

# Section 13. Data Collection

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*For questions about this section or about general data collection policies, procedures, or materials, please contact Karen Patterson <karen@scharp.org> at SCHARP.*

*The purpose of this document is to provide site staff with the information they need to successfully complete and submit HPTN 059 forms.*

## 13.1 DataFax Overview

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

### CRF Transmission

SCHARP's Information Technology (IT) Group works with each site to determine the best solution for data transmission on a site-by-site basis.

### Data Entry/Quality Control

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

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

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

## 13.2 DataFax Form Completion

### 13.2.1 Guidelines

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

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool. Use only one color per form. That is, do not begin completing a form using a blue pen and then switch to a black pen during the same form completion session.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read will result in QC notes.

- Do not type data onto CRFs. Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible while staying within the boundaries of the boxes.
- Record data on the front of CRFs only. DataFax cannot read the back of CRFs.
- Do not record data or make marks in the 0.5-inch/1.5-cm margins at the top, bottom, or sides of the CRF.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction “Mark all that apply.”
- A response is required for every item unless instructed otherwise by a skip pattern.
- **Never** obscure, mark over, or punch holes through the barcode at the top of each CRF. DataFax requires the barcode to identify the CRF.
- **Never** use correction fluid (“white-out”) or correction tape on CRFs.
- Remove any paper clips, staples, or other attachments before faxing CRFs.
- The site staff person who initially completes the form **must** record his/her initials **and** the date in the space provided in the bottom right-hand corner of each CRF page.
- Fax forms as soon as possible after they have been completed and reviewed (within the time period specified for the study).

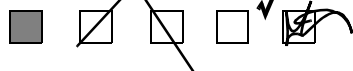
### 13.2.2 How to Mark Response Boxes

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

**Correct:**



**Incorrect:**



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

### 13.2.3 How to Record Numbers

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

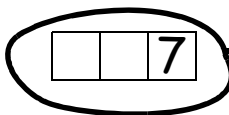
- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

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

**Correct:**

0 0 7

**Incorrect:**



This example would result in a QC note.

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

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

**Correct:**

4

**Incorrect:**

4

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

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

**Easily Identified:**

0 1 2 3 4 5 6 7 8 9

**Difficult to Identify:**

ø 1 2 3 4 7

### 13.2.4 How to Record Dates

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

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

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

For example, June 1, 2003 would be recorded as follows:

0	1	J	U	N	0	3
<i>dd</i>		<i>MMM</i>			<i>yy</i>	

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

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

A diagnosis date of October, 2002 would be recorded as follows:

O	C	T	0	2
<i>MMM</i>			<i>yy</i>	

### 13.2.5 How to Record Time

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

1	4	:	2	5
<i>hr</i>			<i>min</i>	

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

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

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

### 13.2.6 Data Corrections and Additions

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

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

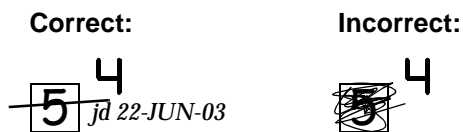
**Note:** If a correction or addition is made to one page of a multiple-page CRF, only refax the page that was changed.

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

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

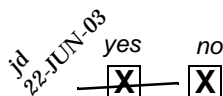
- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it unreadable with multiple cross-outs),
- place the correct or clarified answer near the box, and

- initial and date the correction as shown below:



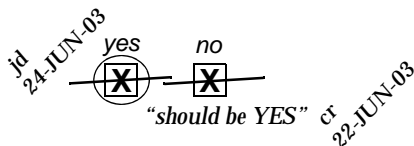
If an **X** is marked in the wrong response box, correct it by doing the following:

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



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

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

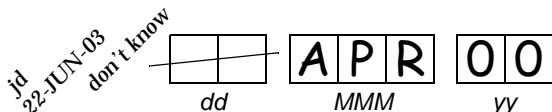


**Note:** The standards above must *always* be followed whenever a CRF is changed, clarified, or amended, even if the change is made *before* the CRF is faxed to SCHARP for the first time.

### 13.2.7 How to Handle Missing and Unknown Data

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

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



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

## 13.3 HPTN 059 Study-Specific Data Collection Information

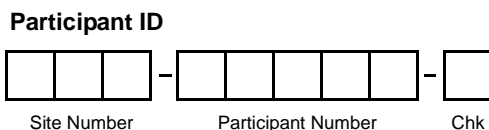
### 13.3.1 Participant ID numbers (PTIDs)

DataFax uses a unique participant identification number (PTID) to identify each study participant in the database. SCHARP provides each site with a list of PTIDs prior to study start-up. The site should assign one PTID to each study participant in sequential order, crossing out each PTID after it has been assigned to ensure that it is used only once. Once a participant has received a PTID, she maintains that same PTID throughout the entire study. If a participant has multiple screening attempts, she must maintain the PTID that was originally assigned to her—she is *never* assigned a new PTID.

PTID boxes are located near the upper left corner of each DataFax CRF. On multiple page CRFs, the PTID must be filled in on each page.

For HPTN 059, each PTID is assigned as part of the Screening Visit. SCHARP will furnish each site with a list of PTIDs before the start of the study. When a participant presents for a Screening Visit, she is assigned the next available PTID on the list. Once assigned, the PTID must **never** be assigned to another participant. Site staff are responsible for maintaining a log linking PTIDs to participant names (PTID-name link log) in accordance with Section 3 of this manual.

The PTIDs used for this study are nine digits and formatted as “XXX-YYYYY-Z.” The PTID consists of three parts: the site number (XXX), the participant number (YYYYY), and a numerical check digit (Z). The check digit (Z) is a number generated by SCHARP with the participant number, and helps ensure that the correct PTID is recorded. Below is an example of the PTID structure used in HPTN 059.



### 13.3.2 Study Visit Timing

#### Screening Attempt

Each time a participant screens (each time she provides written informed consent for screening), it is called a *screening attempt*. Because sites have 56 calendar days to complete screening and enrollment procedures, the visit dates/specimen collection dates on forms completed as part of the same screening attempt may be different from each other. The 56-day screening attempt “clock” starts on and includes the day the consent form for screening is signed or marked by the participant.

#### Multiple Screening Attempts (Re-screens)

If a participant’s screening attempt is unsuccessful, she may re-screen for the study if she chooses. If she does re-screen, ALL screening procedures (except PTID assignment), evaluations, and forms must be repeated, including signing of the written informed consent for screening.

#### Completion of Required Follow-Up Visits

Required follow-up visits are regularly scheduled every four weeks throughout the study follow-up period. Per protocol, study visits should be completed within a one-week window around the target date (i.e.,  $\pm 7$  days from the target date). However, there may be cases when a regularly scheduled visit is made up outside of the visit window. A regularly scheduled follow-up visit is considered “missed” when a participant does not complete any of the required visit evaluations, and the next visit window has opened.

For example, a participant has a Week 4 Visit target date of 17-APR-06 (visit window 10-APR-06 to 24-APR-06). Her Week 8 visit window opens 08-MAY-06, and the participant does not come into the clinic until 10-May-06. Since the participant did not complete the Week 4 Visit within the visit window AND did not make up the missed Week 4 Visit before the Week 8 Visit window opened (08-MAY-06), the Week 4 Visit is considered “missed.” A Missed Visit form is completed and faxed to SCHARP to document the “missed” visit.

### Interim Visits

A clinic visit is considered an Interim Visit when a participant presents at the site for additional clinical/laboratory/pharmacy assessments and/or procedures *outside* of the required evaluations for a scheduled study visit. The following are examples of interim visits for HPTN 059:

1. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the site clinic within the same visit window to request replacement gel cartons for lost study gel.
2. A participant completes all required evaluations for a scheduled study visit within the visit window. She then returns to the clinic outside the visit window to request a pregnancy test.
3. A participant completes all required evaluations for a scheduled study visit outside the visit window (the visit is made up late, after the visit window has closed). She then returns to the clinic 48-72 hours after the visit (still outside the visit window) for a repeat pelvic exam and clinical follow-up of superficial epithelial disruption (abrasion/peeling) noted during the visit pelvic exam.
4. A participant completes all required evaluations for a scheduled study visit outside the visit window (the visit is completed early, before the window has opened, due to participant travel during the visit window). She then returns to the clinic after the visit window has closed (and before the next visit window has opened) to report intermenstrual bleeding.

Phone contact with a participant is also considered an Interim Visit if the phone contact results in reporting of a new Adverse Experience (AE).

- Example: A participant’s target visit date is 17-APR-06. She completes all required evaluations for the visit on 16-APR-06. On 20-APR-06 she calls the clinic to report new symptoms which result in the reporting of a new adverse experience. Although she is still within the visit window (10-APR-06 to 24-APR-06), she has already completed all the required visit evaluations; thus, the 20-APR-06 phone contact is assigned an Interim Visit code.
- Example: A participant’s target visit date is 17-APR-06. She completes all required evaluations for the visit on 16-APR-06. On 26-APR-06 she calls the clinic to report new symptoms which result in the reporting of a new adverse experience. Since she already completed all the required visit evaluations, and since the next visit window has not yet opened, the 26-APR-06 phone contact is assigned an Interim Visit code.

**Note:** Study visits conducted early, before a visit window opens (e.g., due to anticipated travel by the participant during the visit window), or made up late, after a visit window has closed, are not considered Interim Visits. Such visits should be coded using the scheduled study visit code (Week 4=03.0, Week 8=04.0, etc.). All forms documenting required evaluations for a given study visit should be coded using the scheduled study visit code, regardless of whether the visit takes place within the visit window or outside the visit window (early or late). For example, forms documenting all required Week 8 Visit procedures should be coded “04.0,” regardless of whether the required procedures are conducted within or outside the visit window. Consequently, additional visits required to complete scheduled study visit procedures (e.g., because a participant must leave the site before all procedures can be performed) are not considered Interim Visits. Such visits also should be coded using the scheduled study visit code.



For questions about phone contacts and assignment of visit codes to such contacts, please contact the SCHARP HPTN 059 Project Manager.

### 13.3.3 Visit Codes and Page Numbers

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

HPTN 059 has eight scheduled study visits, and an additional three study visits for participants with chronic Hepatitis B. When visit code boxes are provided, site staff are responsible for entering the visit code in the boxes provided in the upper right corner of each page.

The following table lists visit type, timing, and DataFax visit codes for each visit.

**Table 13-1: Visit Timing and Visit Codes**

Visit Type	Timing	Visit Code
Screening	Up to Day -56	01.0
Enrollment	Day 0	02.0
Monthly Follow-up	Week 4	03.0
Monthly Follow-up	Week 8	04.0
Monthly Follow-up	Week 12	05.0
Monthly Follow-up	Week 16	06.0
Monthly Follow-up	Week 20	07.0
Monthly Follow-up	Week 24	08.0
Monthly Follow-up*	Week 28	09.0
Monthly Follow-up*	Week 32	10.0
Monthly Follow-up*	Week 36	11.0

\* Applies to chronic Hepatitis B (CHBV) participants only

#### **Visit Codes for visits that occur over more than one calendar day**

In cases when a participant absolutely cannot complete all required visit evaluations in one day (for example, she is menstruating and a pelvic exam cannot be performed), complete as many of the required evaluations as possible. Schedule the participant for another visit to conduct the remaining required evaluations as soon as possible, and preferably within the visit window. Note that when the participant returns to complete the remaining required evaluations, these are still considered part of her regular visit (regardless of whether or not they occur within visit window); therefore, the forms completed for these remaining evaluations should be assigned the same regular visit code as the previous visit.

- Example: A participant's Week 12 Visit target date is 15-MAY-06 (visit window is 08-MAY-06 to 22-MAY-06). The participant comes to the clinic on 14-MAY-06, but she is menstruating. On 15-MAY-06 (Visit Code = 05.0), complete all study visit evaluations except the pelvic exam and pelvic laboratory assays. Instruct the participant to come back to the clinic on 21-MAY-06 (when menses is expected to have ended) to complete the required pelvic exam and pelvic laboratory assays. The forms completed at the 21-MAY-06 visit are assigned the same Week 12 Visit Code as the 14-MAY-06 forms (Visit Code = 05.0), since the required evaluations for the Week 12 Visit were conducted on both dates.

### Visit codes for interim visits

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

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

Example #1: A participant returns to the site two days after her completed Week 12 Visit (Visit Code = 05.0). She is not yet in her Week 16 visit window. For this interim visit, record the following visit code:

#### Visit Code for this Interim Visit:

Visit Code   .

Example #2: A participant returns one week after her 05.1 interim visit (described in Example #1), and is not yet in her Week 16 visit window. Record the following visit code:

#### Visit Code for this Interim Visit:

Visit Code   .

### Page numbers

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

Page

In the example of the Adverse Experience Log, the participant's first adverse experience would be reported as page 01, the second would be 02, and so on.

### 13.3.4 Staff Initials/Date

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

### 13.3.5 Form Completion Schedule

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

Some SCHARP-provided forms are required to be completed at each visit, while other forms are required only at one visit or only when specifically indicated. The following table (Table 13-2) lists the DataFax and non-DataFax forms that are required to be completed at each study visit.

**Table 13-2: HPTN 059 Form Completion Schedule**

Visit	Timing	Visit Code	Forms	Form Acronym
Screening	Day -56	1.0	Screening Consent Demographics Site-specific Demographics Screening and Enrollment Pelvic Exam Pelvic Laboratory Results Safety Laboratory Results STI Laboratory Results (non-DataFax) Baseline Medical History (non-DataFax) History of Genital Symptoms (non-DataFax) Physical Exam (non-DataFax) Pelvic Exam Diagrams (non-DataFax) Screening Eligibility (non-DataFax) Clinical Eligibility (non-DataFax) Screening Summary (non-DataFax) Specimen Tracking Sheet	SC-1 DM-1 thru DM-2 DMU-1 and DMI-1 SPE-1 thru SPE-2 PLR-1 SL-1 thru SL-2 SLR-1 thru SLR-2 N/A <i>2 pages</i> N/A N/A N/A N/A <i>3 pages</i> N/A N/A <i>2 pages</i> N/A

Table 13-2: HPTN 059 Form Completion Schedule

Visit	Timing	Visit Code	Forms	Form Acronym
Enrollment	Day 0	2.0	Baseline Genital Symptoms Enrollment Behavior Assessment Screening and Enrollment Pelvic Exam Pelvic Laboratory Results STI Laboratory Results Safety Laboratory Results HBV Laboratory Results <i>(for CHBV participants only)</i> Concomitant Medications Log Pre-existing Conditions Enrollment (non-DataFax) Pelvic Exam Diagrams (non-DataFax) Enrollment Eligibility (non-DataFax) Clinical Eligibility (non-DataFax) Specimen Tracking Sheet	BGS-1 EBA-1 thru EBA-4 SPE-1 thru SPE-2 PLR-1 SLR-1 thru SLR-2 SL-1 thru SL-2 HLR-1  CM-1 PRE-1 ENR-1 N/A N/A N/A N/A
Monthly	Weeks 4, 12	3.0, 5.0	Follow-Up Visit Follow-Up Behavior Assessment - <i>Coitally Dependent Arm</i> - <i>Daily Use Arm</i> Acceptability Assessment Follow-up Genital Symptoms Follow-up Pelvic Exam Pelvic Laboratory Results Safety Laboratory Results HBV Laboratory Results <i>(for CHBV participants only, Week 12 only)</i> Pharmacokinetics (non-DataFax) Follow-Up Medical History (non-DataFax) Pelvic Exam Diagrams (non-DataFax) Specimen Tracking Sheet	FV-1  FBC-1 thru FBC-8 FBD-1 thru FBD-8 AA-1 thru AA-5 FGS-1 FPE-1 thru FPE-3 PLR-1 SL-1 thru SL-2 HLR-1  PK-1 N/A 2 pages N/A N/A
Monthly	Weeks 8, 16, 20	4.0, 6.0, 7.0	Follow-Up Visit Follow-up Genital Symptoms Pharmacokinetics <i>(Week 20 only)</i> (non-DataFax) Follow-up Medical History (non-DataFax) Specimen Tracking Sheet	FV-1 FGS-1 PK-1 N/A 2 pages N/A

Table 13-2: HPTN 059 Form Completion Schedule

Visit	Timing	Visit Code	Forms	Form Acronym
Study Exit for non-CHBV participants  Monthly for CHBV participants	Week 24 or Early Termination	8.0 or Early Termination	Follow-Up Visit Follow-Up Behavior Assessment - <i>Coitally Dependent Arm</i> - <i>Daily Use Arm</i> Study Exit Acceptability Assessment Follow-up Genital Symptoms Follow-up Pelvic Exam Pelvic Laboratory Results Safety Laboratory Results STI Laboratory Results HBV Laboratory Results ( <i>CHBV participants only</i> ) (non-DataFax) Follow-up Medical History (non-DataFax) Pelvic Exam Diagrams (non-DataFax) Specimen Tracking Sheet  <i>For non-CHBV participants or participants who are terminating early:</i> Female Study Burden Termination End of Study Inventory	FV-1  FBC-1 thru FBC-8 FBD-1 thru FBD-8 SAA-1 thru SAA-4 FGS-1 FPE-1 thru FPE-3 PLR-1 SL-1 thru SL-2 SLR-1 thru SLR-2 HLR-1  N/A 2 pages N/A N/A  FSB-1 TM-1 ESI-1
Monthly -CHBV	Weeks 28 and 32	9.0, 10.0	CHBV Visit Follow-up Genital Symptoms Safety Laboratory Results HBV Laboratory Results (non-DataFax) Follow-up Medical History	CHB-1 FGS-1 SL-1 thru SL-2 HLR-1 N/A 2 pages
Study Exit-CHBV	Week 36	11.0	CHBV Visit Follow-up Genital Symptoms Safety Laboratory Results HBV Laboratory Results Female Study Burden Termination End of Study Inventory (non-DataFax) Follow-up Medical History	CHB-1 FGS-1 SL-1 thru SL-2 HLR-1 FSB-1 TM-1 ESI-1 N/A 2 pages
If Indicated	Will Vary	Will Vary	Repeat Screening Pelvic Exam Adverse Experience Log Interim Visit Product Hold/Discontinuation Genital Bleeding Assessment HIV Test Results Pregnancy Report and History Pregnancy Outcome Missed Visit	RSP-1 AE-1 IV-1 PH-1 GBA 1-3 HTR-1 PR-1 PO-1 MV-1

### 13.3.6 Site Review of DataFax Forms

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

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

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

**Important:** If a date stamp is used, stamp *only* the back of the CRF, *never* the front. Be sure to date stamp the back of the CRF each time it is faxed, including refaxes.

### 13.3.7 Faxing DataFax Forms

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

It is important that the sites fax completed CRFs to SCHARP within the time period specified in the site's HPTN 059 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. Table 13-3 lists which DataFax forms are required to be faxed to SCHARP DataFax at each HPTN 059 study visit.

For sites wishing to confirm the receipt of faxed forms at SCHARP, the CRF Tracking System (CTS) is available. This system generates e-mails confirming the number of form pages received at SCHARP, and which forms were received at SCHARP for a given PTID and visit. Additionally, sites can go to a web site to view a listing of individual form pages received at SCHARP (<http://crftrack.scharp.org>). Note that a username and password is required for this website.

Please contact the HPTN 059 Project Manager if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

Table 13-3: HPTN 059 DataFax Form Transmission Schedule

Visit	Required DataFax Forms
Screening	None—Screening DataFax forms for the <b>successful</b> screening attempt are faxed only once the participant has enrolled and the Enrollment visit has been completed
Enrollment	<i>Enrolled participants only:</i> Screening Consent Demographics Site-Specific Demographics Safety Laboratory Results STI Laboratory Results HBV Laboratory Results (if indicated) Baseline Genital Symptoms Screening and Enrollment Pelvic Exam Pelvic Laboratory Results Enrollment Pre-existing Conditions Concomitant Medications Enrollment Behavior Assessment
Monthly - Weeks 4 and 12	Follow-Up Visit Safety Laboratory Results Pharmacokinetics HBV Laboratory Results (if indicated) Follow-up Pelvic Exam Follow-up Genital Symptoms Pelvic Laboratory Results Follow-Up Behavior Assessment-Coitally Dependent or Daily Use Acceptability Assessment
Monthly - Weeks 8, 16 and 20	Follow-Up Visit Follow-up Genital Symptoms Pharmacokinetics ( <i>Week 20 only</i> )
Week 24 or Early Termination	Follow-Up Visit Safety Laboratory Results STI Laboratory Results HBV Laboratory Results (if indicated) Follow-up Pelvic Exam Follow-up Genital Symptoms Pelvic Laboratory Results Follow-up Behavior Assessment-Coitally Dependent or Daily Use Study Exit Acceptability Assessment  <i>non-CHBV participants:</i> Female Study Burden Termination Concomitant Medications Log End of Study Inventory

Visit	Required DataFax Forms
CHBV participants - Weeks 28, 32 and 36	CHBV Visit HBV Laboratory Results Safety Laboratory Results Follow-up Genital Symptoms  <i>Week 36 only:</i> Female Study Burden Termination Concomitant Medications Log End of Study Inventory
Interim Visits	Interim Visit

### 13.3.8 Non-DataFax Forms

HPTN 059 sites will receive non-DataFax forms from SCHARP. These forms will be easily identifiable because there will not be a DataFax barcode along the top of the CRF. In place of the barcode, the following text will appear: “NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.”

These forms should not be faxed to SCHARP DataFax. Instead, they should be kept in the participant’s file as a record of the activities recorded on the form. When applicable, the guidelines described above for DataFax CRFs should also be applied when completing non-DataFax CRFs.

## 13.4 Form Supply and Storage

### 13.4.1 Form Supply

Each site will receive packages batched by form, including “as need forms” to be used by any participant during the study.

### 13.4.2 Form Storage

#### Participant Study Notebooks

For each enrolled participant, a notebook should be used to store all SCHARP-provided (DataFax and non-DataFax) forms used during the study. During screening, it may be best to use a thin folder for each participant. Then, once the participant enrolls in the study, the forms can be transferred into a participant notebook (two-ring, three-ring, or four-ring hard-cover binder). Remember, only store forms for successful Screening Attempts in the study notebook. Forms from any failed Screening Attempt can be kept in the thin folder.

The notebooks should be used to store all completed SCHARP-provided forms (DataFax and non-DataFax forms). In addition, the notebook should be used for storing a minimal supply of blank SCHARP-provided forms. It may be helpful to prepare notebooks in 3-month intervals (once the participant is enrolled).

Once these forms are completed and faxed to SCHARP DataFax, they are placed in the participant’s study notebook. A participant’s Screening and Enrollment forms should be placed in her study notebook once



she is enrolled in the study. During screening, smaller file folders can be used to store Screening forms and documentation, including inactive Screening forms for ineligible participants.

## 13.5 How to Complete Interviewer-administered Forms

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

### Interviewing Techniques

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

#### Welcoming the Participant

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

#### Asking Sensitive Questions

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

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

#### Recording Participants' Responses Verbatim

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

#### Pacing the Interview

Every participant is different. Some will know or say the answer to questions very quickly. Others may have to think longer to come up with answers, or may change their answers after giving more thought to the subject.

Always account for this variety when doing an interview. Read items slowly. Let the participant finish thinking before you record her response and go on to the next item.

### **Reading Items Aloud**

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

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

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

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

### **Probing**

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

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

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

- **Repeat Probe:** The repeat probe is used by repeating the item or response categories (if the response categories are part of the question). Although the participant might hear you the first time you ask a question, she may need to hear the question more than once to provide an answer. Instead of rephrasing a question if you notice the participant is confused, always first repeat the item as it is written. Sometimes hearing the question a second time is all that is needed.
- **Echo Probe:** The echo probe involves repeating the participant's exact response. Sometimes hearing the answer with a different voice will help her be more precise. The echo should always be repeated in a neutral, non-judgmental style.
- **Silent Probe:** The silent probe is used by pausing briefly after a participant gives what seems to be an uncertain answer. Although silence can feel awkward, sometimes it is helpful when a participant is trying to determine the most accurate answer to a question. Use a silent probe when the participant sounds unsure of her answer and may need some extra time to think more carefully about the question.
- **Non-verbal Probe:** The non-verbal probe is used by giving hand or facial gestures that may help the participant to come up with an answer. Remember that all such gestures must be neutral and non-judgmental.
- **Specification Probe:** The specification probe is used by asking the participant to give a more precise answer. Although a participant may give an answer that he or she considers accurate, it may not be

specific enough. For example, if an item asks how many times the participant did something and she answers with a range (“5 to 10”). Ranges are not acceptable for this type of interviewing. In this case, the probe, “Can you be more specific?” is often enough to help the participant choose the most accurate response.

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

### **Watching for Non-verbal Cues**

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

### **Checking Your Work**

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

## 13.6 Form-specific Completion Instructions

The form-specific completion instructions include the purpose of each form as well as how each form should be completed. Some items on forms are straightforward and do not require specific instructions. Therefore, you will not see all the items listed in the form-specific completion instructions, but rather, only those items needing detailed explanation. Use the Visit Checklist for a suggested order in which the forms should be completed at each visit.

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SAMPLE. DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

DM-1 (001)

Participant ID

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

Demographics

Visit Date

Visit Date form with boxes for dd, MMM, and yy

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

Question 1: What is your date of birth? Form with boxes for dd, MMM, yy and a field for age in years.

Question 2: What is your gender? Form with checkboxes for male and female.

Question 3: Are you currently married? Form with checkboxes for yes, no, and don't know.

Question 3a: How old is your husband? Form with boxes for years and a checkbox for don't know.

Question 3b: Are you currently living with your husband? Form with checkboxes for yes and no.

Question 3c: Does your husband have more than one wife or sexual partner? Form with checkboxes for yes, no, and don't know.

Question 3d: Does your husband provide you with financial and/or material support? Form with checkboxes for yes and no.

Question 3d1: What is your husband's average monthly income? Record in local currency. Form with a long box for currency and checkboxes for don't know and no income.

Question 3e: What is your husband's highest level of education?

U.S. Education levels list: no schooling, primary school (not complete, complete), secondary (not complete, complete), attended college or university, don't know. Includes instruction to go to item 5 on page 2.

INDIA Education levels list: no schooling, 1-3, 4, complete, 5-9, 10, complete, > 10, don't know. Includes instruction to go to item 5 on page 2.

---

## Demographics (DM-1)

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

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

**Note:** *If a participant is being re-screened, a new Demographics form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

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

### Item-specific Instructions:

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

- **Item 1:** If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. **NOTE:** *participant must be between the ages of 18 and 50 years at the time of enrollment to be eligible for study participation.*
- **Item 3:** Record whether or not the participant is **currently** married.
- **Item 3a:** If the participant does not know her husband's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 3d:** Record whether or not the participant's husband provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 3d1:** Record the husband's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

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

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

If the husband's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 3e:** Record the husband's highest level of education in the box corresponding to the participant's site country (U.S. or India). If the participant does not know her husband's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box that corresponds to the appropriate site country.

SAMPLE. Do NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

DM-2 (002)

Participant ID

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

Demographics

- 4. Do you currently have a male sexual partner?
4a. How old is your partner?
4b. Are you currently living with your partner?
4c. Does your partner have any other sexual partners?
4d. Does your partner provide you with financial and/or material support?
4d1. What is your partner's average monthly income?
4e. What is your partner's highest level of education?
U.S. and INDIA education levels

- 5. Do you earn an income of your own?
5a. What is your average monthly income?
5b. How do you earn your income?

---

## Demographics (DM-2)

### Item-specific Instructions:

- **Item 4:** Record whether or not the participant **currently** has a male sexual partner. If the participant reports that she currently has more than one male sexual partner, inform her that the next set of questions (items 4a through 4e) refer to the male partner she considers to be her primary sexual partner.
- **Item 4a:** If the participant does not know her sexual partner's exact age, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box.
- **Item 4d:** Record whether or not the participant's sexual partner provides her with any financial and/or material support. This will include things such as money, housing, food, household goods, etc.
- **Item 4d1:** Record the sexual 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	2	1	4	5
---	---	---	---	---	---	---

If the sexual partner's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 4e:** Record the male sexual partner's highest level of education in the box corresponding to the participant's site country (U.S. or India). If she does not know her sexual partner's highest level of education, record her best estimate. If she is unable to provide an estimate, mark the "don't know" box that corresponds to the appropriate site country.
- **Item 5a:** Record the participant's **average** monthly income (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros. If the participant's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.
- **Item 5b:** Record whether the participant's source(s) of income are from formal employment (for example: shop clerk, farmer, seamstress, teacher), self-employment (for example: shop owner, artist, restaurant owner), or other type of employment.

*If the participant refuses to give a response to any item(s), draw a line through the response boxes, write "refused," and initial and date the note in the white space next to the item.*

*If the participant is unable to give a response to any item(s), mark the "don't know" box (if provided). Otherwise, draw a line through the response boxes, write "don't know," and initial and date the note in the white space next to the item.*



SAMPLE. DO NOT FAX  
TO DATAFAX



HPTN 059 Ph II Microbe (113)

SC-1 (005)

Participant ID

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

Screening Consent

Visit Date

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

1. Is the participant between the ages of 18 and 50 years old? .....
 

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

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

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

→ **If no, participant is ineligible. End of form.**
  
- 2a. When was the informed consent form for screening marked or signed? .....
 

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	
  
3. Was blood collected for HSV-2 serology? .....
 

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

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

---

## Screening Consent (SC-1)

*This form is used to document that a participant provided written informed consent for screening for this study. This form must be completed for each participant who is assigned an HPTN 059 PTID.*

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

***Note:** If a participant is being re-screened, a new Screening Consent form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### **Item-specific Instructions:**

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

- **Item 1:** According to the protocol, a participant must “be between the ages of 18 and 50 *at the time of enrollment* as verified according to site standard operating procedure (SOP).” However, participants must be at least 18 years of age *at the time of screening* as well, since 18 is the minimum legal age to provide informed consent for clinical trial participation in both the U.S. and India. Participants who are under 18 years or over 50 years of age should not be screened for the study. If a participant reports that she is 50 years of age at screening, her Enrollment Visit must be conducted prior to her next birthday for her to be eligible to enroll per protocol.
- **Item 3:** Specimen collection for HSV-2 serology is required at the Screening Visit. If the required HSV-2 specimen was not collected, mark the “no” box and record the reason why in the Comments section at the bottom of the form.
- **Comments:** Record any necessary or additional information at the bottom of the form.

SAMPLE. DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

DMU-1 (018)

Participant ID

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

Demographics—United States

Visit Date

Visit Date form with boxes for dd, MMM, and yy

1. What is your highest level of education?

- Education level options: no schooling, primary school (not/complete), secondary (not/complete), attended college or university

2. How many people live in your household? ..... [ ] [ ]

2a. How many are children? ..... [ ] [ ]

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

4. Have you ever had an unplanned pregnancy? ..... yes [ ] no [ ] -> If no, go to item 5.

4a. How many unplanned pregnancies have you had? ..... 1 [ ] more than 1 [ ]

5. Do you consider yourself to be Latina or of Hispanic origin? ..... yes [ ] no [ ]

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

- Race categories: American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, White, other, specify: (Note: Latino is not a race.)

7. Interviewer: Where was the participant referred/recruited from? ..... [ ] [ ] code

---

## Demographics—United States (DMU-1)

*This is an interviewer-administered form (with the exception of item 7) that is used to collect additional demographic and socioeconomic information from U.S. participants.*

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

**Note:** *If a participant is being re-screened, a new Demographics-United States form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

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

- **Item 2:** Record the total number of people, including children, living in the participant's household.
- **Item 2a:** Record only the number of children living in the participant's household.
- **Item 3:** Record the **average** monthly income for the household (record in local currency). The participant should include all sources of income. Right justify the response and use leading zeros.

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

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

If the household's average monthly income is greater than 9,999,999 write "9999999" in the boxes provided, and record the actual value in the white space near the item.

- **Item 4:** Record whether or not the participant has ever had a known unplanned pregnancy.
- **Item 5:** *Note: Latina is not a race.*
- **Item 6:** This item asks about race. Read each category aloud and mark the response(s) that apply based on the participant's response. If the participant feels that an appropriate choice is not listed mark the "Other, specify" box and record her response on the line provided.
- **Item 7:** 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.

**If the participant refuses to give a response to any item(s), draw a line through the response boxes, write "refused," and initial and date the note in the white space next to the item.**

**If the participant is unable to give a response to any item(s), mark the "don't know" box (if provided). Otherwise, draw a line through the response boxes, write "don't know," and initial and date the note in the white space next to the item.**

SAMPLE. DO NOT FAX  
TO DATAFAX



HPTN 059 Ph II Microbe (113)

DMI-1 (020)

Participant ID

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

Site Number      Participant Number      Chk

Demographics—India

Visit Date

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

dd      MMM      yy

1. What is your highest level of education?

- no schooling
- 1–3
- 4, complete
- 5–9
- 10, complete
- > 10

2. How many children have you given birth to who were alive at birth? .....

--	--

# of children

yes      no

3. Do you own your home?.....

--	--

4. How many rooms are in your household? .....

--	--

5. What is your ethnic group or tribe? **Read categories aloud. Mark all that apply.**

- Asian
- other, specify:

Marathi: \_\_\_\_\_

English: \_\_\_\_\_

6. What is your religion?

- Hindu
- Muslim
- Christian
- Buddhist
- other, specify:

Marathi: \_\_\_\_\_

English: \_\_\_\_\_

7. **Interviewer:** Where was the participant referred/recruited from?.....

--	--

code

---

## Demographics—India (DMI-1)

*This is an interviewer-administered form (with the exception of item 7) that is used to collect additional demographic and socioeconomic information from participants in India.*

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

**Note:** *If a participant is being re-screened, a new Demographics-India form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

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

- **Item 5:** This item asks about race. Read each category aloud and mark the response(s) that apply based on the participant's response. If the participant feels that an appropriate choice is not listed mark the "other, specify" box and record her response on the line provided.
- **Item 6:** If the participant answers a religion other than the four religions listed, mark the "other, specify" box, record the participant's answer in Marathi on the line provided, and go to item 7. Once the interview is completed, go back and record the English translation of the participant's Marathi response on the English line provided.
- **Item 7:** 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.

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

SAMPLE. DO NOT FAX TO DATAFAX

Visit Code

0

1

HPTN 059 Ph II Microbe (113)

SPE-1 (041)

Participant ID

Site Number - Participant Number - Chk

Exam Date

dd MMM yy

Screening and Enrollment Pelvic Exam

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

no abnormal findings abnormal findings

checkbox

checkbox

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

If no abnormal findings, go to item 2.

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

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

2. Colposcopic exam assessment: ..... Required at Enrollment Visit.

not done no abnormal findings abnormal findings

checkbox

checkbox

checkbox

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

If not done OR no abnormal findings, go to item 3 on page 2.

2a. Abnormal colposcopic findings: Mark all that apply.

- Abnormal vaginal discharge, Abnormal cervical discharge, Blood-tinged discharge, Blood in vagina—no identified source, Blood from cervical os, Bleeding from site of epithelial disruption, Erythema, Ulceration, Laceration, Abrasion, Peeling, Petechia, Ecchymosis, Vesicles, Edema, Abnormal cysts, Grossly white finding, Mass, Warts—on and/or interior to labia minora, Warts—exterior labia minora, Other abnormal findings, specify:

---

## Screening and Enrollment Pelvic Exam (SPE-1)

*This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic (and, when applicable, colposcopy) exams conducted during the Screening and Enrollment Visits. This form should be completed once to document the screening pelvic exam, and once to document the enrollment pelvic/colposcopy exam.*

*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 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 an exclusionary finding at the initial screening pelvic exam that is followed to resolution within the 56-day window for screening). In such cases, use this form to document the initial screening pelvic exam only. Complete a Repeat Screening Pelvic Exam form for each subsequent pelvic exam conducted as part of the same screening attempt. A new Screening and Enrollment Pelvic Exam form should be completed for the Screening 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. For each enrolled participant, only one Screening and Enrollment Pelvic Exam form for the Screening Visit (assigned visit code 1.0), and one Screening and Enrollment Pelvic Exam form for the Enrollment Visit (assigned visit code 2.0) should be faxed to SCHARP DataFax.*

### Item-specific Instructions:

- **Item 1:** Document only those abnormal findings observed during naked eye, speculum, and bimanual examinations. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 1a blank and go to item 2. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed via naked eye, speculum, and bimanual examination **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.
- **Item 2:** Colposcopy is required at the Enrollment Visit. Document any abnormal findings observed during colposcopic examination **only**. If the exam did not include colposcopy, mark the “not done” box, leave item 2a blank and go to item 3. If colposcopy was required but not done, also record the reason it was not done in the Comments section at the bottom of page 2. If no abnormal findings are observed on colposcopy, mark the “no abnormal findings” box, leave item 2a blank and go to item 3. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 2a.
- **Item 2a:** Mark the box to the left of **each** abnormal finding observed on colposcopy **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.



SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [0]

[1]

HPTN 059 Ph II Microbe (113)

SPE-2 (042)

Participant ID

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

Screening and Enrollment Pelvic Exam

- 3. Do any of these exam findings involve generalized erythema or severe edema with an affected area of more than 50% of the vulvar surface or combined vaginal and cervical surface? .....  
yes [ ] no [ ]
- 4. Do any of these exam findings involve deep epithelial disruption? .....  
yes [ ] no [ ] **If no, go to item 5.**
- 4a. Was the deep epithelial disruption observed in more than one distinct area? .....  
yes [ ] no [ ] **If yes to either, participant is ineligible at this time.**
- 5. Cervical Ectopy: Percentage of cervical surface area.  
0% [ ] 1-25% [ ] 26-50% [ ] 51-75% [ ] > 75% [ ]
- 5a. Cervical ectopy assessed by: .....  
naked eye [ ] colposcopy [ ]
- 6. Was a vaginal Gram Stain smear collected? .....  
yes [ ] no [ ]
- 7. Was a cervical Gram Stain smear collected? .....  
[ ] [ ]
- 8. Were cervical swabs collected for cytokine and chemokine testing? ...  
[ ] [ ]
- 9. Was a genital ulcer swab collected? .....  
[ ] [ ] **[ ] # of swabs**
- U.S. only:**
- 10. Was a vaginal swab collected for quantitative culture? .....  
yes [ ] no [ ]

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

---

## Screening and Enrollment Pelvic Exam (SPE-2)

- **Item 5 and 5a:** When colposcopy is performed, cervical ectopy must be assessed by colposcopy and not by naked eye. If colposcopy was performed, item 5a should be marked “colposcopy.” If colposcopy was not performed, item 5a should be marked “naked eye.”
- **Item 6:** Collection of a vaginal Gram Stain smear (duplicate slides) is required as part of the Screening and Enrollment Visit pelvic exams. If a vaginal Gram Stain smear was not collected, mark the “no” box and record the reason the required smear was not collected in the Comments section at the bottom of the form.
- **Item 7:** Collection of a cervical Gram Stain smear (duplicate slides) is required as part of the Enrollment Visit pelvic exam. If a cervical Gram Stain smear was not collected at the Enrollment Visit, mark the “no” box and record the reason the required smear was not collected in the Comments section at the bottom of the form.
- **Item 8:** Collection of cervical swabs for cytokine and chemokine testing is required as part of the Enrollment Visit pelvic exam. If cervical swabs were not collected at the Enrollment Visit, mark the “no” box and record the reason the required swabs were not collected in the Comments section at the bottom of the form.
- **Item 9:** A multiplex PCR swab for genital ulcer disease (GUD) is collected for each genital ulcer, cluster of ulcers, and/or other anogenital finding thought to be Herpetic that is identified upon examination at the Screening and/or Enrollment Visits. If one or more swabs are collected, mark the “yes” box and record the number of swabs collected. If no swab is collected, mark the “no” box and leave the “# of swabs” box blank. If a genital ulcer, cluster of ulcers, and/or other potentially Herpetic anogenital finding thought to be Herpetic is observed, but no swab is collected, mark the “no” box and record the reason in the Comments section.
- **Item 10:** This item should be completed for U.S. participants only as part of the Enrollment Visit pelvic exam; it should be left blank for participants at the Pune site. If no vaginal swab was collected at the Enrollment Visit, mark the “no” box and record the reason the required swab was not collected in the Comments section at the bottom of the form.
- **Comments:** Record any necessary or additional information at the bottom of the form.

SAMPLE. DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

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	
<input type="checkbox"/>	<input type="checkbox"/>	→ <b>If no, participant is ineligible. End of form.</b>
  
- 1a. When was the informed consent form for enrollment marked or signed? .....
 

dd		MMM		yy	
  
2. Was a clinic randomization envelope assigned? .....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ <b>If no, specify reason in Comments. End of form.</b>
  
- 2a. Clinic randomization envelope number:.....
 

--	--	--
  
- 2b. Date assigned:.....
 

dd		MMM		yy	
  
- 2c. Time assigned:.....
 

		:			24-hour clock
hr			min		
  
- 2d. To which dosing frequency was the participant randomized?.....
 

daily use	coitally dependent
<input type="checkbox"/>	<input type="checkbox"/>
  
- 2e. To which randomization code was the participant randomized? .....
 

--	--	--
  
3. Date study gel first dispensed: .....
 

dd		MMM		yy	
  
4. How many cartons of study gel were first dispensed? .....
 

		# of cartons dispensed
--	--	------------------------
  
5. Unique identifying number on the first carton of study gel dispensed to the participant: .....
 

--	--	--	--
  
6. Is this a chronic Hepatitis B (CHBV) participant? .....
 

yes	no
<input type="checkbox"/>	<input type="checkbox"/>
  
7. Was blood collected for the plasma archive? .....
 

<input type="checkbox"/>	<input type="checkbox"/>
--------------------------	--------------------------
  
8. Was blood collected for the serum archive? .....
 

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

Comments: \_\_\_\_\_

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## Enrollment (ENR-1)

*This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants determined to be eligible for the study. This form is faxed to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a clinic randomization envelope), and only after completion of the 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:** If this item is “no” (the participant is not able and willing 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.
- **Item 2:** If a clinic randomization envelope is not assigned, mark the “no” box and specify in the Comments section 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 is not assigned.
- **Item 2a:** Record the 3-digit clinic randomization envelope number present on the clinic randomization envelope assigned to this participant.
- **Item 2b:** 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 HPTN 059 Clinic Randomization Envelope Tracking Record and on the study prescription inside the envelope.
- **Item 2c:** Record the time (using a 24-hour clock) when the clinic randomization envelope was assigned to the participant. This time should match the “time assigned” recorded for this envelope on the HPTN 059 Clinic Randomization Envelope Tracking Record.
- **Item 2d:** Record the participant’s randomized dosing frequency assignment (daily use or coitally dependent) present on the prescription contained in the participant’s clinic randomization envelope.
- **Item 2e:** Record the 3-digit randomization code present on the prescription contained in the participant’s clinic randomization envelope.
- **Item 3:** Record the exact day, month, and year the study gel was first dispensed to this participant.
- **Item 4:** Record the number of study gel cartons first dispensed to the participant. **NOTE:** A standard number of four cartons for daily use participants and eight cartons for coitally dependent participants should be dispensed at the Enrollment Visit. If more than the standard number of cartons are dispensed, record the reason why in the Comments section.
- **Item 5:** From the site pharmacist (or designee), obtain and record the unique 4-digit identifying number present on the carton label of the first carton of study gel dispensed to the participant.
- **Item 6:** The initial response to this item should be based on the results of the Screening and Enrollment Visit Hepatitis B Surface Antigen tests. If the participant tests positive, mark the “yes” box. If the participant tests negative, mark the “no” box. If the participant tests negative at baseline, but has a subsequent positive Hepatitis B Surface Antigen result during on-study follow-up testing, line through the box marked “no,” mark the “yes” box, initial and date, and fax to SCHARP DataFax.
- **Items 7-8:** Record whether or not specimens were collected for the plasma and serum archive (both are required at the Enrollment Visit). If the protocol-required specimens were *not* collected and/or archived at the Enrollment Visit, mark “no” and provide an explanation in the Comments section at the bottom of the form.

SAMPLE. DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

RSP-1 (043)

Participant ID

Participant ID form with Site Number, Participant Number, and Chk fields.

Exam Date

Exam Date form with dd, MMM, and yy fields.

Repeat Screening Pelvic Exam

1. Naked eye, speculum, and bimanual exam assessments: ... no abnormal findings abnormal findings If abnormal findings are noted, consult protocol to determine participant eligibility. If no abnormal findings, go to item 2.

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

- List of 15 checkboxes for abnormal findings: Enlarged/tender inguinal lymph nodes, Abnormal vaginal discharge, Abnormal cervical discharge, Blood-tinged discharge, Blood in vagina—no identified source, Blood from cervical os, Bleeding from site of epithelial disruption, Erythema, Ulceration, Laceration, Abrasion, Peeling, Petechia, Ecchymosis, Vesicles, Edema, Abnormal cysts, Grossly white finding, Mass, Warts—on and/or interior to labia minora, Warts—exterior to labia minora, Adnexal tenderness, Cervical motion tenderness, Uterine tenderness, Other abnormal findings, specify:

- 2. Do any of these exam findings involve generalized erythema or severe edema with an affected area of more than 50% of the vulvar surface or combined vaginal and cervical surface?
3. Do any of these exam findings involve deep epithelial disruption?
3a. Was the deep epithelial disruption observed in more than one distinct area?
4. hCG for pregnancy?
5. Was a vaginal Gram Stain smear collected?
6. Was a genital ulcer swab collected? # of swabs

Comments:

28-JUN-06

01

Language

Staff Initials / Date

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## Repeat Screening Pelvic Exam (RSP-1)

*This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document repeat screening pelvic exams in cases where multiple screening pelvic exams are conducted as part of the SAME screening attempt (within the 56-day window). This form should be completed for each repeat screening pelvic exam conducted as part of the same screening attempt. It is faxed to SCHARP DataFax only if the participant enrolls in the study, and only after completion of her Enrollment Visit.*

**Note:** *If, during the initial screening pelvic exam, a participant has abnormal finding(s) that are exclusionary per protocol - and the participant is otherwise eligible for study participation - an Enrollment Visit should be scheduled at a time within the 56-day window when the exclusionary findings are thought to be resolved. If the exclusionary findings have resolved by the time the participant returns for her next visit (as observed by site clinician on exam), and the participant is otherwise eligible for study participation, the participant may enroll in the study at that time. If she chooses to enroll in the study that same day, the pelvic/colposcopy exam should be considered part of the Enrollment Visit, and should be documented on a Screening and Enrollment Pelvic Exam form assigned visit code 2.0. If the participant chooses to enroll at a later date, or if the participant's exclusionary findings have not yet resolved upon repeat examination, the repeat pelvic exam should be considered a repeat screening pelvic exam, and should be documented on this form. Site staff should reschedule the participant for an Enrollment Visit at a time (still within the 56-day window) when the exclusionary findings are thought to be resolved. If the exclusionary findings have not resolved within the 56-day window for screening, and/or the participant does not complete all Screening Visit procedures within the 56-day window, the participant must be re-screened (with all Screening Visit procedures repeated in their entirety) if she still wishes to participate in the study.*

### Item-specific Instructions:

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

- **Item 1:** Document only those abnormal findings observed during naked eye, speculum, and bimanual examinations. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 1a blank and go to item 2. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed via naked eye, speculum, and bimanual examination **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.
- **Item 4:** A pregnancy test should be conducted at each visit during screening. If the pregnancy specimen was not collected, or the test was not done (collected but no result available), mark the “not done” box and record the reason the required test was not done in the Comments section at the end of the form.
- **Item 5:** Collection of a vaginal Gram Stain smear (duplicate slides) is required as part of the Screening Visit. If a vaginal Gram Stain Smear was already collected for the current screening attempt (e.g., at the initial screening pelvic exam), it does not need to be collected during a repeat screening pelvic exam. If a vaginal Gram Stain smear was not collected at this visit, and was not collected at a previous screening pelvic exam for this screening attempt, mark the “no” box and record the reason the required smear was not collected in the Comments section at the bottom of the form.
- **Item 6:** A multiplex PCR swab for genital ulcer disease (GUD) is collected for each genital ulcer, cluster of ulcers, and/or other anogenital finding thought to be Herpetic that is identified upon examination during screening. If one or more swabs are collected, mark the “yes” box and record the number of swabs collected. If no swab is collected, mark the “no” box and leave the “# of swabs” box blank. If a genital ulcer, cluster of ulcers, and/or other potentially Herpetic anogenital finding thought to be Herpetic is observed, but no swab is collected, mark the “no” box and record the reason in the Comments section.
- **Comments:** Record any necessary or additional information at the bottom of the form.

SAMPLE. DO NOT FAX  
TO DATAFAX



HPTN 059 Ph II Microbe (113)

EBA-1 (072)

Participant ID

Site Number - Participant Number - Chk

Enrollment Behavior Assessment

Visit Date

dd MMM yy

I am now going to ask you some questions about your sexual behavior. Some of these questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. There are no right or wrong answers to these questions. We will ask you these same types of questions during your follow-up visits. Remember, we do not have your name on these papers, and all of your answers will be kept confidential.

There are many different ways people have sex. Some of the questions I am going to ask you are about vaginal sex, and some are about anal sex. By vaginal sex, I mean when a man puts his penis inside your vagina. By anal sex, I mean when a man puts his penis inside your anus.

Shall we continue?

1. In the past month, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex.....

# of partners. If 0, go to item 3.

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

2. In the past week, how many times did you have vaginal sex? .....

# of times. If 0, go to item 3.

I know that you are counseled to use condoms for each act of vaginal sex, but I also know that this is not always possible.

2a. In the past week, how many times did you use a male or female condom during vaginal sex? .....

# of times

3. When was the last time you had vaginal sex? .....

dd MMM yy

NOTE: Date of last penile-vaginal intercourse must be no earlier than 30 days prior to screening for the participant to be eligible to enroll.

---

## Enrollment Behavior Assessment (EBA-1)

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

### Interview tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

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

### Item-specific Instructions:

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

- **Items 1, 2, and 2a:** Use leading zeros when needed so that all the boxes are filled.
- **Item 3:** Note that the date, as reported by the participant, should be no earlier than 30 days prior to the initial screening date (that is, the date that informed consent for screening was obtained for the current screening attempt) in order for the participant to be eligible for the study. If the participant is unable to recall the exact date, obtain her best estimate. At minimum, the month is required.

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



SAMPLE. DO NOT FAX  
TO DATAFAX



HPTN 059 Ph II Microbe (113)

EBA-2 (073)

Participant ID

Site Number			Participant Number						Chk	

Enrollment Behavior Assessment

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

- |  |                          |                          |
|--|--------------------------|--------------------------|
|  | yes                      | no                       |
| 4a. did you or your partner use a male condom? .....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4b. did you use a female condom? .....   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4c. did you wash inside or douche inside your vagina within 2 hours <b>before</b> having vaginal sex? .....                        | <input type="checkbox"/> | <input type="checkbox"/> |
| 4d. did you wash inside or douche inside your vagina within 2 hours <b>after</b> having vaginal sex? .....                         | <input type="checkbox"/> | <input type="checkbox"/> |
| 4e. did you insert paper, cloth, cotton, or cotton wool within 2 hours <b>before</b> having vaginal sex? .....                     | <input type="checkbox"/> | <input type="checkbox"/> |
| 4f. did you insert paper, cloth, cotton, or cotton wool within 2 hours <b>after</b> having vaginal sex? .....                      | <input type="checkbox"/> | <input type="checkbox"/> |
| 4g. did you insert any other object or substance into your vagina within 2 hours <b>before</b> or <b>during</b> vaginal sex? ..... | <input type="checkbox"/> | <input type="checkbox"/> |

**If yes, specify:**

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

- |  |                          |                          |
|--|--------------------------|--------------------------|
|  | yes                      | no                       |
| 4h. did you insert any other object or substance into your vagina within 2 hours <b>after</b> vaginal sex? ..... | <input type="checkbox"/> | <input type="checkbox"/> |

**If yes, specify:**

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

I am now going to ask you some questions about a different way that people have sex. This way is anal sex. These questions may not apply to you, but we ask all participants these same questions. I am asking you these questions because understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

- |                                      |                          |                          |
|--------------------------------------|--------------------------|--------------------------|
|                                      | yes                      | no                       |
| 5. Have you ever had anal sex? ..... | <input type="checkbox"/> | <input type="checkbox"/> |

**If no, go to statement before item 9 on page 3.**

28-JUN-06

Language

Staff Initials / Date

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## Enrollment Behavior Assessment (EBA-2)

### Item-specific Instructions:

- **Item 4:** Read each item 4a–4h aloud and mark the participant’s answer. If ‘yes’ is marked for items 4g or 4h, 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.

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

SAMPLE. DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

EBA-3 (074)

Participant ID

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

Enrollment Behavior Assessment

6. In the past week, did you have anal sex? yes no If no, go to item 7.

I know that you are counseled to use condoms for each act of anal sex, but I also know that this is not always possible.

6a. In the past week, did you ever, even once, have anal sex without a condom? yes no

7. When was the last time you had anal sex? dd MMM yy

8. The last time you had anal sex: yes no

8a. did you or your partner use a male condom? yes no

8b. did you use a lubricant (such as lube, K.Y.)? yes no

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

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

Questions 9a-9g with response options for yes/no and a grid for the number of times in the past week.

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

---

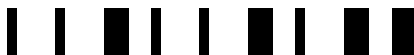
## Enrollment Behavior Assessment (EBA-3)

### Item-specific Instructions:

- **Item 7:** If, after verbal probing, the participant is unable to provide the day she last had anal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.
- **Item 8:** Read each item 8a–8b aloud and mark the participant’s response.
- **Item 9:** Read each item 9a–9g aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many times in the past **week** she has used that particular item. Record the response in the “# of times in **past week**” boxes. If “yes” is marked for item 9g, record the participant’s verbatim (word-for-word) response 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.

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

**SAMPLE**. DO NOT FAX  
TO DATAFAX



HPTN 059 Ph II Microbe (113)

EBA-4 (075)

**Participant ID**

Site Number			Participant Number						Chk		

**Enrollment Behavior Assessment**

10. I know you were asked about family planning during your medical history review, but I need to ask you again. Which family planning method or methods are you currently using? **DO NOT read response categories aloud. Mark "none" or all that apply.**

none  
 vaginal ring  
 spermicide  
 diaphragm  
 sponge

➔ **Participant is ineligible.**

 intrauterine device (IUD)

➔ **If inserted less than 30 days prior to Enrollment, participant is ineligible.**

natural methods such as the withdrawal or rhythm method  
 male condoms  
 female condoms

➔ **Must be combined with another effective method of contraception, as defined in the protocol, for participant to be eligible.**

- family planning pills or birth control pills
- injectable contraceptives (such as Depo-Provera)
- Norplant inserts
- Ortho Evra/The Patch
- surgical sterilization (tubal ligation)
- sex with partner who had a vasectomy
- other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

---

## Enrollment Behavior Assessment (EBA-4)

### Item-specific Instructions:

- **Item 10: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each family planning method the participant reports using. If the participant reports a method not listed, mark the “other, specify” box and 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. **During the visit**, while the participant is still at the site, compare the item 10 response(s) to the family planning method(s) documented on the non-DataFax Baseline Medical History form and/or other local baseline medical history form(s) for this participant. If inconsistencies are noted, attempt to resolve these by asking the participant for clarification. Update the appropriate form(s), as necessary, based on the participant’s response.

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

SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code

□□□.□□

1

HPTN 059 Ph II Microbe (113)

AA-1 (371)

Participant ID

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

Acceptability Assessment

Visit Date

□□ □□□□ □□  
dd MMM yy

One goal of this research is to understand how acceptable study gel use is to women and their partners. I am now going to ask you some questions about your experiences using the study gel and how study gel use has affected your relationship(s) with sexual partners. Your honest answers will be very helpful to us.

Shall we continue?

1. What do you like about your study gel? **DO NOT read response categories aloud. Mark all that apply.**

If only one response box is marked, go to item 2 on page 2.

- no response
- nothing
- may protect against HIV
- may protect against STIs
- can use without partner's knowledge
- other, specify:
- easy to use
- method is under her control
- made sex more pleasurable
- did not interrupt sex
- appearance/smell

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

1a. Which of these do you like most? **DO NOT read response categories aloud.**

- no response
- nothing
- may protect against HIV
- may protect against STIs
- can use without partner's knowledge
- other, specify:
- easy to use
- method is under her control
- made sex more pleasurable
- did not interrupt sex
- appearance/smell

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

---

## Acceptability Assessment (AA-1)

*This form is used to collect gel acceptability information from study participants. This is an interviewer-administered form, and it is administered at the Week 4 and 12 visits.*

### Interview tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- When a participant's response does not match one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Item 1: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reported characteristic the participant likes about the study gel. If the participant gives a response that does not correspond to one of the listed categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response. If "no response" or "nothing" is marked, no other response box should be marked. If only one response box is marked, leave item 1a blank and go to item 2.
- **Item 1a: Do not** read any of the response categories aloud. Instead, read the question, and based on the participant's responses to item 1, record the one characteristic the participant likes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she likes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response.

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



SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

AA-2 (372)

Participant ID

-      -

Site Number

Participant Number

Chk

Acceptability Assessment

2. What do you not like about your study gel? **DO NOT read response categories aloud. Mark all that apply.**

If only one response box is marked, go to item 3 on page 3.

no response

nothing

messy

interrupted sex

made sex less pleasurable

difficult to use, specify:  
*Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

remembering to use it

difficult to store and/or discard

appearance/smell

other, specify:  
*Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

2a. Which of these do you dislike most? **DO NOT read response categories aloud.**

no response

nothing

messy

interrupted sex

made sex less pleasurable

difficult to use

remembering to use it

difficult to store and/or discard

appearance/smell

other, specify:  
*Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

---

## Acceptability Assessment (AA-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 2:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each characteristic the participant does not like about the study gel. If the participant gives a response that does not correspond to one of the listed categories, mark the “other, specify” box and record the verbatim (word-for-word) response. If the participant’s response is “difficult to use,” probe for more specific information as to why the study gel is difficult to use and record the participant’s verbatim (word-for-word) response. If “no response” or “nothing” is marked, no other response box should be marked. If only one response box is marked, leave item 2a blank and go to item 3.
- **Item 2a:** **Do not** read any of the response categories aloud. Instead, read the question and, based on the participant’s responses to item 2, mark the box that corresponds to the one characteristic the participant dislikes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she dislikes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response .

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

SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

AA-3 (373)

Participant ID

-      -   
Site Number Participant Number Chk

Acceptability Assessment

3. Is the study gel easy to apply? .....  yes  no  don't know
4. In general, does the study gel have any effect on sexual intercourse? .....  yes  no  don't know  
→ If no, go to item 5.
- 4a. Does it improve sex for you? .....
- 4b. Does it improve sex for your male partner? .....
- 4c. Does it worsen sex for you? .....
- 4d. Does it worsen sex for your male partner? .....
5. In the past month, did you have sex with a regular male partner? .....  yes  no  
→ If no, go to item 6 on page 4.

**If this is the first time this questionnaire is being administered for this participant, skip item 5a and go to item 5b.**

- 5a. Is this the same partner you had the last time you answered these questions? .....  yes  no  don't know  not applicable
- 5b. In the **past month**, did you have sex with this regular partner while you were using the study gel?  yes  no  
→ If no, go to item 6 on page 4.
- 5c. Did he know you were using the study gel? .....  yes  no  don't know  
→ If no or don't know, go to item 6 on page 4.
- 5d. What was his reaction to the study gel? **DO NOT read response categories aloud.**
- he liked it
  - he did not like it
  - he had no reaction
  - don't know
  - other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

---

## Acceptability Assessment (AA-3)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 4:** Read each item 4a–4d aloud and mark the participant’s response.
- **Item 5:** “Regular male partner” is defined as the individual the participant considers to be her principal or primary male sex partner. If the participant’s response is “no,” leave items 5a–5d blank.
- **Item 5a:** If this is the first time this form is being administered to this participant, leave item 5a blank and go to item 5b. If the participant states she did not have a regular partner the last time she answered these questions, mark “not applicable.”
- **Item 5d:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box that corresponds to the participant’s response. If the participant gives a response that is not listed, mark the “other, specify” box and 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.

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

SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

AA-4 (374)

Participant ID

-      -   
Site Number Participant Number Chk

Acceptability Assessment

6. In the **past month**, did you have sex with any other male partners while you were using the study gel? .....  *yes*  *no* → **If no, go to item 7 on page 5.**

6a. In the **past month**, did you have sex with more than one other male partner (besides a regular partner) while you were using the study gel? .....  *yes*  *no* → **If yes, go to item 6a2.**

6a1. Did your other partner know you were using the study gel? .....  *yes*  *no*  *don't know*  
↓ **If yes, go to item 6a3.** → **If no or don't know, go to item 7 on page 5.**

6a2. The **last time** you used the study gel with one of these other partners, did he know you were using the study gel? .....  *yes*  *no*  *don't know* → **If no or don't know, go to item 7 on page 5.**

6a3. What was his reaction to the study gel? **DO NOT read response categories aloud.**

- he liked it
- he did not like it
- he had no reaction
- don't know
- other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

---

## Acceptability Assessment (AA-4)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 6:** Items 6–6a3 refer to those male sex partner(s) who are **not** considered by the participant to be her regular sex partner (the partner referenced in item 5 on page 3).
- **Item 6a:** This item applies only to those participants who, in item 6, reported “yes” to having had sex with a non-regular male partner while using the study gel in the past month. The intent of this item is to identify whether or not, in the past month, the participant used the study gel with *multiple* non-regular male sex partners in the past month.
  - **For participants who reported having sex with a regular male partner in the past month (item 5 on page 3 is marked “yes”):** If the participant reports that she had sex with her regular male partner and only one other male partner in the past month, then the answer should be marked “no.” If the participant reports that she had sex with her regular male partner and two or more other (non-regular) male partners in the past month - but she did not use the study gel with at least two of these non-regular partners in the past month - then the answer should be marked “no.” If the participant reports that she had sex with her regular male partner and two or more other (non-regular) male partners in the past month – and she reports having used the study gel with at least two of these other (non-regular) male partners in the past month – then the answer should be marked “yes.”
  - **For participants who reported that they did *not* have sex with a regular male partner in the past month (item 5 on page 3 is marked “no”):** If the participant states that she had either no male sex partners or only one (non-regular) male sex partner in the past month, then the answer should be marked “no.” If the participant had two or more (non-regular) male sex partners in the past month - but she did not use the study gel with at least two of these non-regular partners in the past month - then the answer should be marked “no.” If the participant had two or more (non-regular) male sex partners in the past month - and she reports having used the study gel with at least two of these (non-regular) male partners in the past month - then the answer should be marked “yes.”
- **Items 6a3: Do not** read any of the response categories aloud. Instead, read the question and mark the box that corresponds to the participant’s response. If the participant gives a response that is not listed, mark the “other, specify” box and 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.

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

**SAMPLE**. Do NOT FAX  
TO DATAFAX

AA-5 (375) Visit Code

□□□.□□

□  
1

HPTN 059 Ph II Microbe (113)

AA-5 (375)

**Participant ID**

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

**Acceptability Assessment**

7. In general, how important is it that a male sex partner **not** notice that you are using the study gel?  
**READ response categories aloud.**

- very important
- somewhat important
- neutral
- not very important
- not at all important

8. Overall, do you like the study gel? **READ response categories aloud.**

- strongly like
- like
- neutral
- dislike
- strongly dislike

---

## Acceptability Assessment (AA-5)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Items 7–8:** Read each of the response categories aloud, and mark the appropriate response.

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



SAMPLE. Do NOT FAX  
TO DATAFAX



HPTN 059 Ph II Microbe (113)

BGS-1 (030)

Participant ID

Site Number - Participant Number - Chk

Baseline Genital Symptoms

Visit Date

dd MMM yy

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

If yes: Are you currently experiencing this symptom?

1a. Genital sores? yes no
1b. Genital/vaginal itching? yes no
1c. Genital/vaginal burning? yes no
1d. Genital/vaginal pain? yes no
1e. Pain during sex? yes no
1f. Difficulty when urinating? yes no
1g. Burning when urinating? yes no
1h. Abnormal or unusual genital/vaginal discharge? yes no
1i. Unusual genital/vaginal odor? yes no
1j. Abnormal or unusual menstrual cramping? yes no
1k. Other genital symptoms? Specify: yes no
If yes to any, evaluate for STIs/RTIs.
If yes to any, record on Pre-existing Conditions Form.

Local Language:

English:

1l. Vaginal bleeding or spotting between your usual menstrual periods? yes no
1m. Blood-tinged discharge? yes no
If yes to any, evaluate for STIs/RTIs.
If yes to any, record on Pre-existing Conditions Form.

Comments:

28-JUN-06

01

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## Baseline Genital Symptoms (BGS-1)

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

**Note:** *If a participant is being re-screened, a new Baseline Genital Symptoms form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Interview tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

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

### Item-specific Instructions:

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

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

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

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code

Form boxes for Visit Code

Form box for page number 1

HPTN 059 Ph II Microbe (113)

FPE-1 (145)

Participant ID

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

Follow-up Pelvic Exam

Exam Date

Exam Date form boxes: dd, MMM, yy

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

Form for item 1: not done, abnormal findings, no abnormal findings with arrows and instructions

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

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

Note: Complete or update an Adverse Experience Log when applicable.

2. Colposcopic exam assessment:.....

Form for item 2: not done, abnormal findings, no abnormal findings with arrows and instructions

2a. Abnormal colposcopic findings: Mark all that apply.

- List of checkboxes for colposcopic findings: Abnormal vaginal discharge, Abnormal cervical discharge, Blood-tinged discharge, Blood in vagina—no identified source, Blood from cervical os, Bleeding from site of epithelial disruption, Erythema, Ulceration, Laceration, Abrasion, Peeling, Petechia, Ecchymosis, Vesicles, Edema, Abnormal cysts, Grossly white finding, Mass, Warts, Other abnormal findings, specify:

Note: Complete or update an Adverse Experience Log when applicable.

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## Follow-up Pelvic Exam (FPE-1)

*This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic (and, when applicable, colposcopy) exams conducted during study follow-up.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of “03.0,” Week 12 (Month 3) is assigned a visit code of “05.0,” etc.
- **Item 1:** A pelvic exam is required at the Week 4, Week 12, and Week 24/Early Termination Visits, and when clinically indicated. Document only those abnormal findings observed during naked eye, speculum, and bimanual examination. If a pelvic exam was required but not done, mark the “not done” box and record the reason the required pelvic exam was not done in the Comments section at the bottom of page 3. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 1a blank and go to item 2. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed via naked eye, speculum, and bimanual examination **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.
- **Item 2:** Colposcopy is required at the Week 4, Week 12, and Week 24/Early Termination Visits, and when clinically indicated. Document any abnormal findings observed during colposcopic examination **only**. If the exam did not include colposcopy, mark the “not done” box, leave item 2a blank and go to item 3. If colposcopy was required but not done, also record the reason the required colposcopy was not done in the Comments section at the bottom of page 3. If no abnormal findings are observed, mark the “no abnormal findings” box, leave item 2a blank and go to item 3. If one or more abnormal findings are observed, mark the “abnormal findings” box and continue to item 2a.
- **Item 2a:** Mark the box to the left of **each** abnormal finding observed on colposcopy **only**. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.

SAMPLE. Do NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FPE-2 (146)

Participant ID

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

Follow-up Pelvic Exam

3. Do any of these exam findings involve generalized erythema or severe edema with an affected area of more than 50% of the vulvar surface or combined vaginal and cervical surface? .....

yes no  
[ ] [ ]

4. Do any of these exam findings suggest vaginitis?.....

[ ] [ ]

5. Do any of these exam findings involve deep epithelial disruption? .....

[ ] [ ]

If no, go to item 6.

If yes to any, refer to protocol Appendix II.

5a. Was the deep epithelial disruption observed in more than one distinct area? .....

yes no  
[ ] [ ]

6. Do any of these exam findings suggest cervicitis? .....

yes no  
[ ] [ ]

7. Do any of these exam findings involve superficial epithelial disruption (abrasion/peeling)?.....

[ ] [ ]

8. Do any of these exam findings involve disrupted blood vessels? .....

[ ] [ ]

If no, go to item 9.

If yes to any, refer to protocol Appendix II.

8a. Were disrupted blood vessels observed in more than one distinct area? .....

yes no  
[ ] [ ]

9. Do any of these exam findings involve intermenstrual bleeding/spotting? .....

[ ] [ ]

If no, go to item 10.

If yes, refer to protocol Appendix II.

9a. Was the bleeding/spotting observed with no identifiable source? .....

yes no  
[ ] [ ]

If yes, complete Genital Bleeding Assessment form.

10. Cervical Ectopy: Percentage of cervical surface area.  
0% 1-25% 26-50% 51-75% > 75%  
[ ] [ ] [ ] [ ] [ ]

10a. Cervical ectopy assessed by: ..... naked eye colposcopy  
[ ] [ ]

---

## Follow-up Pelvic Exam (FPE-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Items 3–9a:** If the response to any of these items is “yes,” refer to protocol Appendix II for further instructions on study gel use and clinical follow-up.
- **Item 9a:** If intermenstrual bleeding/spotting was observed with no identifiable source, complete a Genital Bleeding Assessment form (unless one has already been completed for this visit).
- **Items 10 and 10a:** When colposcopy is performed, cervical ectopy must be assessed by colposcopy and not by naked eye. If colposcopy is not performed, item 10a should be marked “naked eye.”

**SAMPLE**. DO NOT FAX  
TO DATAFAX



Visit  
Code

.

HPTN 059 Ph II Microbe (113)

FPE-3 (147)

**Participant ID**

-      -   
Site Number Participant Number Chk

**Follow-up Pelvic Exam**

- 11. Was a vaginal Gram Stain smear collected? .....  *yes*  *no*
- 12. Was a cervical Gram Stain smear collected?.....  *yes*  *no*
- 13. Were cervical swabs collected for cytokine and chemokine testing? ...  *yes*  *no*
- 14. Was a genital ulcer swab collected? .....  *yes*  *no*  # of swabs

**U.S. only:**

- 15. Was a vaginal swab collected for quantitative culture? .....  *yes*  *no*

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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## Follow-up Pelvic Exam (FPE-3)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 11:** Collection of a vaginal Gram Stain smear (duplicate slides) is required as part of the Week 4, Week 12, and Week 24/Early Termination Visit pelvic exams. If a vaginal Gram Stain smear was required but not collected, mark the “no” box and record the reason the required smear was not collected in the Comments section at the bottom of the form.
- **Item 12:** Collection of a cervical Gram Stain smear (duplicate slides) is required as part of the Week 4, Week 12, and Week 24/Early Termination Visit pelvic exams. If a cervical Gram Stain smear was required but not collected, mark the “no” box and record the reason the required smear was not collected in the Comments section at the bottom of the form.
- **Item 13:** Collection of cervical swabs for cytokine and chemokine testing is required as part of the Week 4, Week 12, and Week 24/Early Termination Visit pelvic exams. If cervical swabs were required but not collected, mark the “no” box and record the reason the required swabs were not collected in the Comments section at the bottom of the form.
- **Item 14:** A multiplex PCR swab for genital ulcer disease (GUD) is collected for each genital ulcer, cluster of ulcers, and/or other anogenital finding thought to be Herpetic that is identified upon examination. If one or more swabs are collected, mark the “yes” box and record the number of swabs collected. If no swab is collected, mark the “no” box and leave the “# of swabs” box blank. If a genital ulcer, cluster of ulcers, and/or other potentially Herpetic anogenital finding is observed, but no swab is collected, mark the “no” box and record the reason in the Comments section.
- **Item 15:** This item should be completed for U.S. participants only as part of the Week 4, Week 12, and Week 24/Early Termination Visit pelvic exams; it should be left blank for participants at the Pune site. If a vaginal swab was required but not collected, mark the “no” box and record the reason it was not collected in the Comments section at the bottom of the form.

**Comments:** Record any necessary or additional information at the bottom of the form.



SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code

□□□.□□

1

HPTN 059 Ph II Microbe (113)

SLR-1 (131)

Participant ID

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

STI Laboratory Results

Initial Collection Date

□□ □□□ □□  
dd MMM yy

Alternate Collection Date

Not done/  
Not collected dd MMM yy  
□ □□ □□□ □□

1. URINE TESTS

Not done		negative or trace	1+	2+	3+	4+	AE Severity Grade If applicable	AE Log Page #
<input type="checkbox"/>	1a. Protein .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	□□□
<input type="checkbox"/>	1b. Glucose .....	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			
<input type="checkbox"/>	1c. Blood .....	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			
<input type="checkbox"/>	1d. Leukocyte esterase (LE) .....	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			
<input type="checkbox"/>	1e. Nitrites .....	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			
	<i>If BOTH items 1d AND 1e are negative, go to item 2.</i>							
	<i>If item 1d and/or 1e is positive, perform culture AND microscopy.</i>							
	1e1. Culture .....	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			
	1e2. Microscopy .....	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>			
	<i>If positive to any during follow-up, complete AE Log.</i>							

Alternate Collection Date

Not done/  
Not collected dd MMM yy  
□ □□ □□□ □□

2. HIV TEST RESULTS

2a. HIV EIA.....    
negative positive

*If positive, complete HIV Test Results form.*

Comments: \_\_\_\_\_

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## STI Laboratory Results (SLR-1)

*This form is used to document local laboratory results of blood and urine specimens collected at screening, enrollment, study exit/early termination, and when clinically indicated (during the initial 24 weeks of study follow-up). Record specimen test results on this form as they become available. Fax this form to SCHARP DataFax once results for all collected specimens are recorded on this form.*

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **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. Complete date 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. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - 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.
- **AE Severity Grade:** This applies to follow-up visits only. If the visit is a Screening or Enrollment Visit, leave the AE Severity Grade box blank.
  - 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.
- **AE Log Page #:** This applies to follow-up visits only. If the visit is a Screening or Enrollment Visit, leave the AE Log Page # box blank. If a follow-up visit lab value is reported as and/or associated with an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.
- **Items 1d and 1e:** If a urine specimen tests positive for either leukocyte esterase (LE) or nitrites, **both** a urine culture and microscopy are required, per protocol, and items 1e1 and 1e2 must be completed. If a urine specimen tests negative for **both** LE and nitrites, and there is no other clinical indication for performing urine culture and/or microscopy, leave items 1e1 and 1e2 blank and proceed to item 2.
- **Item 2a:** If the HIV EIA result is positive at screening, enrollment, or follow-up, follow the protocol HIV testing algorithm and record the associated test results on the HIV Test Results form.

*Note: A participant must be confirmed HIV uninfected according to the protocol HIV testing algorithm in order to be eligible for study participation.*

SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code

HPTN 059 Ph II Microbe (113)

SLR-2 (132)

Participant ID

-      -   
Site Number Participant Number Chk

STI Laboratory Results

Alternate Collection Date

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

3. STI SEROLOGY

3a. Syphilis RPR screening test  *non-reactive*  *reactive*  
**If non-reactive, go to item 4.**

3a1. Syphilis titer ..... 1:

3b. Syphilis confirmatory test .....  *negative*  *positive*  *indeterminate*  
**If positive, provide treatment. If positive at the Screening Visit, participant must complete treatment and be asymptomatic to enroll. If positive during follow-up, complete AE Log.**

Alternate Collection Date

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

4. OTHER STI TESTS

4a. N. Gonorrhea.....  *negative*  *positive*

4b. C. Trachomatis .....

4c. Hepatitis B Surface Antigen .....  *non-reactive*  *reactive*  
**If reactive, conduct HBV viral load testing per protocol. Record the results on the HBV Laboratory Results form.**

Comments: \_\_\_\_\_

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## STI Laboratory Results (SLR-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of the form for a given participant and visit.
- **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. Complete date 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. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - 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.
- **Item 3:** If the syphilis screening test is reactive, items 3a1 and 3b must be completed.
- **Item 3a1:** Remember to use leading zeros when recording a syphilis titer level. For example, a titer level of 1:20 would be recorded on the form as “1:0020.”
- **Items 3b–4c:** If a result is positive at any time during the study (screening through study exit), provide treatment according to CDC guidelines. If a result is positive at Screening, the participant must complete treatment(s) and be asymptomatic in order to be eligible for enrollment. If a result from an Enrollment specimen is positive (results received after Enrollment Visit), provide treatment and record the relevant infection(s) on the Pre-existing Conditions form. If a result is positive during study follow-up, report the relevant infection(s) as adverse experience(s) on the Adverse Experience Log form.
- **Item 4c:** For participants who have a reactive Hepatitis B Surface Antigen result, Hepatitis B viral load testing should be conducted at the Enrollment, Week 4, Week 12, Week 24/Early Termination, Week 28, Week 32, and Week 36 Visits. All Hepatitis B viral load results should be recorded on the HBV Laboratory Results form and faxed to SCHARP.

**SAMPLE**. DO NOT FAX  
TO DATAFAX



Visit Code

.

HPTN 059 Ph II Microbe (113)

HLR-1 (141)

**Participant ID**

-       -

Site Number

Participant Number

Chk

**HBV Laboratory Results**

**Specimen Collection Date**

/    /

dd

MMM

yy

**Not done/  
Not collected**

1. **HEPATITIS B VIRAL LOAD**

**Mark one:**

IU/mL

<sup>></sup>

=

<sup><</sup>

yes

no

2. Was blood collected for the HBV serum archive? .....

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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## HBV Laboratory Results (HLR-1)

*This form is completed only for Hepatitis B Surface Antigen positive participants and is required at the Enrollment, Week 12, Week 24/Early Termination, Week 28, Week 32, and Week 36 Visits.*

*Record the Hepatitis B viral load result on the form once it becomes available from the central laboratory. Fax this form to SCHARP DataFax once the result is received and items 1 and 2 have been completed.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of “03.0,” Week 12 (Month 3) is assigned a visit code of “05.0,” etc.
- **Item 1:** If the specimen was not done (collected but no result available) or not collected, mark the “Not done/Not collected” box. Explain in the Comments section at the bottom of the form why the result is not available.
- **Item 2:** Record whether or not blood was collected for the HBV serum archive. If the participant consented to long-term specimen storage (for possible future HBV resistance testing) at the time of the visit, a specimen for the HBV serum archive should have been collected. If the participant consented at the time of the visit but no specimen was collected, mark “no” and record the reason why in the Comments section. If the participant did not consent to long-term specimen storage, or withdrew consent as of the time of the visit, no specimen should have been collected and the response should be “no.” If a specimen was collected without consent, mark “yes” and record the reason why in the Comments section. Notify FHI, SCHARP, and CL and report as a protocol event.

SAMPLE. DO NOT FAX  
TO DATAFAX

Visit Code

□□□.□□

1

HPTN 059 Ph II Microbe (113)

PLR-1 (143)

Participant ID

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

Pelvic Laboratory Results

Initial Collection Date

□□ □□□□ □□  
dd MMM yy

Alternate Collection Date

Not done/ Not collected dd MMM yy  
□ □□ □□□□ □□  
Not done

1. VAGINAL WET PREP STUDIES

- 1a. Homogeneous vaginal discharge ..... negative positive
- 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  
□ □□ □□□□ □□

2. PAP SMEAR

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

Comments: \_\_\_\_\_

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## Pelvic Laboratory Results (PLR-1)

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

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of “03.0,” Week 12 (Month 3) is assigned a visit code of “05.0,” etc.
- **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. Complete date 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. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - 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.
- **Item 1:** A vaginal wet prep is required at the Screening, Enrollment, Week 4, Week 12, and Week 24 Early/Termination Visits, and 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 in the Comments section.
- **Item 1a:** Mark the “positive” box if homogeneous vaginal discharge was observed. If positive, mark “abnormal vaginal discharge” in item 1a of the Screening and Enrollment, Repeat Screening, or Follow-up Pelvic Exam form completed for this pelvic exam.
- **Item 1d:** Mark the “positive” box if more than 20% of 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:** Record the Pap Smear result. Mark only one box. **Note:** A Pap Smear result is required at the Screening Visit only, and only for those participants who do not have documentation of a normal Pap test result in the 90 days prior to Screening. Only participants with a negative or ASC-US Pap Smear result will be eligible to enroll in the study; participants with an ASC-H, LSIL, HSIL, AGC, AGC-favor neoplastic, or cancer result should not be enrolled in the study.
  - **negative for intraepithelial lesion or cancer (malignancy):** Includes all normal findings and any findings of infection (trichomonas, candida, etc.), reactive changes/inflammation, glandular changes due to hysterectomy, or atrophic changes.
  - **ASC-US:** Mark this box when abnormal/atypical squamous cells of undetermined significance are reported.
  - **ASC-H:** Mark this box when abnormal/atypical squamous cells that cannot exclude high-grade squamous intraepithelial lesion (HSIL) are reported.
  - **SIL-low grade (LSIL):** Mark this box when low-grade squamous interepithelial lesions are reported. This category includes presence of human papillomavirus (HPV) infection, mild dysplasia, and cervical interepithelial neoplasia (CIN 1).
  - **SIL-high grade (HSIL):** Mark this box when high-grade squamous interepithelial lesions are reported. This category includes the presence of moderate to severe dysplasia, carcinoma in situ (CIS), CIN 2, and CIN 3, or changes suspicious for invasive cancer.
  - **AGC:** Mark this box when atypical/abnormal glandular cells are reported. This category includes endocervical (from cervical canal) atypical cells; endometrial atypical cells; glandular atypical cells.
  - **AGC-favor neoplastic:** Mark this box when atypical/abnormal glandular cells that favor cell growth (neoplastic changes) are reported. This category includes endocervical cells and glandular cells.
  - **cancer:** Mark this box when cancer or adenocarcinoma is reported. This includes endocervical, endometrial, extrauterine, and other (not specified) cancers/adenocarcinomas.



SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code

□□□.□□

1

HPTN 059 Ph II Microbe (113)

SL-1 (151)

Participant ID

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

Safety Laboratory Results

Initial Collection Date

□□ □□□ □□  
dd MMM yy

Alternate Collection Date

Not done/  
Not collected  dd □□ MMM □□□□ yy □□

1. HEMOGRAM

Not done

1a. WBC ..... □□□□.□ x 10<sup>3</sup>/mm<sup>3</sup>

1b. Hemoglobin ..... □□□.□ g/dL

1c. MCV..... □□□□.□ fL

1d. Platelets □□□□□□□□ cells/mm<sup>3</sup>

AE Severity  
Grade  
If applicable

AE Log  
Page #

Alternate Collection Date

Not done/  
Not collected  dd □□ MMM □□□□ yy □□

2. DIFFERENTIAL

Not reported

percentage

Absolute Count  
cells/mm<sup>3</sup>

AE Severity  
Grade  
If applicable

AE Log  
Page #

2a. Neutrophils .....  □□□.□ OR

2b. Lymphocytes .....  □□□.□ OR

2c. Eosinophils .....  □□□.□ OR

2d. Bands .....  □□□.□ OR

Comments: \_\_\_\_\_

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## Safety Laboratory Results (SL-1)

*This form is used to document local safety laboratory results of specimens collected during screening, enrollment, and study follow-up. Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for **all** collected specimens are recorded on the form.*

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of “03.0,” Week 12 (Month 3) is assigned a visit code of “05.0,” etc.
- **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. Complete date 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. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - 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.
  - 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.
- **AE Severity Grade:** This applies to follow-up visits only. If the visit is a Screening or Enrollment Visit, leave the AE Severity Grade boxes blank.
  - 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.
- **AE Log Page #:** This applies to follow-up visits only. If the visit is a Screening or Enrollment Visit, leave the AE Log Page # boxes blank. If a follow-up visit lab value is reported as and/or associated with an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.
- **Item 2:** If a differential specimen was collected but results were not reported for all items, mark the “Not reported” box for each result that was not reported. If lab results are available in both percentage and absolute count, absolute count should be recorded on the form.

SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

SL-2 (152)

Participant ID

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

Safety Laboratory Results

Alternate Collection Date

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

3. LIVER FUNCTION TESTS

3a. Alkaline phosphatase ..... [ ][ ][ ][ ] U/L  
3b. AST (SGOT) ..... [ ][ ][ ][ ] U/L  
3c. ALT (SGPT) ..... [ ][ ][ ][ ] U/L  
3d. GGT ..... [ ][ ][ ][ ] U/L  
3e. Total bilirubin ..... [ ][ ] . [ ] mg/dL

AE Severity Grade If applicable AE Log Page #

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

Alternate Collection Date

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

4. RENAL FUNCTION TESTS

4a. Creatinine ..... [ ][ ] . [ ] mg/dL  
4b. BUN ..... [ ][ ][ ] mg/dL

AE Severity Grade If applicable AE Log Page #

[ ][ ][ ]

Comments: \_\_\_\_\_

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## Safety Laboratory Results (SL-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **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. Complete date 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. Complete date required.
- **Results Reporting**
  - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
  - 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.
  - 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.
- **AE Severity Grade:** This applies to follow-up visits only. If the visit is a Screening or Enrollment Visit, leave the AE Severity Grade boxes blank.
  - 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.
- **AE Log Page #:** This applies to follow-up visits only. If the visit is a Screening or Enrollment Visit, leave the AE Log Page # boxes blank. If a follow-up visit lab value is reported as and/or associated with an AE, record the page number of the AE Log which is most closely associated with the abnormal lab value.

SAMPLE. Do NOT FAX  
TO DATAFAX



Visit Code

HPTN 059 Ph II Microbe (113)

HTR-1 (351)

Participant ID

-       -   
Site Number Participant Number Chk

HIV Test Results

Sample 1

1. HIV Western Blot or IFA  
Not done/Not collected  Specimen Collection Date        
dd MMM yy negative  positive  indeterminate   
If negative, go to item 5.

Sample 2

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

Sample 3

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

Sample 4

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

FINAL HIV STATUS

5. Final status: ..... negative  positive  other, specify: \_\_\_\_\_   
If positive at Screening or Enrollment, participant is ineligible.

6. Was a specimen archived for QA/QC testing? ..... yes  no  If no, end of form.

6a. Date specimen was collected for QA/QC testing: .....        
dd MMM yy

Comments: \_\_\_\_\_

---

## HIV Test Results (HTR-1)

*This form documents confirmatory HIV test results and final HIV status. This form is completed each time a participant has a positive HIV EIA test result.*

*Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once results for **all** required specimens are available and recorded and item 5 has been completed.*

### Item-specific Instructions:

- **Visit Code:** The visit code recorded on this form should be the same visit code recorded on the STI Laboratory Results form documenting the positive HIV test result.
- **Specimen Collection Date:** Record the date the specimen was collected (NOT the date results were reported or recorded on the form). For Sample 1, the Specimen Collection Date should be the same date as the collection date of the HIV EIA positive specimen.
- **not done/not collected:** Mark this box in the event that a specimen is collected, but a result is not available due to specimen loss or damage. Explain in the Comments section at the bottom of the form why the result is not available.
- **Item 5:** Once a participant's HIV status has been determined, record the final HIV status. If the final HIV status is not clearly negative or clearly positive, mark the "other, specify" box and specify reason(s) on the line provided. If the participant's final HIV status is determined to be positive (according to the protocol testing algorithm) during study follow-up, report the HIV infection as an AE on the AE Log.
- **Item 6:** If a second blood draw is required for HIV confirmatory testing (per the protocol algorithm), a specimen from this draw must be archived for QA/QC testing. The archived specimen will be tested in the event that HIV infection is confirmed. If a second blood draw was done, but no specimen was archived, mark "no" and provide an explanation in the Comments section at the bottom of the form.
- **Item 6a:** The response to this item should match the specimen collection date for Sample 2, as recorded on this form. If the response to this item does not match the Sample 2 collection date, provide an explanation in the comments section at the bottom of the form.
- **Comments:** Use this section to document any problems or reasons why expected results are not available; for example, if the sample was lost or damaged.

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FGS-1 (130)

Participant ID

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

Follow-up Genital Symptoms

Visit Date

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

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

If yes: When did you first experience this symptom?

Continuing from previous visit

	yes	no	dd	MMM	yy		
1a. Genital sores?.....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1b. Genital/vaginal itching?.....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1c. Genital/vaginal burning? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1d. Genital/vaginal pain?.....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1e. Pain during sex?.....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1f. Difficulty when urinating?.....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1g. Burning when urinating? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1h. Abnormal or unusual genital/vaginal discharge? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1i. Unusual genital/vaginal odor? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1j. Abnormal or unusual menstrual cramping? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1k. Other genital symptoms? Specify:	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>

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

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

	yes	no	dd	MMM	yy		
1l. Vaginal bleeding or spotting between your usual menstrual periods?	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>
1m. Blood-tinged discharge? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]	[ ][ ][ ]	[ ][ ]	OR	<input type="checkbox"/>

If yes to any, conduct pelvic exam. Complete Genital Bleeding Assessment as needed. Refer to protocol Appendix II.

Comments: \_\_\_\_\_

---

## Follow-up Genital Symptoms (FGS-1)

*This form is interviewer-administered, and is used to document genital symptoms reported by the participant during study follow-up. It is completed at each regularly scheduled follow-up visit (Week 4 through Week 24 for non-CHBV participants, and Week 4 through Week 36 for CHBV participants).*

### Interview tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

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

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0."
- **Item 1:** Read each item 1a-1m aloud. For any item marked "yes," conduct a pelvic exam if clinically indicated (and not already required for the visit). For each item marked "yes," complete an Adverse Experience (AE) Log if this is the **first** time the symptom is reported since the participant enrolled in the study. If this is **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 symptom was first reported on the participant's Baseline Genital Symptoms and Pre-existing Conditions forms and it has not increased in severity or frequency, **do not** complete an AE Log—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.
- **Item 1j:** This item is intended to capture dysmenorrhea reported during follow-up visits. If the participant reports dysmenorrhea and/or any other symptom(s) related to menstruation, probe for further information (i.e., type and severity of symptoms), then compare to participant's usual baseline menstrual symptoms (as documented on the non-DataFAX Baseline Medical History form and Baseline Genital Symptoms form) to determine whether an AE should be reported.
- **Item 1k:** If "yes" is marked, record the participant's verbatim response on the "Local Language" line. If the response is given in a language other than English, provide the English translation on the "English" line.
- **If yes: When did you first experience this symptom?:** For each item marked "yes," record the day, month, and year the participant first began experiencing symptoms; if necessary, use a calendar to probe. If the participant provides a date that is prior to the date of the previous visit, mark "continuing from previous visit" and leave the day, month, and year boxes blank. If the participant states that a symptom began on the exact date of the previous visit, clarify whether or not the symptom was present at the time the visit occurred. If she states that the symptom was present during the previous visit, mark "Continuing from previous visit" and leave the day, month, and year boxes blank. If the participant states that the symptom occurred on the same day as the previous visit, but after she had completed the visit, record the day, month, and year of the previous visit and leave the "continuing from previous visit" box blank.
- **Continuing from previous visit:** Mark this box for symptoms reported as continuing since the time of the previous visit. If this box is marked, leave the "If yes: When did you first experience symptoms?" boxes blank. If a date is recorded, leave the corresponding "continuing from previous visit" box blank.
- **Items 1l-1m:** If the participant reports vaginal bleeding or spotting between usual menstrual periods, or any blood-tinged genital/vaginal discharge, conduct a pelvic exam and follow-up as clinically indicated.





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## Pharmacokinetics (PK-1)

*This form is used to document the required pharmacokinetic (PK) specimen collections at the Week 4, Week 12, and Week 20 Visits.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of “03.0,” Week 12 (Month 3) is assigned a visit code of “05.0,” etc.
- **Item 1:** If a PK specimen was not collected, mark the “no” box and provide an explanation in the Comments section at the bottom of the form. If the specimen was collected but is not available for testing (i.e., due to specimen loss or damage), mark the “yes” box and provide an explanation in the Comments section at the bottom of the form.
- **Item 2:** Record the participant’s height in inches or centimeters, but not both.
- **Item 3:** Record the participant’s weight in pounds or kilograms, but not both.
- **Item 4:** Record the date and time of the participant’s last (most recent) application of study gel prior to the PK draw.
- **Item 5:** Record the time (using a 24-hour clock) when the PK specimen was drawn.

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FSB-1 (161)

Participant ID

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

Female Study Burden Assessment

Visit Date

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

Now I would like to ask a couple of questions about your experiences as a study participant.

- 1. Was the amount of time that you had to wait for your study visits ever a problem? ..... yes no
- 2. Did you feel that the amount of money you were paid to participate was adequate? ..... yes no
- 3. Did you ever have a problem understanding the instructions on how to use the gel? ..... yes no
- 4. Have you had any other problems or concerns as a result of being in the study? ..... yes no  
  → **If no, go to item 5.**

4a. If yes, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

- 5. Is there anything else about participating in this study that you would like us to know? ..... yes no  
  → **If no, end of form.**

5a. If yes, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

Thank you for your time. We very much appreciate you sharing your thoughts with us.

---

## Female Study Burden Assessment (FSB-1)

*The Female Study Burden Assessment form records the participant's assessment of study procedures and requirements. It is an interviewer-administered form that is administered once the participant has completed her participation in the study. To improve participants' ability to speak freely, the questions on this form should be asked by a staff member who has not had previous contact with the participant (if possible). For non-CHBV participants, it should be completed at the Week 24/Early Termination Visit. For CHBV participants, it should be completed at the Week 36/Early Termination Visit.*

### **Interview tips:**

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

### **Item-specific Instructions:**

*Note: There is no visit code field on this form since this form is only administered at study exit.*

- **Item 4:** If “no” is marked, leave item 4a blank and go to item 5. If “yes” is marked, record the participant's verbatim (word-for-word) response in item 4a. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 5:** If “no” is marked, leave item 5a blank. If “yes” is marked, record the participant's verbatim (word-for-word) response in item 5a. If the response is given in a language other than English, provide the English translation in the space provided.

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

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [0]

[1]

HPTN 059 Ph II Microbe (113)

FV-1 (121)

Participant ID

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

Follow-up Visit

Visit Date

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

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

2. Were any new Adverse Experiences reported at this visit? .....  yes  no **If no, go to item 3.**

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

3. At this visit, how many unused tubes did the participant return? ..... [ ][ ][ ] # of tubes returned

4. At this visit, how many cartons of study gel were dispensed to the participant? ..... [ ][ ] # of cartons dispensed

5. Was blood collected for the plasma archive? .....  yes  no

6. Was blood collected for the serum archive? .....  yes  no

Comments: \_\_\_\_\_

---

## Follow-up Visit (FV-1)

*This form is used to document the required (regularly scheduled) follow-up visits through Week 24. It is completed at each regularly scheduled follow-up visit, from Week 4 through Week 24, regardless of whether the visit is conducted within the protocol-specified window or made up outside the visit window.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of “03.0,” Week 12 (Month 3) is assigned a visit code of “05.0,” etc.
- **Item 1:** Record the hCG urine pregnancy test result. If a urine pregnancy test result is not available (specimen not collected and/or test not done), mark the “not done” box and complete item 1a. *Note: A Pregnancy Report and History form must be completed for each pregnancy.* Once a participant tests positive for hCG urine pregnancy and a Pregnancy Report and History form (PR-1) has been completed for this pregnancy, subsequent positive pregnancy test results should not be recorded on a new PR-1 unless they represent a new pregnancy.
- **Item 1a:** Specify the reason(s) why the required pregnancy test was not done.
- **Item 2:** Mark the “yes” box if a new (previously unreported) AE is reported or observed at this visit. If the box is marked “yes,” record in item 2a how many **new** AE Log pages were completed for this visit. For example, if two new AEs were reported, record “02.” Note that the Visit Code recorded in item 10 of these two AE Log pages should be the same as the Visit Code recorded on this form.
- **Item 3:** Record the number of **unused** study gel tubes the participant returned at this visit only. This number may be obtained from the Gel Re-supply Worksheet.
- **Item 4:** Record the number of cartons of study gel given to the participant at this visit. This will be the same amount documented on the Study Gel Request Slip, unless documentation from the pharmacy staff states otherwise. If more than four cartons (for daily use participants) or eight cartons (for coitally-dependent participants) are dispensed to a participant at a given follow-up visit, provide an explanation in the Comments section. If this form is being completed at the Week 24 Visit, the response should be “00.”
- **Items 5-6:** Record whether or not specimens were collected for the plasma and serum archives (required at the Week 24/Early Termination Visit). If the protocol-required specimens were *not* archived at Week 24/Early Termination, provide an explanation in the Comments section at the bottom of the form.

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FBD-1 (171)

Participant ID

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

Follow-up Behavior Assessment—  
Daily Use Arm

Visit Date

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

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

There are many different ways people have sex. Some of the questions I am going to ask you are about vaginal sex, and some are about anal sex. By vaginal sex, I mean when a man puts his penis inside your vagina. By anal sex, I mean when a man puts his penis inside your anus.

Shall we continue?

1. In the **past month**, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex.....

[ ][ ] # of partners  
If 0, go to statement before item 9 on page 3.

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

2. In the **past week**, how many times did you have vaginal sex? .....

[ ][ ] # of times  
If 0, go to item 3.

I know that you are counseled to use condoms for each act of vaginal sex, but I also know that this is not always possible.

2a. In the **past week**, how many times did you use a male or female condom during vaginal sex? .....

[ ][ ] # of times

2b. In the **past week**, how many times did you insert the study gel within 2 hours **before** having vaginal sex? .....

[ ][ ] # of times  
If 0, go to item 3.

2b1. How many of these times did you use a male or female condom? .....

[ ][ ] # of times

3. When was the **last time** you had vaginal sex? .....

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

---

## Follow-up Behavior Assessment—Daily Use Arm (FBD-1)

*This form is used to collect information about the participant's sexual behaviors, vaginal hygiene, and family planning practices while she is taking part in the study. This is an interviewer-administered form (with the exception of items 17-17a), and is administered at the Week 4, Week 12, and Week 24/Early Termination Visits.*

### Interview tips:

See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- When a participant's response does not match one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Items 1:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has had no sexual partners in the past month, record "00" for this item and continue the interview by reading the statement before item 9 on page 3. In this case, do record the Visit Code and PTID on page 2 of this form, and leave all other items on page 2 blank. Do fax all 8 pages of this form to SCHARP DataFax once the form has been completed.
- **Item 2–2b1:** Use leading zeros when needed so that all the boxes are filled.
- **Item 3:** If, after verbal probing, the participant is unable to provide the day she last had vaginal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write "don't know" in the white space next to the item, and initial and date.

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



SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FBD-2 (172)

Participant ID

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

Follow-up Behavior Assessment—Daily Use Arm

4. The last time you had vaginal sex:

- 4a. did you or your partner use a male condom?
4b. did you use a female condom?
4c. did you insert the study gel before having vaginal sex?
4c1. did you insert the study gel within 2 hours before having vaginal sex?
4d. did you wash inside or douche inside your vagina within 2 hours before inserting the study gel?
4e. did you wash inside or douche inside your vagina within 2 hours after inserting the study gel?
4f. did you insert paper, cloth, cotton, or cotton wool within 2 hours before inserting the study gel?
4g. did you insert paper, cloth, cotton, or cotton wool within 2 hours after inserting the study gel?
4h. did you insert any other object or substance into your vagina within 2 hours before inserting the study gel?

If no, go to statement before item 5.

If yes, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

4i. did you insert any other object or substance into your vagina within 2 hours after inserting the study gel?

If yes, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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

- 5. In the past month, did you have anal sex?
6. In the past week, did you have anal sex?

If no, go to statement before item 9 on page 3.

If no, go to item 7 on page 3.

[ ][ ][ ] [x] 28-JUN-06

01

Language

Staff Initials / Date

---

## Follow-up Behavior Assessment—Daily Use Arm (FBD-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 4:** Read each item 4a–4i aloud and mark the participant’s response. If “yes” is marked for items 4h or 4i, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 4c:** If item 4c is marked “no,” leave items 4c1–4i blank and go to the statement above item 5.

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

SAMPLE: DO NOT FAX TO DATAFAX

Visit Code

□□□

1

HPTN 059 Ph II Microbe (113)

FBD-3 (173)

Participant ID

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

Follow-up Behavior Assessment—Daily Use Arm

6a. In the past week, did you ever insert the study gel anally during anal sex? .....

yes no  
□ □

If no, go to statement before item 6b.

6a1. In the past week, how many times did you insert the study gel anally during anal sex? .....

□□ # of times

I know that you are counseled to use condoms for each act of anal sex, but I also know that this is not always possible.

6b. In the past week, did you ever, even once, have anal sex without a condom?.....

yes no  
□ □

7. When was the last time you had anal sex? .....

□□ dd □□□ MMM □□ yy

8. The last time you had anal sex:

8a. did you or your partner use a male condom? .....

yes no  
□ □

8b. did you use a lubricant (such as lube, K.Y.)? .....

□ □

8c. did you insert the study gel anally?.....

□ □

I know that you are counseled to insert the study gel at the same time each day, but I also know that this is not always possible.

9. In the past week, have you been able to insert the study gel at the same time each day? .....

yes no  
□ □

If yes, go to item 10.

9a. If no, specify reason:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

10. In the past week, how many days did you not insert the study gel? .....

□ # of days

If 0, go to statement before item 12 on page 4.

---

## Follow-up Behavior Assessment—Daily Use Arm (FBD-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 7:** If, after verbal probing, the participant is unable to provide the day she last had anal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.
- **Item 8:** Read each item 8a–8c aloud and mark the participant’s response.
- **Items 9–9a:** If “no” is marked for item 9, be sure to record the participant’s verbatim (word-for-word) response in item 9a. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 10:** Record the total number of days in the past week (the last 7 days) that the participant reports not using the study gel. The maximum number of days reported should be 7.

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

SAMPLE: DO NOT FAX  
TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FBD-4 (174)

Participant ID

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

Follow-up Behavior Assessment—  
Daily Use Arm

11. For the days you did not insert the study gel, what were the reasons? **DO NOT read response categories aloud.**  
**Mark all that apply.**

If only one response box is marked, go to statement before item 12.

<input type="checkbox"/> forgot	<input type="checkbox"/> menses
<input type="checkbox"/> no gel available	<input type="checkbox"/> I didn't like it
<input type="checkbox"/> no time to insert it	<input type="checkbox"/> don't use it with that partner
<input type="checkbox"/> worried about side effects	<input type="checkbox"/> my partner didn't like it
<input type="checkbox"/> lack of privacy	<input type="checkbox"/> other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

11a. What was the main reason? **DO NOT read response categories aloud.**

<input type="checkbox"/> forgot	<input type="checkbox"/> menses
<input type="checkbox"/> no gel available	<input type="checkbox"/> I didn't like it
<input type="checkbox"/> no time to insert it	<input type="checkbox"/> don't use it with that partner
<input type="checkbox"/> worried about side effects	<input type="checkbox"/> my partner didn't like it
<input type="checkbox"/> lack of privacy	<input type="checkbox"/> other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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

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

If yes: How many times in the **past week** did you insert this item?

	yes	no	# of times in past week
12a. water? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]
12b. water with vinegar? <b>Note for U.S. sites:</b> This includes all commercial douching products. ....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]
12c. water with soap? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]
12d. paper, cloth, cotton, or cotton wool? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]
12e. tampons? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]
12f. fingers without anything else? .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]
12g. anything else? Specify: .....	<input type="checkbox"/>	<input type="checkbox"/>	[ ][ ]

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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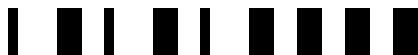
## Follow-up Behavior Assessment—Daily Use Arm (FBD-4)

### 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.
- **Item 11:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reason reported by the participant. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided. If the participant gives only one reason and only one box is marked, leave item 11a blank and go to the statement above item 12.
- **Item 11a:** **Do not** read any of the response categories aloud. Instead, read the question and, based on the response to item 11, mark the one box that corresponds to the main reason why the participant did not use the study gel. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 12:** Read each item 12a–12g aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many times in the **past week** (the last 7 days) she has used that particular item. Record the response in the “# of times in **past week**” boxes. If “yes” is marked for item 12g, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

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

SAMPLE: DO NOT FAX  
TO DATAFAX



Visit Code   .

1

HPTN 059 Ph II Microbe (113)

FBD-5 (175)

Participant ID

-      -   
Site Number Participant Number Chk

Follow-up Behavior Assessment—  
Daily Use Arm

13. I know you were asked about family planning during your medical history review, but I need to ask you again. Which family planning method or methods are you currently using? **DO NOT read response categories aloud. Mark "none" or all that apply.**

none  
 vaginal ring  
 spermicide  
 diaphragm  
 sponge

➔ Reinforce use of protocol-specified methods of effective contraception.

intrauterine device (IUD)  
 natural methods such as the withdrawal or rhythm method  
 male condoms  
 female condoms

➔ If not used in combination with another protocol-specified method of effective contraception, provide appropriate counseling.

family planning pills or birth control pills  
 injectable contraceptives (such as Depo-Provera)  
 Norplant inserts  
 Ortho Evra/The Patch  
 surgical sterilization (tubal ligation)  
 sex with partner who had a vasectomy  
 other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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## Follow-up Behavior Assessment—Daily Use Arm (FBD-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.
- **Item 13: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each family planning method the participant reports using. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

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



SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FBD-6 (176)

Participant ID

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

Follow-up Behavior Assessment—  
Daily Use Arm

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

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

	yes	no	not applicable
14a. your spouse or partner?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14b. people at home/family?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14c. your friends/personal relationships? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14d. people at work? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14e. people at school?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14f. your doctor, nurse, midwife, or other health care provider?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14g. your landlord or property owner? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14h. other people? Specify: .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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

15. Please describe the problem: **Do NOT record the participant's verbatim response.**

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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## Follow-up Behavior Assessment—Daily Use Arm (FBD-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 14:** Read each item 14a–14h aloud and mark the participant’s response. If “yes” is marked for item 14h, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided. If the participant responds “no” to each item 14a–14h, end the form; record the Visit Code and PTID on pages 7 and 8 of this form, and leave the remaining form items (15-17a) blank. Do fax all 8 pages of this form to SCHARP DataFax once the form has been completed.
- **Item 14f:** This item **does not** include members of the site staff.
- **Item 15:** Describe the problem. **Do not** record the participant’s verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.

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



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## Follow-up Behavior Assessment—Daily Use Arm (FBD-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.
- **Items 16a1 and 16b1:** Describe the problem. **Do not** record the participant's verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. Include in the description the type of person who precipitated the problem (e.g., spouse or partner, family member, co-worker, landlord, etc.), and the outcome of the problem, if any. If the response is given in a language other than English, provide the English translation in the space provided.

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

SAMPLE: DO NOT FAX  
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

FBD-8 (178)

Participant ID

-  -   
Site Number Participant Number Chk

Follow-up Behavior Assessment—  
Daily Use Arm

16c. economic/financial harm to you? For example, has this problem resulted in the removal/loss of your home, property, or ability to earn income? .....  yes  no **If no, go to item 16d.**

16c1. Please describe the problem: **Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.**

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

16d. physical or other harm to your children?.....  yes  no **If no, go to item 17.**

16d1. Please describe the problem: **Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.**

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

Complete items 17-17a after the interview.

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

17a. Record AE Log page number(s): ..... 

AE Log Page #	AE Log Page #	AE Log Page #
<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>

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## Follow-up Behavior Assessment—Daily Use Arm (FBD-8)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 16c1 and 16d1:** Describe the problem. Do not record the participant's verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. Include in the description the type of person who precipitated the problem (e.g., spouse or partner, family member, co-worker, landlord, etc.), and the outcome of the problem, if any. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 17:** This is not an interviewer-administered item.
- **Item 17a:** This is not an interviewer-administered item. Record the AE Log page number(s) that correspond to any AEs reported in item 16. Leave any remaining AE Log page number boxes blank.

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

SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FBC-1 (181)

Participant ID

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

Follow-up Behavior Assessment—  
Coitally Dependent Arm

Visit Date

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

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

There are many different ways people have sex. Some of the questions I am going to ask you are about vaginal sex, and some are about anal sex. By vaginal sex, I mean when a man puts his penis inside your vagina. By anal sex, I mean when a man puts his penis inside your anus.

Shall we continue?

1. In the **past month**, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex....

[ ][ ] # of partners  
If 0, go to statement before item 10 on page 4.

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

2. In the **past week**, how many times did you have vaginal sex? .....

[ ][ ] # of times  
If 0, go to item 4 on page 2.

I know that you are counseled to insert the study gel within 2 hours before having vaginal sex, but I also know that this is not always possible.

2a. In the **past week**, how many times did you have vaginal sex more than 2 hours **after** inserting the study gel? .....

[ ][ ] # of times

I know that you are counseled to use condoms for each act of vaginal sex, but I also know that this is not always possible.

2b. In the **past week**, how many times did you use a male or female condom and not the study gel during vaginal sex? .....

[ ][ ] # of times

2c. In the **past week**, how many times did you insert the study gel and not use a male or female condom during vaginal sex?.....

[ ][ ] # of times

2d. In the **past week**, how many times did you insert the study gel and use a male or female condom during vaginal sex? .....

[ ][ ] # of times

2e. In the **past week**, how many times did you use neither the study gel nor a male or female condom during vaginal sex? .....

[ ][ ] # of times  
If 2b AND 2e are 0, go to item 4 on page 2.

13-103

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## Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-1)

*This form is used to collect information about the participant's sexual behaviors, vaginal hygiene, and family planning practices while she is taking part in the study. This is an interviewer-administered form (with the exception of items 16-16a), and is administered at the Week 4, Week 12, and Week 24/Early Termination Visits.*

### Interview tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- When a participant's response does not match one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Item 1:** Use leading zeros when needed so that all the boxes are filled. If the participant reports she has had no sexual partners in the past month, record "00" for this item and continue the interview by reading the statement before item 10 on page 4. In this case, do record the Visit Code and PTID on pages 2 and 3 of this form, and leave all other items on pages 2 and 3 blank. Do fax all 8 pages of this form to SCHARP DataFax once the form has been completed.
- **Items 2–2e:** Use leading zeros when needed so that all the boxes are filled.
- **Items 2b–2e:** After recording the participant's responses, check that the sum of the responses to items 2b–2e equal the response to item 2. If any inconsistency is noted, attempt to resolve it by asking the participant for clarification. Update the responses to items 2 and/or 2b–2e as appropriate.

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



SAMPLE: DO NOT FAX  
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

FBC-2 (182)

Participant ID

-      -   
Site Number Participant Number Chk

Follow-up Behavior Assessment—  
Coitally Dependent Arm

3. For the times you had sex without inserting the study gel, what were the reasons? **DO NOT read response categories aloud. Mark all that apply.**

If only one response box is marked, go to item 4.

<input type="checkbox"/> forgot	<input type="checkbox"/> menses
<input type="checkbox"/> no gel available	<input type="checkbox"/> I didn't like it
<input type="checkbox"/> no time to insert it	<input type="checkbox"/> don't use it with that partner
<input type="checkbox"/> worried about side effects	<input type="checkbox"/> my partner didn't like it
<input type="checkbox"/> lack of privacy	<input type="checkbox"/> other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

3a. What was the main reason? **DO NOT read response categories aloud.**

<input type="checkbox"/> forgot	<input type="checkbox"/> menses
<input type="checkbox"/> no gel available	<input type="checkbox"/> I didn't like it
<input type="checkbox"/> no time to insert it	<input type="checkbox"/> don't use it with that partner
<input type="checkbox"/> worried about side effects	<input type="checkbox"/> my partner didn't like it
<input type="checkbox"/> lack of privacy	<input type="checkbox"/> other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

4. When was the **last time** you had vaginal sex?.....         
dd MMM yy

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

	yes	no
5a. did you or your partner use a male condom? .....	<input type="checkbox"/>	<input type="checkbox"/>
5b. did you use a female condom? .....	<input type="checkbox"/>	<input type="checkbox"/>
5c. did you insert the study gel <b>before</b> having vaginal sex? .....	<input type="checkbox"/>	<input type="checkbox"/>
5c1. did you insert the study gel within 2 hours <b>before</b> having vaginal sex? .....	<input type="checkbox"/>	<input type="checkbox"/>
5d. did you wash inside or douche inside your vagina within 2 hours <b>before</b> inserting the study gel? .....	<input type="checkbox"/>	<input type="checkbox"/>
5e. did you wash inside or douche inside your vagina within 2 hours <b>after</b> inserting the study gel? .....	<input type="checkbox"/>	<input type="checkbox"/>

If no, go to statement before item 6 on page 3.

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## Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 3:** Do not read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reason reported by the participant. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim response. If the response is given in a language other than English, provide the English translation in the space provided. If the participant gives only one reason and only one box is marked, leave item 3a blank and go to item 4.
- **Item 3a:** Do not read any of the response categories aloud. Instead, read the question and, based on the responses to item 3, mark the one box that corresponds to the main reason why the participant did not use the study gel. If the participant reports a reason that is not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 4:** If, after verbal probing, the participant is unable to provide the day she last had vaginal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write “don’t know” in the white space next to the item, and initial and date.
- **Item 5:** Read each item 5a–5e aloud and mark the participant’s response. If item 5c is marked “no,” leave items 5c1–5i blank and proceed to the statement above item 6 on page 3.

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

SAMPLE: DO NOT FAX  
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

FBC-3 (183)

Participant ID

-      -   
Site Number Participant Number Chk

Follow-up Behavior Assessment—  
Coitally Dependent Arm

5f. did you insert paper, cloth, cotton, or cotton wool within 2 hours **before** inserting the study gel? .....  yes  no

5g. did you insert paper, cloth, cotton, or cotton wool within 2 hours **after** inserting the study gel? .....  yes  no

5h. did you insert any other object or substance into your vagina within 2 hours **before** inserting the study gel? .....  yes  no

➔ If yes, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

5i. did you insert any other object or substance into your vagina within 2 hours **after** inserting the study gel? .....  yes  no

➔ If yes, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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

6. In the **past month**, did you have anal sex? .....  yes  no ➔ If no, go to statement before item 10 on page 4.

7. In the **past week**, did you have anal sex? .....  yes  no ➔ If no, go to item 8.

7a. In the **past week**, did you ever insert the study gel anally during anal sex? .....  yes  no ➔ If no, go to statement before item 7b.

7a1. In the **past week**, how many times did you insert the study gel anally during anal sex? .....   # of times

I know that you are counseled to use condoms for each act of anal sex, but I also know that this is not always possible.

7b. In the **past week**, did you ever, even once, have anal sex without a condom? .....  yes  no

8. When was the **last time** you had anal sex? .....          
dd MMM yy

13-107

28-JUN-06

Language

Staff Initials / Date

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## Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-3)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 5f-5g:** Read each item aloud and mark the participant's response.
- **Items 5h-5i:** Read each item aloud and mark the participant's response. If "yes" is marked, be sure to record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 8:** If, after verbal probing, the participant is unable to provide the day she last had anal sex, attempt to record the month and year, at minimum. Draw a line through the unknown response boxes, write "don't know" in the white space next to the item, and initial and date.

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

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FBC-4 (184)

Participant ID

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

Follow-up Behavior Assessment—Coitally Dependent Arm

9. The **last time** you had anal sex: yes no
- 9a. did you or your partner use a male condom? .....
- 9b. did you use a lubricant (such as lube, K.Y.)? .....
- 9c. did you insert the study gel anally?.....

I know that you are counseled to insert the study gel each time you have vaginal sex, up to twice a day, but I also know that this is not always possible.

10. In the **past week**, how many times did you insert the study gel? .....  # of times  
➔ If 0, go to statement before item 11.
- 10a. In the **past week**, how many times did you insert the study gel and **not** have vaginal sex?.....  # of times

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

11. For the next question, I am going to ask you about items that women sometimes insert inside their vaginas. For each item, please tell me if you inserted it inside your vagina in the **past month**. It is possible to answer "yes" more than once.
- If yes:** How many times in the **past week** did you insert this item?
- |  | yes                      | no                       | # of times in <b>past week</b> |
|--|--------------------------|--------------------------|--------------------------------|
| 11a. water?.....   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/>           |
| 11b. water with vinegar? <i>Note for U.S. sites: This includes all commercial douching products.</i> ..... | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/>           |
| 11c. water with soap? .....  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/>           |
| 11d. paper, cloth, cotton, or cotton wool?.....  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/>           |
| 11e. tampons?.....   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/>           |
| 11f. fingers without anything else? .....  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/>           |
| 11g. anything else? Specify:.....  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="text"/>           |

Local Language:

English:

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## Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-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.
- **Item 9:** Read each item 9a–9c aloud and mark the participant’s response.
- **Item 10:** Record the number of times the participant used the study gel in the last 7 days.

*Note: The maximum number of times a coitally dependent participant may use the study gel, per protocol, is twice daily. If the participant reports having used the study gel > 14 times in the past week, provide adherence counseling on proper frequency of use during the counseling portion of the visit.*

- **Item 10a:** The sum of the responses to items 10a, 2c, and 2d should equal the response to item 10. If a discrepancy is noted, attempt to resolve it by asking the participant for clarification. Update the responses on this form as necessary.
- **Item 11:** Read each item 11a–11g aloud and mark the participant’s response. For each item to which she replies “yes,” ask how many times in the **past week** she has used that particular item. Record the response in the “# of times in **past week**” boxes. If “yes” is marked for item 11g, record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

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

SAMPLE: DO NOT FAX  
TO DATAFAX



Visit Code   .

1

HPTN 059 Ph II Microbe (113)

FBC-5 (185)

Participant ID

-      -   
Site Number Participant Number Chk

Follow-up Behavior Assessment—  
Coitally Dependent Arm

12. I know you were asked about family planning during your medical history review, but I need to ask you again. Which family planning method or methods are you currently using? **DO NOT read response categories aloud. Mark "none" or all that apply.**

none  
 vaginal ring  
 spermicide  
 diaphragm  
 sponge

➔ Reinforce use of protocol-specified methods of effective contraception.

intrauterine device (IUD)  
 natural methods such as the withdrawal or rhythm method  
 male condoms  
 female condoms

➔ If not used in combination with another protocol-specified method of effective contraception, provide appropriate counseling.

family planning pills or birth control pills  
 injectable contraceptives (such as Depo-Provera)  
 Norplant inserts  
 Ortho Evra/The Patch  
 surgical sterilization (tubal ligation)  
 sex with partner who had a vasectomy  
 other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

---

## Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-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.
- **Item 12: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each family planning method the participant reports using. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

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



SAMPLE: DO NOT FAX  
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

FBC-6 (186)

Participant ID

-      -   
Site Number Participant Number Chk

Follow-up Behavior Assessment—  
Coitally Dependent Arm

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

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

	yes	no	not applicable
13a. your spouse or partner?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13b. people at home/family?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13c. your friends/personal relationships? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13d. people at work? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13e. people at school?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13f. your doctor, nurse, midwife, or other health care provider?.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13g. your landlord or property owner? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13h. other people? Specify: .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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

14. Please describe the problem. **DO NOT record the participant's verbatim response.**

Local Language: \_\_\_\_\_

\_\_\_\_\_

English: \_\_\_\_\_

\_\_\_\_\_

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## Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-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 13:** Read each item 13a–13h aloud and mark the participant’s response. If “yes” is marked for item 13h, be sure to record the participant’s verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided. If the participant responds “no” to each item 13a–13h, end the form; record the Visit Code and PTID on pages 7 and 8 of this form, and leave the remaining form items (14-16a) blank. Do fax all 8 pages of this form to SCHARP DataFax once the form has been completed.
- **Item 13f:** This item **does not** include members of the site staff.
- **Item 14:** Describe the problem. **Do not** record the participant’s verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. If the response is given in a language other than English, provide the English translation in the space provided.

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

**SAMPLE**. DO NOT FAX  
TO DATAFAX



Visit Code

HPTN 059 Ph II Microbe (113)

FBC-7 (187)

**Participant ID**

-      -   
Site Number Participant Number Chk

**Follow-up Behavior Assessment—  
Coitally Dependent Arm**

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

15a. emotional harm to you? By emotional harm, I mean feeling increased stress, anxiety, worry, or depression as a result of this problem? .....  *yes*  *no* → **If no, go to item 15b.**

15a1. Please describe the problem: **Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.**

*Local Language:* \_\_\_\_\_

\_\_\_\_\_

*English:* \_\_\_\_\_

\_\_\_\_\_

15b. physical harm to you? For example, has anyone physically hurt you as a result of this problem? .....  *yes*  *no* → **If no, go to item 15c.**

15b1. Please describe the problem: **Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.**

*Local Language:* \_\_\_\_\_

\_\_\_\_\_

*English:* \_\_\_\_\_

\_\_\_\_\_

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## Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-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.
- **Items 15a1 and 15b1:** Describe the problem. **Do not** record the participant's verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. Include in the description the type of person who precipitated the problem (e.g., spouse or partner, family member, co-worker, landlord, etc.), and the outcome of the problem, if any. If the response is given in a language other than English, provide the English translation in the space provided.

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

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

FBC-8 (188)

Participant ID

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

Follow-up Behavior Assessment—Coitally Dependent Arm

15c. economic/financial harm to you? For example, has this problem resulted in the removal/loss of your home, property, or ability to earn income? ..... yes [ ] no [ ] If no, go to item 15d.

15c1. Please describe the problem: Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

15d. physical or other harm to your children? ..... yes [ ] no [ ] If no, go to item 16.

15d1. Please describe the problem: Do NOT record the participant's verbatim response. Record the outcome of the problem, if any.

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

Complete items 16-16a after the interview.

16. Did any of the problem(s) require reporting as an Adverse Event (AE)? yes [ ] no [ ] If no, end of form.

16a. Record AE Log page number(s): ..... AE Log Page # [ ][ ] AE Log Page # [ ][ ] AE Log Page # [ ][ ]

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## Follow-up Behavior Assessment—Coitally Dependent Arm (FBC-8)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Items 15c1 and 15d1:** Describe the problem. **Do not** record the participant's verbatim (word-for-word) response—describe the problem in your own words so that the nature of the problem is clear. Include in the description the type of person who precipitated the problem (e.g., spouse or partner, family member, co-work, landlord, etc.), and the outcome of the problem, if any. If the response is given in a language other than English, provide the English translation in the space provided.
- **Item 16:** This is not an interviewer-administered item.
- **Item 16a:** This is not an interviewer-administered item. Record the AE Log page number(s) that correspond to any AEs reported in item 15. Leave any remaining AE Log page number boxes blank.

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

SAMPLE. DO NOT FAX TO DATAFAX

Visit Code

Form boxes for Visit Code

1

HPTN 059 Ph II Microbe (113)

GBA-1 (281)

Participant ID

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

Genital Bleeding Assessment

Visit Date

Visit Date form boxes: dd, MMM, yy

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

- 1. First day of participant's last menstrual period: ... Obtain from Follow-up Medical History form.
2. Last day of participant's last menstrual period: ... Obtain from Follow-up Medical History form.
3. Length in days of participant's last menstrual period (based on dates recorded in items 1 and 2): ... days
4. First day of genital bleeding episode: ... Per participant report or clinical exam.
5. Last day of genital bleeding episode: ... ongoing OR
6. Total number of days of genital bleeding: ... days OR ongoing
7. According to the participant, did she continue to use study gel during this genital bleeding episode? ... yes no N/A If yes or N/A, go to item 9.
8. Number of days between last application of study gel and first day of genital bleeding episode: ... days
9. 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

---

## Genital Bleeding Assessment (GBA-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 (Week 4 through study exit). This form is completed each time an episode of unexpected genital bleeding is self-reported by a study participant and is either not observed during pelvic examination, or is clinically-observed with no identifiable source. Specifically, this form guides clinicians to collect and consider information on the many factors that may contribute to the unexpected genital bleeding event. Study clinicians should review the Baseline Medical History form and refer to SSP Section 10 to determine whether or not an episode of genital bleeding is unexpected.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Item 1:** Mark "amenorrheic" if the participant has been without menses for at least the past three cycle intervals, or the past 6 months, whichever is shorter. If "amenorrheic" is marked, leave items 1–3 blank and go to item 4.
- **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 9:** Mark "unknown" in cases where the information is not known by the participant.



SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code

1

HPTN 059 Ph II Microbe (113)

GBA-2 (282)

Participant ID

-      -   
Site Number Participant Number Chk

Genital Bleeding Assessment

10. According to the participant, what color was the genital blood? *Mark all that apply*.....  
*bright red*  *brown*  *unknown*

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

- 11a. vaginal sex? .....  *yes*  *no*
- 11b. painful vaginal sex? .....  *yes*  *no*
- 11c. application of the study gel? .....  *yes*  *no*  *N/A*
- 11d. painful or uncomfortable application of the study gel? .....  *yes*  *no*  *N/A*
- 11e. painful or uncomfortable insertion or removal of any other vaginal product/preparation? .....  *yes*  *no*  *N/A*
- 11f. a pelvic or colpo exam? .....  *yes*  *no*
- 11g. condom use? .....  *yes*  *no*

**If yes, record date of last pelvic/colpo exam in Comments.**  
**If yes to any, record related details in Comments.**

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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## Genital Bleeding Assessment (GBA-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 10:** Mark “unknown” in cases where the information is not known by the participant.
- **Comments:** Record any necessary or additional information at the bottom of the form.

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

GBA-3 (283)

Participant ID

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

Genital Bleeding Assessment

12. Is the participant currently using injectable contraceptives? *Review Concomitant Medications Log.*      yes      no  
       → **If no, go to item 13.**
- 12a. When was her last injection? .....      dd      MMM      yy
- 12b. When is/was her next injection due? .....                   → **Go to item 14.**
13. Is the participant currently using (non-injectable) hormonal contraceptives? *Review Concomitant Medications Log.*      yes      no  
       → **If no, go to item 14.**
- 13a. Has the participant missed one or more days of contraceptives in the week before the genital bleeding started? .....      yes      no  
       → **If no, go to item 14.**
- 13b. Did the participant miss two or more days of contraceptives? .....      yes      no  
       → **If yes, go to item 14.**
- 13c. **For participants using oral contraceptives only:** Did the participant make up the missed dose of oral contraceptives? .....      yes      no
14. Based on all information available, is this bleeding unexpected? .....      yes      no  
       → **If no, end of form. DO NOT complete AE Log.**
- 14a. Is this unexpected bleeding menstrual, non-menstrual, or hemorrhage?

menstrual

↓

**Complete AE Log. Report as "menorrhagia" or "menometrorrhagia." Grade per "otherwise not specified" row.**

non-menstrual

↓

**Complete AE Log. Report as "IMB." Grade per "IMB" row.**

hemorrhage

↓

**Complete AE Log. Report as "hemorrhage" and include location and/or source. Grade per "hemorrhage" row.**

AE Log Page #

14b. Record Adverse Experience Log page: .....

[ ][ ][ ]

Comments: \_\_\_\_\_

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## Genital Bleeding Assessment (GBA-3)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on page 1 of this form for a given participant and visit.
- **Item 12:** If the participant reports currently using injectable contraceptives, make sure the injectable contraceptives are listed on the participant's Concomitant Medications Log.
- **Item 13:** Non-injectable hormonal contraceptives include oral contraceptives ("the pill"), Ortho-Evra ("the patch"), and vaginal rings. If the participant reports currently using non-injectable hormonal contraceptives, make sure these are listed on the participant's Concomitant Medications Log.
- **Item 13c:** This item applies only to those participants using oral contraceptives. For participants who do not use oral contraceptives, leave item 13c blank and go to item 14.
- **Item 14:** Review the Baseline Medical History form and refer to SSP Section 10 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 row for clinical adverse events not identified elsewhere in the DAIDS AE grading table on page 3.  
*NOTE: unexpected menstrual bleeding is defined as menstrual bleeding that is heavier in volume or longer in duration than the participant's usual menses (as documented on the Baseline Medical History form). Refer to SSP Section 10 for further information.*
  - **non-menstrual** - grade the AE (IMB) using the row for intermenstrual bleeding (IMB) in the DAIDS AE grading table on page 13. *NOTE: unexpected non-menstrual genital bleeding 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). Refer to SSP Section 10 for further information.*
  - **hemorrhage** - grade the AE using the row for hemorrhage (defined as significant acute blood loss) in the DAIDS AE grading table on page 6. When recording the AE on the AE Log form, record "hemorrhage" and include the specific location (e.g., vaginal, cervical, or uterine). If the location is not known, record "genital hemorrhage."
- **Item 14b:** Record the AE Log page number of the AE reported for this unexpected genital bleeding episode. When determining the relationship to study product, carefully review the information recorded in items 11–13c of this form. Record information relevant to the product relatedness determination in the Comments section of the AE Log.

SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code [ ][ ] . [ ]

[ 1 ]

HPTN 059 Ph II Microbe (113)

SAA-1 (472)

Participant ID

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

Study Exit Acceptability Assessment

Visit Date

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

One goal of this research is to understand how acceptable study gel use is to women and their partners. I am now going to ask you some questions about your experiences using the study gel and how study gel use has affected your relationship(s) with sexual partners. Your honest answers will be very helpful to us.

Shall we continue?

1. If your study gel is found to help prevent people from getting HIV, would you want to use it during sex?.....
- yes [ ] no [ ] don't know [ ]
- If yes, go to item 2.

1a. Why not?

Local Language: \_\_\_\_\_

\_\_\_\_\_

English: \_\_\_\_\_

\_\_\_\_\_

2. What do you like about your study gel? **DO NOT read response categories aloud. Mark all that apply.**

If only one response box is marked, go to item 3 on page 2.

- no response
- nothing
- may protect against HIV
- may protect against STIs
- can use without partner's knowledge
- easy to use
- method is under her control
- made sex more pleasurable
- did not interrupt sex
- appearance/smell
- other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

---

## Study Exit Acceptability Assessment (SAA-1)

*This form is used to collect gel acceptability information from study participants. This is an interviewer-administered form, and it is administered at the Study Exit visit.*

### Interview tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

- Help the participant feel comfortable. Develop a rapport or connection with the participant.
- Avoid re-phrasing items, as doing so can change the meaning of the items and make them inconsistent with other interviews.
- Use probes to help the participant remember an answer, clarify a response, or to help report something more accurately.
- When a participant's response does not match one of the listed response categories, record the participant's verbatim (word-for-word) response on the line labeled "Local Language" (even if the participant's response is in English). Record the participant's response in the language spoken by the participant. Once the interview is over, go back and translate the text recorded on the "Local Language" line into English, and record the English translation of the response on the "English" line. If the participant's response was in English originally, leave the "English" line blank.
- It is important for you to review the forms for accuracy and completeness once the interview is complete. By reviewing the form briefly while the participant is still there, you can go back to an item that may have accidentally been skipped.

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of "03.0," Week 12 (Month 3) is assigned a visit code of "05.0," etc.
- **Items 1–1a:** If the participant responds "yes," leave item 1a blank and proceed to item 2. If the participant responds "no," continue to item 1a and record the participant's verbatim (word-for-word) response.
- **Item 2:** Do not read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each reported characteristic the participant likes about the gel. If the participant gives a response that does not correspond to one of the listed categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response. If "no response" or "nothing" is marked, no other response box should be marked. If only one response box is marked, leave item 2a blank and go to item 3.

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

SAMPLE: DO NOT FAX  
TO DATAFAX

■ ■ ■ | ■ ■ | | ■ Visit Code

□ □ . □

1

HPTN 059 Ph II Microbe (113)

SAA-2 (473)

Participant ID

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

Study Exit Acceptability Assessment

2a. Which of these do you like most? **DO NOT read response categories aloud.**

- no response
- nothing
- may protect against HIV
- may protect against STIs
- can use without partner's knowledge
- easy to use
- method is under her control
- made sex more pleasurable
- did not interrupt sex
- appearance/smell
- other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

3. What do you not like about your study gel? **DO NOT read response categories aloud. Mark all that apply.**

- no response
- nothing
- messy
- interrupted sex
- made sex less pleasurable
- difficult to use, specify:
- remembering to use it
- difficult to store and/or discard
- appearance/smell
- other, specify:

If only one response box is marked, go to item 4 on page 3.

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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## Study Exit Acceptability Assessment (SAA-2)

### Item-specific Instructions:

- **Visit Code:** Make sure that the Visit Code recorded on this page matches the Visit Code recorded on all other pages of this form for a given participant and visit.
- **Item 2a: Do not** read any of the response categories aloud. Instead, read the question, and based on the participant's responses to item 2, mark the box that corresponds to the one characteristic the participant likes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she likes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response.
- **Item 3: Do not** read any of the response categories aloud. Instead, read the question and mark the box(es) that correspond to each characteristic the participant does not like about the study gel. If the participant gives a response that does not correspond to one of the listed categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response on the adjacent specify line(s). If the participant's response is "difficult to use," probe for more specific information as to why the study gel is difficult to use and record the participant's verbatim (word-for-word) response on the adjacent specify line(s). If "no response" or "nothing" is marked, no other response box should be marked. If only one response box is marked, leave item 3a (on page 3) blank and go to item 4.

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



SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code [ ][ ] . [ ]

[ 1 ]

HPTN 059 Ph II Microbe (113)

SAA-3 (474)

Participant ID

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

Study Exit Acceptability Assessment

3a. Which of these do you dislike most? **DO NOT read response categories aloud.**

- no response
- nothing
- messy
- interrupted sex
- made sex less pleasurable
- difficult to use
- remembering to use it
- difficult to store and/or discard
- appearance/smell
- other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

4. The **last time** you had sex with a male partner while using the study gel, did he know you were using the study gel? .....  yes  no  don't know

→ If no or don't know, go to item 5 on page 4.

4a. What was his reaction to the study gel? **DO NOT read response categories aloud.**

- he liked it
- he did not like it
- he had no reaction
- don't know
- other, specify:

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

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## Study Exit Acceptability Assessment (SAA-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 3a:** **Do not** read any of the response categories aloud. Instead, read the question, and based on the participant's responses to item 3, mark the box that corresponds to the one characteristic the participant dislikes most about the study gel. If she reports more than one, ask her to choose which of the characteristics she dislikes most. If the participant gives a response that does not correspond to one of the listed response categories, mark the "other, specify" box and record the participant's verbatim (word-for-word) response.
- **Item 4:** This item refers to the last time the participant used the study gel during vaginal sex.
- **Item 4a:** **Do not** read any of the response categories aloud. Instead, read the question and mark the box that corresponds to the participant's response. If the participant gives a response that is not listed, mark the "other, specify" box and record the participant's verbatim (word-for-word) response on the "Local Language" line. If the response is given in a language other than English, provide the English translation of the response on the "English" line.

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

SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

SAA-4 (475)

Participant ID

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

Study Exit Acceptability Assessment

5. During your participation, did you ever use anyone else's study gel? .....  yes  no **If no, go to item 6.**

5a. Approximately how many times did you use someone else's gel?

1 time  2-5 times  6-10 times  > 10 times

5b. Can you tell me why you used another participant's study gel?

Local Language: \_\_\_\_\_

English: \_\_\_\_\_

6. Did anyone else, even someone who wasn't in the study, use your study gel?.....  yes  no  don't know

---

## Study Exit Acceptability Assessment (SAA-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.
- **Item 5b:** Record the participant's verbatim (word-for-word) response. If the response is given in a language other than English, provide the English translation in the space provided.

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

**SAMPLE**. DO NOT FAX  
TO DATAFAX



Visit Code

HPTN 059 Ph II Microbe (113)

CHB-1 (149)

**Participant ID**

-      -

Site Number

Participant Number

Chk

**CHBV Visit**

**Visit Date**

dd

MMM

yy

1. Were any new Adverse Experiences reported at this visit? .....  *yes*  *no* **→ If no, end of form.**

1a. How many **new** AE Log pages were completed for this visit? .....   # of pages

2. At this visit, how many unused tubes did the participant return?    # of tubes

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

---

## CHBV Visit (CHB-1)

*This form is used to document the required (regularly scheduled) Week 28, Week 32, and Week 36 Visits for Hepatitis B Surface Antigen positive participants only. This form is completed at each of these three visits (Weeks 28–36).*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 of the Study-Specific Procedures Manual for more specific information on assigning visit codes. Note that for regularly scheduled follow-up visits, the visit code is equal to the month on study plus 2.0. For example, Week 4 (Month 1) is assigned a visit code of “03.0,” Week 12 (Month 3) is assigned a visit code of “05.0,” etc.
- **Item 1:** 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 1a 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 2:** Record the number of **unused** study gel tubes the participant returned at this visit only.

*Note: No study gel supplies should be dispensed to participants at the Week 28, 32, or 36 Visits. All study participants, including CHBV participants, should have discontinued study gel use as of the Week 24 Visit.*

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

[ 1 ]

HPTN 059 Ph II Microbe (113)

IV-1 (350)

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.**

- in-person visit to report new symptoms → **Complete Adverse Experience Log.**
- phone call from participant to report new symptoms → **Complete Adverse Experience Log.**
- participant needs study gel
- participant is returning study gel
- other, specify: \_\_\_\_\_

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

2a. Specify reason(s): ← [ ]

\_\_\_\_\_  
\_\_\_\_\_

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

- none
- Follow-up Pelvic Exam
- Pelvic Laboratory Results
- STI Laboratory Results
- Adverse Experience Log (new)
- Product Hold/Discontinuation
- Safety Laboratory Results
- Follow-up Genital Symptoms
- Genital Bleeding Assessment

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

other, specify: \_\_\_\_\_

4. At this visit, how many unused tubes did the participant return?..... [ ][ ][ ] # of tubes returned

5. At this visit, how many cartons of study gel were dispensed to the participant? [ ][ ] # of cartons dispensed

6. Was blood collected for the plasma archive?.....  yes     no

7. Was blood collected for the serum archive? .....  yes     no

Comments: \_\_\_\_\_ 13-135

---

## Interim Visit (IV-1)

*This form is used to document interim visits during follow-up. See Section 13.3.2 of the Study-Specific Procedures Manual for a definition and examples of interim visits that require an Interim Visit form to be completed. Note that all DataFax forms completed for an Interim Visit must have the same interim Visit Code as the Interim Visit form.*

### Item-specific Instructions:

- **Visit Code:** The following guidelines should be used for assigning the interim visit code:
  - Record the two-digit whole number visit code for the most recent scheduled regular visit. For example, if the most recent scheduled regular visit was Week 4 (Visit Code = 03.0), record “03” to the left of the decimal point in the visit code field.
  - Record the number that corresponds to the Interim Visit in the third box (the box to the right of the decimal point):
    - XX.1 = First Interim Visit after the most recent scheduled regular visit.
    - XX.2 = Second Interim Visit after the most recent scheduled regular visit.
- **Item 1:** Mark the box to the left of each reason(s) this Interim Visit was conducted. Mark all that apply.
- **Item 2:** A urine pregnancy test is required at each interim visit. Record the hCG urine pregnancy test result. If a required urine pregnancy test result is not available (specimen not collected and/or test not done), mark the “not done” box and complete item 2a..

*Note: A Pregnancy Report and History form must be completed for each pregnancy. Once a participant tests positive for hCG urine pregnancy and a Pregnancy Report and History form (PR-1) has been completed for this pregnancy, subsequent positive pregnancy test results should not be recorded on a new PR-1 (unless they represent a new pregnancy).*
- **Item 3:** For each DataFax form completed for this visit, mark the box to the left of the form name. Mark all boxes that apply. Note that marking a box indicates that a DataFax form with the same visit code as this form will be faxed to SCHARP DataFax.
  - **none:** Mark this box if the Interim Visit form is the **only** DataFax form completed for this visit.
  - **Adverse Experience Log (new):** Mark this box if a new (previously unreported) AE is reported or observed at this visit. If the box to the left of “Adverse Experience Log (new)” is marked, record in item 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.
  - **other, specify:** Mark this box if a DataFax form(s) other than the ones listed was completed for this visit. Specify the form name(s) on the line provided.
- **Item 4:** Record the number of **unused** study gel tubes the participant returned at this visit only. This number may be obtained from the Gel Re-supply Worksheet.
- **Item 5:** Record the number of cartons of study gel given to the participant at this visit. This will be the same amount documented on the Study Gel Request Slip, unless documentation from the pharmacy staff states otherwise. If more than four cartons (for daily use participants) or eight cartons (for coitally dependent participants) are dispensed at a given interim visit, specify in the Comments section the reason why.
- **Item 6:** Record whether or not specimens were collected for the plasma archive.
- **Item 7:** Record whether or not specimens were collected for the serum archive.



SAMPLE. DO NOT FAX  
TO DATAFAX



Visit Code [ ][ ] . [ ]



HPTN 059 Ph II Microbe (113)

PH-1 (410)

Participant ID

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

Product Hold/Discontinuation

1. Date product hold was initiated: ..... [ ][ ] [ ][ ][ ][ ] [ ][ ]  
dd MMM yy

2. Why is product being held?

- pregnancy
- HIV infection
- other adverse experience
- other, specify: \_\_\_\_\_

AE Log page #(s)

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

3. Date of last study gel application: ..... [ ][ ] [ ][ ][ ][ ] [ ][ ]  
dd MMM yy

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

End of form.

In item 4a, record the date on which study gel use would have been resumed if not being held for another reason.

4a. Date participant instructed to resume study gel use: ..... [ ][ ] [ ][ ][ ][ ] [ ][ ]  
dd MMM yy

Visit Code [ ][ ] . [ ]

Comments: \_\_\_\_\_

---

## Product Hold/Discontinuation (PH-1)

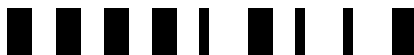
*This form is used to document temporary holds and permanent discontinuations of study gel. This form is completed each time a participant is instructed to temporarily stop (hold) or permanently discontinue study gel use prior to the Week 24 Visit. If, at the same study visit, a product hold/discontinuation is initiated for more than one reason, complete a Product Hold/Discontinuation form for each reason. The same visit code should be used on each form.*

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

### Item-specific Instructions:

- **Visit Code:** Record the visit code at which the participant was instructed by a study staff member to hold or permanently discontinue study gel use. If the product is being held or permanently discontinued as a result of an adverse experience, the Visit Code recorded on this form should match the visit code recorded in item 10 of the AE Log documenting the product hold/permanent discontinuation.
- **Item 1:** Record the date on which the participant was instructed to hold or permanently discontinue study gel use.
- **Item 2:** Mark the box to the left of the one reason which **best** describes why the participant is being instructed to hold or permanently discontinue gel use. Mark only one. If product is being held or discontinued due to an adverse experience, record the page number(s) 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” and record the reason for the hold/discontinuation on the line provided.
- **Item 3:** Record the date the participant last applied study gel. 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 gel use or have determined that she is permanently discontinued from study gel use. Mark this item “yes” if study staff instructed the participant that she can resume use of study gel. If the participant was permanently discontinued from study gel use, mark the “no (permanently discontinued)” box and end the form - leave item 4a blank. 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).” In item 4a, record the date the participant would have been instructed (by site staff) to resume study gel use if it were not held 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 study gel use.

SAMPLE. Do NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

ESI-1 (489)

Participant ID

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

End of Study Inventory

Form Completion Date

Form Completion Date form with boxes for dd, MMM, and yy

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

visit code form with boxes for digits and a decimal point

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

# of interim visits form with boxes for digits

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

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

page # form for 3a

no pages submitted checkbox

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

page # form for 3b

3c. Pre-existing Conditions page #

page # form for 3c

Complete items 4 and 4a for CHBV participants only. For non-CHBV participants, end of form.

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

yes/no checkboxes and arrow pointing to 'If no, end of form.'

4a. When was the informed consent for specimen storage and future research marked or signed? .....

Form completion date boxes for dd, MMM, and yy

Comments: \_\_\_\_\_

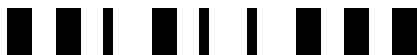
---

## End of Study Inventory (ESI-1)

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

- **Form Completion Date:** Complete date required.
- **Item 1:** Record the highest visit code (last visit for which DataFax forms were submitted). If the participant's last visit was missed (as documented by a Missed Visit form), record the visit code of the missed visit.
- **Item 2:** Record the total number of interim visits conducted for this participant. If no interim visits were conducted for this participant, record "000" in the boxes.
- **Item 3a:** Record the highest page number of the Adverse Experience (AE) Log forms submitted for this participant, even if that page was marked for deletion. If no AE Log form pages were completed for this participant, mark the "no pages submitted" box.
- **Item 3b:** Record the highest page number of the Concomitant Medications Log forms submitted for this participant.
- **Item 3c:** Record the highest page number of the Pre-existing Conditions forms submitted for this participant.
- **Item 4–4a:** These items are completed for chronic Hepatitis B (CHBV) participants only. Mark "yes" if the participant consented to specimen storage and future research at any time during her study participation, AND continued to provide consent as of the date she terminated from the study. If "yes" is marked, record the date she first provided consent to specimen storage and future research in item 4a. If the participant did not consent to specimen storage and future research or consented but then subsequently withdrew consent, mark item 4 "no" and leave item 4a blank.

**SAMPLE**. Do NOT FAX  
TO DATAFAX



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

Page

HPTN 059 Ph II Microbe (113)

CM-1 (423)

**Participant ID**

-       -

Site Number Participant Number Chk

**Concomitant Medications Log**

No medications taken at Screening/Enrollment. \_\_\_\_\_  
Staff Initials/Date

➔ Fax to SCHARP DataFax.

---

No medications taken throughout study. \_\_\_\_\_  
Staff Initials/Date

➔ End of form. Fax to SCHARP DataFax.

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

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

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

13-141

28-JUN-06

Language

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## Concomitant Medications Log (CM-1)

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

When to fax this form:

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

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

**No medications taken at Screening/Enrollment:** Mark this box if no medications were taken by the participant at the time of the Screening or Enrollment visit. Record “Staff Initials/Date.”

**No medications taken throughout study:** Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. Record “Staff Initials/Date.”

**Medication:** Record the generic name for all medications. For combination medications, record the generic names of the first three main active ingredients.

**Indication:** For health supplements, such as multivitamins, record “general health.” For preventive medications, record “prevention of [insert condition]” (e.g., for flu shot, record “prevention of influenza”). For recreational drugs, record “recreation.”

**Date Started:** If the participant is unable to recall the exact date, obtain participant’s best estimate. At a minimum, the year is required.

**Date Stopped:** At the participant’s Termination visit, the “Date Stopped” must be recorded for each medication OR the “Continuing at end of study” box must be marked. At a minimum, the month and year is required.

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

**Route and Frequency:** Below is a list of common route and frequency abbreviations.

- **Route Abbreviations:**

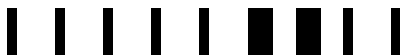
<b>PO</b> oral	<b>IM</b> intramuscular	<b>IV</b> intravenous	<b>TOP</b> topical	<b>IHL</b> inhaled	<b>VAG</b> vaginal	<b>REC</b> rectal
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- **Frequency Abbreviations:**

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

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

**SAMPLE**. DO NOT FAX  
TO DATAFAX



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

Page

HPTN 059 Ph II Microbe (113)

PRE-1 (012)

**Participant ID**

**Form Completion Date**

-      -

Site Number      Participant Number      Chk

**Pre-existing Conditions**

dd                      MMM                      yy

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

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

---

## Pre-existing Conditions (PRE-1)

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

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



SAMPLE: DO NOT FAX TO DATAFAX



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

Page [ ][ ] [ ][ ] [ ][ ]

HPTN 059 Ph II Microbe (113)

AE-1 (420)

Participant ID

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

Adverse Experience Log

Date Reported to Site

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

1. Adverse Experience (AE)

2. Onset Date

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

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

English (if above is in Local Language): \_\_\_\_\_

3. Severity

4. Relationship to Study Product

5. Study Product Administration

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

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

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

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

6. Status/Outcome

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

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

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

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

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

8. Is this AE serious according to ICH guidelines? ..... yes no

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

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

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

English (if Comments above are in Local Language): \_\_\_\_\_

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## Adverse Experience Log (AE-1)

Any Adverse Experience (AE) reported by the participant or clinically observed after initiation of study product, regardless of whether or not it is related to study product, must be documented any time during study participation.

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.

**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.

**Adverse Experience (AE):** 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.”

**Onset Date:** 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.

**Severity:** To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences*.

### Relationship to Study Product:

- **Definitely related:** The adverse event and administration of study agent are related in time, and a direct association can be demonstrated.
- **Probably related:** The adverse event and administration of study agent are reasonably related in time, and the adverse event is more likely explained by study agent than other causes.
- **Possibly related:** The adverse event and administration of study agent are reasonably related in time, and the adverse event can be explained equally well by causes other than study agent.
- **Probably not related:** A potential relationship between study agent and the adverse event could exist (i.e., the possibility cannot be excluded), but the adverse event is most likely explained by causes other than the study agent.
- **Not related:** The adverse event is clearly explained by another cause not related to the study agent.
- **NOTE: IN CASES OF DEATH,** when relationship of study product is under investigation, write “Pending” in the adjacent white space until relationship has been determined. Update accordingly.

**Study Product Administration:** N/A (not applicable) should be marked if the AE occurred after the participant had completed all administration of the study agent, or the study product is held for a different AE, or the AE is Grade 5 - Death.

### Status/Outcome:

- **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 this box only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to “continuing at end of study participation.”
- **Severity/frequency increased:** If an AE increases in severity or frequency after it has been reported on the AE Log, line through the “Continuing” box previously marked and mark “Severity/frequency increased.” Record the date of increase in the “Status/Outcome Date.” Report the increase in severity or frequency as a new AE. For this new AE, the “Onset Date” will be the date that the severity or frequency increased. Note that decreases in severity should not be recorded as new AEs.
- **Continuing at end of study participation:** Mark this box whenever an AE is continuing at the time of participant study termination.

**Status/Outcome Date:** 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.

### AE Revisions and Updates:

- 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).

**Items 8 and 9:** For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS*.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 059 Ph II Microbe (113)

PR-1 (440)

**Participant ID**

-  -   
Site Number Participant Number Chk

**Pregnancy Report and History**

**PREGNANCY REPORT**

1. Date of last menstrual period: .....  <sup>dd</sup>  <sup>MMM</sup>  <sup>yy</sup>

2. Estimated date of delivery: .....  <sup>dd</sup>  <sup>MMM</sup>  <sup>yy</sup>

**PREGNANCY HISTORY**

3. Has the participant ever been pregnant before? .....  <sup>yes</sup>  <sup>no</sup> → **If no, end of form.**

3a. Is this the participant's first pregnancy since enrollment in this study? .....  <sup>yes</sup>  <sup>no</sup> → **If no, end of form.**

3b. Number of full term live births (≥ 37 weeks): .....

3c. Number of premature live births (< 37 weeks): .....

3d. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks): .....

3e. Number of spontaneous abortions (< 20 weeks): .....

3f. Number of therapeutic/elective abortions: .....

3g. Number of ectopic pregnancies: .....

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

Comments: \_\_\_\_\_

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## **Pregnancy Report and History (PR-1)**

*This form is used to report the pregnancy of a study participant post enrollment through termination.*

### **Item-specific Instructions:**

- **Visit Code:** Record the visit code of the visit at which the participant was determined to be pregnant.
- **Item 1:** Record the first day or best estimate of the participant's last menstrual period. Complete date required.
- **Item 2:** Complete date required.

SAMPLE. DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 059 Ph II Microbe (113)

PO-1 (441)

Participant ID

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

Pregnancy Outcome

Outcome unknown at end of study. Staff Initials/Date [ ] [ ] [ ] [ ] [ ] [ ] End of form. Fax to SCHARP DataFax.

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

2. OUTCOME #1

dd MMM yy

2a. Outcome Date [ ][ ] [ ][ ][ ] [ ][ ]

2b. Specify Outcome: Mark only one.

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

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

If only one outcome, end of form.

3. OUTCOME #2

dd MMM yy

3a. Outcome Date [ ][ ] [ ][ ][ ] [ ][ ]

3b. Specify Outcome: Mark only one.

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

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

Comments:

[ ][ ][ ] [x] 28-JUN-06

SAMPLE

01

13-149

Language

Staff Initials / Date

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## Pregnancy Outcome (PO-1)

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

### Item-specific Instructions:

**Visit Code:** Record the visit code of the participant’s corresponding Pregnancy Report and History form.

**Specify Outcome:** If the outcome is therapeutic/elective abortion, note that while the abortion itself is not an adverse experience, if the abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Experience (AE) Log, with “procedure/surgery” marked under “Treatment.”

**Congenital anomalies:** This item should be updated if information becomes available during the mother’s (the study participant’s) study follow-up period regarding a congenital anomaly. If a congenital anomaly is identified, complete an Expedited Adverse Event Reporting form (EAE), but do not complete an AE Log. A congenital anomaly is not considered an adverse experience of the mother (the study participant).

**SAMPLE**: DO NOT FAX  
TO DATAFAX



Visit Code

.

HPTN 059 Ph II Microbe (113)

MV-1 (463)

**Participant ID**

-      -

Site Number

Participant Number

Chk

**Missed Visit**

**Form Completion Date**

dd

MMM

yy

**Instructions:** Record the Visit Code of the scheduled visit that was missed.

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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## Missed Visit (MV-1)

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

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.

**Visit Code:** Record the visit code of the visit that was missed.

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

**Comments:** The comments field may be used to record the reason a visit is missed, or it may be left blank.



SAMPLE: DO NOT FAX TO DATAFAX



HPTN 059 Ph II Microbe (113)

TM-1 (490)

Participant ID

Participant ID form with boxes for Site Number, Participant Number, and 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.

2c. Participant refused further participation, specify:

2d. NOT APPLICABLE FOR THIS PROTOCOL. Participant unable to adhere to visit schedule.

2e. Participant relocated, no follow-up planned.

2f. Investigator decision, specify:

2g. Unable to contact participant.

2h. NOT APPLICABLE FOR THIS PROTOCOL.

2i. Inappropriate enrollment.

2j. Invalid ID due to duplicate screening/enrollment.

2k. Other, specify:

2l. Early study closure.

3. Was termination associated with...

3a. Adverse Experience? yes no don't know Record Adverse Experience Log page: page #

Comments:

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## Termination (TM-1)

The Termination form is 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. A complete date is required, unless termination is due to death.

**Item 2:** Although more than one of the listed reasons may describe why a participant left the study early, 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.

This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

Page 1 of 1

Participant ID

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

Clinical Eligibility

Visit Date

Visit Date form with boxes for dd, MMM, and yy.

Instructions: If yes to any of items 1-3, do not perform any other evaluations at this visit. Provide treatment/follow-up per protocol and SSP.

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

- 1a. chlamydia
1b. gonorrhea
1c. syphilis
1d. symptomatic BV
1e. symptomatic candidiasis (yeast)
1f. trichomoniasis
1g. chancroid
1h. genital HSV-1 or HSV-2 (active lesions)
1i. cervical or vaginal warts (excludes warts exterior to labia minora)
1j. cervicitis
1k. vaginitis
1l. pelvic inflammatory disease (PID)
1m. genital sores or ulcers
1n. any other STI or RTI requiring treatment, specify:

Yes/No checkboxes for items 1a through 1n.

If yes to any, treat STI or RTI per protocol and SSP. Do not enroll participant until treatment is complete and symptoms (if any) have resolved.

2. At this visit, does the participant have an abnormal pelvic exam finding that, per protocol, would exclude her from the study?

Yes/No checkboxes for item 2.

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

3. Is the participant in general good health?

Yes/No checkboxes for item 3.

If no, participant is ineligible. End of form.

Comments:

13-155

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## Clinical Eligibility (nonDF)

*This form is completed at the Screening and Enrollment Visits only, and is used to document the participant's clinical eligibility for the study. It is completed at the Screening Visit, and again at the Enrollment Visit. For the Screening Visit, this form is completed once the Screening Visit pelvic exam(s) and wet mount(s) have been conducted, and is completed based on review of the following Screening Visit forms: STI Laboratory Results, Screening and Enrollment Pelvic Exam, History of Genital Symptoms (non-DataFax), and the Baseline Medical History form (non-DataFax). For the Enrollment Visit, this form is completed once the Enrollment Visit pelvic exam and wet mount have been conducted, and is completed based on review of the following Enrollment Visit forms: STI Laboratory Results, Screening and Enrollment Pelvic Exam, Baseline Genital Symptoms, and the Baseline Medical History form (non-DataFax). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

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

*If a participant is being re-screened, a new Clinical Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

- **Item 1:** For each STI or RTI listed, record whether the participant is **currently** diagnosed with that STI/RTI.
- **Item 1h:** Record whether the participant **currently** has active HSV-1 or HSV-2 anogenital lesion(s).
- **Item 2:** Record whether the participant **currently** has an abnormal pelvic exam finding that, per protocol, makes her ineligible for study participation.
- **Item 3:** Record whether, in the judgment of the site clinician, the participant's current health status is good.

# This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

Page 1 of 3

**Participant ID**

Site Number			Participant Number						Chk	

**Screening Eligibility**

**Form Completion Date**

dd		MMM			yy		

**Complete items 1-3 before the interview.**

1. Was the participant willing and able to provide a written informed consent for screening (as assessed by a site-specific assessment of comprehension)? .....  yes  no **→ If no, participant is ineligible. End of form.**
2. Was the participant previously enrolled in this study? .....  yes  no **→ If yes, participant is ineligible. End of form.**
3. Is documentation of a normal Pap test result in the last 90 days available? .....  yes  no **→ If no, perform Pap test as necessary.**

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

4. Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)? .....  yes  no
5. Have you ever had an adverse or bad reaction to tenofovir (Viread) or adefovir (Hepsera)? .....  yes  no
6. Are you currently taking, or do you plan to take tenofovir (Viread), adefovir (Hepsera), or any other chronic hepatitis B medication while participating in this study? .....  yes  no
7. Have you had a hysterectomy? .....  yes  no
8. Are you breastfeeding? .....  yes  no
9. Do you plan to use a diaphragm or spermicide for birth control at any time during your study participation? .....  yes  no **→ If yes to any, participant is ineligible.**
10. In the last month (30 days), have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina. ....  yes  no **→ If no, participant is ineligible.**
11. In the past 2 weeks, how many times have you had vaginal sex? ...   **→ If > 28, participant is ineligible.**

			x	28-JUN-06
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0	1
Language	

\_\_\_\_\_  
Staff Initials / Date

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## Screening Eligibility – 1 (nonDF)

*This form is used to document the participant's eligibility for the study at screening. This is a mixed form—some of the items are interviewer-administered (items 4–23), while other items are not (items 1–3 and 24). 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 Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

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

***Note:** If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 23. 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-specific Instructions:

- **Items 1–3:** These items are NOT interviewer-administered and should not be read aloud to the participant.
- **Item 2:** Review the Screening and Enrollment Log to verify that the participant has not previously enrolled in the study.
- **Item 3:** According to the protocol, women who “have a normal Pap test result or are able to document a normal Pap test result in the 90 days prior to screening” will be eligible to enroll in the study. If the participant does not provide documentation of a normal Pap test result in the 90 days prior to screening, conduct a Pap Smear test for this participant as part of the Screening Visit pelvic exam.

This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

Participant ID

Site Number			Participant Number						Chk			

Screening Eligibility

12. Have you been without menstrual periods for the past 12 months? .  *yes*     *no* → **If no, go to item 13.**
- 12a. Is it because of the birth control you are using, such as Depo-Provera or Norplant? .....  *yes*     *no* → **If no, participant is ineligible.**
13. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion? .....  *yes*     *no* → **If no, go to item 14.**

13a. When did you last give birth, have a miscarriage or abortion?

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

**If date is within the last 34 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last pregnancy outcome.**

14. In the past 3 months (90 days), have you had any gynecological surgery? This would include such procedures as: dilation and curettage (D&C); surgery of the uterus, ovaries, or fallopian tubes, and biopsy or cryotherapy (freezing) of the cervix. ....  *yes*     *no* → **If no, go to item 15.**

14a. When did you last have gynecological surgery? .....

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

**If date is within the last 34 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within 90 days of last gynecological surgery.**

15. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional? ...  *yes*     *no* → **If no, go to item 16.**

15a. When did you last inject drugs that were not prescribed to you? .....

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

**If date is within the last 309 days, participant is ineligible. Otherwise, schedule enrollment for when participant is no longer within one year of injection drug use.**

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## Screening Eligibility – 2 (nonDF)

*This form is used to document the participant's eligibility for the study at screening. This is a mixed form—some of the items are interviewer-administered (items 4–23), while other items are not (items 1–3 and 24). 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 Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

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

### Item-specific Instructions:

- **Item 12:** According to the protocol, women who “are menopausal or post-menopausal at enrollment (defined as the cessation of menses of 12 calendar months, unless on long-acting progestins) will be excluded from the study.”
- **Item 13:** According to the protocol, women who are “within 90 days of last pregnancy outcome at enrollment will be excluded from the study.”
- **Item 14:** According to the protocol, women who “have had a gynecological surgical procedure in the 90 days prior to enrollment will be excluded from the study.”
- **Item 15:** According to the protocol, women who “have injected non-therapeutic drugs intravenously in the 12 calendar months prior to enrollment will be excluded from the study.”



# This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

### Participant ID

Site Number			Participant Number						Chk		

### Screening Eligibility

16. In the past month (30 days), have you participated in any study that uses spermicides, vaginal microbicides, or any other device or drug? .....

yes

no

**If no, go to item 17.**

16a. When did you last participate in one of these studies? .....

dd		MMM			yy					

**Schedule enrollment when participant is no longer within 30 days of other study participation.**

17. Do you agree to not participate in any study that uses spermicides, vaginal microbicides, or any other device or drug while participating in this study? .....

yes

no

18. For the duration of the study, are you willing to use one of the following types of birth control? Depo-Provera ("the shot"), hormonal contraceptives ("the pill"), Ortho-Evra ("the patch"), an intrauterine device (IUD - inserted at least 30 days prior to enrollment), female sterilization, or have vaginal sex with a male partner who has had a vasectomy? .....

19. Do you agree to use study-provided condoms each time you have intercourse for the duration of the study? .....

20. Are you willing to use the study product, which is Tenofovir gel or placebo gel, either once a day or with each act of vaginal sex? .....

21. While you are using the study gel, do you agree to use only study-provided panty liners and/or menstrual pads, if necessary, to protect from product leakage? .....

22. Are you willing to attend all scheduled study visits? .....

23. Are you willing to undergo all study evaluations, including a pelvic exam, colposcopy (when a clinician looks inside your vagina with a magnifying instrument), urine testing, and blood draws? .....

**If no to any, participant is ineligible.**

**Complete item 24 when screening urine hCG result is available.**

24. Is the participant pregnant? .....

yes

no

**If yes, participant is ineligible.**

			x	28-JUN-06
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0	1
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Language

Staff Initials / Date

13-161

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## Screening Eligibility – 3 (nonDF)

*This form is used to document the participant's eligibility for the study. This is a mixed form—some of the items are interviewer-administered (items 4–23), while other items are not (items 1–3 and 24). 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 Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

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

### Item-specific Instructions:

- **Item 16:** According to the protocol, women who “have participated in any other spermicide and/or vaginal microbicide study or any device or drug study 30 days prior to enrollment” will be excluded from the study.
- **Item 24:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Screening Visit urine hCG result here.

**This is not a DataFax form. Please do not fax to DataFax.**

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Page 1 of 2

**Participant ID**

Site Number			Participant Number						Chk	

**Screening Summary**

**Form Completion Date**

dd		MMM			yy		

1. Is the participant eligible based on review of all screening data? .....  <sup>yes</sup>  <sup>no</sup>
- **If yes, end of form.**
2. The participant is ineligible because she: **Mark all that apply.**
- 2a. is not between the ages of 18 and 50 at the time of enrollment
  - 2b. is not able and willing to provide written informed consent to be screened for and to take part in the study
  - 2c. is not in general good health
  - 2d. is HIV-infected
  - 2e. has an abnormal Pap test result
  - 2f. is not sexually active (has not had vaginal intercourse at least once in the 30 days prior to screening)
  - 2g. is unwilling to use an effective method of contraception (as defined in the protocol) during the study
  - 2h. inserted an IUD in the 30 days prior to enrollment
  - 2i. is unwilling to undergo all study related assessments (clinical and laboratory)
  - 2j. is unwilling to adhere to follow-up visit schedule
  - 2k. is unwilling to use tenofovir gel or placebo as required by the protocol
  - 2l. does not agree to refrain from participation in another study that uses spermicides, vaginal microbicides, or any other device or drug, while enrolled in the study
  - 2m. is unwilling to use study-provided condoms for each act of intercourse while on study
  - 2n. is unwilling to use only study-provided panty liners and menstrual pads to protect from product leakage
  - 2o. is menopausal or post-menopausal
  - 2p. has had a hysterectomy
  - 2q. has a history of adverse reaction to latex
  - 2r. plans to use a diaphragm and/or spermicide for contraception
  - 2s. is taking or plans to take Tenofovir (Viread), adefovir (Hepsera) or any other chronic hepatitis B medication while participating in the study
  - 2t. has a history of adverse reaction to tenofovir and/or adefovir

---

## Screening Summary – 1 (nonDF)

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

**Note:** *If a participant is being re-screened, a new Screening Summary form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

- **Item 2:** If the participant is NOT eligible for enrollment in the study, *mark all* of the listed reasons that apply:
  - **Item 2a:** Review Demographics form, item 1.
  - **Item 2b:** Review Screening Consent form, items 2 and 2a; *and* Enrollment form, items 1 and 1a.
  - **Item 2c:** Review Clinical Eligibility form, item 3, from the Screening and Enrollment Visits.
  - **Item 2d:** Review STI Laboratory Results form, item 2a from the Screening Visit, **OR** if an HIV Test Results form is completed at the Screening visit, review the HIV Test Results form, item 5.
  - **Item 2e:** Review Pelvic Laboratory Results form, item 2, from the Screening Visit.
  - **Item 2f:** Review Screening Eligibility form, item 10.
  - **Item 2g:** Review Screening Eligibility form, item 18.
  - **Item 2h:** Review Enrollment Eligibility form, item 3.
  - **Item 2i:** Review Screening Eligibility form, item 23; *and* Enrollment Eligibility form, item 9.
  - **Item 2j:** Review Screening Eligibility form, item 22.
  - **Item 2k:** Review Screening Eligibility form, item 20.
  - **Item 2l:** Review Screening Eligibility form, item 17.
  - **Item 2m:** Review Screening Eligibility form, item 19.
  - **Item 2n:** Review Screening Eligibility form, item 21.
  - **Item 2o:** Review Screening Eligibility form, items 12 and 12a; *and* Enrollment Eligibility form, items 10 and 10a.
  - **Item 2p:** Review Screening Eligibility form, item 7.
  - **Item 2q:** Review Screening Eligibility form, item 4.
  - **Item 2r:** Review Screening Eligibility form, item 9.
  - **Item 2s:** Review Screening Eligibility form, item 6; *and* Enrollment Eligibility form, item 6.
  - **Item 2t:** Review Screening Eligibility form, item 5.

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**Participant ID**

Site Number			Participant Number						Chk	

**Screening Summary**

- 2u. has a history of prior participation in the study
- 2v. has a Grade 3 or higher laboratory abnormality, or creatinine level > 1.25 x ULN
- 2w. had a gynecological surgical procedure within 90 days of enrollment
- 2x. is pregnant
- 2y. is within 90 days of last pregnancy outcome at enrollment
- 2z. has an abnormal pelvic exam finding that is exclusionary, per protocol
- 2aa. is diagnosed with a current STI and/or other RTI requiring treatment according to CDC guidelines
- 2ab. has a history of non-therapeutic injection drug use in the 12 months prior to enrollment
- 2ac. participated in another study that uses spermicides, vaginal microbicides, or any other device or drug in the 30 days prior to enrollment
- 2ad. has had vaginal sex more than an average of 2 times per day in the 2 weeks prior to screening
- 2ae. is breastfeeding
- 2af. exceeded the 56-day screening window
- 2ag. has any other condition that, in the opinion of the Investigator or designee, would preclude provision of informed consent, make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives

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## Screening Summary – 2 (nonDF)

### Item-specific Instructions:

- **Item 2u:** Review Screening Eligibility form, item 2; *and* Screening and Enrollment Log.
- **Item 2v:** Review Safety Laboratory Results form, items 1–4 from the Screening Visit.
- **Item 2w:** Review Screening Eligibility form, items 14 and 14a; *and* Enrollment Eligibility form, item 5.
- **Item 2x:** Review Screening Eligibility form, item 24; *and* Enrollment Eligibility form, item 11.
- **Item 2y:** Review Screening Eligibility form, items 13 and 13a; *and* Enrollment Eligibility form, item 7.
- **Item 2z:** Review Screening and Enrollment Pelvic Exam forms, items 1 and 2, from both the Screening and Enrollment Visits; **and** the Clinical Eligibility forms, item 2, from both the Screening and Enrollment Visits.
- **Item 2aa:** Review Clinical Eligibility forms, item 1, from both the Screening and Enrollment Visits.
- **Item 2ab:** Review Screening Eligibility form, items 15 and 15a; *and* Enrollment Eligibility form, item 8.
- **Item 2ac:** Review Screening Eligibility form, items 16 and 16a; *and* Enrollment Eligibility form, item 2.
- **Item 2ad:** Review Screening Eligibility form, item 11.
- **Item 2ae:** Review Screening Eligibility form, item 8; *and* Enrollment Eligibility form, item 4.
- **Item 2af:** Review Screening Consent form, item 2a; *and* date of enrollment as recorded on the Enrollment form.
- **Item 2ag:** Review Enrollment Eligibility form, item 12.

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HPTN 059 Ph II Microbe (113)

Participant ID

Participant ID form with Site Number, Participant Number, and Chk fields.

Enrollment Eligibility

Form Completion Date

Form Completion Date form with dd, MMM, and yy fields.

Complete item 1 before the interview.

1. Was the participant willing and able to provide a written informed consent for enrollment (as assessed by a site-specific assessment of comprehension)?

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

- 2. In the past month (30 days), have you participated in any study that uses spermicides, vaginal microbicides, or any other device or drug?
3. In the past 30 days, have you inserted an intrauterine device (IUD)?
4. Are you breastfeeding?
5. In the past 3 months (90 days), have you had any gynecological surgery?
6. Are you currently taking, or do you plan to take tenofovir (Viread), adefovir (Hepsera), or any other chronic hepatitis B medication while participating in this study?
7. In the past 3 months (90 days), have you given birth, or had a miscarriage or abortion?
8. In the past year (12 months), have you used a needle to inject drugs that were not prescribed to you by a medical professional?
9. Are you willing to undergo all study evaluations, including a pelvic exam, colposcopy (when a clinician looks inside your vagina with a magnifying instrument), urine testing, and blood draws?
10. Have you been without menstrual periods for the past 12 months?
10a. Is it because of the birth control you are using, such as Depo-Provera or Norplant?

Complete item 11 when enrollment urine HCG result is available.

11. Is the participant pregnant?
Complete item 12 after reviewing all Screening forms.

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

---

## Enrollment Eligibility – 1 (nonDF)

*This form is used to document the participant's eligibility for the study at enrollment. This is a mixed form—some of the items are interviewer-administered (items 2–10a), while other items are not (items 1 and 11-12). 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 Eligibility form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 13.5 of the Study-Specific Procedures Manual for detailed interviewing techniques.*

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

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

### Item-specific Instructions:

- **Item 1:** This item is NOT interviewer-administered and should not be read aloud to the participant.
- **Items 2–10a:** These items were also asked during the Screening visit. They must be asked again in order to confirm the participant's eligibility for the study per the inclusion/exclusion criteria stated in the protocol. If the participant provides a response indicating that she is ineligible for the study, continue to administer this form through item 10a. 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 11:** This item is NOT interviewer-administered and should not be read aloud to the participant. Record the Enrollment Visit urine hCG result here.
- **Item 12:** This item is NOT interviewer-administered and should not be read aloud to the participant. This item should be completed by the site investigator or his/her designee once the Screening Visit has been completed. If, for some reason other than those listed on any of the screening forms, the investigator or designee feels the participant is **not** a good candidate for the study, mark the “yes” box, record the reason in the participant's chart notes, and do not enroll the participant in the study.



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**Participant ID**

Site Number			Participant Number						Chk	

**Baseline Medical History**

**Visit Date**

dd		MMM		yy	

			<i>If yes, date diagnosed</i>		<i>Description:</i>	<i>Ongoing?</i>	
	yes	no	MMM	yy		yes	no
HE (head/eyes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
ENT (ears/nose/throat)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Liver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Renal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Endocrine/Metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Hematologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Drug allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Other allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
<i>If yes to any at the time of enrollment, record on Pre-existing Conditions form.</i>							
Alcohol use	<input type="checkbox"/>	<input type="checkbox"/>	_____			<input type="checkbox"/>	<input type="checkbox"/>
Drug use	<input type="checkbox"/>	<input type="checkbox"/>	_____			<input type="checkbox"/>	<input type="checkbox"/>

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## Baseline Medical History – 1 (nonDF)

*This form is used to document a participant's baseline medical history, prior to randomization. It is first completed at the initial Screening 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 Section 13.3.2 of the Study-Specific Procedures Manual 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:

- **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.
- **Description:** Provide a description of each reported diagnosis in the space provided.
- **Ongoing?:** For each organ system/disease marked “yes,” determine if the diagnosed condition 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.
- **Alcohol use:** Record information about the participant's current level of alcohol use.
- **Drug use:** Record information about the participant's current level of recreational drug use.

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

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HPTN 059 Ph II Microbe (113)

Participant ID

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

Baseline Medical History

Menstrual History

Usual menstrual cycle: .....  *regular*       *irregular*

Usual length of menstrual cycle (days): .....  # of days

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

Age of menarche: .....  years

First day of last menstrual period: .....  *dd*       *MMM*       *yy*      } *amenorrheic*

Last day of last menstrual period: .....                   } **OR**

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

Usual menstrual symptoms (document type and severity, if any): \_\_\_\_\_

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

Reproductive history: \_\_\_\_\_

History of contraception/family planning use: \_\_\_\_\_

Additional Notes: \_\_\_\_\_

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## Baseline Medical History – 2 (nonDF)

### Item-specific Instructions:

- **Usual length of menstrual cycle (days):** Record the average number of days between the start dates of two consecutive menstrual cycles. If the participant is amenorrheic, refer to her previous menstrual cycles that occurred prior to the amenorrhea.
- **Usual number of bleeding days:** Record as a range the average number of days (minimum and maximum) the participant reports bleeding during her menses. If the participant is amenorrheic, refer to her previous menstrual cycles that occurred prior to the amenorrhea.
- **Age of menarche:** Record the participant's age of first menstrual period.
- **First day of last menstrual period:** Record the first day of the participant's last menstrual period. Use a calendar to probe for the day, month, and year.
- **Last day of last menstrual period:** Record the last day of the participant's last menstrual period. Use a calendar to probe for the day, month, and year.
- **amenorrheic:** Mark "amenorrheic" if the participant has been without menses for at least the past three cycle intervals or the past six months, whichever is shorter. If "amenorrheic" is marked, leave the "First day of last menstrual period" and "Last day of last menstrual period" boxes blank.
- **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.
- **Reproductive history:** Record the total number, date, and outcome (for example, full-term live birth, premature live birth, spontaneous abortion, etc.) of each of the participant's pregnancies. This should include any gynecologic and obstetrical procedures/surgeries.
- **History of contraception/family planning use:** Record the method(s) of contraception/family planning the participant reports using in the past and currently. If the participant reports current use of hormonal contraception, be sure to record the hormonal contraception on the participant's Concomitant Medications Log.
- **Additional Notes:** Record any necessary or additional information at the bottom of the form.

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

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**Participant ID**

Site Number			Participant Number						Chk	

**History of Genital Symptoms**

**Visit Date**

dd		MMM		yy	

Genital Symptoms	If yes, onset date/ date diagnosed		Description:	Ongoing?		
	yes	no		MMM	yy	yes
Genital sores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genital/vaginal itching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genital/vaginal burning	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Genital/vaginal pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pain during sex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty when urinating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Burning when urinating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abnormal or unusual genital/ vaginal discharge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unusual genital/ vaginal odor	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abnormal or unusual menstrual cramping (dysmenorrhea)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other genital symptoms	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vaginal bleeding or spotting between usual menstrual periods	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Blood-tinged discharge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

*If yes to any evaluate for STIs/RTIs.* ←

Additional Notes: \_\_\_\_\_

13-173

28-JUN-06

Language

Staff Initials / Date

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## History of Genital Symptoms – 1 (nonDF)

*This form is used to document a participant's history of genital symptoms at the Screening Visit. If the Screening Visit occurs over multiple days, be sure to update this form at each visit related to the same screening attempt. 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 History of Genital Symptoms form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 of the Study-Specific Procedures Manual 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:** *Responses to all of the items on this form are based on participant recall at the time of the Screening Visit. Once the participant has completed the Screening Visit, do not make any further updates or changes to the responses recorded on this form.*

### Item-specific Instructions:

- **yes/no:** For each genital symptom listed, mark the “yes” box if the participant reports having experienced that symptom **since becoming sexually active**. Mark the “no” box for symptoms not reported.
- **If yes, onset date/date diagnosed:** For each symptom marked “yes,” record the month and year the participant began experiencing symptoms.
- **Description:** Provide a description of each reported symptom in the space provided.
- **Ongoing?:** For each symptom marked “yes,” determine if the symptom/condition is ongoing or resolved. Mark the “yes” box if the condition is ongoing (not resolved), and “no” if the condition is resolved. If the response is “yes,” evaluate for STIs/RTIs per the protocol and SSP. If the participant is diagnosed with an STI/RTI that is exclusionary per protocol, do **not** enroll the participant. Provide treatment as necessary (per CDC guidelines) and do not enroll the participant until such treatment is completed and any associated symptoms have resolved.

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

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**Participant ID**

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

Site Number      Participant Number      Chk

**Physical Exam**

**Exam Date**

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

dd      MMM      yy

**VITAL SIGNS**

Staff Initials / Date

Weight	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> kg <b>or</b> <input type="checkbox"/> lbs	BP	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	mmHg
Height	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> cm <b>or</b> <input type="checkbox"/> in	Pulse	<input type="text"/>		<input type="text"/>	<input type="text"/>	per minute
Oral Temp	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> °C <b>or</b> <input type="checkbox"/> °F	Respirations	<input type="text"/>		<input type="text"/>	<input type="text"/>	per minute

**FINDINGS**

Staff Initials / Date

*not evaluated*    *normal*    *abnormal*    **→ If items 1–11 not evaluated or abnormal, please specify.**

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	1. HE (head/eyes) _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	2. ENT (ears/nose/throat) _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	3. Neck _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	4. Lymph Nodes _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	5. Heart _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	6. Lungs _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	7. Abdomen _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	8. Extremities _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	9. Neurological _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	10. Skin _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	11. Breast Exam _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	12. Other, specify: _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	13. Other, specify: _____
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	14. Other, specify: _____

**→ If abnormal and ongoing for any at Enrollment, record on Pre-existing Conditions form.**

Comments: \_\_\_\_\_

---

## Physical Exam (nonDF)

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

***Note:** If a participant is being re-screened, a new Physical Exam form must be completed as part of the subsequent screening attempt. See Section 13.3.2 of the Study-Specific Procedures Manual for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

- **Vital Signs:** When recording weight, height, oral temp, blood pressure (BP), pulse, and respirations, remember to use leading zeros when needed. Mark the correct units box for weight, height, and oral temperature values. The staff member who completes these items should initial and date in the space provided next to "Vital Signs."
- **Findings:** The staff member who completes these items should initial and date in the space provided next to "Findings."
- **Items 1–11:** For each item marked "not evaluated" or "abnormal," specify the reason the organ system was not evaluated (since evaluation of all listed organ systems is required) or was abnormal in the space provided. Record any abnormalities ongoing at Enrollment on the participant's Pre-existing Conditions form.
- **Items 12–14:** Use these items to list any additional organ systems that were evaluated. If no other organ systems other than the ones listed in items 1-11 were evaluated, mark items 12–14 as "not evaluated." Record any abnormalities ongoing at Enrollment on the participant's Pre-existing Conditions form.



**This is not a DataFax form. Please do not fax to DataFax.**

HPTN 059 Ph II Microbe (113)

Page 1 of 1

**Participant ID**

-      -   
 Site Number                  Participant Number                  Chk

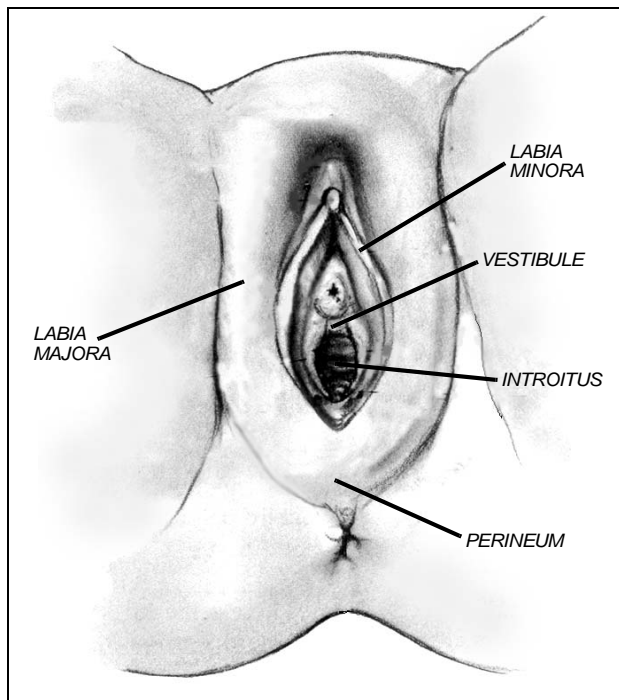
**Pelvic Exam Diagrams**

no normal variants or abnormal findings observed

**Exam Date**

/    /    
 dd                  MMM                  yy

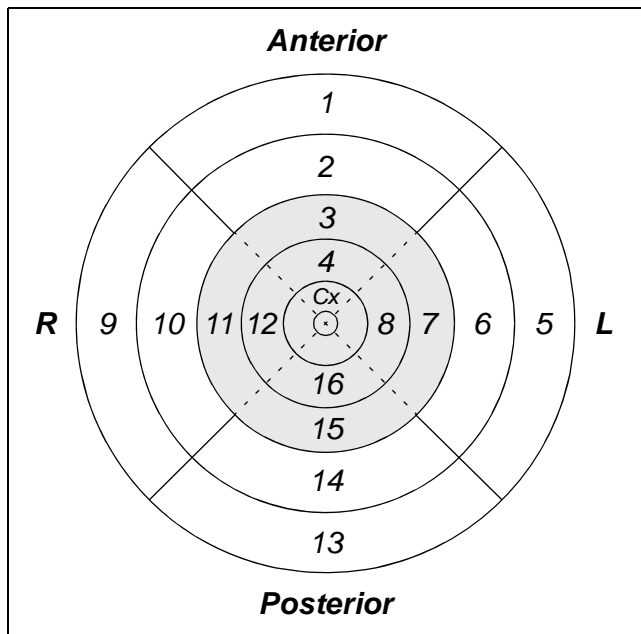
**External Genitalia**



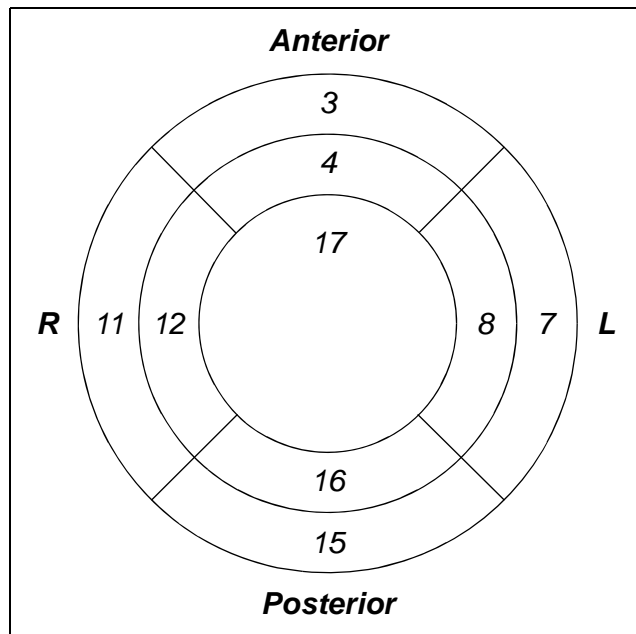
**Legend for Vagina/Cervix**

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

**Vagina**



**Cervix**



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## **Pelvic Exam Diagrams (nonDF)**

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

### **Item-specific Instructions:**

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

**This is not a DataFax form. Please do not fax to DataFax.**

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Page 1 of 2

**Participant ID**

Site Number			Participant Number						Chk	

**Follow-up Medical History**

**Visit Date**

dd		MMM		yy	

			<i>If yes, onset date</i>			<i>OR continuing from previous visit</i>	<i>Description:</i>
	yes	no	dd	MMM	yy		
HE (head/eyes)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
ENT (ears/nose/throat)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Lymphatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Liver	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Renal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Endocrine/Metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Hematologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Cancer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Drug allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Other allergy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	_____

➔ *If yes to any, update or complete Adverse Experience Log when applicable.*

Alcohol use	<input type="checkbox"/>	<input type="checkbox"/>	_____
Drug use	<input type="checkbox"/>	<input type="checkbox"/>	_____

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## Follow-up Medical History – 1 (nonDF)

*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 (Week 4 through Week 24 for non-CHBV participants, and Week 4 through Week 36 for CHBV participants). 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.*

*If you need additional space for notation, use the space provided at the bottom of page 2.*

**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.
- **Description:** Provide a description of each observed/reported condition in the space provided. Provide a diagnosis along with reported symptoms whenever possible. If the condition is continuing from a previous visit, use the same text to describe the condition.
- **Alcohol use:** Record information about the participant's current level of alcohol use. If there have been no changes since the previous visit record "no changes."
- **Drug use:** Record information about the participant's current level of drug use. If there have been no changes since the previous visit record "no changes."
- **If yes to any, update or complete Adverse Experience Log when applicable:** For each item marked as "yes," complete an Adverse Experience (AE) Log form if this is the **first** time the condition has been reported since the participant enrolled in the study. If this is **not** the first time the condition has been reported since enrollment, an AE Log form should already have been completed for this condition—review the previously completed AE Log form and either update any relevant information, or complete a new AE Log form 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 form—do record on this form that the condition has not increased in severity or frequency since enrollment/baseline.

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

# This is not a DataFax form. Please do not fax to DataFax.

HPTN 059 Ph II Microbe (113)

### Participant ID

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

### Follow-up Medical History

### Menstrual Information

	<i>dd</i>	<i>MMM</i>	<i>yy</i>	} →	<b>OR</b>	<input type="checkbox"/>	↓	If amenorrheic, is it due to an unexpected or unknown cause?				
First day of last menstrual period:	<input type="text"/>	<input type="text"/>	<input type="text"/>						<b>yes</b>	<input type="checkbox"/>	<b>no</b>	<input type="checkbox"/>
Last day of last menstrual period:	<input type="text"/>	<input type="text"/>	<input type="text"/>									

After review of previous menstrual information, is pregnancy likely?

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

↓

**If yes, perform pregnancy test.**

Reproductive history: \_\_\_\_\_

\_\_\_\_\_

Additional Notes: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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## Follow-up Medical History – 2 (nonDF)

### Item-specific Instructions:

- **Menstrual Information**
  - **First day of last menstrual period:** Record the first day of the participant's last menstrual period. Use a calendar to probe for the day, month, and year.
  - **Last day of last menstrual period:** Record the last day of the participant's last menstrual period. Use a calendar to probe for the day, month, and year.
  - **amenorrheic:** Mark "amenorrheic" if the participant has been without menses for at least the past three menstrual cycles or the past six months, whichever is shorter. If "amenorrheic" is marked, leave the "First day of last menstrual period" and the "Last day of last menstrual period" boxes blank and provide a response to the question, "If amenorrheic, is it due to an unexpected or unknown cause?" Amenorrhea that occurs during study follow-up (in other words, is not present at baseline), should be reported as an adverse experience on an AE Log form if it is due to an unexpected or unknown cause.
  - **Is pregnancy likely?:** Review previous menstrual information to determine if the participant may be pregnant. If, based on this information, it is likely the participant may be pregnant, mark the "yes" box to item "After review of previous menstrual information, is pregnancy likely?" and perform a urine pregnancy test if not already done.
- **Reproductive History:** Record any relevant information on the participant's pregnancy or reproductive history since her last follow-up visit.
- **Additional Notes:** Record any necessary or additional information at the bottom of the form.

**DO NOT FAX THIS FORM TO DATAFAX**

# HPTN 059

## LDMS Specimen Tracking Sheet

Group: HPTN

Visit Code

Participant ID:

-  -   
 Site Number Participant Number Chk

Specimen Collection Date

dd MMM yy

Protocol #: 059.0

# of TUBES (or Specimens)	PRIMARY SPECIMEN TYPE	ADDITIVE
<input type="checkbox"/>	Vaginal Gram Stain Slide (VAG)	<input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____
<input type="checkbox"/>	Cervical Gram Stain Slide (CXS)	<input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____
<input type="checkbox"/>	Cervical Swab (CXS)	<input type="checkbox"/> PBS <input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____
<input type="checkbox"/>	<b>U.S. Only:</b> Vaginal Swab (VAG)	<input type="checkbox"/> PAC <input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____
<input type="checkbox"/>	GUD Swab (GLU)	<input type="checkbox"/> Viral Transport Medium (VTM) <input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____
<input type="checkbox"/>	Blood (BLD)	<p><i>If more than one additive is used, write in each box the number of tubes collected for each additive.</i></p> <p><input type="checkbox"/> SST <input type="checkbox"/> EDT <input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____</p> <p>Plasma aliquot instructions:  <input type="checkbox"/> Screening specimen—lab to make at least two (2) 1.0 mL aliquots  <input type="checkbox"/> Enrollment specimen—lab to make at least five (5) 1.0 mL aliquots  <input type="checkbox"/> Follow-up specimen—lab to make at least four (4) 0.75 mL aliquots</p> <p>Serum aliquot instructions:  <input type="checkbox"/> Enrollment and follow-up specimen—lab to make at least four (4) 1.0 mL aliquots</p>
<input type="checkbox"/>	Other, specify : _____	<input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____

Comments: \_\_\_\_\_

Clinic Staff Initials: \_\_\_\_\_  
Sending Staff

LDMS Data Entry Date:   /   
dd MMM yy

13-183  
Receiving Staff

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## LDMS Specimen Tracking Sheet (non-DataFax)

*This form documents entry of specimens into the Laboratory Data Management System (LDMS). Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax. Please see the "Laboratory Procedures" section of this SSP for information on what specimens get collected at each study visit, which specimens get entered into LDMS, and how this form is used by the site and the site's LDMS laboratory once it has been completed.*

*This form is completed by clinic study staff. The form accompanies the LDMS specimens in their original collection containers to the site's LDMS laboratory, where it is used to enter the LDMS specimens into LDMS. Once the specimens have been entered into LDMS, this form is kept on file at the local laboratory. If the site chooses, a copy of this completed form may be made (once the specimens have been entered into LDMS) and the copy kept in the participant's study notebook.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code of the visit at which the LDMS specimens were collected.
- **# of Tubes (or Specimens):** For each primary specimen type collected, record the # of tubes or specimens of that primary type that were collected in the corresponding box. For example, if two Vaginal Gram Stain slides were collected, write "2" in the corresponding "# of TUBES (or Specimens)" box. If a primary specimen type is not collected, leave the "# of TUBES (or Specimens)" box and the corresponding additive boxes blank.
- **Additive:** A response is required for each primary specimen type collected. If a primary specimen type was collected but no additional additive was used, please mark "No additive." If an additive was used but is not one of the categories listed, please mark "Other, specify:" and write in the name of the additive used on the adjacent line. If no tubes/specimens were collected for a given primary specimen type, please leave the corresponding "Additive" boxes blank.
  - **Blood (BLD):** If blood is collected in tubes containing different additives (e.g., SST and EDTA tubes), record the number of tubes collected for each additive in the appropriate additive box. For example, if two SST tubes and two EDTA tubes of blood were collected, write "2" in the "SST" box and "2" in the "EDT" box. If blood was collected but a particular additive was not used, leave the additive box blank. For example, if two SST tubes and no other blood tubes were collected, write "2" in the "SST" box and leave the "EDT," "No Additive," and "Other, specify" boxes blank. If blood is collected for plasma and /or serum, refer to the Plasma aliquot and Serum aliquot instructions listed below the blood additives. Mark the box corresponding to the appropriate visit and aliquot instructions. For example, if blood was collected for the Enrollment Visit, mark "Enrollment specimen-lab to make at least five (5) 1.0 mL aliquots" under Plasma aliquot instructions, and mark "Enrollment and follow-up specimen-lab to make at least four (4) 0.75 mL aliquots" under Serum aliquot instructions.
- **Comments:** Record any important information regarding the specimens listed on this form.
- **Clinic Staff Initials:** The clinic staff person who completed the form and/or who is sending the LDMS form and specimens to the LDMS entry lab records his or her initials here.
- **LDMS Data Entry Date:** Record the date the specimens listed on this form were entered into LDMS.
- **Receiving Staff:** The LDMS laboratory staff person who received this form (and the LDMS specimens accompanying this form) records his or her initials here.