, in the local language, the problem, including all relevant details, and the outcome, if any,. Also provide the English translation in the space provided.
- **Items 21 and 21a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) PTR-1 (144)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

PAP Test Result

Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Not done/ Not collected ☐

1. PAP SMEAR

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

→ ***Consult protocol and SSP Manual for guidance on study eligibility (if Screening Part 2 Visit) and clinical management.***

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

PAP Test Result (PTR-1)

Purpose: This form is used to document results of Pap specimens collected during the Screening Part 2 and Product Use End Visit pelvic exams, and during follow-up when clinically indicated (at sites where Pap smears are the standard of care for women, and where cytopathology and referral services for dysplasia are available).

General Information/Instructions: Record test results on this form as they become available. If a test result recorded on this form indicates that the participant has a condition requiring further evaluation, record the result as a pre-existing condition on the Pre-existing Conditions form (if ongoing at enrollment), or an adverse experience on the Adverse Experience Log (for follow-up visit test result(s) only). Do not use this Pap smear to diagnose STIs, such as trichomoniasis.

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Specimen Collection Date:** Record the date that the specimen was *collected* (NOT the date results were reported or recorded on the form) for this visit. If the required specimen was not collected, record the date specimen collection should have occurred. A complete date is required.
- **Not Done/Not Collected:** Mark *either* the "Not Done/Not Collected" box *or* enter a test result. If the "Not Done/Not Collected" box is marked, please explain in Comments line.

Item-specific Instructions:

- **Item 1:** Record the Pap Smear result. Mark only one box.
  - **negative for intraepithelial lesion or cancer (malignancy):** Includes all normal findings and any findings of infection (trichomonas, candida, etc.), reactive changes/inflammation, glandular changes due to hysterectomy, or atrophic changes.
  - **ASCUS:** 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

MTN003 VOICE (160) PRC-1 (466)

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: _____

_____

☐ ☐ ☐ ☒ 17-MAR-09

0 1

Language

_____

Staff Initials / Date

Participant Receipt (PRC-1)

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

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 and/or Study-Specific Procedures (SSPs) Manual.

Item-specific instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) PT-1 (465)

Participant ID

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

Site Number Participant Number Chk

Participant Transfer

Form Completion Date

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

dd *MMM* *yy*

1. Name of transferring study site: _____

2. Name of receiving study site: _____

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

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

dd *MMM* *yy*

Comments: _____

_____

[ ][ ][ ][X] 17-MAR-09

[0][1] Language

_____ Staff Initials / Date

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 and/or Study-Specific Procedures (SSPs) Manual.

Item-specific instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) PPA-1 (270)

Participant ID

Site Number – Participant Number – Chk

Perceived Product Assessment

Visit Date

dd MMM yy

Items 1–2 are completed by the site clinician prior to the interview. If participant is in the vaginal group, go to item 2.

1. *As you know, none of the study staff know which participants are taking tenofovir tablets, which participants are taking Truvada tablets, and which are taking placebo tablets. We would like you to say which study tablets you think the participant has been taking: tenofovir, Truvada, or placebo?*

tenofovir ☐ *Truvada* ☐ *placebo* ☐ →

If participant completed a Product Use End Visit, go to item 3. If participant did not complete a Product Use End Visit, end of form.

2. *As you know, none of the study staff know which participants are inserting tenofovir gel and which are inserting placebo gel. We would like you to say which gel you think the participant has been inserting: tenofovir or placebo? .....*

tenofovir ☐ *placebo* ☐ →

If participant completed a Product Use End Visit, go to item 4. If participant did not complete a Product Use End Visit, end of form.

3. As you know, none of the women taking tablets in this study know if they were given tenofovir tablets, Truvada tablets, or placebo tablets. Now that you have finished taking the tablets, I would like you to say which study tablets you think you were taking: tenofovir, Truvada, or placebo?

tenofovir ☐ *Truvada* ☐ *placebo* ☐ → ***End of form.***

4. As you know, none of the women inserting gel in this study know if they were given tenofovir gel or placebo gel. Now that you have finished inserting the gel, I would like you to say which gel you think you were inserting: tenofovir or placebo?

tenofovir ☐ *placebo* ☐

Perceived Product Assessment (PPA-1)

Purpose: This form is used to collect information about the site clinician's perception and the participant's perception of which product the participant was given. This a mixed form. Some items are completed by the site clinician (items 1–2) and some items are interviewer-administered (items 3–4). It is administered only once to each enrolled participant as part of her Product Use End Visit. If the participant did not complete a Product Use End Visit (for example, she is lost to follow up), complete this form when the site has determined that she has permanently discontinued study product use.

General Information/Instructions:

- **Visit Date:** If the participant completes a Product Use End Visit (PUEV), record the date when the PUEV is conducted. If the participant terminates from the study and does not complete a PUEV, record the date when this form is completed.

Item-specific Instructions:

- **Item 3:** This item should be answered by all participants taking tablets during the study. The participant should make her best guess, as there is no option for "don't know."
- **Item 4:** This item should be answered by all participants using gel during the study. The participant should make her best guess, as there is no option for "don't know."

SAMPLE: DO NOT FAX TO DATAFAX

MTN 003 VOICE (160) PRE-1 (012)

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

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Pre-existing Conditions

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

1.

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

2.

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

3.

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

4.

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

5.

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

6.

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

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Pre-existing Conditions (PRE-1)

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

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

Item-specific Instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ Outcome Number ☐

MTN003 VOICE (160) PO-1 (442)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Pregnancy Outcome

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

If Outcome Number recorded above is 2 or greater, go to item 2.

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

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

3. Place of delivery/outcome:
   - ☐ home
   - ☐ hospital
   - ☐ clinic
   - ☐ unknown
   - ☐ other, specify: _____

4. Specify Outcome: *Mark only one.*
   - ☐ 4a. full term live birth (≥ 37 weeks)
   - ☐ 4b. premature live birth (< 37 weeks)
   - ☐ 4c. stillbirth/intrauterine fetal demise (≥ 20 weeks)
   - ☐ 4d. spontaneous abortion (< 20 weeks)
   - ☐ 4e. ectopic pregnancy
   - ☐ 4f. therapeutic/elective abortion
   - ☐ 4g. other, specify: _____

   → 4a1. **Method:** *C-section* ☐ *vaginal* ☐

   If full term live birth, go to item 6 on page 2.

   → *If the pregnancy or outcome was associated with maternal complications or symptoms that would otherwise be reported as an AE, report these on an AE Log. Complete an EAE Reporting form, if applicable.*

5. Provide a brief narrative of the circumstances: _____

_____

_____

☐ ☐ ☒ ☐ 12-AUG-10

0 1 Language

Staff Initials / Date

Pregnancy Outcome (PO-1)

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

General Information/Instructions: A Pregnancy Outcome form is required for each Pregnancy Report and History form that is completed for a participant.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the participant's corresponding Pregnancy Report and History form.
- **Outcome Number:** A pregnancy outcome can be an infant or fetus. The conception of twins, for example, will result in reporting of two outcomes. For pregnancies resulting in one pregnancy outcome, record "1" here. For pregnancies with multiple outcomes, record the outcome number matching the outcome data recorded on the form.
- **Outcome unobtainable:** If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and fax both pages of this form to SCHARP DataFax.
- **Item 1:** If a pregnancy results in two outcomes, complete two Pregnancy Outcome forms (one for each outcome). Both Outcome forms will have the same visit code but different outcome numbers (for example, one Outcome form will have an outcome number =1 and the second form will have an outcome number = 2).
- **Item 4:** If the outcome is spontaneous fetal death, still birth, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an Adverse Experience. If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, if prior to termination, with "procedure/surgery" marked under item 7, "Treatment." If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-Specific Procedures (SSP) Manual, and *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2* for guidance on AE and expedited AE reporting requirements.
- **Item 5:** Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ Outcome Number ☐

MTN003 VOICE (160) PO-2 (443)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Pregnancy Outcome

☐ No data recorded on this page.

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

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

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

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

6b. Describe the congenital anomaly/defect: _____

_____

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

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

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

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

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

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

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

☐ ☐ ☒ ☐ 12-AUG-10

0 1 Language _____ Staff Initials / Date

Pregnancy Outcome (PO-2)

Item-specific Instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) PR-1 (440)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Pregnancy Report and History

PREGNANCY REPORT

		dd	MMM	yy
1.	First day of last menstrual period:	☐☐	☐☐☐	☐☐
2.	Estimated date of delivery:	☐☐	☐☐☐	☐☐

		yes	no
3.	What information was used to estimate the date of delivery?		
3a.	last menstrual period	☐	☐
3b.	initial ultrasound < 20 weeks	☐	☐
3c.	initial ultrasound ≥ 20 weeks	☐	☐
3d.	physical examination	☐	☐
3e.	conception date by assisted reproduction	☐	☐
3f.	other, specify: _____	☐	☐

PREGNANCY HISTORY

		yes	no
4.	Has the participant ever been pregnant before?	☐	☐ → ***If no, end of form.***
4a.	Is this the participant's first pregnancy since enrollment in this study?	☐	☐ → ***If no, go to item 5.***
4b.	Number of full term live births (≥ 37 weeks):	☐☐	
4c.	Number of premature live births (< 37 weeks):	☐☐	
4d.	Number of spontaneous fetal deaths and/or still births (≥ 20 weeks):	☐☐	
4e.	Number of spontaneous abortions (< 20 weeks):	☐☐	
4f.	Number of therapeutic/elective abortions:	☐☐	
4g.	Number of ectopic pregnancies:	☐☐	
5.	Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	☐	☐ → ***If no, end of form.***
5a.	If yes, specify: _____		

Comments: _____

☐☐☐☒ 17-MAR-09

0 1
Language

Staff Initials / Date

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: A Pregnancy Report and History form is required for each new pregnancy that the participant experiences during the study.

- **Visit Code:** Record the visit code of the visit at which study staff became aware that the participant is/was pregnant.

Item-specific instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

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

MTN003 VOICE (160) PH-1 (410)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Product Hold/Discontinuation Log

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

2. Why is study product being held?

   ☐ pregnancy

   ☐ breastfeeding

   ☐ HIV positive result

   ☐ creatinine clearance < 50 mL/min

   ☐ Hepatitis B infection

   ☐ other adverse experience

   → *AE Log page #* ☐☐☐

   ☐ other, specify: _____

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

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

   In item 4a, record the date and visit code on which the participant would have been instructed to resume product use if not being held for another reason.

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

Comments: _____

☐☐☐☒ 17-MAR-09

01 Language

_____ Staff Initials / Date

Product Hold/Discontinuation Log (PH-1)

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

General Information/Instructions: This form is completed each time a participant is instructed to temporarily stop (hold) or permanently discontinue study product use prior to her expected Product Use End Visit. If, at the same study visit, a product hold/discontinuation is initiated for more than one reason, complete a Product Hold/Discontinuation Log page for each reason. The same visit code should be used on each Log page.

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

Item-specific Instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) PRD-1 (080)

Participant ID

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

Product Re-supply and Re-issues

Visit Date

☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

RETURNED

1. Did the participant return any **unused** study product at this visit?

NO LONGER APPLICABLE FOR THIS PROTOCOL.

1a. Number of **unused applicators** of study gel returned: .....

1b. Number of **TDF or placebo tablets** returned: .....

1c. Number of **FTC/TDF or placebo tablets** returned: .....

1d. Date study product was returned: .....

RE-SUPPLY

2. Was any study product re-supplied to the participant at this visit? *If no, refer to instructions on back for Reason Code.* — *yes* ☐ *no* ☐ → *Reason Code* ☐ — *Go to item 3. If "9" (other), record reason in Comments.*

2a. Number of **applicators** of study gel re-supplied: ..... ☐☐ *applicators* **OR** *N/A* ☐

2b. Number of **TDF or placebo tablets** re-supplied: ..... ☐☐ *tablets* **OR** *N/A* ☐

2c. Number of **FTC/TDF or placebo tablets** re-supplied: ..... ☐☐ *tablets* **OR** *N/A* ☐

2d. Date study product was re-supplied: ..... ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

RE-ISSUED

3. Was any study product re-issued to the participant at this visit? *yes* ☐ *no* ☐ → ***If no, end of form.***

3a. Number of **applicators** of study gel re-issued: ..... ☐☐ *applicators* **OR** *N/A* ☐

3b. Number of **TDF or placebo tablets** re-issued: ..... ☐☐ *tablets* **OR** *N/A* ☐

3c. Number of **FTC/TDF or placebo tablets** re-issued: ..... ☐☐ *tablets* **OR** *N/A* ☐

3d. Date study product was re-issued: ..... ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

Comments: _____

☐ ☐ ☒ ☐ 12-AUG-10

0 1
Language

Staff Initials / Date

Product Re-supply and Re-issues (PRD-1)

Purpose: This form is used to document when study product is dispensed and/or re-issued during the study. Completion of this form is required at each monthly follow-up visit prior to the PUEV/early termination visit, and at each interim visit when study product is re-supplied and/or re-issued. Completion of this form is also required at interim visits when study product is returned and a Product Returns form is completed.

General Information/Instructions:

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

Item-specific Instructions:

- **Item 2:** If no study product was dispensed to the participant at this visit, record the Reason Code from the table below in the space provided. Provide additional relevant details on the Comments line at the bottom of the form. If the code is not listed below, record "9" and specify the reason on the Comments line.

Reason	Code
Site-initiated product hold/discontinuation	1
Participant complained of side effects	2
Husband/Regular sex partner does not want her to continue study product use	3
Family member does not want her to continue study product use	4
Other *(specify reason on Comments line at bottom of the form)*	9

- **Item 2a:** Record the number of newly dispensed **applicators** of study gel given to the participant at this visit. This will be the same amount documented on the **Participant-specific Pharmacy Dispensing Record**. Mark the "N/A" box if the participant was randomized to the oral group.
- **Item 2b:** Record the number of newly dispensed **TDF or placebo study tablets** given to the participant at this visit. This will be the same amount documented on the **Participant-specific Pharmacy Dispensing Record**. Mark the "N/A" box if the participant was randomized to the vaginal group.
- **Item 2c:** Record the number of newly dispensed **FTC/TDF or placebo study tablets** given to the participant at this visit. This will be the same amount documented on the **Participant-specific Pharmacy Dispensing Record**. Mark the "N/A" box if the participant was randomized to the vaginal group.
- **Item 3a:** Record the number of **applicators** of study gel returned by and given back to the participant at this visit. Mark the "N/A" box if the participant was randomized to the oral group.
- **Item 3b:** Record the number of **TDF or placebo study tablets** returned by and given back to the participant at this visit. Mark the "N/A" box if the participant was randomized to the vaginal group.
- **Item 3c:** Record the number of **FTC/TDF or placebo study tablets** returned by and given back to the participant at this visit. Mark the "N/A" box if the participant was randomized to the vaginal group.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) PRT-1 (079)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Product Returns

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

If the participant is randomized to vaginal study product, go to item 5.

ORAL PRODUCTS RETURNED

		# bottles returned	*# tablets returned*
1.	Returned **TDF or placebo**:	☐	☐☐

		# bottles returned	*# tablets returned*
2.	Returned **FTC/TDF or placebo**:	☐	☐☐

		*# bottles **not** returned*	*# tablets **not** returned*
3.	Unused **TDF or placebo** not returned:	☐	☐☐

		*# bottles **not** returned*	*# tablets **not** returned*	
4.	Unused **FTC/TDF or placebo** not returned:	☐	☐☐ →	***End of form.***

VAGINAL PRODUCTS RETURNED

		# applicators returned
5.	Returned **unused applicators**:	☐☐

		*# applicators **not** returned*
6.	**Unused applicators** not returned:	☐☐

Comments: _____

_____

_____

☐ ☐ ☐ ☒ 12-AUG-10

0 1
Language

_____
Staff Initials / Date

Product Returns (PRT-1)

Purpose: This form is used to document study product returns. Clinic staff complete this form by transcribing information from a completed MTN-003 Unused Product Returns Slip onto this CRF for a given participant visit. Completion of this form is required at every monthly study visit during the product use period, at the PUEV/early termination visit, and at interim visits when study product is returned. Completion of this form is also required at interim visits when study product is re-supplied and/or re-issued, and a Product Re-supply and Re-issues form is completed.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Form Completion:** Complete the items on this form by transcribing information from the MTN-003 Unused Product Returns Slip provided by pharmacy staff. Note that pharmacy staff have been instructed to include only study product dispensed and re-issued at the participant's last visit. If a participant did not return any product (for example, she did not return any TDF bottles or tablets), pharmacy staff will document this by recording zeros in the applicable boxes on the slip. If the participant returns product that was dispensed or re-issued to her prior to her last visit, pharmacy staff will record these returns in the Pharmacy staff comments section only of the slip.
- **Questions:** If clinic staff have any questions about any of the information contained on the slip, they should contact the pharmacy staff member who completed the slip and resolve any questions/discrepancies before completing this CRF. Any corrections to completed slips must be made by pharmacy staff, and must be made to both parts of the slip (the white original and yellow copy).

Item-specific Instructions:

- **Items 1–4:** Complete these items only for participants assigned to oral study product. For participants assigned to vaginal study product, leave items 1-4 blank.
- **Items 5 and 6:** Complete these items only for participants assigned to vaginal study product. For participants assigned to oral study product, leave items 5 and 6 blank.
- **Comments:** Use this section to provide any additional comments. If relevant comments are provided in the Pharmacy staff comments section of the slip, transcribe those comments here as needed.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) PEV-1 (280)

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number Participant Number Chk

Product Use End Visit

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Was the Product Use End Visit conducted? ..... *yes* ☐ *no* ☐ → ***If no, go to item 1b.***

1a. Visit Code when Product Use End Visit was conducted: ☐☐ . ☐ → ***End of form.***

dd *MMM* *yy*

1b. Date the site determined that the participant was permanently discontinued from study product use: ..... ☐☐ ☐☐☐ ☐☐

1c. Specify the reason the visit was not conducted: _____

_____

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Product Use End Visit (PEV-1)

Purpose: This form is used to document the required Product Use End Visit. It is administered only once to each enrolled participant as part of her Product Use End Visit. If the participant did not complete a Product Use End Visit (for example, she is lost to follow up), complete this form when it is determined that she has permanently discontinued study product use.

General Information/Instructions:

- **Visit Date:** If the participant completes a Product Use End Visit (PUEV), record the date when the PUEV is conducted. If the participant does not complete a PUEV, record the date when this form is completed.

Item-specific Instructions:

- **Item 1a:** Record the visit code assigned to the follow-up month when the Product Use End Visit is completed. For example, if the PUEV is completed at Month 33, record the Month 33 visit code (36.0). Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Item 1b:** This item is completed only for those participants who do not complete a PUEV. It is used to capture the date when **site staff** permanently discontinue a participant from study product use (either because of a safety reason, as documented on a Product Hold/Discontinuation Log, or because the participant has completed her expected study product use period). If site staff permanently discontinue study product use early due to a safety reason, record the date in item 4a of the Product Hold/Discontinuation Log documenting the permanent discontinuation. For all other participants, record the target date of the month in follow-up (Month 33, for example) when the participant was expected to complete the PUEV.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) SL-1 (151)

Participant ID

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

Safety Laboratory Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

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

1. HEMOGRAM

Not reported			Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
☐	1a.	WBC ..... ☐☐☐.☐ *x10³/mm³*	☐	☐☐☐	OR ☐
☐	1b.	Hemoglobin ..... ☐☐.☐ *g/dL*	☐	☐☐☐	OR ☐
☐	1c.	Hematocrit ..... ☐☐.☐ *%*			
☐	1d.	MCV ..... ☐☐☐.☐ *fL*			
☐	1e.	Platelets ..... ☐☐☐☐.☐ *x10³/mm³*	☐	☐☐☐	OR ☐

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

2. DIFFERENTIAL

Not reported			*percentage*		Absolute Count *cells/mm³*	Severity Grade *If applicable*	AE Log Page #	Not reportable as an AE
☐	2a.	Neutrophils	☐☐.☐	AND	☐☐☐☐☐	☐	☐☐☐	OR ☐
☐	2b.	Lymphocytes			☐☐☐☐	☐	☐☐☐	OR ☐
☐	2c.	Monocytes			☐☐☐☐			
☐	2d.	Eosinophils			☐☐☐☐			
☐	2e.	Basophils			☐☐☐☐			

Comments: _____

☐☐☐☒ 17-MAR-09

0 1
Language

_____
Staff Initials / Date

Safety Laboratory Results (SL-1)

Purpose: This form is used to document local safety laboratory results of specimens collected during screening, enrollment, and study follow-up.

General Information/Instructions: Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for **all** 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 (if ongoing at Enrollment), or an adverse experience on an Adverse Experience (AE) Log (for follow-up visit test result(s) only).

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. 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. Record a complete date.
- **Alternate Collection Date**: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. Record a complete date.
- **Not Done/Not Collected:** For the hemogram and differential, mark *either* the "Not done/Not collected" box *or* enter a test result. If the "Not Done/Not Collected" box is marked, record reason on the Comments line.
- **Not reported:** If a hemogram or differential was done but a given result was not reported, mark the "Not reported" box.

Results Reporting:

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

Severity Grade:

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

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

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

Item-specific Instructions:

- Item 2a: Neutrophils must be recorded as both a percentage and absolute count.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) SL-2 (152)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Safety Laboratory Results

3. BLOOD CHEMISTRIES

Not done/ Not collected	Alternate Collection Date dd	MMM	yy		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 ☐☐☐			
☐	☐☐	☐☐☐	☐☐	3d. Weight	☐☐☐ kg			
					mg/dL	Severity Grade If applicable	AE Log Page #	Not reportable as an AE
☐	☐☐	☐☐☐	☐☐	3e. Phosphorus (Phosphate)	☐☐.☐	☐	☐☐☐	OR ☐

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

4. URINE TESTS

Not done		negative	trace	1+	2+	3+	4+	Severity Grade If applicable	AE Log Page #	Not reportable as an AE
☐	4a. Protein	☐	☐	☐	☐	☐	☐	☐	☐☐☐	OR ☐
☐	4b. Glucose	☐	☐	☐	☐	☐	☐	☐	☐☐☐	OR ☐

		negative	positive
☐	4c. Leukocyte esterase (LE)	☐	☐
☐	4d. Nitrites	☐	☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

01

Language

Staff Initials / Date

Safety Laboratory Results (SL-2)

Item-specific Instructions:

- **Item 3c1:** When calculating the participant's creatinine clearance, use the age and weight of the participant at the time the blood specimen is drawn. If the participant was not weighed at the visit when the blood specimen was drawn, but was weighed at a previous visit (within the allowable window for creatinine clearance per the SSP Manual), record the weight from the previous visit. Also, record in the "Alternative Collection Date" boxes the date of the previous visit when the participant was weighed. If the participant has a creatinine value but cannot have her creatinine clearance calculated (due to missing weight data), line through the response boxes and initial and date.
- **Item 4:** If a dipstick urinalysis was done but a given result was not reported, mark the "Not done" box.
- **Item 4b:** Grade the severity of the urine glucose value according to the "Proteinuria, random collection" row of the *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*.
- **Items 4c–4d:** If the result is negative or trace, mark the "negative" box. If the result is 1+ or greater, mark the "positive" box.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) SEH-1 (034)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Screening and Enrollment HIV Test Results

Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. HIV TEST RESULTS

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

If positive for both, participant is ineligible. End of form. If discordant, notify Network Lab and perform Western blot.

Not done		*negative*	*positive*	*indeterminate*
☐	1c. HIV Western Blot	☐	☐	☐

If positive, participant is ineligible.

If indeterminate, participant is ineligible at this time. Repeat testing in approximately one month. Notify Network Lab.

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Screening and Enrollment HIV Test Results (SEH-1)

Purpose: This form is used to document local laboratory HIV test results of blood collected during the Screening and Enrollment Visits.

General Information/Instructions: 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.

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

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

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

Item-specific Instructions:

- **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 1c:** Mark *either* the “Not done” box *or* enter the test result.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) SPE-1 (041)

Participant ID

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

Screening and Enrollment Pelvic Exam

Exam Date

☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

		abnormal findings	*no abnormal findings*
1.	Pelvic exam assessments:	☐	☐

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
- ☐ Cervical friability
- ☐ Edema
- ☐ Abnormal cysts
- ☐ Mass
- ☐ Warts
- ☐ Adnexal tenderness
- ☐ Cervical motion tenderness
- ☐ Uterine tenderness
- ☐ Other abnormal findings, specify: _____

Record abnormal findings observed on Pre-existing Conditions form, if applicable.

		yes	*no*
2.	Are any of these exam findings a severity Grade 2 or higher?.....	☐	☐

If yes, participant is ineligible at this time.

3. Cervical Ectopy: Percentage of cervical surface area.

0%	*1–25%*	*26–50%*	*51–75%*	*> 75%*	*N/A*
☐	☐	☐	☐	☐	☐

			not done
4.	Weight:	☐☐☐ *kg* **OR**	☐

		dd	*MMM*	*yy*
5.	First day of last menstrual period:	☐☐	☐☐☐	☐☐
6.	Last day of last menstrual period:	☐☐	☐☐☐	☐☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Screening and Enrollment Pelvic Exam (SPE-1)

Purpose: This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic exam conducted during the Screening Part 2 Visit and the Enrollment Visit, if applicable. This form should be completed once for each participant to document the Screening Part 2 pelvic exam. If a pelvic exam is conducted as part of the Enrollment Visit, complete a new form to document the enrollment pelvic exam.

General Information/Instructions: This form is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment Visit.

Note: For each enrolled participant, only one Screening and Enrollment Pelvic Exam form for the Screening Part 2 Visit (assigned visit code 02.0) should be faxed to SCHARP DataFax. There may be cases where multiple screening pelvic exams are conducted as part of the SAME screening attempt (e.g., in cases where an otherwise eligible participant has a symptomatic STI at the initial screening pelvic exam that requires a second screening pelvic exam (prior to enrollment) within the 56-day window for screening). In such cases, use this form to document the initial screening pelvic exam only, and document the second screening exam in the chart notes only. A new Screening and Enrollment Pelvic Exam form should be completed for the Screening Part 2 Visit **only** if the participant re-screens for the study. If a participant does screen 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.

Item-specific Instructions:

- **Item 1:** If a pelvic exam is conducted at the Enrollment Visit, complete a new Screening and Enrollment Pelvic Exam form (assigned visit code 03.0) to document the enrollment exam.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding on the line provided.
- **Item 3:** Mark the “N/A” box if the participant does not have an intact cervix.
- **Item 4:** Participant weight is required at the Screening Part 2 Visit. Transcribe the participant’s weight from the non-DataFax Physical Exam form or other applicable source documentation. Remember to use leading zeros when needed and round to the nearest whole number. If participant weight was required but not done, mark the “not done” box and specify the reason on the Comments line.
- **Items 5–6:** Complete these items based on source documentation recorded in the participant’s Baseline Medical and Menstrual History.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) SC-1 (005)

Participant ID

Site Number – Participant Number – Chk

Screening Consent

Visit Date

dd MMM yy

1. Is the participant within the protocol-specified age range for study eligibility, as verified per site SOPs? ..... yes ☐ no ☐ → ***If no, participant is ineligible. End of form.***

2. Is the participant within the site local age range for study eligibility, per site SOPs? ..... yes ☐ no ☐ → ***If no, participant is ineligible. End of form.***

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

3a. When was the informed consent form for screening marked or signed? ..... ☐☐ ☐☐☐ ☐☐
dd MMM yy

Comments: _____

☐ ☐ ☒ ☐ 31-JAN-11

0 1
Language

Staff Initials / Date

Screening Consent (SC-1)

Purpose: 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 003 Participant ID.

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

Note: There is no visit code field on this form, since this form is only completed at the Screening Part 1 Visit. 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 Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.

Item-specific Instructions:

- **Item 1:** Per protocol version 1.0, a participant must be between the ages of 18 and 40 years (inclusive) *at the time of screening* as verified according to site standard operating procedures (SOPs). Per protocol version 2.0, a participant must be between the ages of 18 and 45 years (inclusive) *at the time of screening* as verified according to SOPs. Participants who are not within the eligible age range, per the applicable version of the protocol, should not be screened for the study.
- **Item 3a:** If the participant marks the informed consent form using her thumbprint, record the date the thumbprint was made.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) SCR-1 (147)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Seroconverter Laboratory Test Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

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

1. T CELL SUBSETS

Unable to analyze

1a. Absolute CD4+ ..... ☐ **OR** *cells/mm^3* ☐☐☐☐

not available

1a1. CD4+ % ..... ☐ **OR** ☐☐.☐ *%*

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

2. HIV RNA

2a. HIV RNA PCR > ☐ = ☐ < ☐ *viral copies/mL* ☐☐☐☐☐☐☐☐

2b. HIV RNA PCR kit lower limit of detection: ..... *50* ☐ *400* ☐ **OR** *viral copies/mL* ☐☐☐

Comments: _____

_____

_____

☐ ☐ ☐ ☒ 17-MAR-09

01 Language

_____ Staff Initials / Date

Seroconverter Laboratory Test Results (SCR-1)

Purpose: This form is used to document CD4+ and HIV RNA test results obtained during the study.

General Information/Instructions: Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax when results for all collected specimens are available and recorded.

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. 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 Initial Specimen Collection Date. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.
- **Not done/Not collected:** For every test, mark *either* the "Not done/Not collected" box *or* enter a test result. If the "Not done/Not collected" box is marked, record reason on the Comments lines.

Item-specific Instructions:

- **Item 1a1:** If automatically calculated, record the CD4+ percentage that was reported for the specimen in item 1a. If the CD4+ percentage is not available (was not reported and would have to be manually calculated), mark the "not available" box.
- **Item 2**: Note that the ">" symbol is "greater than" and the "<" symbol is "less than."
- **Item 2a:** Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay. For example, if a participant is tested with an assay that has 400 viral copies/mL as the lower limit of detection, and the lab reports her result as "238 viral copies/mL," mark the "=" box and record "00000238" viral copies/mL for item 2a.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) SS-1 (161)

Participant ID

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

Specimen Storage/PK

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

SPECIMEN STORAGE

Alternate Collection Date (*dd* *MMM* *yy*)		*not required*	*stored*	*not stored*	*Reason:*
☐☐ ☐☐☐ ☐☐	1. Plasma	☐	☐	☐→	_____
☐☐ ☐☐☐ ☐☐	2. Gram stain (vaginal)	☐	☐	☐→	_____
☐☐ ☐☐☐ ☐☐	3. Vaginal swab for biomarker analyses	☐	☐	☐→	_____

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

Alternate Collection Date (*dd* *MMM* *yy*)		*not required*	*stored*	*not stored*	*Reason:*
☐☐ ☐☐☐ ☐☐	4. Endocervical swab for biomarker analyses	☐	☐	☐→	_____

	yes	*no*	*N/A*
4a. Was blood visible on the swab?	☐	☐	☐

Alternate Collection Date (*dd* *MMM* *yy*)			*not done*
☐☐ ☐☐☐ ☐☐	5. Height	☐☐☐ *cm*	☐→

At Screening Part 2 or Enrollment Visit, end of form.

PK INFORMATION

	dd	*MMM*	*yy*	*24-hour clock* *hr*	*min*	*N/A*
6. Date and time of last study gel insertion:	☐☐	☐☐☐	☐☐	☐☐ :	☐☐	**OR** ☐
7. Date and time of last dose of **darker** tablet:	☐☐	☐☐☐	☐☐	☐☐ :	☐☐	**OR** ☐
8. Date and time of last dose of **lighter** tablet:	☐☐	☐☐☐	☐☐	☐☐ :	☐☐	**OR** ☐

If N/A to all, end of form.

	best estimate	*source documentation*
9. Is the time of the last dose/insertion a best estimate, or did the participant provide source documentation?	☐	☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

_____
Staff Initials / Date

Specimen Storage/PK (SS-1)

Purpose: This form is used to document collection and storage of MTN 003 specimens that will be tested at a lab other than the local site laboratory.

General Information/Instructions: Check the information on this form against the MTN 003 LDMS Specimen Tracking Sheet completed for this visit to make sure the information is the same.

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- **Initial Specimen Collection Date:** Record the date that the first specimen(s) was *collected* for this visit. A complete date is required.
- **Alternate Collection Date**: This date is to be completed ONLY if the specimen was collected on a different day than the Initial Specimen Collection Date. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

Item-specific Instructions:

- **Items 1–4**: If the specimen is not required to be collected and stored at this visit, mark "not required." If the specimen is required to be stored, but for some reason it is not stored at this visit, mark "not stored" and record the reason why on the line provided.
- **Item 3a:** Mark the "N/A" box if a vaginal swab was not collected at this visit.
- **Item 4a:** Mark the "N/A" box if an endocervical swab was not collected at this visit.
- **Item 5:** Participant height may be transcribed from the Physical Exam (non-DataFax) form, if completed for this visit. Participant height is required at the Screening Part 2, semi-annual, annual, and Product Use End Visits.
- **Items 6–8:** Documentation of the date and time of last dose is required at each quarterly visit and the Product Use End Visit.
    - **Item 6:** Mark the "N/A" box if the participant is in the oral group or if the participant is in the vaginal group and has not yet used study gel.
    - **Items 7 and 8:** Mark the "N/A" box if the participant is in the vaginal group or if the participant is in the oral group and has not yet taken the study tablets. The "darker tablet" refers to Truvada or placebo, and the "lighter tablet" refers to tenofovir or placebo.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) 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* ☐☐

1. STI SEROLOGY

		non-reactive	*reactive*
1a.	Syphilis RPR screening test	☐	☐

If non-reactive, go to item 2.

1a1. Syphilis titer ..... **1:** ☐☐☐☐

		negative	*positive*	*indeterminate*
1b.	Syphilis confirmatory test ..... (MHA-TP or TPHA)	☐	☐	☐

If positive at Screening, participant must complete treatment and be asymptomatic to enroll.
If positive during follow-up, consult SSP for further guidance on treatment and AE reporting requirements.

2. OTHER STI TESTS

Alternate Collection Date

Not done/ Not collected ☐ *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

		negative	*positive*
2a.	*N. gonorrhea*	☐	☐
2b.	*C. trachomatis*	☐	☐

If positive at Screening, participant must complete treatment and be asymptomatic to enroll.
If newly positive during follow-up, complete Adverse Experience Log.

Alternate Collection Date

Not done/ Not collected ☐ *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

		non-reactive	*reactive*
2c.	Hepatitis B Surface Antigen	☐	☐
2d.	Hepatitis B Surface Antibody	☐	☐

Offer participant HBV vaccination unless contraindicated. Refer to protocol Appendix IV.

If reactive at Screening, participant is ineligible. If reactive during follow-up, complete Product Hold/ Discontinuation Log and Adverse Experience Log.

Comments: _____

☐ ☐ ☐ ☒ 31-JAN-11

0 1 Language

Staff Initials / Date

STI Laboratory Results (SLR-1)

Purpose: This form is used to document local STI laboratory results of specimens collected during screening and study follow-up.

General Information/Instructions: Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for **all** 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, or an adverse experience on an Adverse Experience (AE) Log (for follow-up visit test result(s) only).

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. 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. Record a complete date.
- **Alternate Collection Date**: This date is to be completed ONLY if the specimen is collected after the Initial Specimen Collection Date for this same visit. Record a complete date.
- **Not Done/Not Collected:** For every test, mark *either* the "Not done/Not collected" box *or* enter a test result. If the "Not done/Not collected" box is marked, record reason on the Comments line.

Item-specific Instructions:

- **Item 1a:** If the syphilis screening test is reactive, items 1a1 and 1b must be completed.
- **Item 1a1:** Use leading zeros when recording a syphilis titer level. For example, a titer level of 1:16 would be recorded on the form as "1:0016."
- **Items 1b, 2a–2b:** If a result is positive at any time during the study (screening through study exit), provide treatment if applicable, per the SSP. Document treatment on the Concomitant Medications Log.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code 8 9 . 0 1

MTN003 VOICE (160) SBA-1 (260)

Participant ID

Site Number – Participant Number – Chk

Study Exit Behavior Assessment

Visit Date

dd MMM yy

Thank you for coming today for the study. Your participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the **past 2 months**, have you had vaginal sex? ..... yes ☐ no ☐ → *If no, go to statement above item 4 on page 2.*

The next question is about vaginal sex in the **past 7 days**.

2. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... # of acts ☐☐ → *If 00, go to item 3.*

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

2a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ***Use visual aid.*** ..... # of acts with condom ☐☐ → *If 00, go to statement above item 4 on page 2.*

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** yes ☐ no ☐ → *If no, go to statement above item 4 on page 2.*

3a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... male condom ☐ female condom ☐

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Study Exit Behavior Assessment (SBA-1)

Purpose: This form is used to collect information about the participant's sexual behavior and possible problems (emotional, physical, social, or other difficulties) experienced while she took part in the study. This is an interviewer-administered form, and it is administered only once to each enrolled participant as part of her Study Exit Visit.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code 8 9 . 0 1

MTN003 VOICE (160) SBA-2 (261)

Participant ID

Site Number – Participant Number – Chk

Study Exit Behavior Assessment

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

4. In the **past 2 months**, have you had any problems with the following people as a result of being in this study:

		yes	no	N/A
4a.	your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
4b.	people at home/family?	☐	☐	☐
4c.	your friends/personal relationships?	☐	☐	☐
4d.	people at work?	☐	☐	☐
4e.	people at school?	☐	☐	☐
4f.	a nurse or clinician or doctor outside of the study?	☐	☐	☐
4g.	your landlord or property owner?	☐	☐	☐
4h.	anyone else? If yes, specify:	☐	☐	☐

*Local Language:*_____ *English:* _____

If no or N/A to all, end of form.

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Study Exit Behavior Assessment (SBA-2)

Item-specific Instructions:

- **Item 4:** Read each item 4a–4h aloud and mark the participant's answer. If "yes" is marked for item 4h, record the participant's verbatim response. Also provide the English translation in the space provided. If items 4a through 4h are all "no" or "N/A," end the form. Mark the "No data recorded on this page" box in the upper right corner of page 3. Also record the Visit Code, PTID, and staff initials and date on page 3 of this form. Leave all other items on page 3 blank. Fax all 3 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code 8 9 . 0 | 1

MTN003 VOICE (160) SBA-3 (262)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Study Exit Behavior Assessment

☐ No data recorded on this page.

5. Has this problem/have any of these problems resulted in:

		yes	no
5a.	emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem.	☐	☐
5b.	physical harm to you? For example, has anyone physically hurt you as a result of this problem?	☐	☐
5c.	economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income?	☐	☐
5d.	physical or other harm to your children?	☐	☐

6. Please describe the problem, including outcome, if any. ***Do not record the participant's verbatim response.***

Local Language: _____

_____

_____

_____

English: _____

_____

_____

_____

End of interview.

Interviewer: *Complete items 7–7a after the interview.*

7. *Did any of the problem(s) require reporting as an Adverse Event (AE)?* yes ☐ no ☐ → ***If no, end of form.***

7a. *Record AE Log page number(s):*

AE Log page # [ ][ ][ ] *AE Log page #* [ ][ ][ ] *AE Log page #* [ ][ ][ ]

Study Exit Behavior Assessment (SBA-3)

Item-specific Instructions:

- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 6:** Do not record the participant's verbatim response; describe the problem and outcome, if any, in the local language. Also provide the English translation in the space provided.
- **Items 7 and 7a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code 8 9 . 0 1

MTN003 VOICE (160) SEV-1 (221)

Participant ID

Site Number – Participant Number – Chk

Study Exit Visit

Visit Date

dd MMM yy

1. Was the Study Exit Visit conducted? ..... yes ☐ no ☐

   → ***If yes, go to item 2.***

   1a. Specify the reason the visit was not conducted: _____

   → ***End of form.***

2. hCG for pregnancy: ..... negative ☐ positive ☐ not done ☐

   → ***If negative or positive, go to item 3. If newly positive, complete Pregnancy Report and History form.***

   2a. Specify the reason the pregnancy test was not done: _____

3. Were any **new** adverse experiences reported at this visit? ..... yes ☐ no ☐ → ***If no, go to item 4.***

   3a. How many **new** AE Log pages were completed for this visit? ..... ☐☐ *# of **new AE Log** pages*

4. Did the participant complete the ACASI Follow-up Questionnaire at this visit? ..... yes ☐ no ☐ → ***If no, specify reason in Comments. Go to item 5.***

   4a. Date ACASI Follow-up Questionnaire was completed: ..... dd MMM yy

5. Did the participant receive a Hepatitis B vaccination (initial or follow-up) at this visit? ..... yes ☐ no, vaccination not indicated ☐ no, participant refused ☐

   → ***If yes, record the vaccination on the Concomitant Medications Log.***

   → ***If "no, vaccination not indicated" or "no, participant refused," end of form.***

   5a. Which dose did she receive at this visit? ..... 0 (initial dose) ☐ 1–2 months ☐ 4–6 months ☐

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

Language 0 1

Staff Initials / Date

Study Exit Visit (SEV-1)

Purpose: This form is used to document the required Study Exit/Termination Visit. It is completed once for each study participant at either the scheduled Study Exit Visit or when it is determined that the participant is no longer participating in the study.

General Information/Instructions:

- **Visit Date:** If the participant completes a Study Exit Visit, record the date when the Study Exit Visit is conducted (regardless of whether the Study Exit Visit occurs prior to, on, or after the month when the participant is expected to terminate from the study). If the participant does not complete a Study Exit Visit, record the date when this form is completed.

Item-specific Instructions:

- **Item 1:** If the participant did not complete a Study Exit Visit (e.g., due to loss to follow-up), mark the "no" box and complete item 1a.
- **Item 2:** Pregnancy testing is required at the Study Exit/Termination Visit. 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 2a. ***Note:*** *A Pregnancy Report and History form must be completed for each new pregnancy.*
- **Item 3:** 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 3a** 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 4:** Completion of the ACASI Follow-up Questionnaire is required at the Study Exit/Termination Visit. If the questionnaire was not done, mark the "no" box and record reason on the Comments lines.
- **Item 5:** If a Hepatitis B vaccination was indicated per protocol but not offered, line through the response boxe, initial and date. Record reason on the Comments lines. If the participant has already completed the series, or is between shots at this visit, mark the "no, vaccination not indicated" box.

SAMPLE: DO NOT FAX TO DATAFAX

MTN003 VOICE (160) 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.***
- ☐ 2c. participant refused further participation, specify: _____
- 2d. participant unable to adhere to visit schedule **NOT APPLICABLE FOR THIS PROTOCOL.**
- ☐ 2e. participant relocated, no follow-up planned
- ☐ 2f. investigator decision, specify: _____
- ☐ 2g. unable to contact participant
- 2h. HIV infection **NOT APPLICABLE FOR THIS PROTOCOL.**
- ☐ 2i. inappropriate enrollment → ***End of form.***
- ☐ 2j. invalid ID due to duplicate screening/enrollment → ***End of form.***
- ☐ 2k. other, specify: _____
- ☐ 2l. early study closure → ***End of form.***

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: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

_____
Staff Initials / Date

Termination (TM-1)

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

Item-specific Instructions:

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

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) VPA-1 (230)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Thank you for coming today for the study. Your continued participation in this research study is important to help us try to find ways to protect women from getting HIV through sex. There are no right or wrong answers, and every answer is important, so I need you to be as honest and as accurate as you can. Some of the questions may seem very personal, but please remember that all of your answers will be kept confidential and none of your answers will affect your ability to participate in this research study.

The first few questions are about vaginal sex. By vaginal sex, I mean when a man puts his penis inside your vagina.

1. In the **past 3 months**, have you had vaginal sex? ..... *yes* ☐ *no* ☐ → *If no, go to statement below item 3a.*

The next question is about vaginal sex in the **past 7 days**.

2. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... *# of acts* ☐☐ → *If 00, go to item 3.*

I know you have been counseled to use condoms, but I also know some people find it difficult to use condoms every time they have sex.

2a. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ***Use visual aid.*** ..... *# of acts with condom* ☐☐ → *If 00, go to statement below item 3a.*

3. Now I would like to ask you about your most recent vaginal sex act, that is, the very last vaginal sex act that you had, including today. During the **last act** of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** *yes* ☐ *no* ☐ → *If no, go to statement below item 3a.*

3a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... *male condom* ☐ *female condom* ☐

If the participant was not re-supplied/re-issued study product <u>and</u> did not having any remaining unused product (regardless of expiry) in her possession in the past 4 weeks or more, go to statement above item 15 on page 6.

Vaginal Product Adherence and Behavior Assessment (VPA-1)

Purpose: This form is used to collect information about the participant's vaginal product use and possible problems (emotional, physical, social, or other difficulties) experienced while she is taking part in the study. This is an interviewer-administered form, and it is administered at each quarterly visit and at the Product Use End Visit.

General Information/Instructions:

- **Visit Code:** Record the visit code assigned to the visit. Refer to the Study-Specific Procedures (SSP) Manual for more specific information on assigning visit codes.
- Per the instruction below item 3a, items 4–14 should be left blank for participants who were not exposed to study product in the past 4 or more weeks. This applies to product holds/discontinuations *initiated by site staff*. It also applies to cases where a participant chooses on her own to stop product use *and* has refused to receive product.

Item-specific Instructions:

- **Item 2:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not had vaginal sex in the past 7 days, record "00" for this item.
- **Item 2a:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has not used a male or female condom during vaginal sex in the past 7 days, record "00" for this item.

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

I will now ask some questions about inserting study gel. We need to understand how women in the study are inserting their gel. We know that some women insert their gel every day while others miss some days or stop inserting gel for some time. Do not worry about telling me if there were times when you were not able to insert your gel every day. I would like to know what is really happening for you.

4. In the **past 4 weeks**, at what time of day did you typically insert gel? ***Read response categories aloud. Use visual aid.***

   ☐ morning

   ☐ afternoon

   ☐ evening

5. In the **past 4 weeks**, how often did you insert your gel at about the same time each day? ***Read response categories aloud. Showcard #1***

always	*sometimes*	*never*
☐	☐	☐

6. Different women have different ways of remembering to insert their gel. In the **past 4 weeks**, what has helped you remember to insert your gel? ***Do <u>not</u> read response categories aloud. Mark all that apply.***

   ☐ 6a. nothing → ***If nothing, go to item 7 on page 3.***

   ☐ 6b. calendar

   ☐ 6c. alarm/bell/cell phone ringer/pager

   ☐ 6d. husband/primary sex partner

   ☐ 6e. family member or friend

   ☐ 6f. association with a daily activity

   ☐ 6g. association with having sex

   ☐ 6h. association with taking Oral Contraceptives

   ☐ 6i. association with taking other pills or medications

   ☐ 6j. other, specify: *Local Language:* _____ *English:* _____

Vaginal Product Adherence and Behavior Assessment (VPA-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.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Items 4–14:** If the site permanently discontinued the participant's study product use 4 or more weeks ago, or has held the participant's study product use for the past 4 weeks, leave items 4–14 blank. Mark the "No data recorded on this page" box in the upper-right corner of pages 2–5, then proceed to the statement above item 15 on page 6.
- **Item 4:** Read each response category aloud and mark the participant's answer.
- **Item 5:** Read each response category aloud and mark the participant's answer.
- **Item 6:** Do not read responses 6a–6j aloud. If the participant reports a response other than those listed, mark item 6j and record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) VPA-3 (232)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

7. Different circumstances may prevent women from inserting their gel every day. Thinking about your experience in the **past 4 weeks**, please tell me **all** of the reasons that kept you from inserting your gel. ***Do not read response categories aloud. Mark all that apply.***

☐ 7a. not applicable—participant inserted gel every day → ***Go to item 8 on page 4.***

☐ 7b. participant didn't have the gel with her

☐ 7c. participant felt sick/was concerned about getting sick from the gel

☐ 7d. participant ran out of or lost the gel

☐ 7e. participant got tired of inserting the gel every day

☐ 7f. participant gave/sold/traded the gel to someone else

☐ 7g. participant had a change in her daily routine

☐ 7h. participant forgot or was too busy

☐ 7i. participant was on menses

☐ 7j. participant did not have sex/was not intending to have sex

☐ 7k. participant had difficulty inserting the gel

☐ 7l. participant didn't like the smell or feel of the gel

☐ 7m. someone else took/stole some of participant's gel

☐ 7n. participant's primary sex partner did not approve of her inserting the gel

☐ 7o. family member or friend did not approve of her inserting the gel

☐ 7p. other, specify: *Local Language:* _____ *English:* _____

Vaginal Product Adherence and Behavior Assessment (VPA-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.
- **No data recorded on this page:** Mark this box if all items on the page are left blank.
- **Item 7:** Do not read responses 7a–7p aloud. If the participant reports a response other than those listed, mark item 7p and record the participant's verbatim response. Also provide the English translation in the space provided.
- **Item 7p:** If the participant did not insert gel due to a product hold/discontinuation, mark the "other, specify" box and record the reason in the space provided. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) VPA-4 (233)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

8. In the **past 4 weeks**, how often did you insert the gel? Was it...
Read response categories aloud. Showcard #2

- ☐ every day
- ☐ usually (most days)
- ☐ sometimes (some days)
- ☐ rarely (not many days)
- ☐ never → ***If never, go to item 10.***

# of days

9. In the **past 4 weeks**, what is the longest **number of days** in a row that you did **not** insert the gel? ☐☐

10. Different circumstances may lead women to insert the study gel **more** than once per day. Thinking about your experience inserting gel in the **past 4 weeks**, please tell me **all** of the reasons that led you to insert gel **more** than once on any single day. ***Do <u>not</u> read response categories aloud. Mark all that apply.***

- ☐ 10a. not applicable—never inserted study gel more than once per day → ***If not applicable, go to item 12 on page 5.***
- ☐ 10b. participant forgot she had inserted gel already
- ☐ 10c. participant did not understand the instructions for inserting gel
- ☐ 10d. participant wanted to have the correct number of applicators at her next study visit
- ☐ 10e. participant had sex without a condom/had risky sex
- ☐ 10f. participant had a new partner
- ☐ 10g. participant wanted to make up for not inserting gel on earlier days
- ☐ 10h. participant thought it would protect her more
- ☐ 10i. participant's husband/primary sex partner asked her to insert more gel
- ☐ 10j. participant thought that the gel leaked out
- ☐ 10k. other, specify: *Local Language:* _____ *English:* _____

☐☐☐☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Vaginal Product Adherence and Behavior Assessment (VPA-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 all items on the page are left blank.
- **Item 8:** Read each response category aloud and mark the participant's answer.
- **Item 9:** Use leading zeros when needed so that all the boxes are filled. If the participant reports that she inserted gel every day, record "00" for this item.
- **Item 10:** Do not read responses 10a–10k aloud. If the participant reports a response other than those listed, mark item 10k and record the participant's verbatim response. Also provide the English translation in the space provided.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) VPA-5 (234)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

# of days

11. In the **past 4 weeks**, on how many days did you insert gel **more** than once per day? ..... ☐☐

12. Please rate your ability, over the **past 4 weeks**, to insert gel exactly as you were instructed. ***Read response categories aloud. Showcard #3***

- ☐ very poor
- ☐ poor
- ☐ fair
- ☐ good
- ☐ very good
- ☐ excellent

Now I will ask about inserting gel in the **past 7 days** (not including today).

13. In the **past 7 days** (not including today),...

# of days

13a. on how many days did you **not** insert gel? ..... ☐

# of days

13b. on how many days did you insert gel **once** per day? ..... ☐

# of days

13c. on how many days did you insert gel **more than once per day**? ..... ☐

This next question is about the **last time** you inserted the gel.

14. The **last time** you inserted the gel, was it in the morning, afternoon, or evening?

- ☐ morning
- ☐ afternoon
- ☐ evening

☐☐☐☒ 17-MAR-09

01

Language

Staff Initials / Date

Vaginal Product Adherence and Behavior Assessment (VPA-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 all items on the page are left blank.
- **Item 11:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she never inserted gel more than once per day, record "00" for this item.
- **Item 12:** Read each response category aloud and mark the participant's answer.
- **Items 13a–13c:** If the participant reports "none" or "zero," record "0." The sum of the responses to 13a–13c should equal "7."

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) VPA-6 (235)

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

For the last set of questions, I will ask you about problems you may have had or are having while in this study. By problem, I mean any emotional, physical, social, or other difficulties.

15. In the **past 3 months**, have you had any problems with the following people as a result of being in this study:

		yes	*no*	*N/A*
15a.	your primary sex partner? By primary sex partner, I mean a man you have sex with on a regular basis, or who is your husband, or who you consider to be your main partner.	☐	☐	☐
15b.	people at home/family?	☐	☐	☐
15c.	your friends/personal relationships?	☐	☐	☐
15d.	people at work?	☐	☐	☐
15e.	people at school?	☐	☐	☐
15f.	a nurse or clinician or doctor outside of the study?	☐	☐	☐
15g.	your landlord or property owner?	☐	☐	☐
15h.	anyone else? If yes, specify: ..... *Local Language:*_____ *English:* _____	☐	☐	☐

If no or N/A to all, end of form.

16. Has this problem/have any of these problems resulted in:

		yes	*no*
16a.	emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem.	☐	☐
16b.	physical harm to you? For example, has anyone physically hurt you as a result of this problem?	☐	☐
16c.	economic/financial harm to you? For example, has this problem resulted in the loss of your home, property, or ability to earn income?	☐	☐
16d.	physical or other harm to your children?	☐	☐

☐☐☐☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Vaginal Product Adherence and Behavior Assessment (VPA-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.
- **Item 15:** Read each item 15a–15h aloud and mark the participant's answer. If "yes" is marked for item 15h, record the participant's verbatim response. Also provide the English translation in the space provided. If items 15a through 15h are all "no" or "N/A," end the form. Mark the "No data recorded on this page" box in the upper right corner of page 7. Also record the Visit Code, PTID, and staff initials and date on page 7 of this form. Leave all other items on page 7 blank. Fax all 7 pages of this form to SCHARP DataFax once the form has been completed.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐

1

MTN003 VOICE (160) VPA-7 (236)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Product Adherence and Behavior Assessment

☐ No data recorded on this page.

17. Please describe the problem, including outcome, if any. ***Do not record the participant's verbatim response.***

Local Language: _____

_____

_____

_____

English: _____

_____

_____

_____

End of interview.

Interviewer: *Complete items 18–18a after the interview.*

	yes	*no*	
18. *Did any of the problem(s) require reporting as an Adverse Event (AE)?*	☐	☐ →	***If no, end of form.***

18a. *Record AE Log page number(s):*

AE Log page #	*AE Log page #*	*AE Log page #*
☐☐☐	☐☐☐	☐☐☐

☐☐☐☒ 17-MAR-09

01

Language

Staff Initials / Date

Vaginal Product Adherence and Behavior Assessment (VPA-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 all items on the page are left blank.
- **Item 17:** Do not record the participant's verbatim response. Instead, listen to the participant's response and probe as necessary. Describe, in the local language, the problem, including all relevant details, and the outcome, if any,. Also provide the English translation in the space provided.
- **Items 18 and 18a:** These items are not interviewer-administered. Complete these items after the interview.

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code ☐☐.☐ 1

MTN003 VOICE (160) VTR-1 (143)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Vaginal Test Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Alternate Collection Date

Not done/ Not collected ☐ *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

1. VAGINAL WET PREP STUDIES

Not done

			negative	*positive*
☐	1a.	Homogeneous vaginal discharge	☐	☐
☐	1b.	pH ..... ☐.☐ → ***If > 4.5 mark as positive.***		→ ☐
☐	1c.	Whiff test	☐	☐
☐	1d.	Clue cells ≥ 20%	☐	☐
☐	1e.	*Trichomonas vaginalis*	☐	☐
☐	1f.	Buds and/or hyphae (yeast)	☐	☐

Alternate Collection Date

Not done/ Not collected ☐ *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

			negative	*positive*
☐	**2.**	**Trichomonas Rapid Test**	☐	☐
☐	**3.**	**BV Rapid Test**	☐	☐

At Screening:
If participant is diagnosed with trichomoniasis, symptomatic bacterial vaginosis, or symptomatic vulvo-vaginal candidiasis, she must complete treatment and be asymptomatic (within 56-day screening window) to enroll.

During Follow-up:
If participant is diagnosed with trichomoniasis, symptomatic bacterial vaginosis, or symptomatic vulvo-vaginal candidiasis, complete an Adverse Experience Log. Note: asymptomatic bacterial vaginosis and asymptomatic vulvo-vaginal candidiasis are not reportable as AEs.

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Vaginal Test Results (VTR-1)

Purpose: This form is used to document results of specimens collected during the Screening Part 2, Enrollment, (if applicable), and follow-up pelvic exams.

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

- **Visit Code:** Record the visit code assigned to the visit. If this visit is the Study Exit Visit, record visit code 89.0. 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.
- **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. Record the reason why the result is not available on the Comments lines. For item 1, mark the "Not done/Not collected" box only if no vaginal wet prep results are available.

Item-specific Instructions:

- **Item 1:** A vaginal wet prep is required only when clinically indicated. If a vaginal wet prep was performed but not all assays were completed, mark the "Not done" box for each uncompleted wet prep assay. If any and/or all assays were required but not completed, record the reason on the Comments lines. If a positive result from a Screening Part 2 or Enrollment Visit sample confirms a diagnosis of symptomatic vaginal candidiasis, symptomatic bacterial vaginosis (BV), or trichomoniasis, the participant must complete treatment and be asymptomatic to enroll. If a positive result from a follow-up sample confirms a diagnosis of symptomatic vaginal candidiasis, symptomatic bacterial vaginosis (BV), or trichomoniasis, record as an adverse experience on the Adverse Experience Log.
- **Item 1a:** Mark the "positive" box if homogeneous vaginal discharge was observed.
- **Item 1d:** Mark the "positive" box if 20% or more of the cells were clue cells.
- **Item 1e:** Mark the "positive" box if trichomonads were observed.
- **Item 1f:** Mark the "positive" box if yeast buds and/or hyphae were observed.
- **Item 2:** A Trichomonas Rapid Test is required at the Screening Part 2 Visit, annual visits, the Product Use End Visit, and when clinically indicated during study follow-up.
- **Item 3:** A BV Rapid Test is required only when clinically indicated, or when necessary to confirm participant eligibility for study participation.

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

MTN003 VOICE (160)

Participant ID ☐☐☐-☐☐☐☐☐-☐
Site Number Participant Number Chk

Enrollment Medical Eligibility

Visit Date ☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1. At any time during the Screening Part 1, Screening Part 2, and Enrollment Visits, was the participant diagnosed by study staff with any of the following conditions requiring treatment per protocol:

		yes	no	**If yes:** Has condition been treated and have any associated symptoms resolved as of the day of enrollment? yes	no
1a.	urinary tract infection (UTI)	☐	☐	☐	☐
1b.	chlamydia	☐	☐	☐	☐
1c.	gonorrhea	☐	☐	☐	☐
1d.	syphilis	☐	☐	☐	☐
1e.	symptomatic BV	☐	☐	☐	☐
1f.	symptomatic vaginal candidiasis	☐	☐	☐	☐
1g.	trichomoniasis	☐	☐	☐	☐
1h.	active genital herpes lesions	☐	☐	☐	☐
1i.	genital warts requiring treatment per protocol	☐	☐	☐	☐
1j.	pelvic inflammatory disease (PID)	☐	☐	☐	☐
1k.	any other STI or RTI requiring treatment, specify: _____	☐	☐	☐	☐

If no to any, participant is ineligible. Treat per protocol and SSP Manual. Participants found to meet all other eligibility criteria may be enrolled (or have another screening attempt) after treatment is completed and symptoms (if any) have resolved.

Enrollment Medical Eligibility (non-DataFax) - Page 1

This form is completed at the Enrollment Visit only, and is used to document the participant's medical eligibility for the study. This form is completed based on review of all clinical and lab test results documentation from the participant's Screening Part 1, Screening Part 2, and Enrollment Visits. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: *None of the UTI/STIs/RTIs listed on this form should be documented on the Pre-existing Conditions form, even if the participant tested positive for one or more of these UTI/STIs/RTIs during screening. Because a participant is not eligible for enrollment if she is currently diagnosed with a UTI/ STI/RTI requiring treatment, and because the Pre-existing Conditions form only documents ongoing conditions at the time of enrollment, none of the UTI/STIs/RTIs recorded on this form should be documented on the Pre-existing Conditions form.*

If a participant is being re-screened, a new Enrollment Medical Eligibility 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.

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

MTN003 VOICE (160)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Enrollment Medical Eligibility

2. Please answer the following questions based on the participant's Baseline Medical and Menstrual History.

		yes	no
2a.	Did the participant report any pathologic bone fracture not related to trauma (ever)?	☐	☐
2b.	Did the participant report receiving post-exposure prophylaxis (PEP) for HIV exposure within 6 months prior to enrollment?	☐	☐
2c.	Did the participant report any gynecologic or genital procedure (e.g., biopsy, tubal ligation, dilation and curettage, piercing) in the past 6 weeks (42 days)?	☐	☐
2d.	Did the participant report that she is currently using spermicide; interferon or interleukin therapy; medication(s) with significant nephrotoxic potential, including but not limited to amphotericin B, aminoglycosides, cidofovir, foscarnet and systemic chemotherapy; medication(s) that may inhibit or compete for elimination via active renal tubular secretion (including but not limited to probenecid)?	☐	☐
2e.	Did the participant report, as determined by the IoR/designee, any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease, including active tuberculosis?	☐	☐
3.	Does the participant have a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff)? *Note: Cervical bleeding associated with speculum insertion and/or specimen collection judged to be within the range of normal according to the clinical judgment of the IoR/ designee is considered expected non-menstrual bleeding and is not exclusionary.*	☐	☐

If yes to any, participant is ineligible.

		yes	no	N/A
4.	Does the participant have documentation of a normal Pap result from a Pap Smear done during this screening attempt, or in the last 12 months?	☐	☐	☐
4a.	Does participant have a Grade 2 or higher Pap result?	☐	☐	

If yes or N/A, go to item 5 on page 3.

_____

_____

_____

_____

_____

If yes, participant may be ineligible. Participants with abnormal Pap results who are found to meet all other eligibility criteria may be enrolled upon completion of the initial phase of evaluation if no current treatment is indicated. If grade 2 or higher Pap result, specify evaluation and treatment plan in the space provided, clearly noting whether treatment is currently indicated.

Enrollment Medical Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 4:** Mark the “yes” box if the participant has documentation of a Pap result from a Pap Smear done at this visit, or in the last 12 months, that is negative for intraepithelial lesion or cancer (malignancy). Mark the “no” box if the participant has a Pap result from a Pap Smear done at this visit, or in the last 12 months, that is anything other than negative for intraepithelial lesion or cancer (malignancy). Mark the “N/A” box if a Pap result is not required per protocol to determine the participant’s eligibility.

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

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Enrollment Medical Eligibility

		yes	*no*
5.	Is the participant pregnant?	☐	☐
6.	Is the participant HIV-infected per the screening algorithm in protocol Appendix II?	☐	☐

Answer item 7 based on all available screening information.

7.	Does the participant have any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives?	☐	☐

If yes to any, participant is ineligible.

Enrollment Medical Eligibility (non-DataFax) - Page 3

No additional instructions.

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

MTN003 VOICE (160)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Genital Bleeding Assessment

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:.....
Obtain from Follow-up Medical and Menstrual History.
dd ☐☐ *MMM* ☐☐☐ *yy* ☐☐ **OR** ☐ *amenorrheic*
If amenorrheic, go to item 4.

2. Last day of participant's last menstrual period:.....
Obtain from Follow-up Medical and Menstrual History.
dd ☐☐ *MMM* ☐☐☐ *yy* ☐☐

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.
dd ☐☐ *MMM* ☐☐☐ *yy* ☐☐

5. Last day of genital bleeding episode:.....
dd ☐☐ *MMM* ☐☐☐ *yy* ☐☐ **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? ..... ☐ *normal* ☐ *lighter* ☐ *heavier* ☐ *unknown* ☐ *N/A*

8. According to the participant or the clinician, what color was the genital blood? *Mark "unknown," or all that apply.*..... ☐ *bright red* ☐ *brown* ☐ *unknown*

9. According to the participant, did she continue to use the study product during this genital bleeding episode?..... ☐ *yes* ☐ *no* ☐ *N/A*
If yes or N/A, go to item 11 on page 2.

☐☐☐☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Genital Bleeding Assessment (non-DataFax) - Page 1

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

Item-specific Instructions:

- **Item 1:** Mark the "amenorrheic" box 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 the "unknown" box cases where the information is not known by the participant. Mark the "N/A" box if the genital bleeding was not reported by the participant, but was observed during the pelvic examination only.
- **Item 8:** Mark the "unknown" box in cases where the information is not known by the participant or the clinician.
- **Item 9:** Mark the "NA" box if the participant's study product use was held or permanently discontinued prior to this genital bleeding episode.

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

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Genital Bleeding Assessment

10. Number of days between last dose of study product 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?	[ ]	[ ]	
11b.	painful vaginal sex?	[ ]	[ ]	
11c.	last dose of the study product?	[ ]	[ ]	
11d.	painful or uncomfortable insertion or removal of the study gel?	[ ]	[ ]	*N/A* [ ]
11e.	painful or uncomfortable insertion or removal of any other vaginal product/preparation?	[ ]	[ ]	
11f.	a pelvic exam?	[ ]	[ ]	

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

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

		yes	*no*
11g.	condom use?	[ ]	[ ]

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

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

13. Is the participant currently using (non-injectable) hormonal contraceptives? *Review Contraceptives Log.* *yes* [ ] *no* [ ] → *If no, go to item 14 on page 3.*

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 3.*

13b. Did the participant miss two or more days of contraceptives? ..... *yes* [ ] *no* [ ] → *If yes, go to item 14 on page 3.*

Genital Bleeding Assessment (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 11d:** Mark the "N/A" box if the participant is not in the vaginal group.
- **Item 12:** If the participant reports currently using injectable contraceptives, make sure the injectable contraceptives are listed on the participant's Contraceptives Log.
- **Item 12b:** If the participant is currently overdue for an injection, record the date when she was supposed to have her next injection, per her injection schedule.
- **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 Contraceptives Log.

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

MTN003 VOICE (160)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Genital Bleeding Assessment

13c. **For participants using oral contraceptives only:** Did the participant make up the missed dose of oral contraceptives? ..... *yes* ☐ *no* ☐

14. Based on all information available, is this bleeding unexpected? ..... *yes* ☐ *no* ☐ → ***If no, end of form. DO NOT complete AE Log.***

14a. Is this unexpected bleeding menstrual or non-menstrual?

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

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

Comments: _____

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Genital Bleeding Assessment (non-DataFax) - Page 3

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 participant's Baseline Medical and Menstrual History and refer to the Study-specific Procedures Manual (SSP) to determine whether or not the genital bleeding is unexpected.
- **Item 14a:** If the unexpected genital bleeding is:
  - **menstrual** - grade the AE of menorrhagia [defined as prolonged (more than 7 days) or excessive (>80 mL) uterine bleeding] or menometrorrhagia (defined as prolonged uterine bleeding occurring at irregular intervals) using the "menorrhagia" row of the *Female Genital Grading Table for Use in Microbicide Studies***.**

    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 in the participant's Baseline Medical and Menstrual History). Refer to the Study-specific Procedures Manual (SSP) for further information.*
  - **non-menstrual** - grade an AE of metrorrhagia (intermenstrual bleeding) using the "metrorrhagia" row of the *Female Genital Grading Table for Use in Microbicide Studies*. Grade an AE of postcoital bleeding using the "postcoital bleeding" row of the *Female Genital Grading Table for Use in Microbicide Studies*.

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

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

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Participant-reported Baseline Medical and Menstrual History

Visit Date dd MMM yy

	Medical problem? yes	no	*If yes, date diagnosed* MMM	yy	***Description:***	***Ongoing?*** yes	no	***Severity Grade***
HE (head/eyes)	☐	☐				☐	☐	
	☐	☐				☐	☐	
	☐	☐				☐	☐	
ENT (ears/ nose/throat)	☐	☐				☐	☐	
	☐	☐				☐	☐	
	☐	☐				☐	☐	
Lymphatic	☐	☐				☐	☐	
	☐	☐				☐	☐	
	☐	☐				☐	☐	
Cardiovascular	☐	☐				☐	☐	
	☐	☐				☐	☐	
	☐	☐				☐	☐	
Respiratory	☐	☐				☐	☐	
	☐	☐				☐	☐	
	☐	☐				☐	☐	
Liver	☐	☐				☐	☐	
	☐	☐				☐	☐	
	☐	☐				☐	☐	

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

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 1

This form is used to document a participant's baseline medical history, since becoming sexually active. It is first completed at the Screening Part 2 Visit. It is then updated at any subsequent visits related to the same screening attempt, and updated again at the Enrollment Visit. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

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

It may be helpful to use a calendar as a probe to help participants recall dates.

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

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

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

Site Number | Participant Number | Chk

Participant-reported Baseline Medical and Menstrual History

	Medical problem? *yes*	*no*	*If yes, date diagnosed* *MMM*	*yy*	***Description:***	***Ongoing?*** *yes*	*no*	***Severity Grade***
Renal *(including urinary symptoms)*	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Gastrointestinal	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Musculoskeletal *(including bone fractures)*	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Neurologic	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Skin	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Endocrine/ Metabolic	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	

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

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 2

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

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

Participant-reported Baseline Medical and Menstrual History

	Medical problem? *yes*	*no*	*If yes, date diagnosed* *MMM*	*yy*	***Description:***	***Ongoing?*** *yes*	*no*	***Severity Grade***
Hematologic	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Cancer	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Drug Allergy	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Other Allergy	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
Mental Illness	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	
	☐	☐	☐☐☐	☐☐		☐	☐	

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

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 3

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Participant-reported Baseline Medical and Menstrual History

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

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

☐ symptomatic vaginal candidiasis
☐ abnormal pap
☐ symptomatic BV
☐ PID
☐ HSV-1/HSV-2
☐ Syphilis
☐ Gonorrhea
☐ Chlamydia
☐ HPV
☐ Trichomoniasis
☐ other vaginitis
☐ chancroid
☐ cervicitis
☐ other

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

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 4

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Participant-reported Baseline Medical and Menstrual History

Genital Symptoms	yes	no	***If yes, date diagnosed*** MMM	yy	***Description:***	***Ongoing?*** yes	no	***Severity Grade***
Genital sores?	☐	☐	☐☐☐	☐☐		☐	☐	
Genital/vaginal itching?	☐	☐	☐☐☐	☐☐		☐	☐	
Genital/vaginal burning?	☐	☐	☐☐☐	☐☐		☐	☐	
Genital/vaginal pain? (other than during sex)	☐	☐	☐☐☐	☐☐		☐	☐	
Pain during sex?	☐	☐	☐☐☐	☐☐		☐	☐	
Abnormal genital/ vaginal discharge?	☐	☐	☐☐☐	☐☐		☐	☐	
Unusual genital/ vaginal odor?	☐	☐	☐☐☐	☐☐		☐	☐	
Lower abdominal pain?	☐	☐	☐☐☐	☐☐		☐	☐	
Other genital symptoms? Specify:	☐	☐	☐☐☐	☐☐		☐	☐	

If yes to any, evaluate for STIs/RTIs.

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

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

If yes, evaluate for eligibility.

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

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

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

☐ ☐ ☒ ☐ 02-SEP-09

0 1 Language

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 5

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number | Participant Number | Chk

Participant-reported Baseline Medical and Menstrual History

Menstrual History

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

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

	regular	*irregular*
Usual menstrual cycle:	☐	☐

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

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

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

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

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

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

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

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 6

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

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

Site Number Participant Number Chk

Participant-reported Baseline Medical and Menstrual History

Pregnancy History

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

Contraceptive History

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

Note: To be eligible for study participation, participant must report at enrollment use of an effective method of contraception (hormonal methods, intrauterine contraceptive device, or sterilization of participant or her partner) for the next 24 months. Reported use of spermicide, vaginal ring, diaphragm, or other vaginal products is exclusionary per protocol.

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

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number | Participant Number | Chk

Participant-reported Baseline Medical and Menstrual History

History of sexual assault (if any):_____

_____

_____

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

_____

_____

_____

_____

Participant-reported Baseline Medical and Menstrual History (non-DataFax) - Page 8

No additional instructions.

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

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Participant-reported Follow-up Medical and Menstrual History

Visit Date dd MMM yy

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

Update or complete Adverse Experience Log when applicable.

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 1

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

It may be helpful to use a calendar as a probe to help participants recall dates.

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

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Participant-reported Follow-up Medical and Menstrual History

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

Update or complete Adverse Experience Log when applicable.

Any changes in alcohol use since last study visit?

Any changes in recreational drug use since last study visit?

☐ ☐ ☐ ☒ 17-MAR-09

0 1
Language

Staff Initials / Date

Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 2

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Participant-reported Follow-up Medical and Menstrual History

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

Genital Symptoms	*yes*	*no*	*If yes, onset date* dd	MMM	yy	*OR continuing from previous visit*	***Description*** *(include severity grade and outcome date, if applicable)*
Genital sores?	☐	☐				☐	
Genital/vaginal itching?	☐	☐				☐	
Genital/vaginal burning?	☐	☐				☐	
Genital/vaginal pain? (other than during sex)	☐	☐				☐	
Pain during sex?	☐	☐				☐	
Abnormal genital/ vaginal discharge?	☐	☐				☐	
Unusual genital/ vaginal odor?	☐	☐				☐	
Menstrual symptoms worse than her usual menstrual symptoms?	☐	☐				☐	
Lower abdominal pain?	☐	☐				☐	
Other genital symptoms? Specify: _____	☐	☐				☐	

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

Vaginal bleeding or spotting between her usual menstrual periods?	☐	☐				☐	
Blood-tinged discharge?	☐	☐				☐	
Post-coital bleeding?	☐	☐				☐	

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

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

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

☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 3

Item-specific Instructions:

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

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

MTN003 VOICE (160)

Participant ID

☐☐☐ - ☐☐☐☐☐ - ☐

Site Number Participant Number Chk

Participant-reported Follow-up Medical and Menstrual History

Did the participant have a bone fracture since her last study visit? ..... *yes* ☐ *no* ☐

Is there suspicion of lactic acidosis? ..... ☐ ☐

If yes to either, refer to protocol and SSP Manual for guidance on clinical management and study product administration. Complete Adverse Experience Log and Product Hold/ Discontinuation Log if applicable.

Menstrual Information

First day of last menstrual period: ..... *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

Last day of last menstrual period: ..... ☐☐ ☐☐☐ ☐☐

no menses since last visit **OR** ☐

If no menses since last visit, is it unexpected or unexplained? ..... *yes* ☐ *no* ☐

If yes, document Severity Grade here:_____
and complete Adverse Experience Log, when applicable.

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

Item-specific Instructions:

- **No menses since last visit:** If the participant has not had a menstrual period since her last study visit, mark this box and leave the date boxes (ddMMMyy) blank for First and Last day of last menstrual period.

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

MTN003 VOICE (160)

Participant ID

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

Site Number Participant Number Chk

Participant-reported Follow-up Medical and Menstrual History

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

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

Additional Notes:

Participant-reported Follow-up Medical and Menstrual History (non-DataFax) - Page 5

No additional instructions.

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

MTN003 VOICE (160)

Participant ID

Site Number – Participant Number – Chk

Pelvic Exam Diagrams

Exam Date

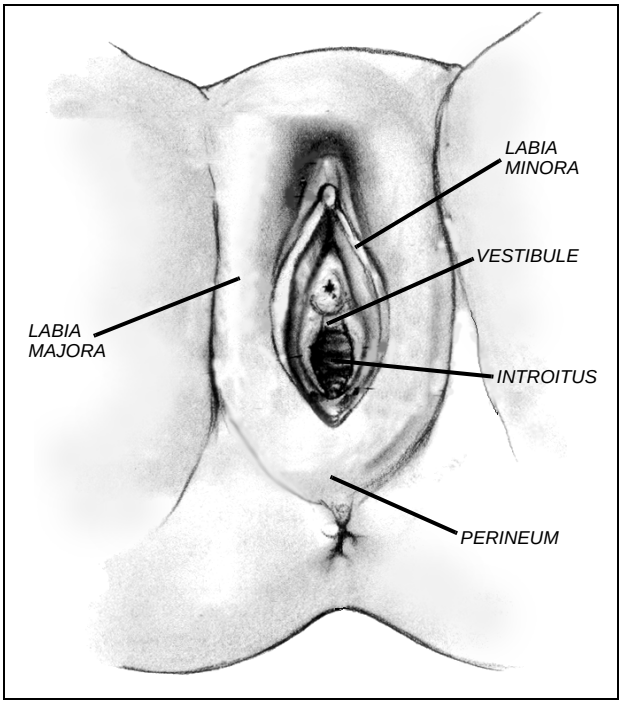
dd MMM yy

☐ no normal variants or abnormal findings observed

Speculum Type (screening only) *Pederson* ☐ *Graves* ☐ *Cusco* ☐

Speculum Size (screening only) *small* ☐ *medium* ☐ *large* ☐

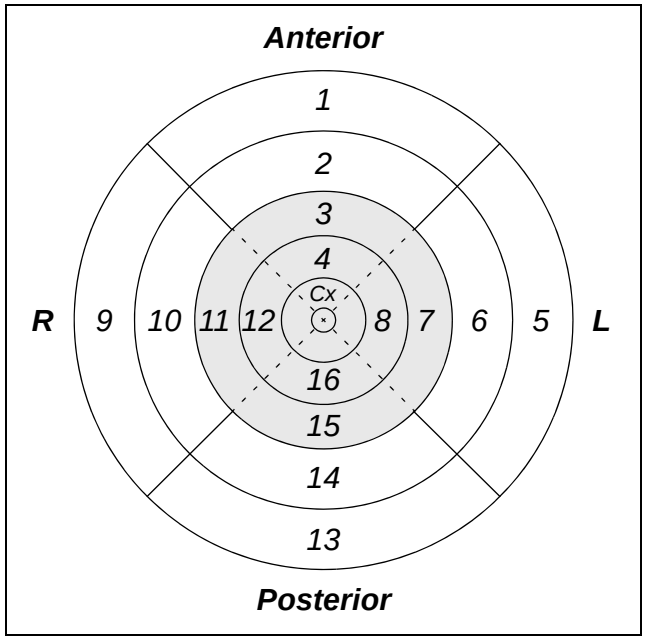
External Genitalia



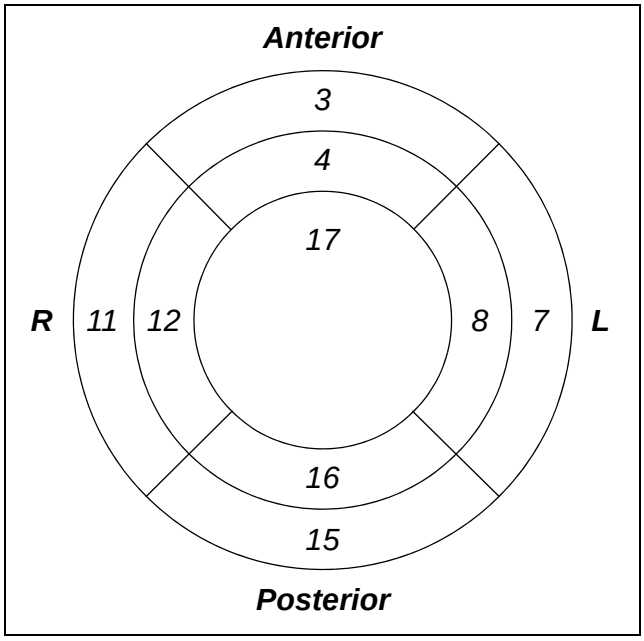
Legend for Vagina/Cervix

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



☐ ☐ ☐ ☒ 17-MAR-09

0 1 Language

Staff Initials / Date

Pelvic Exam Diagrams (non-DataFax) - Page 1

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. 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.**

MTN003 VOICE (160)

Participant ID ☐☐☐-☐☐☐☐☐-☐ (Site Number / Participant Number / Chk)

Physical Exam

Exam Date ☐☐ dd ☐☐☐ MMM ☐☐ yy

VITAL SIGNS

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

Weight	☐☐☐ kg	BP	☐☐☐ / ☐☐☐ mmHg
Height	☐☐☐ cm	Pulse	☐☐☐ per minute
Oral Temp	☐☐.☐ °C	Respirations	☐☐ per minute

Vital Signs: Staff Initials / Date _____

FINDINGS

If abnormal, please specify. Include severity grade, if applicable.

not evaluated	normal	abnormal		
☐	☐	☐	2.	General appearance _____
☐	☐	☐	3.	Abdomen _____
☐	☐	☐	4.	HEENT _____
				_____
☐	☐	☐	5.	Lymph Nodes _____
☐	☐	☐	6.	Neck _____
☐	☐	☐	7.	Heart _____
☐	☐	☐	8.	Lungs _____
☐	☐	☐	9.	Breast Exam _____
☐	☐	☐	10.	Extremities _____
☐	☐	☐	11.	Skin _____
☐	☐	☐	12.	Neurological _____
☐	☐	☐	13.	Musculoskeletal (including bone fractures): _____
☐	☐	☐	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 _____

Physical Exam (non-DataFax) - Page 1

This form is used to document the participant's vital signs and physical exam findings at Screening Part 2 and during study follow-up. 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 and round to the nearest whole number. The staff member who completes these items should initial and date on the line provided.
- **Findings:** The staff member who completes these items should initial and date on the line provided.
- **Items 14–15:** Use these items to list any additional organ systems that were evaluated. If no other organ systems other than the ones listed in items 2–13 were evaluated, mark these items as "not evaluated."

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

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Part 1 Eligibility

Form Completion Date

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

dd *MMM* *yy*

I am now going to ask some questions about you, your sexual behaviors and your health. There are no right or wrong answers, and every answer is important, so please be as honest and as accurate as you can. Some of the questions may seem personal, but please remember that all of your answers will be kept confidential.

1. Have you ever had a bad reaction to latex (such as latex condoms or gloves)? ..... *yes* ☐ *no* ☐ → *If yes, participant is ineligible.*

2. Have you ever used tenofovir gel, tenofovir tablets, or Truvada tablets? ***Use visual aid.*** ..... ☐ ☐ → *If no, go to item 4.*

3. Have you ever had a bad reaction to tenofovir gel, tenofovir tablets, or Truvada tablets?***Use visual aid.*** ..... ☐ ☐ → *If yes, participant is ineligible.*

4. In the **past year** (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? ☐ ☐ → *If yes, participant is ineligible.*

5. In the **past 3 months**, have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina. ..... ☐ ☐ → *If no, participant is ineligible. Go to item 9.*

6. In the **past 7 days** (not including today), how many acts of vaginal sex did you have? ..... [ ][ ] *# of vaginal sex acts*
   → *If 00, go to item 8.*

7. In the **past 7 days** (not including today), during how many acts of vaginal sex was a male or female condom used? ..... [ ][ ] *# of vaginal sex acts with condom*

8. Now I would like to ask you about your most recent vaginal sex act. That is, the very **last vaginal sex act** that you had, including today. During the last act of vaginal sex that you had, was a male or female condom used? ***Use visual aid.*** ..... *yes* ☐ *no* ☐ → *If no, go to item 9.*

   8a. What type of condom was used during the **last act** of vaginal sex that you had? ***Use visual aid.*** ..... *male condom* ☐ *female condom* ☐

9. In the **past 6 weeks** (42 days), have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated? ..... *yes* ☐ *no* ☐ → *If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after last pregnancy outcome.*

☐ ☐ ☐ ☒ 17-MAR-09

[0][1] Language

Staff Initials / Date

Screening Part 1 Eligibility (non-DataFax) - Page 1

This form is used to document the participant's eligibility for the study at the Screening Part 1 Visit. This is a mixed form—some of the items are interviewer-administered (items 1–19), while other items are not (items 20–22). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

***Note:** If a participant is being re-screened, a new Screening Part 1 Eligibility form must be completed as part of the subsequent Screening Attempt. See the Data Collection Section of the Study-specific Procedures (SSP) Manual (SSP) for more instructions regarding re-screening form completion and transmission procedures.*

Item-specific Instructions:

- **Items 1–19:** If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 19. 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.
- **Item 2:** Mark the "no" box if the participant does not recall having ever used tenofovir gel, tenofovir tablets, or Truvada tablets.
- **Item 3:** Mark the "no" box if the participant does not recall having had an adverse reaction to tenofovir gel, tenofovir tablets, or Truvada tablets

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

MTN003 VOICE (160)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐
Site Number Participant Number Chk

Screening Part 1 Eligibility

	yes	no	don't know	
10. Are you breastfeeding now?	☐	☐		*If yes, participant is ineligible.*
11. Do you and your partner intend to have a child in the future?	☐	☐	☐	*If no or don't know, go to item 13.*

12. When do you and your partner intend to have your future child? # ☐☐ ☐ *months from now* **OR** ☐ *years from now*

	yes	no	don't know	
13. If you were to join this research study, would you be willing to use a reliable method of contraception for the next 2 years (24 months)? The methods that are considered reliable include: oral contraceptive pills, contraceptive injections (for example, depo-provera), contraceptive implants (for example, norplant or jadelle), contraceptive patches, intrauterine contraceptive devices, and surgical sterilization of you or your partner(s).	☐	☐		*If no, participant is ineligible.*
14. Do you plan to move away from this area in the next 2 years (24 months)?	☐	☐	☐	*If yes, participant is ineligible.*
15. Do you plan to be away from this area for more than 8 weeks in a row in the next two years (24 months)? This includes seasonal travel, and travel for farming, trade, or other purposes.	☐	☐	☐	*If yes, participant is ineligible.*
16. In the past 30 days, have you taken part in any other research study of medicines, medical devices, or vaginal products?	☐	☐		*If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 31 days after exit from other study.*
17. If you were to join this study, would you agree to not take part in any other research study of medicines, medical devices, or vaginal products for the next 2 years (24 months)?	☐	☐		*If no, participant is ineligible.*

Screening Part 1 Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 12:** Record in months or years the amount of time expected to pass before the participant gives birth to a future child. For example, if the participant reports that she plans to give birth to a future child in a year and a half, record “18” in the “#” boxes and mark the “months from now” box. Record her best estimate.
- **Item 16:** Mark the “no” box if the participant does not recall having participated in another research study of medicines, medical devices, or vaginal products in the past 30 days.

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

MTN003 VOICE (160)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Screening Part 1 Eligibility

18. Do you currently have tuberculosis, also known as TB? ..... *yes* ☐ *no* ☐ *don't know* ☐

19. Are you currently taking any medication used to treat tuberculosis or TB? *yes* ☐ *no* ☐ *don't know* ☐

If yes, refer participant to site medical officer.

If no or don't know, and participant's response to item 18 is "yes" or "don't know," refer participant to site medical officer. If site medical officer determines that participant has active TB, participant is ineligible.

End of interview. Site staff to complete items 20–22.

20. *Per the site Investigator of Record or designee, does the participant currently have active tuberculosis (TB)?* ..... *yes* ☐ *no* ☐ *If yes, participant is ineligible.*

21. *Based on the urine hCG test result, is the participant pregnant?* ..... *yes* ☐ *no* ☐ *If yes, participant is ineligible.*

22. *Transcribe, in months, the response recorded for item 12 here:* ..... ☐☐ *months from now*

If 33 months or less, participant is ineligible.

Screening Part 1 Eligibility (non-DataFax) - Page 3

No additional instructions.

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

MTN003 VOICE (160)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐
Site Number Participant Number Chk

Screening Part 2 Medical Eligibility

Form Completion Date

☐☐ ☐☐☐ ☐☐
dd *MMM* *yy*

1. At Screening Part 1 or Screening Part 2, was the participant diagnosed by study staff with any of the following conditions requiring treatment per protocol:

		yes	*no*
1a.	urinary tract infection (UTI)	☐	☐
1b.	chlamydia	☐	☐
1c.	gonorrhea	☐	☐
1d.	syphilis	☐	☐
1e.	symptomatic BV	☐	☐
1f.	symptomatic vaginal candidiasis	☐	☐
1g.	trichomoniasis	☐	☐
1h.	active herpes lesions	☐	☐
1i.	genital warts requiring treatment per protocol	☐	☐
1j.	pelvic inflammatory disease (PID)	☐	☐
1k.	any other STI or RTI requiring treatment, specify: _____	☐	☐

If yes to any, treat per protocol and SSP Manual. Participant is ineligible until treatment is completed and symptoms (if any) have resolved. Participants found to meet all other eligibility criteria may be enrolled after treatment is completed and symptoms (if any) have resolved within the 56-day screening window.

2. Please answer the following questions based on the participant's Baseline Medical and Menstrual History.

		yes	*no*
2a.	Did the participant report any pathologic bone fracture not related to trauma (ever)?	☐	☐

If yes, participant is ineligible.

		yes	*no*
2b.	Did the participant report taking post-exposure prophylaxis (PEP) for HIV exposure within the past 6 months?	☐	☐

If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 6 months after last use of PEP.

Screening Part 2 Medical Eligibility (non-DataFax) - Page 1

This form is completed at the Screening Part 2 Visit and is used to document the participant's medical eligibility for the study. It is completed based on review of all Screening Part 1 and Part 2 clinical and lab test results documentation.

Note: *None of the UTI/STIs/RTIs listed on this form should be documented on the Pre-existing Conditions form, even if the participant tested positive for one or more of these UTI/STIs/RTIs during screening. Because a participant is not eligible for enrollment if she is currently diagnosed with a UTI/ STI/RTI requiring treatment, and because the Pre-existing Conditions form only documents ongoing conditions at the time of enrollment, none of the UTI/STIs/RTIs recorded on this form should be documented on the Pre-existing Conditions form.*

If a participant is being re-screened, a new Screening Part 2 Medical Eligibility 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.

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

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Part 2 Medical Eligibility

2c. Did the participant report any gynecologic or genital procedure (e.g., biopsy, tubal ligation, dilation and curettage, piercing) in the past six weeks (42 days)?

yes ☐ no ☐

If yes, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after procedure.

2d. Did the participant report that she is currently using spermicide; interferon or interleukin therapy; medication(s) with significant nephrotoxic potential, including but not limited to amphotericin B, aminoglycosides, cidofovir, foscarnet and systemic chemotherapy; medication(s) that may inhibit or compete for elimination via active renal tubular secretion (including but not limited to probenecid)?

yes ☐ no ☐

If yes, participant is ineligible for as long as she uses the reported medication(s).

2e. Did the participant report, as determined by the IoR/ designee, any significant uncontrolled active or chronic cardiovascular, renal, liver, hematologic, neurologic, gastrointestinal, psychiatric, endocrine, respiratory, immunologic disorder or infectious disease, including active tuberculosis?.....

yes ☐ no ☐

If yes, participant is ineligible.

3. Does the participant have a clinically apparent Grade 2 or higher pelvic exam finding (observed by study staff)?.....
Note: Cervical bleeding associated with speculum insertion and/or specimen collection judged to be within the range of normal according to the clinical judgment of the IoR/ designee is considered expected non-menstrual bleeding and is not exclusionary.

yes ☐ no ☐

If yes, participant is currently ineligible. Provide treatment if clinically indicated. Participants with exclusionary pelvic exam findings who are found to meet all other eligibility criteria may be enrolled after the exclusionary pelvic exam findings have improved to a non-exclusionary severity grade or have resolved.

4. Does the participant have documentation of a normal Pap result from a Pap Smear done during this visit, or in the last 12 months? .....

yes ☐ no ☐ N/A ☐ → ***If N/A, go to item 5 on page 3.***

If yes and participant meets all other eligibility criteria, schedule Enrollment Visit to occur within 12 months of normal Pap result. Go to item 5 on page 3.

4a. Does participant have a Grade 2 or higher Pap result?

yes ☐ no ☐

If yes, participant may be ineligible. Participants with abnormal Pap results who are found to meet all other eligibility criteria may be enrolled upon completion of the initial phase of evaluation if no current treatment is indicated. If grade 2 or higher Pap result, specify evaluation and treatment plan in the space provided, clearly noting whether treatment is currently indicated.

_____

_____

_____

_____

_____

Screening Part 2 Medical Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Item 4:** Mark the “yes” box if the participant has documentation of a Pap result from a Pap Smear done at this visit, or in the last 12 months, that is negative for intraepithelial lesion or cancer (malignancy). Mark the “no” box if the participant has a Pap result from a Pap Smear done at this visit, or in the last 12 months, that is anything other than negative for intraepithelial lesion or cancer (malignancy). Mark the “N/A” box if a Pap result is not required per protocol to determine the participant’s eligibility.

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

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Part 2 Medical Eligibility

5. Please answer the following questions based on the participant's laboratory results from the Screening Part 1 and Screening Part 2 Visits.

		yes	*no*
5a.	Is the participant pregnant?	☐	☐
5b.	Is the participant HIV-infected per the screening algorithm in protocol Appendix II?	☐	☐
5c.	Is the participant's AST or ALT greater than 1.5 times the site lab upper limit of normal (ULN)?	☐	☐
5d.	Is the participant's calculated creatinine clearance < 60 mL/min?	☐	☐
5e.	Is the participant's serum creatinine greater than the site lab ULN for women? ***Note**: If the serum creatinine is less than the site LLN, creatinine testing must be repeated during the screening period.*	☐	☐
5f.	Is the participant's hemoglobin less than 10.0g/dl?	☐	☐
5g.	Is the participant's platelet count less than 100,000/mm^3?	☐	☐
5h.	Is the participant's serum phosphate level below the site lab lower limit of normal (LLN)?	☐	☐
5i.	Did the participant test positive for Hepatitis B surface antigen (HBsAg)?	☐	☐
5j.	Is the participant's dipstick urinalysis for protein 2+ or greater from a single visit?	☐	☐
5k.	Does the participant have at least two dipstick urinalysis protein results of 1+ or greater at separate visits?	☐	☐
5l.	Is the participant's dipstick urinalysis result for glucose 2+ or greater from a single visit?	☐	☐
5m.	Does the participant have at least two dipstick urinalysis glucose results of 1+ or greater at separate visits?	☐	☐

If yes to any, participant is ineligible. For all exclusionary test results, except HIV infection and Hepatitis B infection, participant may be retested and enrolled (or have another screening attempt) if the retest result is not exclusionary per protocol. Dipstick urinalysis should only be retested if abnormal results are attributable to urinary tract infection or menses, according to the judgment of the IoR/designee.

6. Does the participant have any other condition that, in the opinion of the IoR/designee, would preclude informed consent, make participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving study objectives? *yes* ☐ *no* ☐

If yes, participant is ineligible.

Screening Part 2 Medical Eligibility (non-DataFax) - Page 3

No additional instructions.

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

MTN003 VOICE (160)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Screening Part 2/Enrollment Behavioral Eligibility

Form Completion Date

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

dd *MMM* *yy*

I am now going to ask some questions about you, your sexual behaviors and your health. I know that you have been asked these questions before, but I need to ask them again to confirm your eligibility for the study. There are no right or wrong answers, and every answer is important, so we need you to be as honest and as accurate as you can. Some of the questions may seem personal, but please remember that all of your answers will be kept confidential.

1. In the **past six weeks** (42 days), have you been pregnant, given birth (including stillbirth) or had a pregnancy terminated?..... *yes* ☐ *no* ☐ → *If yes at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 43 days after last pregnancy outcome.* *If yes at enrollment, participant is ineligible.*

2. Are you breastfeeding now?..... ☐ ☐ → *If yes, participant is ineligible.*

3. What method(s) of contraception or family planning are you currently using? ***Mark all that apply.***

- ☐ Oral contraceptive pills
- ☐ Contraceptive injections
- ☐ Contraceptive implants
- ☐ Contraceptive ring → *If "Contraceptive ring" is reported at enrollment, participant is ineligible.*
- ☐ Contraceptive patch
- ☐ Intrauterine contraceptive device
- ☐ Surgical sterilization of participant (as verified per site SOP)
- ☐ Surgical sterilization of partner(s) (as verified per site SOP)
- ☐ Other, specify: _____ → *If "Other" is reported at enrollment, evaluate for eligibility.*
- ☐ None → *If "None" is reported at enrollment, participant is ineligible.*

Screening Part 2/Enrollment Behavioral Eligibility (non-DataFax) - Page 1

This form is used to document the participant's eligibility for the study at the Screening Part 2 and Enrollment Visits. It is completed once at the Screening Part 2 Visit, and again at the Enrollment Visit. This is a mixed form—some of the items are interviewer-administered (items 1–6), while other items are not (item 7). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.

Note: *If a participant is being re-screened, a new Screening Part 2/Enrollment Behavioral Eligibility 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:

- **Items 1–6:** Many of these items were also asked during the Screening Part 1 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 6. 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.**

MTN003 VOICE (160)

Participant ID

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

Site Number Participant Number Chk

Screening Part 2/Enrollment Behavioral Eligibility

4. If you were to join this study, would you be willing to use a reliable method for the next 2 years (24 months)? The methods that are considered reliable include: oral contraceptive pills, contraceptive injections (for example, depo provera), contraceptive implants (for example, norplant or jadelle), contraceptive patches, intrauterine contraceptive devices, and surgical sterilization of you or your partner(s).

yes ☐ *no* ☐ → *If no, participant is ineligible.*

5. In the past 30 days, have you taken part in any other research study of medicines, medical devices, or vaginal products? .....

☐ ☐ → *If yes at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, schedule Enrollment Visit (or another screening attempt) to occur at least 31 days after exit from other study.*

If yes at Enrollment, participant is ineligible.

6. If you were to join this study, would you agree to not take part in any other research study of medicines, medical devices, or vaginal products for the next 2 years (24 months)? .....

yes ☐ *no* ☐ → *If no, participant is ineligible.*

End of interview. Complete item 7 after the interview.

7. *Was the participant willing and able to provide adequate locator information as defined in site SOPs? .....*

yes ☐ *no* ☐ → *If no at Screening Part 2, participant may be ineligible. If participant is found to meet all other eligibility criteria, and only needs more time to provide adequate locator information, schedule Enrollment Visit (or another screening attempt) to occur when adequate locator information is available.*

If no at Enrollment, participant is ineligible.

Screening Part 2/Enrollment Behavioral Eligibility (non-DataFax) - Page 2

Item-specific Instructions:

- **Items 1–6:** Many of these items were also asked during the Screening Part 1 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 6. 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.
- **Item 7:** This item is NOT interviewer-administered and should not be read aloud to the participant.