

## Section 13. Data Collection

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*For questions about this section or about general data collection policies, procedures, or materials, please contact both Corey Leburg <corey@scharp.org> and Missy Cianciola <missy@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 035 forms.*

NOTE: Effective with Version 2.0 of this section, prior references to the HIV Prevention Trials Network (HPTN) have been replaced where applicable with references to the Microbicide Trials Network (MTN).

### 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).

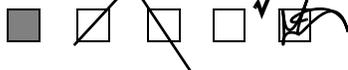
### 13.2.2 How to Mark Response Boxes

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:

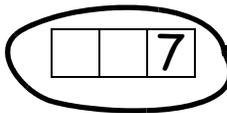
- Right justify **all** numbers and fill in any blank leading boxes with zeroes. If boxes are left blank, a QC note will be applied asking for the boxes to be filled in.

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 Round Laboratory Values

For some lab results the values received from the testing lab have more digits than what is provided on the CRFs. In these cases one must “round” the lab values in order to record them on the CRFs. For example, the lab may report a value of 1.82, but the form only allows one to record X.X. When recording laboratory results on CRFs, the rule for rounding is as follows:

- If the number ends in 0 through 4 then you round down.
- If the number ends in 5 through 9 then you round up.

For example, if the lab value is 1.80, 1.81, 1.82, 1.83, or 1.84 the recorded value will be 1.8. However, if the lab value is 1.85, 1.86, 1.87, 1.88, or 1.89 the recorded value will be 1.9.

### 13.2.5 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>	

### 13.2.6 How to Record Time

Time is recorded on DataFax CRFs using the 24-hour clock, 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

### 13.2.7 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.

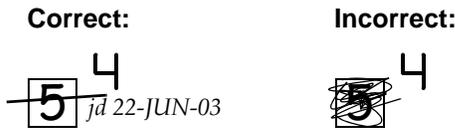
**Note:** If a correction or addition is made to one page of a multiple-page CRF, only refax the page that was changed.

**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:

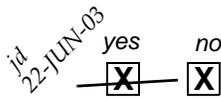
- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it unreadable with multiple cross-outs),
- place the correct or clarified answer near the box, and

- initial and date the correction as shown below:



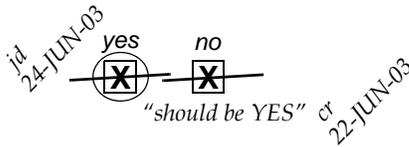
If an **X** is marked in the wrong response box, correct it by doing the following:

- 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:



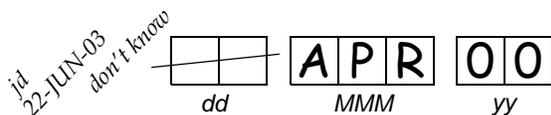
**Note:** The standards above must *always* be followed whenever a CRF is changed, clarified, or amended, even if the change is made *before* the CRF is faxed to SCHARP for the first time.

**Note:** When making corrections or additions to case report forms, sometimes it is necessary to write corrected or new information in white space on the form that is not directly adjacent to the original entry. In such cases, it is allowable to use arrows to link the corrected/new information to the original entry.

### 13.2.8 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.

## 13.3 HPTN 035 Study-Specific Data Collection Information

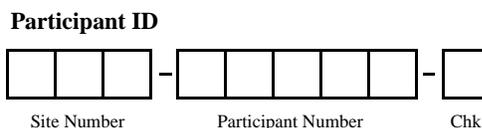
### 13.3.1 Participant ID numbers (PTIDs)

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 this study, each PTIDs are assigned during the Screening Part 1 visit. SCHARP will furnish each site with a list of PTIDs before the start of the study. When a participant comes for a Screening Part 1 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 035.



### 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 30 calendar days to complete screening and enrollment procedures, the visit dates/specimen collection dates on forms completed at Screening Part 1, Screening Part 2, and Enrollment may be different from each other. As stated in Section 4, the 30-day screening attempt “clock” starts on and includes the day the consent form for screening is signed or marked by the participant. All Screening Part 1, Screening Part 2, and Enrollment forms completed during the 30-day screening period are considered the same screening attempt, and the same Screening Attempt box should be marked on each of the forms completed during that 30-day screening period.

#### 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 (Monthly and Quarterly visits)

Required follow-up visits are regularly scheduled throughout the study follow-up period on the monthly anniversary dates of participants’ study enrollment dates. For example, for a participant enrolled on

September 15, follow-up visits will be targeted to take place on October 15, November 15, December 15, etc. For participants enrolled on the last day of a month with 31 days, follow-up visits will be targeted to take place on the last day of all subsequent months (e.g., February 28, April 30, June 30, September 30, November 30). Visits may be completed within a four-week window around the target date (i.e.,  $\pm 2$  weeks from the target date).

A Monthly or Quarterly follow-up visit is considered “missed” when a participant does not complete any of the required visit evaluations within the study visit window. The “missed” visit is documented using a Missed Visit form.

### **Interim Visits**

A clinic visit is considered an Interim Visit in the following two cases.

1. A participant reports to the clinic on a date that is OUTSIDE of any visit window.
  - Example: A participant’s target visit date is October 15, with a visit window from October 1–29. She comes to the clinic on October 31. She is past the October visit window, but is not yet in the November visit window (= November 1-29).
2. A participant completes all required evaluations at her scheduled study visit. She returns to the clinic within the same visit window for additional clinical follow-up and/or for more gel supplies.
  - Example: Her target visit date is October 15. She completes all required evaluations for the October visit on October 7. On October 23, she returns to the clinic to get additional gel supplies. Since October 23 is within the October visit window (= October 1-29), and she has already completed all required visit evaluations, the October 23 visit is an Interim Visit. You cannot perform any November visit evaluations since the November visit window (= November 1-29) has not yet opened.

Under certain circumstances phone contact with a participant may be considered an Interim Visit. If a participant does not present to the study clinic within the visit window, the visit is a missed visit and a Missed Visit form is completed. If any phone contacts were made during the participant’s missed visit window and DataFax data is collected during the phone call (for example, the participant reports a new AE), the phone call is documented as an interim visit using an Interim Visit form. Phone calls alone are not documented using the Monthly or Quarterly Visit form - only an Interim Visit form.

- Example: Her target visit date is October 15. She completes all required evaluations for the October visit on October 7. On October 29, she calls the clinic to report new symptoms which result in report of a new adverse experience. Since October 29 is within the October visit window (= October 1-29), and she has already completed all required visit evaluations, the October 29 phone contact is assigned an Interim Visit code.

For questions about missed visits, phone contacts and assignment of visit codes to such contacts, please contact the SCHARP HPTN 035 Project Managers (PMs).

### **13.3.3 Visit Codes and Page Numbers**

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

HPTN 035 has thirty-two scheduled study visits. When visit code boxes are provided, site staff are responsible for entering the visit code in the boxes provided at the top 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 Part 1	Up to Day -30	01.0
Screening Part 2	Day 0	02.0
Enrollment	Day 0	02.0
Monthly Follow-up	Month 1	03.0
Monthly Follow-up	Month 2	04.0
Quarterly Follow-up	Month 3	05.0
Monthly Follow-up	Month 4	06.0
Monthly Follow-up	Month 5	07.0
Quarterly Follow-up	Month 6	08.0
Monthly Follow-up	Month 7	09.0
Monthly Follow-up	Month 8	10.0
Quarterly Follow-up	Month 9	11.0
Monthly Follow-up	Month 10	12.0
Monthly Follow-up	Month 11	13.0
Quarterly Follow-up	Month 12	14.0
Monthly Follow-up	Month 13	15.0
Monthly Follow-up	Month 14	16.0
Quarterly Follow-up	Month 15	17.0
Monthly Follow-up	Month 16	18.0
Monthly Follow-up	Month 17	19.0
Quarterly Follow-up	Month 18	20.0
Monthly Follow-up	Month 19	21.0
Monthly Follow-up	Month 20	22.0
Quarterly Follow-up	Month 21	23.0
Monthly Follow-up	Month 22	24.0
Monthly Follow-up	Month 23	25.0
Quarterly Follow-up	Month 24	26.0
Monthly Follow-up	Month 25	27.0
Monthly Follow-up	Month 26	28.0
Quarterly Follow-up	Month 27	29.0
Monthly Follow-up	Month 28	30.0
Monthly Follow-up	Month 29	31.0
Quarterly Follow-up	Month 30	32.0

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

In cases when a participant absolutely cannot complete all required Quarterly 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 and schedule the participant for a visit to conduct the remaining required evaluations as soon as possible and within the visit window. Note that when the participant returns to complete part of the required evaluations, this is still considered part of her regular Quarterly visit (if the visit occurs within that visit window), and, therefore, any required Quarterly visit evaluations performed at this visit are assigned the same Visit Code as the Quarterly visit.

- Example 1: Her Month 9 target date is June 22 (visit window is June 8 - July 6). The participant reports to the clinic on June 18, but she is menstruating. On June 18 (Visit Code = 11.0), all Quarterly visit evaluations except the pelvic exam and pelvic laboratory assays are completed. The participant is instructed to come back to the clinic on June 21 (when she will not be menstruating) to complete the required pelvic exam and pelvic laboratory assays. The forms completed at the June 21 visit are assigned the same Visit Code as the June 18 forms (11.0).

### Visit codes for interim visits

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

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

Example #1: A participant returns to the site two days after her completed Month 3 visit (Visit Code = 05.0). She is not yet in her Month 4 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 Month 4 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 035 Form Completion Schedule**

Visit	Timing	Visit Code	Forms	Form Acronym
Screening Part 1	Day -30	automatic 1.0	Screening Consent Demographics Site-Specific Demographics (non-DataFax) Screening Part 1 Eligibility Screening Part 1 Laboratory Results Screening Safety Laboratory Results	SC-1 DM-1 thru DM-2 DM_-1 N/A 2 pages SLR-1 thru SLR-2 SSL-1 thru SSL-2
Screening Part 2	Day 0 (can be anytime between Day-30 and Day 0)	automatic 2.0	(non-DataFax) Screening Part 2 Eligibility (non-DataFax) Baseline Medical History (non-DataFax) Physical Exam (non-DataFax) Pelvic Exam Diagrams Screening Pelvic Exam Screening Part 2 Laboratory Results (non-DataFax) Clinical Eligibility (non-DataFax) Screening Summary (non-DataFax) Specimen Tracking Sheet	N/A N/A 2 pages N/A N/A SPE-1 ELR-1 thru ELR-2 N/A N/A N/A
Enrollment	Day 0	automatic 2.0	Enrollment Concomitant Medications Log Enrollment Behavior Assessment Pre-existing Conditions  <i>Select sites only:</i> Pap Test Result  <i>Participants assigned to study gel only - completed and stored by pharmacy staff:</i> Pharmacy Randomization	ENR-1 CM-1 EBA-1 thru EBA-4 PRE-1  PTR-1  PHR-1
Monthly	Month 1, 2, 4, 5, 7, 8, 10, 11, 13, 14, 16, 17, 19, 20, 22, 23, 25, 26, 28, 29	= Study Month + 2.0	Monthly or Quarterly Visit (non-DataFax) Follow-up Medical History  <i>Phase II participants only, Months 1 and 2 only:</i> Safety Laboratory Results (non-DataFax) Pelvic Exam Diagrams Pelvic Exam Pelvic Laboratory Results	MQV-1 N/A 2 pages  SL-1 thru SL-2 N/A PE-1 PLR-1

**Table 13-2: HPTN 035 Form Completion Schedule**

Visit	Timing	Visit Code	Forms	Form Acronym
Quarterly	Month 3, 6, 9, 12, 15, 18, 21, 24, 27	= Study Month + 2.0	<p>Monthly or Quarterly Visit (non-DataFax) Follow-up Medical History Follow-up Laboratory Results (non-DataFax) Pelvic Exam Diagrams Pelvic Exam Pelvic Laboratory Results Follow-up Behavior Assessment (non-DataFax) Specimen Tracking Sheet</p> <p><i>All participants, Month 3 only:</i> Acceptability Assessment Safety Laboratory Results</p> <p><i>All participants, Months 12 and 24 only:</i> Safety Laboratory Results</p> <p><i>Select sites only, last Quarterly only:</i> Pap Test Result</p>	<p>MQV-1 N/A 2 pages FLR-1 N/A PE-1 PLR-1 FBA-1 thru FBA-6 N/A</p> <p>AA-1 thru AA-2 SL-1 thru SL-2</p> <p>SL-1 thru SL-2</p> <p>PTR-1</p>
Study Exit	Will Vary	Will Vary	<p>Monthly or Quarterly Visit (non-DataFax) Follow-up Medical History Follow-up Laboratory Results Follow-up Behavior Assessment Safety Laboratory Results Study Exit Acceptability Assessment Termination End of Study Inventory (non-DataFax) Specimen Tracking Sheet</p> <p><i>Participants assigned to study gel only:</i> Product Hold/Discontinuation</p>	<p>MQV-1 N/A 2 pages FLR-1 FBA-1 thru FBA-6 SL-1 thru SL-2 SAA-1 thru SAA-2 TM-1 ESI-1 N/A</p> <p>PH-1</p>
If Indicated	Will Vary	Will Vary	<p>Repeat Screening Pelvic Exam Adverse Experience Log Interim Visit Product Hold/Discontinuation (non-DataFax) Genital Bleeding Assessment HIV Test Results HSV-2 Test Result Pregnancy Report and History Pregnancy Outcome Missed Visit Participant Transfer Participant Receipt Enrollment Specimen HIV Status Ongoing Informed Consent Comprehension</p>	<p>RPE-1 AE-1 IV-1 PH-1 N/A 3 pages HTR-1 HSR-1 PR-1 PO-1 MV-1 PT-1 PRC-1 ESS-1 ICC-1</p>

### 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.

**Important:** Use *only* the back of the CRF for a date stamp, *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

Forms can be directly faxed to SCHARP using the following email address: <datafax@scharp.org>.

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 035 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 035 study visit.

For sites wishing to confirm the receipt of faxed forms at SCHARP, the CRF Tracking System (CTS) is available. This system requires the site to use special cover pages (distributed by SCHARP) when faxing forms to SCHARP DataFax. When such cover pages are used, sites will receive a confirmation email confirming how many form pages were received at SCHARP. 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 035 Project Managers if you would like to use the CRF Tracking System or for more information about the CRF Tracking System.

Table 13-3: HPTN 035 DataFAX Form Transmission Schedule

Visit	Required DataFAX Forms
Screening Part 1	None—Screening Part 1 DataFAX forms for the <b>successful</b> screening attempt are faxed only once the participant has enrolled and the Enrollment visit has been completed
Screening Part 2	None—Screening Part DataFAX forms for the <b>successful</b> screening attempt are faxed only once the participant has enrolled and the Enrollment visit has been completed
<p>Enrollment</p> <p><i>Forms marked with * should all have the same Screening Attempt box marked for a given participant.</i></p>	<p><i>Enrolled participants only:</i></p> <ul style="list-style-type: none"> <li>*Screening Consent</li> <li>*Demographics</li> <li>*Site-Specific Demographics</li> <li>*Screening Part 1 Laboratory Results</li> <li>*Screening Safety Laboratory Results</li> <li>*Screening Pelvic Exam</li> <li>*Screening Part 2 Laboratory Results</li> </ul> <p>Enrolment</p> <p>Pre-existing Conditions</p> <p>Enrollment Behavior Assessment</p> <p><i>Select sites only:</i></p> <p>Pap Test Result</p> <p><i>Participants assigned to study gel only; completed and faxed by pharmacy staff:</i></p> <p>Pharmacy Randomization</p>
Monthly	<p>Monthly or Quarterly Visit</p> <p><i>Phase II participants only, Months 1 and 2 only:</i></p> <ul style="list-style-type: none"> <li>Safety Laboratory Results</li> <li>Pelvic Exam</li> <li>Pelvic Laboratory Results</li> </ul>
Quarterly	<p>Monthly or Quarterly Visit</p> <ul style="list-style-type: none"> <li>Follow-up Laboratory Results</li> <li>Pelvic Exam</li> <li>Pelvic Laboratory Results</li> <li>Follow-up Behavior Assessment</li> </ul> <p><i>All participants, Month 3 only:</i></p> <ul style="list-style-type: none"> <li>Acceptability Assessment</li> <li>Safety Laboratory Results</li> </ul> <p><i>All participants, Months 12 and 24 only:</i></p> <ul style="list-style-type: none"> <li>Safety Laboratory Results</li> </ul> <p><i>Select sites only, last Quarterly Visit only:</i></p> <ul style="list-style-type: none"> <li>Pap Test Result</li> </ul>

Visit	Required DataFax Forms
Study Exit	Monthly or Quarterly Visit Follow-up Laboratory Results Follow-up Behavior Assessment Safety Laboratory Results Study Exit Acceptability Assessment Termination Concomitant Medications Log End of Study Inventory HSV-2 Test Result  <i>Participants assigned to study gel only (form kept in the Pharmacy):</i> Product Hold/Discontinuation
Interim Visits	Interim Visit

### 13.3.8 Non-DataFax Forms

HPTN 035 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 collated visit packets for Screening Part 1, Screening Part 2, Enrollment, Monthly, Quarterly, and Study Exit. Each packet includes a cover page which lists all the forms included in the packet. Additionally, each site will be supplied with packages of “as needed” batch forms (such as Missed Visit, Interim Visit, AE Log, HIV Test Results, etc.), to be used for any participant during the study.

After each site receives the initial form supply, each site will be responsible for ordering all future shipments through SCHARP using the CRF Request form. Please note that for a given order:

- (1) when ordering the “as needed” forms please order a minimum of \*100\* copies,
- (2) when ordering the visit packets please order a minimum of \*200\* packets at a time, and
- (3) please try to limit the number of orders to 2 per month.

In addition, please allow 2 weeks for processing and shipping of each order.

## 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. Updates and clarifications issued in Communiqués #1 through #11 have been incorporated into the updated forms instructions when applicable.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) DM-1 (001)

**Participant ID**

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

**Demographics**

**Visit Date**

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

<b>Screening Attempt:</b>	<input type="checkbox"/>	1st	<input type="checkbox"/>	2nd	<input type="checkbox"/>	3rd	<input type="checkbox"/>	4th	<input type="checkbox"/>	5th	<input type="checkbox"/>	other, specify: _____
---------------------------	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----------------------

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

1. What is your date of birth? 

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

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

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

} → **If complete date of birth is not available:**  
How old are you in completed years? ..... 

<input type="text"/>	<input type="text"/>
years	
2. Are you currently married?..... 

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

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

→ **If no, go to item 3 on page 2.**
  - 2a. How old is your husband? ..... 

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

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

*don't know*
  - 2b. Are you currently living with your husband? ..... 

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

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

*yes*

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

*no*
  - 2c. Does your husband have more than one wife or sexual partner? ..... 

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

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

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

*don't know*
  - 2d. Does your husband provide you with financial and/or material support? ..... 

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

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

*yes*

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

*no*
  - 2d1. What is your husband's average monthly income?..... 

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

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

*don't know*  
**Record in local currency.**
  - 2e. What is your husband's highest level of education?
    - no schooling
    - primary school, not complete
    - primary school, complete
    - secondary, not complete
    - secondary, complete
    - attended college or university
    - don't know→ **Go to item 4 on page 2.**

---

## Demographics (DM-1), Page 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 for more instructions regarding re-screening form completion, and transmission procedures.*

### General Interviewer Tips:

*See Section 13.5 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.*

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 1:** When possible, record the participant's complete date of birth (**day, month, and year**). If the participant does not know her complete date of birth, leave all the date boxes blank (this will not generate a QC note) and record the participant's age in completed years in the boxes provided. Use the participant's best estimate if the exact number of years is unknown. If necessary, record the interviewer's best estimate. Do not record both a full or partial date of birth and completed years—this may generate a QC note.
- **Item 2:** Record whether or not the participant is **currently** married.
- **Item 2a:** 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 2d:** 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 2d1:** 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. If the husband is unemployed write "0000000" in the boxes provided.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) DM-2 (002)

**Participant ID**

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

**Demographics**

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

3. Do you currently have a male sexual partner? .....  *yes*  *no* → **If no, go to item 4.**  
*don't know*
- 3a. How old is your partner? .....  *years*  *don't know*
- 3b. Are you currently living with your partner? .....  *yes*  *no*
- 3c. Does your partner have any other sexual partners? .....  *yes*  *no*  *don't know*
- 3d. Does your partner provide you with financial and/or material support? .....  *yes*  *no*
- 3d1. What is your partner's average monthly income? .....   
*Record in local currency.*  *don't know*
- 3e. What is your partner's highest level of education?
- no schooling
  - primary school, not complete
  - primary school, complete
  - secondary, not complete
  - secondary, complete
  - attended college or university
  - don't know

4. Do you earn an income of your own? .....  *yes*  *no* → **If no, end of form.**
- 4a. What is your average monthly income? .....   
*Record in local currency.*
- 4b. How do you earn your income? **Mark all that apply.**.....  *formal employment*  *self-employed*  *other, specify: \_\_\_\_\_*

---

## Demographics (DM-2) Page 2

### Item-specific Instructions:

- **Screening Attempt Box:** The screening attempt marked on this page must match the screening attempt marked on page 1 of this form.
- **Item 3:** 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 (item 3a through 3e) should be answered for the partner she considers to be her primary sexual partner.
- **Item 3a:** 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 3d:** 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 3d1:** 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. If the partner is unemployed write "0000000" in the boxes provided.

- **Item 4a:** 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 4b:** 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.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) DMM-1 (013)

**Participant ID**

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

**Demographics—Malawi**

**Visit Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

1. What is your highest level of education?

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

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

yes      no

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

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

yes      no

5. Do you have electricity in your home? .....

6. What is your ethnic group or tribe?

**Read categories, mark all that apply.**

- Chewa
- Lomwe
- Yao
- Tumbuka
- White
- other African tribe, specify: \_\_\_\_\_
- other, specify: \_\_\_\_\_

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

code

---

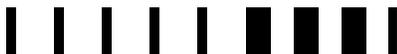
## Demographics—Malawi (DMM-1)

### Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 3:** Record whether or not the participant (or someone in her family) owns the house she lives in.
- **Item 6:** This item asks about ethnic group or tribe. Read each category to the participant 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 either the "Other African tribe, specify" box or the "Other, specify" box and record her response on the line provided for that option.
- **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 category 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 035 Ph II/IIb Microbe (013) DMZ-1 (014)

**Participant ID**

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

**Demographics—Zimbabwe**

**Visit Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

1. What is your highest level of education?

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

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

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, mark all that apply.**

- Shona
- Ndebele
- White
- other African tribe, specify: \_\_\_\_\_
- other, specify: \_\_\_\_\_

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

code

---

## Demographics—Zimbabwe (DMZ-1)

### Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 3:** Record whether or not the participant (or someone in her family) owns the house she lives in.
- **Item 5:** This item asks about ethnic group or tribe. Read each category to the participant 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 either the "Other African tribe, specify" box or the "Other, specify" box and record her response on the line provided for that option.
- **Item 6:** 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 category 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 035 Ph II/IIb Microbe (013) DMS-1 (015)

**Participant ID**

-      -

Site Number Participant Number Chk

**Demographics—South Africa**

**Visit Date**

dd MMM yy

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

1. What is your highest level of education?

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

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

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, mark all that apply.**

- Zulu
- Xhosa
- Indian
- Colored
- White
- other African tribe, specify: \_\_\_\_\_
- other, specify: \_\_\_\_\_

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

code

---

## Demographics—South Africa (DMS-1)

### Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 3:** Record whether or not the participant (or someone in her family) owns the house she lives in.
- **Item 5:** This item asks about ethnic group or tribe. Read each category to the participant 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 either the "Other African tribe, specify" box or the "Other, specify" box and record her response on the line provided for that option.
- **Item 6:** 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 category 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 035 Ph II/IIb Microbe (013) DMB-1 (016)

**Participant ID**

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

**Demographics—Zambia**

**Visit Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

1. What is your highest level of education?

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

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

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, mark all that apply.**

- Bemba
- Nyanja
- Tonga
- Lozi
- White
- other African tribe, specify: \_\_\_\_\_
- other, specify: \_\_\_\_\_

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

code

---

## Demographics—Zambia (DMB-1)

### Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** Record the total number of reported live births, not the total number of pregnancies, or other birth outcomes.
- **Item 3:** Record whether or not the participant (or someone in her family) owns the house she lives in.
- **Item 5:** This item asks about ethnic group or tribe. Read each category to the participant 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 either the "Other African tribe, specify" box or the "Other, specify" box and record her response on the line provided for that option.
- **Item 6:** 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 category 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 035 Ph II/IIb Microbe (013) DMU-1 (018)

**Participant ID**

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

**Demographics—United States**

**Visit Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

1. What is your highest level of education?

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

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. ....

4. Have you ever had an unplanned pregnancy? .....  yes  no

*1 more than 1*

→ **If no, go to item 5.**

4a. How many unplanned pregnancies have you had? .....  yes  no

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

6. What is your race? **Read categories, mark all that apply.**

- 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)

### Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **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 to the participant 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 or is unable to give a response to any item(s), draw a line through the response category 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 035 Ph II/Ib Microbe (013) SC-1 (005)

**Participant ID**

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

**Screening Consent**

**Visit Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

1. Is the participant of legal age to provide independent informed consent for research per local regulations and guidelines? .....  *yes*  *no* → **If no, participant is ineligible. End of form.**

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

2a. When was the informed consent form for screening marked or signed? .....   *dd*    *MMM*   *yy*

3. Was the participant able and willing to provide adequate locator information for study retention purposes, as defined by local standard operating procedures? .....  *yes*  *no* → **If no, participant is ineligible. End of form.**

4. Is this a Phase II participant? .....  *yes*  *no*

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 035 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 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.*

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 1:** No exceptions should be made regarding a participant's age and eligibility. If a participant is younger than the legal age per local regulations and guidelines on the day of screening, she can not be screened for the study.
- **Comments:** Record any necessary comments on the comments lines at the bottom of the form.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/Ib Microbe (013) SLR-1 (010)

**Participant ID**

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

**Screening Part 1 Laboratory Results**

**Initial Collection Date**

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

<b>Screening Attempt:</b>	<input type="checkbox"/>	1st	<input type="checkbox"/>	2nd	<input type="checkbox"/>	3rd	<input type="checkbox"/>	4th	<input type="checkbox"/>	5th	<input type="checkbox"/>	other, specify: _____
---------------------------	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----------------------

**Specimen Collection Date**

If different from Initial Collection Date

Not done/  
Not collected

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

**1. URINE TESTS**

Not done

negative positive

1a. Leukocyte esterase (LE).....

1b. Nitrites.....

**Specimen Collection Date**

If different from Initial Collection Date

Not done/  
Not collected

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

**2. PREGNANCY TEST**

negative positive

2a. Test result.....

**Specimen Collection Date**

If different from Initial Collection Date

Not done/  
Not collected

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

**3. HIV Tests**

negative positive

3a. Rapid test 1 .....

3b. Rapid test 2 .....

4. HIV EIA.....

indeterminate

5. HIV Western Blot.....

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

---

## Screening Part 1 Laboratory Results (SLR-1), Page 1

*This form is used to record local laboratory results of specimens collected at the Screening Part 1 visit. Record specimen test results on this form as they become available from the local lab.*

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

**Note:** *If a participant is being re-screened, a new Screening Part 1 Laboratory Results form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 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.*

- **Initial Collection Date:** Record the first date any specimens on this two-page form were collected. For example, if the urine specimen was collected on 25-Feb-05 and all other specimens on this form were collected on 27-Feb-05, record “25-Feb-05” as the Initial Collection Date. Remember to always record a specimen **collection** date and not the date results became available or were recorded on the form.
- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant’s sixth or greater screening attempt, mark the “other, specify” box and clearly write the number on the line provided.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the “Not done/Not collected” box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank.
- **Items 1a and 1b:** If a urine specimen was collected but not tested for both leukocyte esterase (LE) and nitrites, mark the “Not done” box to the left of the urine test that was not performed.
- **Item 2:** Record Quidel QuickVue OneStep hCG urine pregnancy test result.
- **Items 3a and 3b:** In the unlabeled boxes to the right of “Rapid test 1” and “Rapid test 2,” record the assigned two-digit rapid test kit code. As of November 2004, the rapid test kit codes are as follows. **Note:** *More test kit codes may be added to the list below as the study proceeds. For the most complete listing of rapid test kit codes, see SSP Section 12.5.2.*

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

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/Ib Microbe (013) SLR-2 (011)

**Participant ID**

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

**Screening Part 1 Laboratory Results**

	<i>1st</i>	<i>2nd</i>	<i>3rd</i>	<i>4th</i>	<i>5th</i>	<i>other, specify: _____</i>
<b>Screening Attempt:</b>	<input type="checkbox"/>					

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

*dd MMM yy*

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

**6. STI SEROLOGY**

6a. Syphilis screening test ..... *non-reactive*  *reactive*

**If non-reactive, go to item 7.**

6a1. Syphilis titer ..... 1:

6b. Syphilis confirmatory test ..... *negative*  *positive*

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

*dd MMM yy*

<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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**7. OTHER STI TESTS**

7a. N. Gonorrhea ..... *negative*  *positive*

7b. C. Trachomatis .....

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

\_\_\_\_\_

09-NOV-04

**SAMPLE**

Language

Staff Initials / Date

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## Screening Part 1 Laboratory Results (SLR-2), Page 2

### Item-specific Instructions:

- **Screening Attempt Box:** The screening attempt marked on this page must match the screening attempt marked on page 1 of this form.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the “Not done/Not collected” box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank
- **Item 6:** If the syphilis screening test is reactive, items 6a1 and 6b must be completed.
- **Item 6a1:** Remember to use leading zeros when recording syphilis titer level. For example, a titer level of 1:20 would be recorded on the form as “1:0020.”

**SAMPLE: DO NOT FAX TO DATAFAX**



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

HPTN 035 Ph II/IIb Microbe (013) PRE-1 (012)

Participant ID

-      -

Site Number Participant Number Chk

Pre-existing Conditions

Form Completion Date

dd MMM yy

No pre-existing conditions reported or observed. —▶ End of form. Fax to SCHARP DataFax.

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

---

## 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." STIs/RTIs listed on the Clinical ELigibility form should not be recorded on this form because participants must have completed treatment and be free of symptoms before enrollment.*

**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 used to record severity grade and frequency of the condition reported. The space can also be used 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**



HPTN 035 Ph II/IIb Microbe (013) SSL-1 (021)

**Participant ID**

-      -   
 Site Number Participant Number Chk

**Initial Collection Date**

dd MMM yy

**Screening Safety Laboratory Results**

**Screening Attempt:**  1st  2nd  3rd  4th  5th  other, specify: \_\_\_\_\_

**Specimen Collection Date**

If different from Initial Collection Date

Not done/ Not collected

dd MMM yy

Not done

**1. HEMOGRAM**

**AE Severity Grade**  
If applicable

1  2  3  4

1a. Hemoglobin .....    g/dL

1b. Hematocrit .....   %

1c. MCV .....   fL

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

**Specimen Collection Date**

If different from Initial Collection Date

Not done/ Not collected

dd MMM yy

**2. WHITE BLOOD CELLS**

**AE Severity Grade**  
If applicable

1  2  3  4

2a. WBC     x10<sup>3</sup>/mm<sup>3</sup>

OR       cells/mm<sup>3</sup>

**Specimen Collection Date**

If different from Initial Collection Date

Not done/ Not collected

dd MMM yy

**3. DIFFERENTIAL**

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

**AE Severity Grade**  
If applicable

1  2  3  4

3a. Neutrophils .....     AND

3b. Lymphocytes .....  N/A

3c. Monocytes .....  N/A

3d. Eosinophils .....  N/A

3e. Basophils .....  N/A

3f. Bands .....  N/A

3g. Atypical lymphocytes  N/A

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

09-NOV-04

SAMPLE

Language

Staff Initials / Date

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## Screening Safety Laboratory Results (SSL-1), Page 1

*This form is used to document local screening safety laboratory results of specimens collected at the Screening Part 1 visit. Record specimen test results on this form as they become available from the local lab.*

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

***Note:** When screening safety labs are repeated within a Screening Attempt, update the original Screening Safety Laboratory Results form so results from the latter specimen collection (the specimen collected closest to the enrollment/randomization date) are recorded. If a participant is being re-screened, a new Screening Safety Laboratory Results form (both pages) must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 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.*

***Note:** When laboratory reported values must be rounded to be recorded, and the rounded value is a higher severity grade than the laboratory reported value, note this in the Comments section of this form. For example, the lab reports a PT INR value of 1.35. This value is recorded as 1.4. The range for severity grade 1 is 1.375 to 1.875. Technically this INR value is below the grade 1 severity grade cutoff. To document this on the CRF, please add a note in the Comments section to the effect "PT INR value reported by the lab is 1.35 which is below severity grade 1 cutoff."*

- **Initial Collection Date:** Record the first date any specimens on this two-page form were collected. For example, if the hemogram specimen was collected on 25-Feb-05 and all other specimens on this form were collected on 27-Feb-05, record "25-Feb-05" as the Initial Collection Date. Remember to always record a specimen **collection** date and not the date results became available or were recorded on the form.
- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the "Not done/Not collected" box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank.
- **AE Severity Grade:** For items with AE Severity Grade boxes present, the result must be assessed for severity using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events. If the result is not a grade 1 or higher severity grade, leave the AE Severity Grade boxes blank.
- **Item 2a:** Record the white blood cell (WBC) count in one set of boxes only (either  $\times 10^3/\text{mm}^3$  or  $\text{cells}/\text{mm}^3$ )—do not record a count in both sets of boxes. When recording a result in the  $\times 10^3/\text{mm}^3$  boxes, be sure to record the hundredths digit as reported by your local lab (ex.  $114.74 \times 10^3/\text{mm}^3$ ). If your local lab reports WBC results to the tenths digit only (only one digit to the right of the decimal is reported), record a zero in the hundredths box (for example, a lab result of  $114.7 \times 10^3/\text{mm}^3$  would be recorded on the form as  $114.70 \times 10^3/\text{mm}^3$ ).
- **Item 3:** If a differential specimen was collected but results were not reported for all items, mark the "Not reported" box for each item result that was not reported.
- **Item 3a:** Record both the percentage neutrophils and the absolute neutrophil count.
- **Items 3g and 3g:** These assays are not required as determined by the protocol team. Mark the "not reported" box.



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## Screening Safety Laboratory Results (SSL-2), Page 2

### Item-specific Instructions:

- **Screening Attempt Box:** The screening attempt marked on this page must match the screening attempt marked on page 1 of this form.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the “Not done/Not collected” box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank
- **AE Severity Grade:** For items with AE Severity Grade boxes present, the result must be assessed for severity using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events. If the result is not a grade 1 or higher severity grade, leave the AE Severity Grade boxes blank.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/Ib Microbe (013) ELR-1 (031)

**Participant ID**

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

**Screening Part 2 Laboratory Results**

**Initial Collection Date**

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

<b>Screening Attempt:</b>	<input type="checkbox"/>	1st	<input type="checkbox"/>	2nd	<input type="checkbox"/>	3rd	<input type="checkbox"/>	4th	<input type="checkbox"/>	5th	<input type="checkbox"/>	other, specify: _____
---------------------------	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----	--------------------------	-----------------------

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

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

**1. URINE TESTS**

Not done

1a. Leukocyte esterase (LE).....

negative positive

1b. Nitrites.....

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

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

**2. PREGNANCY TEST**

2a. Test result.....

negative positive

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

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

**3. VAGINAL WET PREP STUDIES**

Not done

3a. Homogeneous vaginal discharge.....

negative positive

3b. pH  .

→ *If > 4.5 mark as positive.* →

3c. Whiff test.....

3d. Clue cells ≥ 20% .....

3e. Trichomonads .....

3f. Buds and/or hyphae (yeast)...

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

---

## Screening Part 2 Laboratory Results (ELR-1), Page 1

*This form is used to document local laboratory results of specimens collected at the Screening Part 2 visit. Record specimen test results on this form as they become available from the local lab.*

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

***Note:** If a participant is being re-screened, a new Screening Part 2 Laboratory Results form (both pages) must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 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.*

***Note:** When a participant reports for the Screening Part 2 visit, has a pregnancy test, but is unable to complete the screening pelvic exam due to menses, record the pregnancy test result on this form (initial collection date = date of pregnancy test collection). When the participant returns on a different day and completes the screening pelvic exam, record the screening pelvic exam wet mount results on the ELR-1 form originally completed (with the previous visit's pregnancy test result), recording the date of the wet mount specimen collection in the "Specimen Collection Date" field of item 3. Document the pregnancy test result from this second Screening Part 2 visit in the participant's chart notes or on the visit checklist. **DO NOT** complete a second ELR form for the wet mount results - only one ELR form must be completed for each participant for each screening attempt.*

- **Initial Collection Date:** Record the first date any specimens on this two-page form were collected. For example, if the urine specimen was collected on 25-Feb-05 and all other specimens on this form were collected on 27-Feb-05, record "25-Feb-05" as the Initial Collection Date. Remember to always record a specimen **collection** date and not the date results became available or were recorded on the form.
- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the "Not done/Not collected" box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank.
- **Items 1a and 1b:** If a urine specimen was collected but not tested for both leukocyte esterase (LE) and nitrites, mark the "Not done" box to the left of the urine test that was not performed.
- **Item 2:** Record Quidel QuickVue OneStep hCG urine pregnancy test result. If the Screening Part 2 and Enrollment visits are not completed on the same day, record the Enrollment pregnancy test result on the Enrollment visit checklist or chart notes, not on this form.
- **Item 3:** If vaginal wet prep was performed but not all assays were completed, mark the "Not done" box for each uncompleted wet prep assay.
- **Item 3a:** Mark the "positive" box if homogeneous vaginal discharge was observed. If positive, be sure to mark "abnormal vaginal discharge" in item 1a of the Screening Pelvic Exam form completed for this pelvic exam.
- **Item 3d:** Mark the "positive" box if 20% or more of cells were clue cells.
- **Item 3e:** Mark the "positive" box if trichomonads were observed.
- **Item 3f:** Mark the "positive" box if yeast buds and/or hyphae were observed.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/Ib Microbe (013) ELR-2 (032)

**Participant ID**

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

**Screening Part 2 Laboratory Results**

	<i>1st</i>	<i>2nd</i>	<i>3rd</i>	<i>4th</i>	<i>5th</i>	<i>other, specify: _____</i>
<b>Screening Attempt:</b>	<input type="checkbox"/>					

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

*dd MMM yy*

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

**4. STI SEROLOGY**

4a. Syphilis screening test ..... *non-reactive*  *reactive*

**If non-reactive, go to item 5.**

4a1. Syphilis titer ..... 1:

4b. Syphilis confirmatory test ..... *negative*  *positive*

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

*dd MMM yy*

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

**5. OTHER STI TESTS**

*negative*  *positive*

5a. N. Gonorrhea .....

5b. C. Trachomatis .....

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

---

## Screening Part 2 Laboratory Results (ELR-2), Page 2

### Item-specific Instructions:

- **Screening Attempt Box:** The screening attempt marked on this page must match the screening attempt marked on page 1 of this form.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the “Not done/Not collected” box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank
- **Item 4:** If the syphilis screening test is reactive, items 4a1 and 4b must be completed.
- **Item 4a1:** Remember to use leading zeros when recording syphilis titer level. For example, a titer level of 1:20 would be recorded on the form as “1:0020.”

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) RPE-1 (045)

Participant ID

Site Number, Participant Number, Chk

Repeat Screening Pelvic Exam

Exam Date

dd, MMM, yy

Screening Attempt: 1st, 2nd, 3rd, 4th, 5th, other, specify:

1. Pelvic exam assessment: abnormal findings, no abnormal findings. If no abnormal findings, go to item 4.

1a. Abnormal findings: Mark all that apply.

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

2. Do any of these exam findings involve deep epithelial disruption?
3. Do any of these exam findings involve disrupted blood vessels?
3a. Were disrupted blood vessels observed in more than one distinct area?

4. hCG for pregnancy
5. Was a gram stain smear collected?
6. Was a pap smear collected?

Comments:

---

## Repeat Screening Pelvic Exam (RPE-1)

*This form, along with the non-DataFax Pelvic Exam Diagrams form, is used to document the repeat screening pelvic (and, when applicable, colposcopy) exam. A repeat screening pelvic/colposcopy exam is only required if there are abnormalities present at the screening pelvic/colposcopy exam (conducted as part of the Screening Part 2 visit) that make the participant ineligible.*

### Item-specific Instructions:

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

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 1:** If there are no abnormal findings observed during the pelvic/colposcopy exam at this visit, mark the "no abnormal findings" box and go to item 4. If one or more abnormal findings are observed, mark the "abnormal findings" box and go to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box and describe the abnormal finding in the space provided.
- **Item 2:** Record whether any of the observed abnormal findings involve deep epithelial disruption.  
*Note: If deep epithelial disruption is present, the participant is not eligible for the study at this time.*
- **Item 4:** A pregnancy test is required at every visit during screening. If the pregnancy test was not collected or 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 bottom of the form.
- **Item 5:** Collection of a gram stain smear is required at the repeat screening pelvic exam. If a 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.
- **Comments:** Record any necessary or additional comments on the comments lines at the bottom of the form.

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) SPE-1 (041)

Participant ID

Site Number, Participant Number, Chk

Screening Pelvic Exam

Exam Date

dd, MMM, yy

Screening Attempt: 1st, 2nd, 3rd, 4th, 5th, other, specify:

1. Pelvic exam assessment: abnormal findings, no abnormal findings. If no abnormal findings, go to item 4.

1a. Abnormal findings: Mark all that apply.

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

2. Do any of these exam findings involve deep epithelial disruption?
3. Do any of these exam findings involve disrupted blood vessels?
3a. Were disrupted blood vessels observed in more than one distinct area?
4. Was a gram stain smear collected?
5. Was a pap smear collected?
6. Cervical Ectopy: Percentage of cervical surface area
6a. Cervical ectopy assessed by:
7. Is this a Phase II colposcopy participant?

Comments:

---

## Screening Pelvic Exam (SPE-1)

*This form, along with the non-DataFax Pelvic Exam Diagrams, is used to document the pelvic (and, when applicable, colposcopy) exam conducted during the Screening Part II visit.*

***Note:** If a participant is being re-screened, a new Screening Pelvic Exam form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 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.*

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 1:** If there are no abnormal findings observed during the pelvic/colposcopy exam at this visit, mark the "no abnormal findings" box and go to item 4. If one or more abnormal findings are observed, mark the "abnormal findings" box and go to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed. If an observed abnormal finding is not listed, mark the "other abnormal findings, specify" box and describe the abnormal finding in the space provided.
- **Item 2:** Record whether any of the observed abnormal findings involve deep epithelial disruption.  
***Note:** If deep epithelial disruption is present, the participant is not eligible for the study at this time.*
- **Item 4:** Collection of a gram stain smear is required at the screening pelvic exam. If a 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 5:** Collection of the pap smear is required at selected sites at the screening pelvic exam. If a pap 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. If your site is not performing pap smears mark the "no" box, and record "N/A" in the comments section.  
***Note:** Because the Lilongwe site is not performing pap smears, this site does not need to record a reason in the comments section.*
- **Items 6 and 6a:** When colposcopy is performed, cervical ectopy must be assessed by colposcopy and not by naked eye. If colposcopy was performed, item 6a should be marked "colposcopy." If colposcopy was not performed, item 6a should be marked "naked eye." When cervical ectopy can not be assessed, draw a single horizontal line through all response boxes for both items. Write "N/A" in the white space and initial and date. Record the reason in the comments section.
- **Comments:** Record any necessary or additional comments on the comments line at the bottom of the form.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

1

HPTN 035 Ph II/IIb Microbe (013) SL-1 (051)

**Participant ID**

--  
Site Number Participant Number Chk

**Initial Collection Date**

dd MMM yy

**Safety Laboratory Results**

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

dd MMM yy

Not done

**1. HEMOGRAM**

**AE Severity Grade**  
*If applicable*

1 2 3 4

1a. Hemoglobin.....   g/dL

1b. Hematocrit .....  %

1c. MCV.....  fL

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

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

dd MMM yy

**2. WHITE BLOOD CELLS**

**AE Severity Grade**  
*If applicable*

1 2 3 4

2a. WBC   x10<sup>3</sup>/mm<sup>3</sup>

OR  cells/mm<sup>3</sup>

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

dd MMM yy

**3. DIFFERENTIAL**

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

**AE Severity Grade**  
*If applicable*

1 2 3 4

3a. Neutrophils .....    AND

3b. Lymphocytes .....  N/A

3c. Monocytes .....  N/A

3d. Eosinophils .....  N/A

3e. Basophils .....  N/A

3f. Bands .....  N/A

3g. Atypical lymphocytes  N/A

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

09-NOV-04

**SAMPLE**

01  
Language

Staff Initials / Date

---

## Safety Laboratory Results (SL-1), Page 1

*This form is used to document local safety laboratory results of specimens collected during 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 the participant has a laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on an Adverse Experience (AE) Log form.*

### Item-specific Instructions:

***Note:** When laboratory reported values must be rounded to be recorded, and the rounded value is a higher severity grade than the laboratory reported value, note this in the Comments section of this form. For example, the lab reports a PT INR value of 1.35. This value is recorded as 1.4. The range for severity grade 1 is 1.375 to 1.875. Technically this INR value is below the grade 1 severity grade cutoff. To document this on the CRF, please add a note in the Comments section to the effect "PT INR value reported by the lab is 1.35 which is below severity grade 1 cutoff."*

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study plus 2.0. For example, Month 3 is assigned a visit code of "05.0," Month 6 is assigned a visit code of "08.0," etc.
- **Initial Collection Date:** Record the first date any specimens on this two-page form were collected. For example, if the hemogram specimen was collected on 25-Feb-05 and all other specimens on this form were collected on 27-Feb-05, record "25-Feb-05" as the Initial Collection Date. Remember to always record a specimen **collection** date and not the date results became available or were recorded on the form.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the "Not done/Not collected" box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank.
- **AE Severity Grade:** For items with AE Severity Grade boxes present, the result must be assessed for severity using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events. If the result is not a grade 1 or higher severity grade, leave the AE Severity Grade boxes blank.
- **Item 2a:** Record the white blood cell (WBC) count in one set of boxes only (either  $\times 10^3/\text{mm}^3$  or  $\text{cells}/\text{mm}^3$ )—do not record a count in both sets of boxes. When recording a result in the  $\times 10^3/\text{mm}^3$  boxes, be sure to record the hundredths digit as reported by your local lab (ex.  $114.74 \times 10^3/\text{mm}^3$ ). If your local lab reports WBC results to the tenths digit only (only one digit to the right of the decimal is reported), record a zero in the hundredths box (for example, a lab result of  $114.7 \times 10^3/\text{mm}^3$  would be recorded on the form as  $114.70 \times 10^3/\text{mm}^3$ ).
- **Item 3:** If a differential specimen was collected but results were not reported for all items, mark the "Not reported" box for each item result that was not reported.
- **Item 3a:** Record both the percentage neutrophils and the absolute neutrophil count.
- **Items 3g and 3g:** These assays are not required as determined by the protocol team. Mark the "not reported" box.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) SL-2 (052)

**Participant ID**

--  
Site Number Participant Number Chk

**Safety Laboratory Results**

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

dd MMM yy

**4. LIVER FUNCTION TESTS**

4a. Alkaline phosphatase .....  U/L  
4b. AST (SGOT) .....  U/L  
4c. ALT (SGPT) .....  U/L  
4d. GGT .....  U/L  
4e. Total bilirubin ..... .  mg/dL

**AE Severity Grade**  
*If applicable*

1 2 3 4

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

dd MMM yy

**5. RENAL FUNCTION TESTS**

5a. Creatinine ..... .  mg/dL  
5b. BUN .....  mg/dL

**AE Severity Grade**  
*If applicable*

1 2 3 4

**Specimen Collection Date**

*If different from Initial Collection Date*

Not done/  
Not collected

dd MMM yy

**6. COAGULATION STUDIES**

6a. PT ..... .  seconds  
6b. PT INR ..... .   
6c. aPTT ..... .  seconds

**AE Severity Grade**  
*If applicable*

1 2 3 4

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

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## Safety Laboratory Results (SL-2), Page 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.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the “Not done/Not collected” box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank.
- **AE Severity Grade:** For items with AE Severity Grade boxes present, the result must be assessed for severity using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events. If the result is not a grade 1 or higher severity grade, leave the AE Severity Grade boxes blank.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) ENR-1 (070)

**Participant ID**

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

<input type="text"/>					
<i>dd</i>	<i>MMM</i>		<i>yy</i>		
  
2. Was the participant able and willing to provide written informed consent for specimen storage and future research?.....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ <b>If no, go to item 3.</b>

  - 2a. When was the informed consent form for specimen storage and future research marked or signed? .....
 

<input type="text"/>					
<i>dd</i>	<i>MMM</i>		<i>yy</i>		
  
3. 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>

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

<input type="text"/>	<input type="text"/>	<input type="text"/>
----------------------	----------------------	----------------------
  - 3b. Date assigned:.....
 

<input type="text"/>					
<i>dd</i>	<i>MMM</i>		<i>yy</i>		
  - 3c. Time assigned:.....
 

<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<i>24-hour clock</i>
<i>hr</i>			<i>min</i>		
  - 3d. To which study arm was the participant randomized? .....
 

<i>gel</i>	<i>condom only (no gel)</i>	
<input type="checkbox"/>	<input type="checkbox"/>	

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

---

## Enrollment (ENR-1)

*This form is used to document a participant's study enrollment/randomization. This form is completed at the Enrollment Visit for participants determined to be eligible for the study. This form is faxed to SCHARP DataFax only if the participant is enrolled (that is, she is assigned a 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 willing and able to provide written informed consent for enrollment), end the form. Do NOT fax this or any other forms completed for this participant to SCHARP DataFax.
- **Item 3:** If a clinic randomization envelope is not assigned, mark the “no” box and specify in the Comments field 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 3a:** Record the 3-digit clinic randomization envelope number present on the clinic randomization envelope assigned to this participant.
- **Item 3b:** Record the date the clinic randomization envelope was assigned to the participant. This date should match the “date assigned” recorded for this envelope on the HPTN 035 Clinic Randomization Envelope Tracking Record.
- **Item 3c:** Record the time (using a 24-hour clock) the clinic randomization envelope was assigned to the participant. This time should match the “time assigned” recorded for this envelope on the HPTN 035 Clinic Randomization Envelope Tracking Record.
- **Item 3d:** Record the participant's randomization assignment present on the prescription contained in the participant's clinic randomization envelope.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) EBA-1 (071)

**Participant ID**

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

**Enrollment Behavior Assessment**

**Visit Date**

<input type="text"/>							
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 every 3 months while you are in the study. 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 3 months, how many sex partners have you had?  
By sex partner, I mean someone with whom you have had vaginal or anal sex. ....

<input type="text"/>	<input type="text"/>	# of partners
----------------------	----------------------	---------------

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? .....

<input type="text"/>	<input type="text"/>	# 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? .....

<input type="text"/>	<input type="text"/>	# of times
----------------------	----------------------	------------

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

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

---

## Enrollment Behavior Assessment (EBA-1), Page 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 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.

### 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. Review these items for mathematical accuracy while the participant is still present. Update the responses accordingly if applicable.
- **Item 3:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had vaginal sex, 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**



HPTN 035 Ph II/IIb Microbe (013) EBA-2 (072)

**Participant ID**

Site Number			Participant Number						Chk	

**Enrollment Behavior Assessment**

4. The last time you had vaginal sex:
- |   | <i>yes</i>   | <i>no</i>                |
|---|--|--------------------------|
| 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 one hour before having vaginal sex? .....                 | <input type="checkbox"/>   | <input type="checkbox"/> |
| 4d. did you wash inside or douche inside your vagina within one hour after having vaginal sex? .....                  | <input type="checkbox"/>   | <input type="checkbox"/> |
| 4e. did you insert paper, cloth, cotton, or cotton wool? .....  | <input type="checkbox"/>   | <input type="checkbox"/> |
| 4f. did you insert any other object or substance into your vagina within one hour before or during vaginal sex? ..... | <input type="checkbox"/>   | <input type="checkbox"/> |
|   | <b>→ If yes, specify:</b><br><i>Local Language:</i> _____<br><i>English:</i> _____ |                          |
| 4g. did you insert any other object or substance into your vagina within one hour after vaginal sex? .....            | <input type="checkbox"/>   | <input type="checkbox"/> |
|   | <b>→ If yes, specify:</b><br><i>Local Language:</i> _____<br><i>English:</i> _____ |                          |
| 4h. did you receive money, gifts, material goods, drugs, or shelter for this vaginal sex? .....                       | <input type="checkbox"/>   | <input type="checkbox"/> |

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.

- |                                      | <i>yes</i>   | <i>no</i>                |
|--------------------------------------|--|--------------------------|
| 5. Have you ever had anal sex? ..... | <input type="checkbox"/>                                 | <input type="checkbox"/> |
|                                      | <b>→ If no, go to statement before item 9 on page 3.</b> |                          |

---

## Enrollment Behavior Assessment (EBA-2), Page 2

### Item-specific Instructions:

- **Item 4:** Read each item 4a–4h aloud and mark the participant’s answer. If ‘yes’ is marked for items 4f or 4g, be sure to record the participant’s verbatim response. Also 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



HPTN 035 Ph II/IIb Microbe (013) EBA-3 (073)

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:

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

8c. did you receive money, gifts, material goods, drugs, or shelter for this anal sex? 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?

9a-9g. List of items with yes/no checkboxes and # of times boxes

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

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

---

## Enrollment Behavior Assessment (EBA-3), Page 3

### Item-specific Instructions:

- **Item 7:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had anal sex, draw a line through the unknown response boxes, and 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 answer.
- **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” boxes. If yes is marked for item 9g, be sure to record the participant’s verbatim response. Also 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**



HPTN 035 Ph II/IIb Microbe (013) EBA-4 (074)

**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? **Mark "none" or all that apply.**

- none
- family planning pills or birth control pills
- injectable contraceptives (such as Depo-Provera)
- Norplant inserts
- vaginal ring
- natural methods such as the withdrawal or rhythm method
- male condoms
- spermicide
- surgical sterilization (tubal ligation)
- other, specify:  
*Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

---

## Enrollment Behavior Assessment (EBA-4), Page 4

### Item-specific Instructions:

- **Item 10:** These response options are not read aloud to the participant. Mark the box(es) for all reported family planning methods being used by the participant. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim response. Also 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**



HPTN 035 Ph II/IIb Microbe (013) ESS-1 (076)

**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

**Enrollment Specimen HIV Status**

**Specimen Test Date**

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

1. Visit code of HIV Test Results (HTR-1) form documenting positive HIV status: ..... **Visit Code** .

2. Was the Enrollment Specimen tested?.....  *yes*  *no*

**If no, specify reason(s). End of form.** ←

---



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**Specimen Collection Date**

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

3. Enrollment Specimen HIV Test Results

<input type="checkbox"/>	<b>Not done</b>		<i>negative</i>	<i>positive</i>	
<input type="checkbox"/>	3a. Rapid test 1	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3b. Rapid test 2	<input type="text"/> <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<input type="checkbox"/>	3c. HIV EIA .....		<input type="checkbox"/>	<input type="checkbox"/>	<i>indeterminate</i>
<input type="checkbox"/>	3d. HIV Western Blot .....		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Enrollment Specimen HIV Status  *negative*  *positive*  *indeterminate*

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

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## Enrollment Specimen HIV Status (ESS-1)

The Enrollment Specimen HIV Status form documents a participant's HIV status at enrollment. This form is *ONLY* used for participants who test HIV-positive at their first follow-up visit (in most cases this will be the Month 3 visit). See Section 12.5.2.3 for more information on HIV antibody testing performed on the plasma sample stored at the Enrollment Visit.

### Item-specific Instructions:

- **Specimen Test Date:** Record the date the stored plasma specimen was *tested* (NOT the date the specimen was collected, nor the date the result was reported or recorded on the form).
- **Item 1:** Record the visit code from the HIV Test Results form documenting the positive HIV status.
- **Item 2:** In the event that a specimen is lost or damaged, and therefore can not be tested, indicate this by marking the “no” box and record an explanation on the lines provided.
- **Item 3:** Record the date the enrollment plasma specimen was *collected* (NOT the date the specimen was tested, nor the date the result was reported or recorded on the form).
- **Items 3a and 3b:** In the unlabeled boxes to the right of “Rapid test 1” and “Rapid test 2,” record the assigned two-digit rapid test kit code. As of November, 2004, the rapid test kit codes are as follows. **Note:** *More test kit codes may be added to the list below as the study proceeds. For the most complete listing of rapid test kit codes, see Section 12.5.2.*

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

- **Comments:** Use the comments lines at the bottom of the form to document any problems or reasons why expected results are not available.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code   .

HPTN 035 Ph II/IIb Microbe (013) MQV-1 (121)

**Participant ID**

-      -   
Site Number Participant Number Chk

**Monthly or Quarterly 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.**

2. At this visit, did the participant report any genital bleeding or spotting in between her usual menstrual periods? .....

*yes*  *no*

**If yes, complete Genital Bleeding Assessment form.**

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
- Pelvic Exam
- Pelvic Laboratory Results
- Follow-up Laboratory Results
- Follow-up Behavioral Assessment
- Adverse Experience Log (new)
- Product Hold/Discontinuation
- Safety Laboratory Results
- other, specify: \_\_\_\_\_

3a. How many **new** AE Log forms were completed for this visit?

**Condom-only cohort, end of form.**

4. How many unused applicators is the participant estimated to have at this time?

5. At this visit, how many cartons of study gel were ordered or dispensed by clinic staff? .....

**If more than 6, specify reason in Comments.**

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

---

## Monthly or Quarterly Visit (MQV-1)

*This form is used to document the required Monthly and Quarterly (regularly scheduled) follow-up visits. This form is completed at each Monthly visit and at each Quarterly visit.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for more specific information on assigning visit codes. Note that for Monthly or Quarterly visits, the visit code is equal to the month on study plus 2.0. For example, Month 3 is assigned a visit code of “05.0,” Month 6 is assigned a visit code of “08.0,” etc.
- **Item 1:** Record Quidel QuickVue OneStep hCG urine pregnancy test result. If a urine pregnancy test is not done or not collected, mark the “not done” box and complete item 1a. **Note:** A Pregnancy Report and History form must be completed for each pregnancy, not for each positive pregnancy test result.
- **Item 1a:** Specify the reason(s) why the required pregnancy test was not done.
- **Item 2:** If the participant reports any genital bleeding or spotting requiring reporting per SSP Figure 10.2a, mark the “yes” box and complete a Genital Bleeding Assessment non-DataFax form.
- **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 Monthly or Quarterly Visit form is the **only** DataFax form completed for this visit.
  - **Pelvic Exam/Pelvic Laboratory Results/Follow-up Laboratory Results/Follow-up Behavioral Assessment:** These boxes should be marked at **every** Quarterly visit, as each of these forms document required Quarterly visit evaluations. Even if these evaluations are not done at a Quarterly Visit, the forms are still required to be sent to SCHARP DataFax (see individual form completion instructions for information on how to complete these forms when the evaluations are not done).
  - **Adverse Experience Log (new) and item 3a:** 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 forms 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 forms should be the same as the Visit Code recorded on this form. If an AE Log form is marked for delete do not update this number, deleted AEs will still be counted.
  - **Safety Laboratory Results:** When safety lab specimens are collected, mark this box before faxing this form even though the Laboratory Results form will be faxed later.
  - **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.
- **Items 4 and 5:** Leave these items blank for participants assigned to the condom-only (no gel) arm
- **Item 4:** Record the estimated number of **unused** gel applicators the participant possesses at this time. Obtain this number from the Gel Check source document. **Do not** include any applicators dispensed at this visit - these gel supplies will be documented in item 5. For participants on product hold adjust this number at each visit per participant report.
- **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 Product Request Slip, unless documentation from the pharmacy staff says otherwise. If 10 or more cartons were given to the participant, draw a horizontal line through the response boxes and write the number of cartons dispensed in the white space and initial and date. If more than 6 cartons were given, specify in the Comments section the reason why. For participants on product hold record “00.”

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

[ 1 ]

HPTN 035 Ph II/IIb Microbe (013) FLR-1 (131)

Participant ID

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

Initial Collection Date

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

Follow-up Laboratory Results

Specimen Collection Date

If different from Initial Collection Date

Not done/ Not collected

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

Not done

[ ]

1. URINE TESTS

negative positive

1a. Leukocyte esterase (LE)..... [ ] [ ]

1b. Nitrites..... [ ] [ ]

Specimen Collection Date

If different from Initial Collection Date

Not done/ Not collected

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

2. HIV Tests

negative positive

2a. Rapid test 1 [ ][ ] ..... [ ] [ ]

2b. Rapid test 2 [ ][ ] ..... [ ] [ ]

3. HIV EIA..... [ ] [ ]

If positive for any, complete HIV Test Results form.

4. STI SEROLOGY

non-reactive reactive

4a. Syphilis screening test..... [ ] [ ]

If non-reactive, go to item 5.

4a1. Syphilis titer ..... 1: [ ][ ][ ][ ]

4b. Syphilis confirmatory test..... [ ] [ ]

Specimen Collection Date

If different from Initial Collection Date

Not done/ Not collected

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

5. OTHER STI TESTS

negative positive

5a. N. Gonorrhea ..... [ ] [ ]

5b. C. Trachomatis ..... [ ] [ ]

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

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## Follow-up Laboratory Results (FLR-1)

*This form is used to document local laboratory results of blood and urine specimens collected during study follow-up. Record specimen test results on this form as they become available from the local lab. 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 the participant has a laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on the Adverse Experience Log form.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study plus 2.0. For example, Month 3 is assigned a visit code of "05.0," Month 6 is assigned a visit code of "08.0," etc.
- **Initial Collection Date:** Record the first date any specimens on this two-page form were collected. For example, if the urine specimen was collected on 25-Feb-05 and all other specimens on this form were collected on 27-Feb-05, record "25-Feb-05" as the Initial Collection Date. Remember to always record a specimen **collection** date and not the date results became available or were recorded on the form.
- **Not done/Not collected and Specimen Collection Date:** If the specimen was not done (collected but no result available) or not collected, mark the "Not done/Not collected" box. If the specimen was collected on a date other than the Initial Collection Date, record the specimen collection date. If the specimen was collected on the Initial Collection Date, leave the Not done/Not collected and Specimen Collection Date boxes blank.
- **Items 1a and 1b:** If a urine specimen was collected but not tested for both leukocyte esterase (LE) and nitrites, mark the "Not done" box to the left of the urine test that was not performed.
- **Items 2a and 2b:** In the unlabeled boxes to the right of "Rapid test 1" and "Rapid test 2," record the assigned two-digit rapid test kit code. As of November, 2004, the rapid test kit codes are as follows. **Note:** *More test kit codes may be added to the list below as the study proceeds. For the most complete listing of rapid test kit codes, see Section 12.5.2.*

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

- **Item 4:** If the syphilis screening test is reactive, items 4a1 and 4b must be completed.
- **Item 4a1:** Remember to use leading zeros when recording syphilis titer level. For example, a titer level of 1:20 would be recorded on the form as "1:0020."

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 035 Ph II/IIb Microbe (013) PE-1 (141)

Participant ID

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

Pelvic Exam

Exam Date

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

1. Pelvic exam assessment: .....  
For some Phase II participants this includes colposcopy assessment.

not done [ ] abnormal findings [ ] no abnormal findings [ ]  
If not done, comment below. End of form. If no abnormal findings, go to item 4.

1a. Abnormal findings: Mark all that apply.

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

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

- 2. Do any of these exam findings involve deep epithelial disruption?..... yes [ ] no [ ] If no, go to item 3.
2a. Was deep epithelial disruption observed in more than one distinct area? ..... [ ] [ ]
3. Do any of these exam findings involve disrupted blood vessels?..... yes [ ] no [ ] If no, go to item 4.
3a. Were disrupted blood vessels observed in more than one distinct area? ..... [ ] [ ]
4. Was a gram stain smear collected?..... [ ] [ ]
5. Was a pap smear collected? ..... [ ] [ ]
6. Was a genital ulcer swab collected?..... [ ] [ ] # of swabs [ ]

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

7a. Cervical ectopy assessed by:
naked eye [ ] colposcopy [ ]

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

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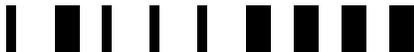
## Pelvic Exam (PE-1)

*This form, along with the non-DataFax Pelvic Exam Diagrams form, 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 for more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study plus 2.0. For example, Month 3 is assigned a visit code of “05.0,” Month 6 is assigned a visit code of “08.0,” etc.
- **Item 1:** If the pelvic exam is not done at a quarterly visit, mark the “not done” box and record the reason the required pelvic exam was not done in the comments section at the bottom of the form. If no abnormal findings were observed, mark the “no abnormal findings” box and go to item 4. If one or more abnormal findings were observed, mark the “abnormal findings” box and go to item 1a.
- **Item 1a:** Mark the box to the left of **each** abnormal finding observed. If an observed abnormal finding is not listed, mark the “other abnormal findings, specify” box and describe the abnormal finding in the space provided.
- **Item 2:** Record whether any of the observed abnormal findings involve deep epithelial disruption.
- **Item 6:** A multiplex PCR swab for genital ulcer disease (GUD) is collected for each genital ulcer or cluster of ulcers observed. If one or more swabs are collected, record the number collected. If a genital ulcer is observed, but a swab is not collected, mark the “no” box and record the reason in the comments section.
- **Items 7 and 7a:** When colposcopy is performed, cervical ectopy must be assessed by colposcopy and not by naked eye. If colposcopy is not performed, item 7a should be marked “naked eye.” When cervical ectopy can not be assessed, draw a single horizontal line through all response boxes for both items. Write “N/A” in the white space and initial and date. Record the reason in the comments section.
- **Comments:** Record any necessary or additional comments on the comments line at the bottom of the form.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

1

HPTN 035 Ph II/IIb Microbe (013) PLR-1 (143)

**Participant ID**

--

Site Number

Participant Number

Chk

**Pelvic Laboratory Results**

**Initial Collection Date**

dd

MMM

yy

**Specimen Collection Date**

*If different from Initial 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. Trichomonads .....
- 1f. Buds and/or hyphae (yeast)...

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

\_\_\_\_\_

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## Pelvic Laboratory Results (PLR-1)

*This form is used to document results of specimens collected at 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 the participant has a laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse experience on the Adverse Experience (AE) Log form.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study plus 2.0. For example, Month 3 is assigned a visit code of “05.0,” Month 6 is assigned a visit code of “08.0,” etc.
- **Initial Collection Date:** Record the date the vaginal wet prep specimens were collected. Remember to always record a specimen **collection** date and not the date results became available or were recorded on the form. If a vaginal wet prep was required but was not done or not collected, record the date of the visit the wet prep was required to be done and record in the comments section at the bottom of the form why the wet prep was not done/not collected.
- **Not done/Not collected and Specimen Collection Date:** If the vaginal wet prep was not done (specimens collected but no result available) or not collected, mark the “Not done/Not collected” box. Because the vaginal wet prep is the only specimen listed on this form, always leave the “Specimen Collection Date” boxes blank.
- **Item 1: Item 3:** If vaginal wet prep was performed but not all assays were completed, mark the “Not done” box for each uncompleted wet prep assay.
- **Item 1a:** Mark the “positive” box if homogeneous vaginal discharge was observed. If positive, be sure to mark “abnormal vaginal discharge” in item 1a of the Pelvic Exam form completed for this pelvic exam.
- **Item 1d:** Mark the “positive” box if 20% or more 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.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) ICC-1 (151)

**Participant ID**

-  -   
 Site Number Participant Number Chk

**Ongoing Informed Consent Comprehension**

**Visit Date**

dd MMM yy

**Instructions:** For each ongoing informed consent comprehension checklist sub-item listed below, mark the "yes" box if a tick mark is present on the completed checklist. If no tick mark is present on the checklist, mark the "no" box.

	yes	no		<b>Comments:</b>
Item 1a .....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 1b .....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 2a .....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 2b .....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 2c.....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 3a .....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 4a .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> N/A	_____
Item 4b .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> N/A	_____
Item 4c.....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 5a .....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 6a .....	<input type="checkbox"/>	<input type="checkbox"/>		_____
Item 7a .....	<input type="checkbox"/>	<input type="checkbox"/>		_____

**No LONGER APPLICABLE FOR THIS PROTOCOL.**  
7C

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## Ongoing Informed Consent Comprehension (ICC-1)

*This DataFax form is used to document the results of ongoing informed consent comprehension assessments performed during study follow-up. This form is NOT interviewer-administered; rather, the data present on the HPTN 035 Ongoing Informed Consent Comprehension Checklist is transcribed on to this DataFax form for inclusion in the study database. See HPTN 035 SSP section 5.6 for information on when these assessments are required to be completed.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit.
- **Items 1a through 3a, and 4c through 7c:** Mark a response for each item. If a tick mark is present on the HPTN 035 Ongoing Informed Consent Comprehension Checklist, mark the “yes” box. If no tick mark is present on the checklist, mark the “no” box.
- **Items 4a and 4b:** If a tick mark is present on the HPTN 035 Ongoing Informed Consent Comprehension Checklist, mark the “yes” box. If “N/A” or “not applicable” is recorded on the checklist (indicating the participant is in the condom-only arm), mark the “N/A” box. If no tick mark or “N/A” is present, mark the “no” box.
- **Comments:** Use these lines to transcribe any comments present for the item on the HPTN 035 Ongoing Informed Consent Comprehension Checklist source document.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) FBA-1 (181)

**Participant ID**

--  
Site Number Participant Number Chk

**Follow-up 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 questions every 3 months while you are in the study. 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 3 months, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex.....

# of partners

**If 0, go to statement before item 9 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 3 on page 2.**

**All Gel cohorts, go to statement before item 2b.**

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

**Condom-only cohort, go to item 3 on page 2.**

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 use study gel and not a male or female condom during vaginal sex? .....

# of times

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

# of times

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

# of times

---

## Follow-up Behavior Assessment (FBA-1), Page 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, and it is administered at each Quarterly visit and at the Study Exit visit.*

### Interview tips:

*See Section 13.5 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. This is particularly important for items 2 through 2e.

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for a more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study + 2.0. For example, Month 3 is assigned a visit code of "05.0," Month 6 is assigned a visit code of "08.0," 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 3 months, record "00" for this item and continue the interview by reading the statement before item 9 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 6 pages of this form to SCHARP DataFax once the form has been completed.
- **Item 2:** Use leading zeros when needed so that all the boxes are filled.
- **Item 2a:** This item is completed only for participants assigned to condom-only (no gel). Use leading zeros when needed so that all the boxes are filled. Once this item has been completed for condom-only participants, check that the responses are consistent with the response to item 2, and go to item 3. For participants assigned to study gel, leave this item blank and go to the statement before item 2b.
- **Items 2b-2e:** These items are completed only for participants assigned to study gel. Use leading zeros when needed so that all the boxes are filled. After recording the participant's responses, check that the responses are consistent with the response to item 2. For participants assigned to condom-only, leave these items blank.

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

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 035 Ph II/IIb Microbe (013) FBA-2 (182)

Participant ID

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

Follow-up Behavior Assessment

3. When was the last time you had vaginal sex? ..... [ ][ ] [ ][ ][ ] [ ][ ]  
dd MMM yy

4. The last time you had vaginal sex: yes no

4a. did you or your partner use a male condom? ..... [ ] [ ]

4b. did you use a female condom? ..... [ ] [ ]

4c. did you use study gel? ..... [ ] [ ]

4d. did you wash inside or douche inside your vagina within one hour before having vaginal sex? ..... [ ] [ ]

4e. did you wash inside or douche inside your vagina within one hour after having vaginal sex? ..... [ ] [ ]

4f. did you insert paper, cloth, cotton, or cotton wool? ..... [ ] [ ]

4g. did you insert any other object or substance into your vagina within one hour before or during vaginal sex? ..... [ ] [ ]  
If yes, specify:

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

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

4h. did you insert any other object or substance into your vagina within one hour after vaginal sex? ..... [ ] [ ]  
If yes, specify:

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

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

4i. did you receive money, gifts, material goods, drugs, or shelter for this vaginal sex? ..... [ ] [ ]

---

## Follow-up Behavior Assessment (FBA-2), Page 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:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had vaginal sex, 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 4:** Read each item 4a–4i aloud and mark the participant’s answer. If yes is marked for items 4g or 4h, be sure to record the participant’s verbatim response. Also 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 and write “don’t know” or “refused,” and initial and date the item in the white space next to the item.*

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 035 Ph II/IIb Microbe (013) FBA-3 (183)

Participant ID

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

Follow-up Behavior Assessment

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 3 months, did you have anal sex? ... [ ] yes [ ] no If no, go to statement before item 9 on page 4.
5a. In the past 3 months, did you ever use study gel anally during anal sex? ... [ ] yes [ ] no If no, go to item 6.
5b. How many times did you use study gel anally during anal sex? ... [ ][ ]
6. In the past week, did you have anal sex? ... [ ] yes [ ] no If no, go to item 7.
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:
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
8c. did you receive money, gifts, material goods, drugs, or shelter for this anal sex? ... [ ] yes [ ] no

---

## Follow-up Behavior Assessment (FBA-3), Page 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 5b:** Use leading zeros when needed so that all the boxes are filled.
- **Item 7:** If, after verbal probing, the participant is unable to provide the day (or month, or year) she last had anal sex, draw a line through the unknown response boxes, and 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.

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

SAMPLE: DO NOT FAX TO DATAFAX



Visit Code [ ][ ] . [ ]

1

HPTN 035 Ph II/IIb Microbe (013) FBA-4 (184)

Participant ID

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

Follow-up Behavior Assessment

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?

	yes	no	# of times
9a. water? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9b. water with vinegar? <i>Note for U.S. site: This includes all commercial douching products.</i> .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9c. water with soap? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9d. paper, cloth, cotton, or cotton wool? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9e. tampons? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9f. fingers without anything else? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
9g. anything else? Specify: .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/> <input type="text"/>
<i>Local Language:</i> _____			
<i>English:</i> _____			

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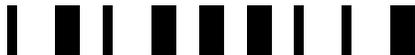
## Follow-up Behavior Assessment (FBA-4), Page 4

### 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–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” boxes. If yes is marked for item 9g, be sure to record the participant’s verbatim response. Also 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 and write “don’t know” or “refused,” and initial and date the item in the white space next to the item.*

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/Ib Microbe (013) FBA-5 (185)

**Participant ID**

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

**Follow-up Behavior Assessment**

10. Which family planning method or methods are you currently using? **Mark "none" or all that apply.**

- none
- family planning pills or birth control pills
- injectable contraceptives (such as Depo-Provera)
- Norplant inserts
- vaginal ring
- diaphragm
- natural methods such as the withdrawal or rhythm method
- male condoms
- spermicide
- surgical sterilization (tubal ligation)
- other, specify:  
*Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

---

## Follow-up Behavior Assessment (FBA-5), Page 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 10:** Family planning methods reported at previous visits should always be reviewed before asking this question. These response options are not read aloud to the participant. Mark the box(es) for all reported family planning methods being used by the participant. If the participant reports a method not listed, mark the “other, specify” box and record the participant’s verbatim response. Also 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 and write “don’t know” or “refused,” and initial and date the item in the white space next to the item.*

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) FBA-6 (186)

**Participant ID**

--  
Site Number Participant Number Chk

**Follow-up Behavior Assessment**

For this last question, I am going to ask you about experiences you may have had or are having while in this study.

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

	<i>yes</i>	<i>no</i>
11a. your spouse or partner? .....	<input type="checkbox"/>	<input type="checkbox"/>
11b. people at home/family? .....	<input type="checkbox"/>	<input type="checkbox"/>
11c. your friends/personal relationships? .....	<input type="checkbox"/>	<input type="checkbox"/>
11d. people at work? .....	<input type="checkbox"/>	<input type="checkbox"/>
11e. people at school? .....	<input type="checkbox"/>	<input type="checkbox"/>
11f. your doctor, nurse, midwife, or other health care provider? .....	<input type="checkbox"/>	<input type="checkbox"/>
11g. your landlord or property owner? .....	<input type="checkbox"/>	<input type="checkbox"/>
11h. other people? Specify: .....	<input type="checkbox"/>	<input type="checkbox"/>

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

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

→ **If no to all, end of form.**

12. Please describe the problem:

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

\_\_\_\_\_

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

\_\_\_\_\_

---

## Follow-up Behavior Assessment (FBA-6), Page 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 11:** Read each item 11a–11h aloud and mark the participant’s response. If “yes” is marked for item 11h, be sure to record the participant’s verbatim response. Also provide the English translation in the space provided. If the participant responds “no” to each item 11a-11h, end the form and leave item 12 blank.
- **Item 12:** Describe the problem. Do **not** record the participant’s verbatim response - describe the problem in your own words so that the nature of the problem is clear. 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 and write “don’t know” or “refused,” and initial and date the item in the white space next to the item.*

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

1

HPTN 035 Ph II/IIb Microbe (013) FBA-7 (187)

**Participant ID**

-      -   
Site Number Participant Number Chk

**Follow-up Behavior Assessment**

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

13a. 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 13b.**

13a1. Please describe the problem:

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

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

13b. physical harm to you? For example, has anyone physically hurt you as a result of this problem?.....  yes  no

**If no, go to item 13c.**

13b1. Please describe the problem:

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

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

13c. 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 13d.**

13c1. Please describe the problem:

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

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

13d. physical or other harm to your children?.....  yes  no

**If no, go to item 14.**

13d1. Please describe the problem:

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

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

14. Interviewer: Did any of these problem(s) require reporting as an Adverse Event (AE)?.....  yes  no

**AE Log Page #**

---

## Follow-up Behavior Assessment (FBA-7), Page 7

### Item-specific Instructions:

*If no social harms were reported by the participant at this visit (that is, form items 11a through 11h are all marked “no”), do not complete this page and do not fax this form page to SCHARP DataFax. Do be sure to fax all other form pages (pages 1 through 6) to SCHARP DataFax.*

- **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 13a1, 13b1, 13c1, and 13d1:** Briefly 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.
- **Item 14:** This is not an interviewer-administered item. If any of the problems described in items 13a-13d resulted in an untoward physical event to the study participant requiring reporting as an adverse event, mark the “yes” box and record the matching AE Log page number in the box provided. If the social harm resulted in more than one AE Log page, contact SCHARP for instructions on how to document additional AE Log page numbers. If no AEs resulted from the social harm, mark the “no” box and leave the “AE Log Page #” box 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**



HPTN 035 Ph II/Ib Microbe (013) HSR-1 (331)

**Participant ID**

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

**HSV-2 Test Result**

**ENROLLMENT SPECIMEN**

**Specimen Collection Date**

Not done/  
Not collected

*dd MMM yy*

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

1. HSV-2 optical density ratio.....   .

**STUDY EXIT SPECIMEN**

**Specimen Collection Date**

Not done/  
Not collected

*dd MMM yy*

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

2. HSV-2 optical density ratio.....   .

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

\_\_\_\_\_

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## HSV-2 Test Result (HSR-1)

*This form is used to document local laboratory HSV-2 test results.*

*Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once all required results are available and recorded on this form.*

### Item-specific Instructions:

- **Specimen Collection Date:** Record the date the specimen was collected (NOT the date results were reported or recorded on the form).
- **not done/not collected:** Mark this box in the event that a specimen was not done (collected but no result available) or not collected. Explain in the comments section at the bottom of the form why the result is not available or why the specimen was not collected.
- **STUDY EXIT SPECIMEN:** The Study Exit Specimen is ONLY tested if the Enrollment Specimen is NEGATIVE. If the Enrollment Specimen is positive, do NOT test the Study Exit Specimen and mark the not done/not collected box (no comment is necessary in this case).
- **Comments:** Use this line 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 035 Ph II/IIb Microbe (013) PTR-1 (341)

**Participant ID**

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

**Pap Test Result**

**Specimen Collection Date**

□□ □□□ □□  
*dd MMM yy*

1. Pap smear result:

- result not available
- 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: \_\_\_\_\_

\_\_\_\_\_

---

## Pap Test Result (PTR-1)

*This form is used to document a local laboratory Pap smear test result.*

*Record specimen test results on this form as they become available from the local lab. Fax this form to SCHARP DataFax once a result is available and recorded.*

### Item-specific Instructions:

- **Visit Code:** For pap smear specimens collected at the Screening Part 2 visit, record a Visit Code of “02.0.”
- **Specimen Collection Date:** Record the date the pap smear specimen was collected, not the date results became available or was recorded on the form).
- **Item 1:** Record the pap smear result. Mark only one box.
  - **result not available:** Mark this box in the event that a pap smear specimen was collected, but a pap smear result is not available due to specimen loss, specimen damage, or the specimen was not able to be read (specimen was not satisfactory for evaluation). Explain on the comments section at the bottom of the form why the result is not available and whether another pap specimen was collected.
  - **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.

***Note:** If a participant’s Screening Part 2 pap test result is abnormal, this must be recorded on the Pre-existing Conditions form.*

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) 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.**

- participant missed her last required pelvic exam and is outside of any visit window
- participant missed her last required HIV test and is outside of any visit window
- in-person visit to report new symptoms → **Complete Adverse Experience Log.**
- participant needs study gel
- phone call from participant to report new symptoms → **Complete Adverse Experience Log.**
- other, specify: \_\_\_\_\_

not done      negative      positive

2. hCG for pregnancy:    → **If positive, complete Pregnancy Report and History form.**

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
- Pelvic Exam
- Pelvic Laboratory Results
- Follow-up Laboratory Results
- Adverse Experience Log (new) → 3a. How many **new** AE Log forms were completed for this visit?...
- Product Hold/Discontinuation
- Safety Laboratory Results
- other, specify: \_\_\_\_\_

**Condom-only cohort, end of form.**

4. At this visit, how many cartons of study gel were ordered or dispensed by clinic staff? .....

→ **If more than 6, specify reason in Comments.**

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

---

## Interim Visit (IV-1)

*This form is used to document interim visits during follow-up that result in new DataFax form(s) completion. See Section 13.3.2 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 Month 3 (Visit Code = 05.0), record “05” to the left of the decimal point in the visit code field.

*Note: Use this code even when that scheduled visit was missed.*
  - 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:** If a urine pregnancy test was done, record Quidel QuickVue OneStep hCG urine pregnancy test result. **Note:** A Pregnancy Report and History form must be completed for each pregnancy, not for each positive pregnancy test result.
- **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) and item 3a:** 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 forms 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 forms should be the same as the Visit Code recorded on this form. If an AE Log form is marked for delete do not update this number, deleted AEs will still be counted.
  - **Safety Laboratory Results:** When safety lab specimens are collected, mark this box before faxing this form even though the Laboratory Results form will be faxed later.
  - **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 cartons of study gel given to the participant at this visit. This will be the same amount documented on the Study Product Request Slip, unless documentation from the pharmacy staff says otherwise. If 10 or more cartons were given to the participant, draw a horizontal line through the response boxes and write the number of cartons dispensed in the white space and initial and date. If more than 6 cartons were given, specify in the Comments section the reason why. For participants on product hold record “00.”

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/Ib Microbe (013) HTR-1 (351)

**Participant ID**

--  
Site Number Participant Number Chk

**HIV Test Results**

**SAMPLE 1**

**Specimen Collection Date**

*dd MMM yy*

*not done/  
not collected*   *negative*   *positive*   *indeterminate*

1. HIV Western Blot: .....

**If negative, go to item 5.**

**SAMPLE 2**

**Specimen Collection Date**

*dd MMM yy*

*not done/  
not collected*   *negative*   *positive*   *indeterminate*

2. HIV Western Blot: .....

**If positive, go to item 5.**

**SAMPLE 3**

**Specimen Collection Date**

*dd MMM yy*

*not done/  
not collected*   *negative*   *positive*   *indeterminate*

3. HIV Western Blot: .....

**If positive, go to item 5.**

**SAMPLE 4**

**Specimen Collection Date**

*dd MMM yy*

*not done/  
not collected*   *negative*   *positive*   *indeterminate*

4. HIV Western Blot: .....

**FINAL HIV STATUS**

*negative*   *positive*   *other, specify: \_\_\_\_\_*

5. Final status:.....

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

---

## HIV Test Results (HTR-1)

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

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

***Note:** For cases when the required sample(s) (after Sample #1) can not be collected readily (i.e. within 2 months of the positive HIV rapid test(s)), complete and fax the HTR form with all available results and specimen collection dates. For item 5 mark the "other" response box and record "algorithm incomplete." In the comments section of the form, record a brief explanation such as, "ppt. refuses to return to clinic," "ppt. scheduled for Sample 2 blood draw on ddMMMyy," etc. If and when, additional results are available, please update the form and refax it to SCHARP.*

### Item-specific Instructions:

- **Visit Code:** The visit code recorded on this form should be the same visit code recorded on the Follow-up 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 rapid 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.
- **Items 3 and 4:** If the Sample 2 result is "negative" or "indeterminate," but Sample(s) 3 and/or 4 are not collected mark the "not done/not collected" box(es) for each applicable sample, leaving the specimen collection date blank. Record the reason the sample(s) were not collected (e.g. "Sample 3 not collected per Central Lab instruction").
- **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.
- **Comments:** Use this line 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

HPTN 035 Ph II/IIb Microbe (013) AA-1 (371)

**Participant ID**

--  
Site Number Participant Number Chk

**Acceptability Assessment**

**Visit Date**

dd MMM yy

**Item 1 is for condom-only cohort. All Gel cohorts, go to item 2.**

1. If a gel like the ones being tested in this study is found to help prevent people from getting HIV, would you want to use it during sex? .....

yes  no

1a. Why not?

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

\_\_\_\_\_

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

\_\_\_\_\_

**If yes, end of form.**

**End of form.**

2. If your study gel is found to help prevent people from getting HIV, would you want to use it during sex? .....

yes  no

2a. Why not?

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

\_\_\_\_\_

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

\_\_\_\_\_

**If yes, go to item 3.**

3. What do you like about your study gel? **Mark all that apply.**

may protect against HIV

may protect against STDs/STIs

can use without partner's knowledge

easy to use

method is under her control

made sex more pleasurable

it does not interrupt sex

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

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

---

## Acceptability Assessment (AA-1), Page 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 first Quarterly visit (Month 3) visit only.*

### Interview tips:

*See Section 13.5 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.

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for a more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study + 2.0. For example, Month 3 is assigned a visit code of "05.0," Month 6 is assigned a visit code of "08.0," etc.
- **Item 1:** This item is completed only for participants assigned to condom-only (no gel). When item 1 is completed (condom-only participants), end the form. Record the Visit Code and PTID on page 2 of this form and fax all pages of this form to SCHARP DataFax. If the participant is assigned to study gel, skip item 1 (leave it blank) and start the interview with item 2.
- **Item 3:** If a participant randomized to study gel reports that she has not yet used the gel draw a single vertical line through all the responses, and initial and date. If the participant responds "nothing" to this item (meaning there is nothing she likes about the gel), mark the "other, specify" box and record "nothing" on the line provided.

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

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) AA-2 (372)

**Participant ID**

--  
Site Number Participant Number Chk

**Acceptability Assessment**

4. What do you not like about your study gel? **Mark all that apply.**

- messy
- interrupts sex
- difficult to use, specify: *Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_
- remembering to use it before sex
- other, specify: *Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

5. The last time you used your study gel, what were your partner's reactions to the gel? **Mark all that apply.**

- he liked it
- he did not like it
- he did not know I used the gel
- he knew I used the gel, but he had no reaction
- I don't know
- other, specify: *Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

---

## Acceptability Assessment (AA-2), Page 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. **For participants assigned to the condom-only arm,** record the Visit Code and PTID on this page, leave the rest of the page blank, and fax both pages of this form to SCHARP DataFax.
- **Items 4 and 5:** If a participant randomized to study gel reports that she has not yet used the gel draw a single vertical line through all the responses, and initial and date. If the participant responds “nothing” to these items (meaning there is nothing she does not like about the gel), mark the “other, specify” box and record “nothing” on the line provided.

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

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) 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

adverse experience

HIV infection

study termination

other, specify: \_\_\_\_\_

AE Log page #(s)

2a. Date of last study gel application:

*dd                  MMM                  yy*

3. Did the participant return unused product applicators?      *yes*      *no*      *not applicable*      *none left to return*

                                                      → **If no, not applicable, or none left to return, go to item 4.**

3a. Date unused product applicators returned:

*dd                  MMM                  yy*

3b. How many unused product applicators were returned?  applicators

4. Was product use resumed?      *yes*      *no (permanently discontinued)*      *no (hold continuing for another reason)*

**End of form.**

→ **In item 4a, record the date on which product use would have been resumed if not being held for another reason.**

4a. Date participant told to resume product use:

*dd                  MMM                  yy*

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 (due to study termination, for example).*

*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 event, the Visit Code recorded on this form should match the visit code recorded in item 10 of the AE Log form 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. If the form is being completed to document permanent discontinuation of study gel due to study termination, record the Termination Date as it appears on the Termination form.
- **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 form 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 2a:** If product is being held due to an adverse experience, record the date of last study gel application. Use a best estimate if the actual date cannot be determined.
- **Item 3:** Record whether the participant returned her unused gel applicators. If the participant was not asked to bring in her unused applicators, mark “not applicable” and follow the skip pattern instruction. If the participant was asked to bring in her unused applicators, but she reported she did not have any unused applicators left to bring in, mark “none left to return” and follow the skip pattern instruction. If the participant is asked to bring in her unused applicators, wait until the applicators are brought in before completing this item.
- **Item 3b:** This value must be directly obtained from the pharmacy staff, not the clinic staff.
- **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 gel use, mark the “no (permanently discontinued)” box and end the form; leave item 4a blank. If the reason for the hold (as marked in item 2) has resolved, but the participant will remain on product hold due to a concurrent reason (e.g., pregnancy), mark the “no (hold continued for another reason)” box; make sure that a Product Hold/Discontinuation form documenting the reason for continuing the product hold is completed.
- **Item 4a:** Record the date on which the participant was told by a study staff member that she could resume study gel use. If “no (hold continued for another reason)” is marked in item 4, record the date on which product use would have been resumed if not being held for another reason.

**SAMPLE: DO NOT FAX TO DATAFAX**



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

Page

HPTN 035 Ph II/IIb Microbe (013) AE-1 (420)

**Participant ID**

-      -   
Site Number Participant Number Chk

**Adverse Experience Log**

**Date Reported to Site**

dd MMM yy

**1. Adverse Experience (AE)**

**2. Onset Date**

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

dd MMM yy

**3. Severity**

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

**4. Relationship to Study Product**

- Definitely related
- Probably related
- Possibly related
- Probably not related
- Not related  
*Record reason why AE is "not related" in Comments below.*

**5. Study Product Administration**

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

**6. Status/Outcome**

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

**6a. Status/Outcome Date**

Leave blank if Status/Outcome is "Continuing."

dd MMM yy

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

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

**8. Is this AE Serious according to ICH guidelines?**

yes no

**9. Has this AE been reported to the DAIDS Safety Office?**

yes no

**10. This AE was first reported at visit:**

Visit code required (regular or interim).

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

\_\_\_\_\_

\_\_\_\_\_

## Adverse Experience Log (AE-1)

Any Adverse Experience (AE) reported by the participant or clinically observed after randomization, regardless of whether or not it is related to study product, must be documented. Do not record a condition as an AE if it existed prior to randomization 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.

**Date Reported to Site:** This is the visit date corresponding to the visit code recorded in item 10. For laboratory AEs, record the specimen collection date here, NOT the date the result was reported to the clinic.

**Item 1:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, decreased hematocrit or increased ALT. Include anatomical locations for AEs known to occur in more than one location.

**Item 2:** At minimum, month and year are required. Record one of the following, as appropriate:

- the date on which the participant reports first experiencing the AE;
- if the AE is discovered during the study visit exam, record the date of the study visit exam;
- if the AE is an abnormal lab result, record the date on which the specimen was collected.

**Item 3:** To grade the severity of an AE, consult the current Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events (also referred to as the Toxicity Table).

**Item 4:** Record the clinicians assessment of the causal association (relationship) between the AE and study product (study gel). Consult the current Manual for Expedited Reporting of Adverse Events to DAIDS, Section 2.4 (Relationship to Study Agent) for a definition of listed response options.

- **For participants assigned to Condom-only (no gel):** Mark the Not related box unless there is clear evidence that the condom-only participant had access to study gel.
- **For AEs resulting in death (Severity grade 5):** If relationship of study product is under investigation, write Pending in the adjacent white space until relationship has been determined. Update accordingly.

**Item 5:** Study Product Administration

- **For participants assigned to Condom-only (no gel):** Always mark the N/A (not applicable) box.
- **All gel participants:** Only mark "held" when product is held (or would be held, if already being held for another reason) for this specific AE. Complete a Product Hold/Discontinuation form whenever the Held box is marked. Complete or update a Product Hold/Discontinuation form whenever the Permanently discontinued box is marked.
- **For gel participants who experience an AE after permanently discontinuing from study gel:** Mark the N/A (not applicable) box. In these cases, the AE Onset Date must be on or after the date of study gel permanent discontinuation.
- **For gel participants who experience an AE while on product hold:** Mark the No change box.
- **For gel participants who die while receiving study gel (AE is severity grade 5):** Mark the Permanently Discontinued box.

**Item 6:** Status/Outcome

- **Continuing:** AE is continuing at the time it is reported.
- **Resolved:** Condition is no longer present or has returned to baseline (pre-enrollment) severity/frequency. If a participant is taking a medication to control an AE, the AE is not considered resolved.
- **Death:** Mark this box when the AE results in death (Severity 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 using the exact same text in item 1. For this new AE, the Onset Date will be the date that the severity or frequency increased. Note: Decreases in severity are not be recorded as new AEs.
- **Continuing at end of study participation:** Mark this box whenever an AE is continuing at the time of participant study termination.

**Item 6a:** At minimum, month and year are required.

- **For Resolved:** Record the date of the study visit or specimen collection date at which the AE is first noted as resolved - that is, the date the participant is no longer experiencing the AE or the date the AE returned to baseline (pre-enrollment) severity/frequency.
- **For Death:** Record the date of death.
- **For Severity/frequency increased:** Refer to instructions for Item 6 above.

**Item 8:** See Section 2.1 of the DAIDS Manual for Expedited Reporting of Adverse Events to DAIDS for a definition of what qualifies as a serious adverse event according to ICH guidelines.

**Item 9:** Mark yes if an EAE form has been completed and sent to the DAIDS Safety Office (RCC) for this AE.

**AE Log form 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. Mark the other AE Log pages for the symptoms for delete and note on the form Deleted due to diagnosis on p. x.

Version 3.0, 31-JAN-07

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**SAMPLE: DO NOT FAX TO DATAFAX**



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

Page

HPTN 035 Ph II/IIb Microbe (013) 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**       OR  Continuing at end of study

*dd MMM yy* *dd MMM yy*

**Dose/Units** \_\_\_\_\_ **Route** PO IM IV TOP IHL other, specify: \_\_\_\_\_  
 Mark only one.        \_\_\_\_\_

**Frequency**  prn  qd  tid  qhs  qxh: every \_\_\_hrs    
 Mark only one.  once  bid  qid  other, specify: \_\_\_\_\_

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

**Medication (generic name)**

**Indication** \_\_\_\_\_ **Staff Initials/Log Entry Date** \_\_\_\_\_

**Date Started**       **Date Stopped**       OR  Continuing at end of study

*dd MMM yy* *dd MMM yy*

**Dose/Units** \_\_\_\_\_ **Route** PO IM IV TOP IHL other, specify: \_\_\_\_\_  
 Mark only one.        \_\_\_\_\_

**Frequency**  prn  qd  tid  qhs  qxh: every \_\_\_hrs    
 Mark only one.  once  bid  qid  other, specify: \_\_\_\_\_

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

**Medication (generic name)**

**Indication** \_\_\_\_\_ **Staff Initials/Log Entry Date** \_\_\_\_\_

**Date Started**       **Date Stopped**       OR  Continuing at end of study

*dd MMM yy* *dd MMM yy*

**Dose/Units** \_\_\_\_\_ **Route** PO IM IV TOP IHL other, specify: \_\_\_\_\_  
 Mark only one.        \_\_\_\_\_

**Frequency**  prn  qd  tid  qhs  qxh: every \_\_\_hrs    
 Mark only one.  once  bid  qid  other, specify: \_\_\_\_\_

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

---

## 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. If a medication of the exact same dose, route, frequency, and duration is taken for more than one indication, record the medication as a single item.

**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.

**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 table-spoon).

**Route and Frequency:** Below is a list of common route and frequency abbreviations.

- **Route Abbreviations:**

For medications administered via a skin patch, mark the "other, specify" box and record "transdermal."

<b>PO</b> oral	<b>IM</b> intramuscular	<b>IV</b> intravenous	<b>TOP</b> topical	<b>IHL</b> inhaled
----------------	-------------------------	-----------------------	--------------------	--------------------

- **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>qxh</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. If a medication taken at baseline is later taken for an AE (at the same dose and frequency) this item must be updated to "yes" and record the appropriate AE Log page number, and initial and date.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) 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: \_\_\_\_\_

---

## Pregnancy Report and History (PR-1)

*This form is used to report the pregnancy of a study participant during follow-up. This form is completed **once** for each pregnancy experienced by a participant during the study follow-up period (post-enrollment until study termination). **Do not** complete this form each time the participant has a positive pregnancy test - instead, complete the form when a negative pregnancy test is followed by a positive pregnancy test, or a pregnancy outcome is followed by a positive pregnancy test.*

### Item-specific Instructions:

- **Visit Code:** Record the visit code of the form (Monthly or Quarterly Visit form or Interim Visit form) that documents the participant's positive pregnancy test result.
- **Item 1:** REcord the first day (or best estimate) of the participant's last menstrual period.
- **Item 3:** If the participant has never been pregnant before, mark "no" and end the form as the rest of the items on this form collect information on prior pregnancies.
- **Item 3a:** If this is **not** the participant's first pregnancy since enrollment (that is, a Pregnancy Report and History form has already been completed at least once for this participant), mark "no" and end the form as the rest of the items on this form have already been completed for the participant on a prior Pregnancy Report and History form.
- **Items 3a-3e:** Be sure to use leading zeros when needed so that all boxes are filled.
- **Item 4:** If the participant has a prior history (before study enrollment) of pregnancy complications or fetal/infant congenital abnormalities, record details (if not already present) on the participant's Baseline Medical History form.

**SAMPLE: DO NOT FAX TO DATAFAX**



Visit Code

HPTN 035 Ph II/IIb Microbe (013) PO-1 (441)

**Participant ID**

--  
Site Number Participant Number Chk

**Pregnancy Outcome**

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 ( $\geq 37$  weeks)
  - premature live birth ( $< 37$  weeks)
  - spontaneous fetal death and/or still birth ( $\geq 20$  weeks)
  - spontaneous abortion ( $< 20$  weeks)
  - ectopic pregnancy
  - therapeutic/elective abortion
- 2b1. Method:  C-section  vaginal
- Complete AE Log. Gel participants only: Complete EAE 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 ( $\geq 37$  weeks)
  - premature live birth ( $< 37$  weeks)
  - spontaneous fetal death and/or still birth ( $\geq 20$  weeks)
  - spontaneous abortion ( $< 20$  weeks)
  - ectopic pregnancy
  - therapeutic/elective abortion
- 3b1. Method:  C-section  vaginal
- Complete AE Log. Gel participants only: Complete EAE form.**

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

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

---

## 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. 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 EAE form, 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 035 Ph II/IIb Microbe (013) 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: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

---

## 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.*

### Item-specific Instructions:

- **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 035 Ph II/IIb Microbe (013) PT-1 (465)

**Participant ID**

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

**Participant Transfer**

**Form Completion Date**

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

**Instructions:** The **transferring** study site completes this form when a participant transfers to another study site.

1. Name of transferring study site: \_\_\_\_\_

2. Name of receiving study site: \_\_\_\_\_

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

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

dd                  MMM                  yy

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

---

## Participant Transfer (PT-1)

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

- **Comments:** Record any necessary comments on the comments line at the bottom of the form.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) PRC-1 (466)

**Participant ID**

-      -

Site Number

Participant Number

Chk

**Participant Receipt**

**Form Completion Date**

dd

MMM

yy

**Instructions:** The **receiving** study site completes this form when a participant transfers from another study site. Record the Participant ID assigned by the transferring study site (i.e., keep original Participant ID). **Do not** assign a new Participant ID.

1. Name of receiving study site: \_\_\_\_\_

2. Name of transferring study site: \_\_\_\_\_

3. Date informed consent signed at receiving study site:

dd

MMM

yy

yes

no

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

4a. Date informed consent for specimen storage signed:

dd

MMM

yy

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

---

## Participant Receipt (PRC-1)

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

- **Comments:** Record any necessary comments on the comments line at the bottom of the form.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) SAA-1 (471)

**Participant ID**

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

**Study Exit Acceptability Assessment**

**Visit Date**

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

**Items 1–2b are for condom-only cohort. All Gel cohorts, go to item 3.**

1. If a gel like the ones being tested in this study is found to help prevent people from getting HIV, would you want to use it during sex? .....

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

**If yes, go to item 2.**

1a. Why not?

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

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

2. During your participation, did you ever use anyone else's gel? .....

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

**If no, end of form.**

2a. Approximately how many times did you use someone else's gel?

1 time	2–5 times	6–10 times	> 10 times
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2b. Can you tell me why you used another participant's gel?

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

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

**Condom-only cohort, end of form.**

3. If your study gel is found to help prevent people from getting HIV, would you want to use it during sex? .....

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

**If yes, go to item 4.**

3a. Why not?

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

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

---

## Study Exit Acceptability Assessment (SAA-1), Page 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 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.

### Item-specific Instructions:

- **Visit Code:** Record the visit code assigned to the visit. See Section 13.3.2 for a more specific information on assigning visit codes. Note that for regularly scheduled (Monthly or Quarterly) visits, the visit code is equal to the month on study + 2.0. For example, Month 3 is assigned a visit code of "05.0," Month 6 is assigned a visit code of "08.0," etc.
- **Items 1 and 2:** These items are completed only for participants assigned to condom-only (no gel). When items 1 and 2 are completed (condom-only participants), end the form. Record the Visit Code and PTID on pages 2 and 3 of this form and fax all 3 pages of this form to SCHARP DataFax. If the participant is assigned to study gel, skip these items (leave them blank) and start the interview with item 3.

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

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) SAA-2 (472)

**Participant ID**

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

Site Number

Participant Number

Chk

**Study Exit Acceptability Assessment**

4. What do you like about your study gel? **Mark all that apply.**

- may protect against HIV
- may protect against STDs/STIs
- can use without partner's knowledge
- easy to use
- method is under her control
- made sex more pleasurable
- it does not interrupt sex
- other, specify: *Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

5. What do you not like about your study gel? **Mark all that apply.**

- messy
- interrupts sex
- difficult to use, specify: *Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_
- remembering to use it before sex
- other, specify: *Local Language:* \_\_\_\_\_  
*English:* \_\_\_\_\_

---

## Study Exit Acceptability Assessment (SAA-2), Page 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. **For participants assigned to the condom-only arm,** record the Visit Code and PTID on this page, leave the rest of the page blank, and fax all 3 pages of this form to SCHARP DataFax.
- **Items 4 and 5:** If a participant randomized to study gel reports that she has not yet used the gel draw a single vertical line through all the responses, and initial and date. If the participant responds “nothing” to these items (meaning there is nothing she likes or does not like about the gel), mark the “other, specify” box and record “nothing” on the line provided.

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

SAMPLE: DO NOT FAX TO DATAFAX



HPTN 035 Ph II/IIb Microbe (013) SAA-3 (473)

Participant ID

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

Study Exit Acceptability Assessment

6. The last time you used your study gel, what were your partner's reactions to the gel? Mark all that apply.

- 6. The last time you used your study gel, what were your partner's reactions to the gel? Mark all that apply.
- he liked it
- he did not like it
- he did not know I used the gel
- he knew I used the gel, but he had no reaction
- I don't know
- other, specify: Local Language: English:

7. As you know, none of the participants in this study know whether they were given BufferGel, PRO 2000 Gel, or placebo gel. Now that your participation in the study is over, we would like you to say which study gel you think you got. Of the three gels used in this study, which one do you think you have been using: BufferGel, PRO 2000 Gel, or placebo gel? .....

Form for question 7 with checkboxes for BufferGel, Pro 2000 Gel, and placebo

8. During your participation, did you ever use anyone else's gel? .....

Form for question 8 with checkboxes for yes and no, and instruction 'If no, go to item 9.'

8a. Approximately how many times did you use someone else's gel?

Form for question 8a with checkboxes for 1 time, 2-5 times, 6-10 times, and > 10 times

8b. Can you tell me why you used another participant's gel?

Form for question 8b with lines for Local Language and English responses

9. Do you know if anyone else, even someone who wasn't in the study, used your gel? .....

Form for question 9 with checkboxes for yes and no

---

## Study Exit Acceptability Assessment (SAA-3), Page 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. **For participants assigned to the condom-only arm,** record the Visit Code and PTID on this page, leave the rest of the page blank, and fax all 3 pages of this form to SCHARP DataFax.
- **Item 6:** If a participant randomized to study gel reports that she has not yet used the gel draw a single vertical line through all the responses, and initial and date.
- **Item 7:** This item is completed only for participants assigned to study gel. “Don’t know” is **not** an acceptable response for this item—please work with the participant to identify which study gel she thinks she has been using, and mark the corresponding response box.

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

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) ESI-1 (489)

**Participant ID**

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

**End of Study Inventory**

**Form Completion Date**

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

1. What is the visit code of the participant's last completed visit form?.....

**Visit Code** .

2. What is the page number of the last Adverse Experience Log (AE-1) page completed for this participant?.....

page # OR  no AEs

3. How many Interim Visit (IV-1) forms were completed for this participant? .....

# of Interim Visit forms

**Condom-only cohort: End of form.**

**Item 4 to be completed by clinician performing the participant's last pelvic exam.**

4. As you know, none of the study staff know which participants are using BufferGel, which are using PRO 2000/5 Gel (P), and which are using placebo gel. We would like you to say which study gel you think the participant has been using. If you had to pick just one of the gels as the one the participant has been using, which one would it be?.....

<i>BufferGel</i>	<i>PRO 2000/5 Gel (P)</i>	<i>placebo</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

---

## End of Study Inventory (ESI-1)

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

### Item-specific Instructions:

- **Form Completion Date:** Record the date the form was completed. The Form Completion Date should be on or after the participant's Termination Date.
- **Item 1:** Record the visit code of the **last** visit for which DataFax forms were completed. If the participant's last visit was an interim visit (as documented by an Interim Visit DataFax form), record the interim visit code. 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 page number of the **last** Adverse Experience Log form completed for this participant (that is, record the highest AE Log form page number for this participant). If no Adverse Experience Log forms were completed, mark the "no AEs" box and leave the page number boxes blank.
- **Item 3:** Record the total number of Interim Visit DataFax forms completed for the participant. If no Interim Visit forms were completed for the participant, record "00" in the boxes.
- **Item 4:** If the participant is in the condom-only (no gel) arm, leave this item blank. For participants assigned to gel, this item is to be completed by the clinician who performed the participant's last pelvic exam. Please do not leave this item blank for participants assigned to gel, and mark only one response box.

**SAMPLE: DO NOT FAX TO DATAFAX**



HPTN 035 Ph II/IIb Microbe (013) TM-1 (490)

**Participant ID**

Site Number			Participant Number						Chk

**Termination**

1. Termination Date: *dd* *MMM* *yy*

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

*Date the site determined that the participant was no longer in the study.*

2. Reason for termination. *Mark only one.*

2a. Scheduled exit visit/end of study. —————> **End of form.**

2b. Death. *Indicate date and cause if known.*

2b1. Date of death *dd* *MMM* *yy*

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

OR  Date unknown

2b2. Cause of death \_\_\_\_\_

OR  Cause unknown

**Complete or update Adverse Experience Log.**

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*

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

—————> **Record Adverse Experience Log page(s):** *page #*

--	--	--

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

---

## 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.*

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

- **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.
- **Comments:** Record any necessary or additional comments on the comments line at the bottom of the form.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

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

**Screening Part 1 Eligibility**

**Visit Date**

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

<b>Screening Attempt:</b>	1st	2nd	3rd	4th	5th	other, specify: _____
	<input type="checkbox"/>					

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?

- Are you currently participating in any other study of a vaginally-applied product? .....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	
→		<b>If yes, participant is ineligible.</b>
- Have you ever had an adverse or bad reaction to latex (such as latex condoms or gloves)? .....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	
→		<b>If yes, participant is ineligible.</b>
- In the past 6 weeks, have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated? .....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	
→		<b>If yes, participant may be ineligible at this time.</b>
- Do you plan to become pregnant in the next 30 months (2 1/2 years)? .....
 

yes	no	don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
→		<b>If yes, participant is ineligible.</b>
- Do you plan to move away from this area in the next 30 months (2 1/2 years)? .....
 

yes	no	don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
→		<b>If yes, participant is ineligible.</b>
- Do you plan to be away from this area for more than 3 months in a row (this includes seasonal travel) in the next 30 months (2 1/2 years)? .....
 

yes	no	don't know
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
→		<b>If yes, participant is ineligible.</b>
- In the past 12 months (1 year), have you used a needle to inject drugs that were not prescribed to you by a medical professional? .....
 

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

---

## Screening Part 1 Eligibility (non-DataFax), Page 1

*This interviewer-administered form is used to document the participant's eligibility for the study. If, at any point during the administration of this form, the participant is found to be ineligible, continue administering both pages of this form so that the interview is not stopped abruptly. Because this form is a non-DataFax form, this form should NOT be faxed to SCHARP DataFax.*

**Note:** *If a participant is being re-screened, a new Screening Part 1 Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 13.5 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.*

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 2:** This item is intended to determine if the participant has had any adverse or bad (that is, allergic or irritant) reactions to latex.
- **Item 7:** This item is intended to determine if the participant has used *non-therapeutic* injection drugs (that is, has she injected drugs that were not given to her for a medical purpose) in the 12 months prior to this visit.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

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

**Screening Part 1 Eligibility**

	<i>1st</i>	<i>2nd</i>	<i>3rd</i>	<i>4th</i>	<i>5th</i>	<i>other, specify: _____</i>
<b>Screening Attempt:</b>	<input type="checkbox"/>					

I am now going to ask you some questions about your sexual behavior. These questions are personal and sensitive, but understanding sexual behavior is important for HIV prevention. Remember, all of your answers will be kept confidential.

Are you ready to continue?

8. In the past 3 months, 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.**
9. In the past 2 weeks, how many times have you had vaginal sex? .....  → **If > 28, participant is ineligible.**

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

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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## Screening Part 1 Eligibility (non-DataFax), Page 2

### Item-specific Instructions:

- **Screening Attempt Box:** The screening attempt marked on this page must match the screening attempt marked on page 1 of this form.
- **Item 8:** This item determines if the participant is sexually active as defined by the protocol.
- **Comments:** Record any necessary comments on the comments lines at the bottom of the form.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

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

**Screening Part 2 Eligibility**

**Visit Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

- Is this visit being conducted within 30 days of when the participant provided written informed consent for screening? ...
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
- Is the participant HIV-negative based on testing performed by study staff? .....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
- Does the participant have documented negative pregnancy tests performed by study staff at all Screening Visits, including this one? .....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If no, participant is ineligible. End of form.
- Phase II participants only:** Does the participant have any Grade 3 or higher laboratory abnormalities based on hematology, liver and renal function, and coagulation testing performed by study staff? .....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If yes, participant is ineligible. End of form.
- Phase IIb participants only:** Does the participant have any Grade 4 or higher laboratory abnormalities based on hematology and coagulation testing performed by study staff? .....
 

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

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

- Are you currently participating in any other study of a vaginally-applied product? .....
 

yes	no	
<input type="checkbox"/>	<input type="checkbox"/>	→ If yes, participant is ineligible.
- In the past 6 weeks, have you been pregnant, given birth (including stillbirth), or had a pregnancy terminated? .....
 

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

**Complete item 8 after reviewing all Screening forms.**

- Does the participant have any condition that, based on 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? .....
 

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

**If yes, participant is ineligible. Specify reason:**

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## Screening Part 2 Eligibility (non-DataFax)

*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 6 and 7), while other items are not. 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 for more instructions regarding re-screening form completion and transmission procedures.*

### General Interviewer Tips:

*See Section 13.5 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:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Items 1–5:** These items are NOT interviewer administered and should not be read aloud to the participant.
- **Item 4:** This item is completed only for participants screening for the Phase II portion of the study. If the participant is being screened for phase IIb, skip item 4 (leave it blank).
- **Item 5:** This item is completed only for participants screening for the Phase IIb portion of the study. If the participant is being screening for Phase II, skip item 5 (leave it blank).
- **Items 6 and 7:** These items were also asked during the Screening Part 1 visit. They must be asked again in order to confirm the participant's eligibility for the study per the inclusion/exclusion criteria stated in the protocol.
- **Item 8:** This is NOT an interviewer-administered item. This item should be completed by the site investigator or his/her designee once the Screening Part 2 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 qualified candidate for the study, mark the "yes" box, record the reason in the space provided, and do not enroll the participant in the study.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

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

**Baseline Medical History**

**Visit Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

	If yes, date diagnosed		Description:	Ongoing?		
	yes	no		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"/>
<b>If yes to any, record on Pre-existing Conditions form after Enrollment.</b>						
Alcohol use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>
Drug use	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>

---

## Baseline Medical History (non-DataFax), Page 1

*This form is used to document participant's medical history as part of the Screening Part 2 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 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.*

***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.***

### Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **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.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/Ib Microbe (013)

**Participant ID**

Site Number			Participant Number						Chk	

**Baseline Medical History**

	<i>1st</i>	<i>2nd</i>	<i>3rd</i>	<i>4th</i>	<i>5th</i>	<i>other, specify: _____</i>
<b>Screening Attempt:</b>	<input type="checkbox"/>					

**Menstrual History**

	<i>regular</i>	<i>irregular</i>		<i>dd</i>	<i>MMM</i>	<i>yy</i>
Usual menstrual cycle:	<input type="checkbox"/>	<input type="checkbox"/>	First day of last menstrual period:	<input type="text"/>	<input type="text"/>	<input type="text"/>
Usual length of menstrual cycle (days):	<input type="text"/>	<i># of days</i>	Last day of last menstrual period:	<input type="text"/>	<input type="text"/>	<input type="text"/>
Usual number of bleeding days:	<input type="text"/>	<i># of days</i>	Usual type of menstrual flow (at the heaviest day of menses):	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Age of menarche:	<input type="text"/>	<i>years</i>		<i>light</i>	<i>moderate</i>	<i>heavy</i>

**Genital Symptoms**

			<i>If yes, date diagnosed</i>		<i>Description:</i>	<i>Ongoing?</i>	
	<i>yes</i>	<i>no</i>	<i>MMM</i>	<i>yy</i>		<i>yes</i>	<i>no</i>
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 genital/vaginal discharge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	_____	<input type="checkbox"/>	<input type="checkbox"/>
Other genitourinary	<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, record on Pre-existing Conditions form after Enrollment.** ←

Reproductive history: \_\_\_\_\_

History of contraception/family planning use: \_\_\_\_\_

Additional Notes: \_\_\_\_\_

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## Baseline Medical History (non-DataFax), Page 2

*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*

### Item-specific Instructions:

- **Screening Attempt Box:** The screening attempt marked on this page must match the screening attempt marked on page 1 of this form.
- **Usual length of menstrual cycle (days):** Record the average number of days between the start dates of two consecutive menstrual cycles.
- **Usual number of bleeding days:** Record the average number of days the participant reports bleeding during menses.
- **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.  
*Note: For amenorrheic participants complete all sections in Menstrual History except for “First day of last period” and “Last day of last period.” Line through these boxes, record “N/A,” and initial and date. Complete all other fields under Menstrual History based on the participant’s periods before she became amenorrheic. Also, in the “Additional notes” section record the reason for amenorrhea. For example, “Participant currently amenorrheic due to \_\_\_\_\_ (record reason). Details in Menstrual History describe participant’s periods before becoming amenorrheic.*
- **yes/no:** For each genital symptom listed, mark the “yes” box if there is evidence (either by participant report or by medical records) that the participant has ever experienced that symptom. Mark the “no” box for symptoms not reported or documented in medical records.
- **If yes, 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. 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.
- **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:** 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.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

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Page 1 of 1

**Participant ID**

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

**Exam Date**

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

**Physical Exam**

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

**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"/>	<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"/>	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 (non-DataFax)

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

*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 for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **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 onto 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 onto the participant's Pre-existing Conditions form.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

-      -   
 Site Number                      Participant Number                      Chk

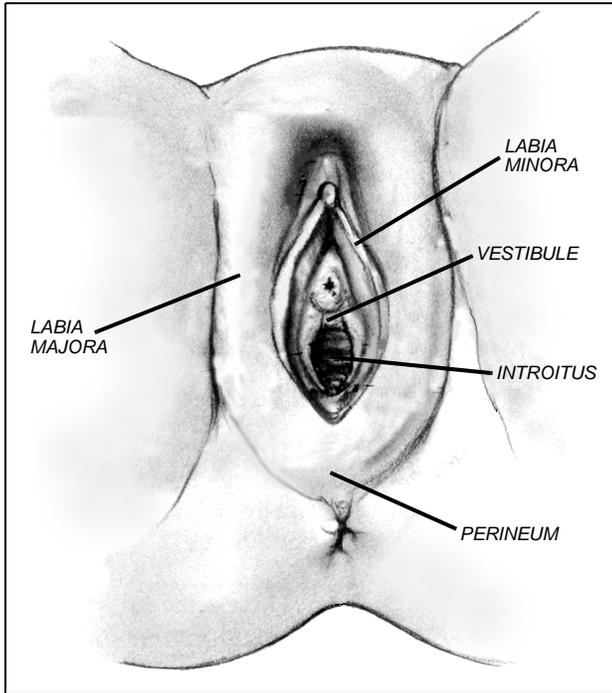
**Pelvic Exam Diagrams**

no normal variants or abnormal findings observed

**Exam Date**

/    /    
 dd                      MMM                      yy

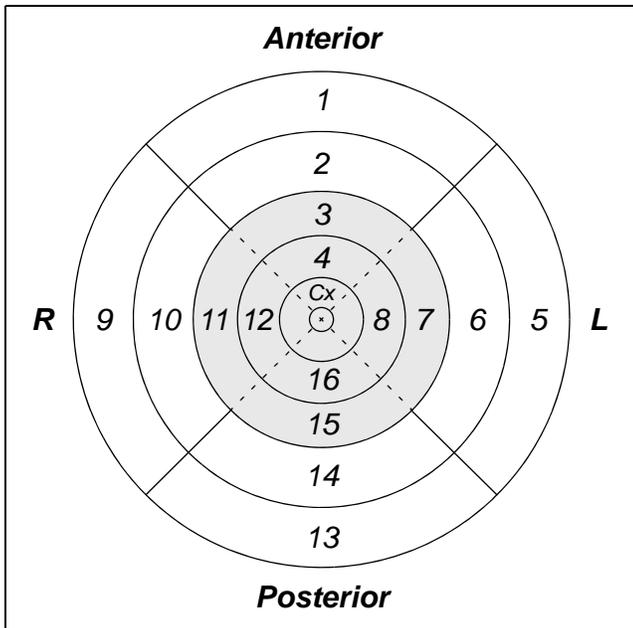
**External Genitalia**



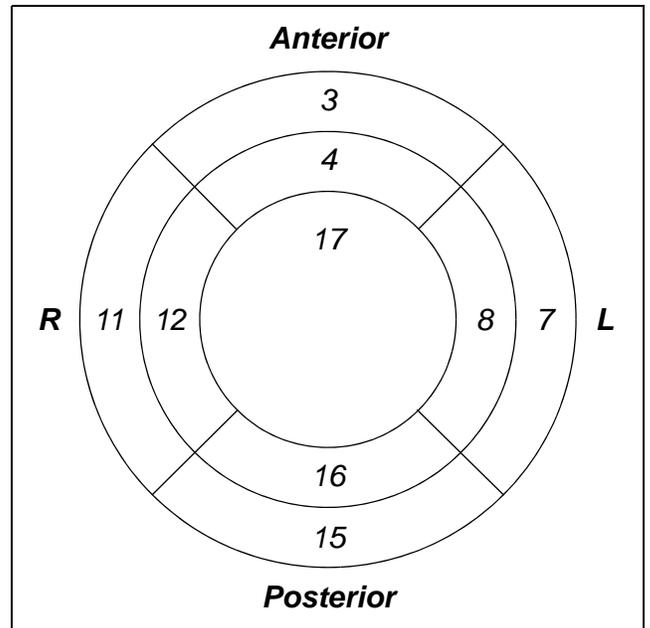
**Legend for Vagina/Cervix**

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

**Vagina**



**Cervix**



---

## Pelvic Exam Diagrams (non-DataFax)

*This form is used to document all variants of normal and all abnormal findings observed during pelvic exams. This form is completed whenever 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.*

*Colored pens (in addition to black and blue) can be used on this particular form.*

### 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).
- Documenting cervical or vaginal discharge or blood in vagina: Record "cerv discharge," "vag discharge," or "blood in vag" on or near the appropriate diagram.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

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

**Clinical Eligibility**

**Visit Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

**Instructions:** If yes to any of items 1–2, do not perform any other Screening Part 2 evaluations at this visit. Provide treatment/follow-up per protocol and SSPs.

1. At this visit, was the participant diagnosed by study staff with any of the following STDs or reproductive tract infections (RTIs):

	yes	no
1a. chlamydia.....	<input type="checkbox"/>	<input type="checkbox"/>
1b. gonorrhea.....	<input type="checkbox"/>	<input type="checkbox"/>
1c. syphilis .....	<input type="checkbox"/>	<input type="checkbox"/>
1d. symptomatic BV .....	<input type="checkbox"/>	<input type="checkbox"/>
1e. symptomatic candidiasis (yeast) .....	<input type="checkbox"/>	<input type="checkbox"/>
1f. trichomoniasis .....	<input type="checkbox"/>	<input type="checkbox"/>
1g. any other STD or RTI requiring treatment, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>

**If yes to any, treat STD or RTI per protocol and SSPs. Do not enroll participant until treatment is complete and symptoms (if any) have resolved.**

2. At this visit, does the participant have a clinically apparent pelvic exam finding involving deep epithelial disruption? .....

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

**If yes, do not enroll participant until all deep epithelial disruption findings have resolved.**

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

---

## Clinical Eligibility (non-DataFax)

*This form is used to document the participant's clinical eligibility for the study. This form is completed once the screening pelvic exam and wet mount have been completed, and is completed based on review of the Screening Part 1 Laboratory Results, Screening Pelvic Exam, and Screening Part 2 Laboratory Results forms as well as the Repeat Screening Pelvic Exam form (if a repeat Screening Pelvic Exam was performed).*

*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 Clinical Eligibility form must be completed as part of the subsequent Screening Attempt. See Section 13.3.2 for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

- **Screening Attempt Box:** See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.
- **Item 1:** For each STD or RTI listed, record whether the participant is **currently** diagnosed with that STD/RTI.
- **Item 2:** Record whether the participant **currently** has a clinically apparent pelvic exam finding involving deep epithelial disruption. If enrollment does not happen on the same day as Screening Part 2, **and** a pelvic exam is not done, item 2 is not applicable, but must be reviewed on the day of enrollment. In these cases write "N/A - no pelvic exam done at enrollment" in the white space near the item and initial and date.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

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

**Screening Summary**

**Form Completion Date**

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

	1st	2nd	3rd	4th	5th	other, specify: _____
<b>Screening Attempt:</b>	<input type="checkbox"/>					

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 of legal age to provide independent informed consent
  - 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 able and willing to provide adequate locator information for study retention purposes
  - 2d. is enrolled in any other study of a vaginally applied product
  - 2e. has a history of adverse reaction to latex
  - 2f. is within 42 days of last pregnancy outcome
  - 2g. has plans to become pregnant in the next 30 months
  - 2h. has plans to relocate away from the study site in the next 30 months
  - 2i. has plans to travel away from the site for more than 3 consecutive months in the next 30 months
  - 2j. has a history of non-therapeutic injection drug use in the 12 months prior to screening
  - 2k. is not sexually active (has not had vaginal intercourse at least once in the 3 months prior to screening)
  - 2l. has had vaginal sex more than an average of 2 times per day in the 2 weeks prior to screening
  - 2m. exceeded the 30-day screening window
  - 2n. is HIV-infected
  - 2o. is pregnant
  - 2p. 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
  - 2q. is diagnosed with a current STD and/or other RTI requiring treatment according to WHO guidelines
  - 2r. has a clinically apparent pelvic exam finding involving deep epithelial disruption
  - 2s. Phase II participants only: has a Grade 3 or higher laboratory abnormality
  - 2t. Phase IIb participants only: has a Grade 4 or higher laboratory abnormality

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## Screening Summary (non-DataFax), page 1

*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 Part 1 and Screening Part 2 evaluations and forms/documentation have been completed and reviewed. For ineligible participants, this form documents the reason(s) the participant was not eligible for enrollment. 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 for more instructions regarding re-screening form completion and transmission procedures.*

### Item-specific Instructions:

**Screening Attempt Box:** *See Section 13.3.2 for the definition of a screening attempt. Mark whether this is the first (1st), second (2nd), third (3rd), etc. screening attempt for this participant. If this is the participant's sixth or greater screening attempt, mark the "other, specify" box and clearly write the number on the line provided.*

- **Item 2:** If the participant is NOT eligible for enrollment in the study, *mark all* of the listed reasons that apply:
  - **Item 2a:** Review Screening Consent form, item 1; *and* Demographics form, item 1.
  - **Item 2b:** Review Screening Consent form, items 2 and 2a; *and* Enrollment form, items 1 and 1a.
  - **Item 2c:** Review Screening Consent form, item 3.
  - **Item 2d:** Review Screening Part 1 Eligibility form, item 1; *and* Screening Part 2 Eligibility form, item 6.
  - **Item 2e:** Review Screening Part 1 Eligibility form, item 2.
  - **Item 2f:** Review Screening Part 2 Eligibility form, item 7.
  - **Item 2g:** Review Screening Part 1 Eligibility form, item 4.
  - **Item 2h:** Review Screening Part 1 Eligibility form, item 5.
  - **Item 2i:** Review Screening Part 1 Eligibility form, item 6.
  - **Item 2j:** Review Screening Part 1 Eligibility form, item 7.
  - **Item 2k:** Review Screening Part 1 Eligibility form, item 8.
  - **Item 2l:** Review Screening Part 1 Eligibility form, item 9.
  - **Item 2m:** Review Screening Part 2 Eligibility form, item 1.
  - **Item 2n:** Review Screening Part 2 Eligibility form, item 2.
  - **Item 2o:** Review Screening Part 2 Eligibility form, item 3.
  - **Item 2p:** Review Screening Part 2 Eligibility form, item 8.
  - **Item 2q:** Review Clinical Eligibility form, items 1a-1g.
  - **Item 2r:** Review Clinical Eligibility form, item 2.
  - **Item 2s:** Review Screening Part 2 Eligibility form, item 4.
  - **Item 2t:** Review Screening Part 2 Eligibility form, item 5.

**SAMPLE: DO NOT FAX TO DATAFAX**

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**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>	<b>Description:</b>	
	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"/>	_____	
<p>➔ <b>If yes to any, update or complete Adverse Experience Log when applicable.</b></p>								
Alcohol use	<input type="checkbox"/>	<input type="checkbox"/>						_____
Drug use	<input type="checkbox"/>	<input type="checkbox"/>						_____

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## Follow-up Medical History (non-DataFax), Page 1

*This form is used to document participants' follow-up medical history during the study (that is, her medical history since her last study visit). Because this form is a non-DataFax form, this form should not be faxed to SCHARP DataFax.*

*It may be helpful to use a calendar as a probe to help participants recall dates.*

*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.*

*If you need additional space for notation, use the space provided at the bottom of page 2.*

### Item-specific Instructions:

- **Yes/No boxes:** The first time this form is completed for a participant (at her first follow-up visit), review the participant's Pre-existing Conditions form. For each ongoing condition, review the condition with the participant and record updated information about the condition on this form. For all visits after the first follow-up visit, review the Follow-up Medical History form completed at the previous visit and record updated information on all conditions that were ongoing at the last visit.
- **If yes, onset date:** For each item marked "yes," record the day, month, and year the participant was diagnosed with the condition or began experiencing symptoms. When applicable, complete an Adverse Experience Log form for the condition recording this date as the AE Onset Date (item 2 of the Adverse Experience Log form).
- **Continuing from previous visit:** Mark this box for items that are continuing from a previous visit (that is, the Onset Date of the 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 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 form should already have been completed for this condition—review the previously completed AE Log form and update any relevant information. 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 frequency or severity since enrollment/baseline.



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## Follow-up Medical History (non-DataFax), Page 2

### 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.
  - **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 urine pregnancy test if not already done.
- **Genital Symptoms:** 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 form if this is the **first** time the condition 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 form should already have been completed for this condition—review the previously completed AE Log form and update any relevant information. 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 frequency or severity since enrollment/baseline.
- **If the participant reports vaginal bleeding or spotting between usual menstrual periods, or any blood-tinged genital/vaginal discharge,** complete a Genital Bleeding Assessment non-DataFax form.
- **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 comments on the lines at the bottom of the page.

**SAMPLE** *Do NOT FAX TO DATAFAX*

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

Site Number			Participant Number						Chk	

**Genital Bleeding Assessment**

**Visit Date**

dd		MMM			yy		

This form is not to 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 bleeding.

1. First day of participant's last menstrual period:.....  
*Obtain from Follow-up Medical History form.*      dd      MMM      yy      amenorrheic  

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

   OR
- If amenorrheic, go to item 4.** ←
2. Last day of participant's last menstrual period:.....  
*Obtain from Follow-up Medical History form.*      dd      MMM      yy  

--	--	--	--	--	--	--
3. Length in days of participant's last menstrual period  
(based on dates recorded in items 1 and 2): .....      

--	--

 days
4. First day of genital bleeding episode: .....  
*Per participant report or clinical exam.*      dd      MMM      yy  

--	--	--	--	--	--	--
5. Last day of genital bleeding episode:.....      

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

   OR     ongoing
6. Total number of days of genital bleeding: .....      

--	--

 days    OR     ongoing
7. According to the participant, was the amount of genital blood a normal amount, lighter amount, or heavier amount when compared to the heaviest flow day of her regular menses? .....  

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

   normal    lighter    heavier    unknown    N/A
8. According to the participant or the clinician, what color was the genital blood? *Mark all that apply.* .....  

--	--	--

   bright red    brown    unknown
9. According to the participant, did she continue to use study gel during this genital bleeding episode?.....  

--	--	--

   yes    no    N/A
10. Number of days between last application of study gel and first day of genital bleeding episode:.....  

--	--

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

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## Genital Bleeding Assessment (non-DataFax), Page 1

*This form is completed by the study clinician and used to guide study clinicians' assessment of both participant-reported genital bleeding events and clinician-observed genital bleeding events that occur during follow-up. Specifically, this form guides clinicians to collect and consider information on the many factors that may contribute to the genital bleeding event.*

*This form is completed each time a participant reports genital bleeding or spotting in between her usual menstrual periods. If a participant reports more than one episode since a previous visit, complete one Genital Bleeding Assessment form for each reported episode. This form is also completed any time genital bleeding is clinically-observed with no identifiable source.*

*Because this is a non-DataFax form, this form is not faxed to SCHARP DataFax.*

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

- **Item 1:** Mark “amenorrheic” if the participant has been without menses for at least the past three cycle intervals, or the past 6 months, whichever is shorter. If “amenorrheic” is marked, leave items 2 and 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 “N/A” if the participant is assigned to condom-only (no gel).

**SAMPLE**. Do NOT FAX TO DATAFAX

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**Participant ID**

Site Number			Participant Number						Chk	

**Genital Bleeding Assessment**

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

	yes	no	
11a. vaginal sex? .....	<input type="checkbox"/>	<input type="checkbox"/>	
11b. painful vaginal sex? .....	<input type="checkbox"/>	<input type="checkbox"/>	N/A
11c. application of the study gel? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11d. painful or uncomfortable application of the study gel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11e. painful or uncomfortable insertion or removal of any other vaginal product/preparation? .....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11f. a pelvic or colpo exam? .....	<input type="checkbox"/>	<input type="checkbox"/>	→ <i>If yes, record date of last pelvic/colpo exam in Comments.</i>
11g. condom use? .....	<input type="checkbox"/>	<input type="checkbox"/>	→ <i>If yes to any, record related details below.</i>

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

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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## Genital Bleeding Assessment (non-DataFax), Page 2

### Item-specific Instructions:

- **Items 11c and 11d:** Mark “N/A” if the participant is assigned to condom-only (no gel).
- **Comments:** Record any necessary or additional comments relating to item 15 on the comments line at the bottom of the form.

**SAMPLE**. Do NOT FAX TO DATAFAX

**NOT A DATAFAX FORM. DO NOT FAX TO DATAFAX.**

HPTN 035 Ph II/IIb Microbe (013)

**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? .....

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? .....

      → **If no, go to item 14.**

13b. Did the participant miss two or more days of contraceptives? .....

      → **If yes, go to item 14.**

13c. **For participants using oral contraceptives only:** Did the participant make up the missed dose? .....

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 or source. Grade per "hemorrhage" row.**

---

## Genital Bleeding Assessment (non-DataFax), Page 3

### Item-specific Instructions:

- **Item 12:** If the participant reports currently using injectable contraceptives, make sure the injectable contraceptives are listed on the participant's Concomitant Medications Log.
- **Item 13:** Non-injectable hormonal contraceptives include oral contraceptives ("the pill"), Ortho-Evra ("the patch"), and vaginal rings. If the participant reports currently using non-injectable hormonal contraceptives, make sure these are listed on the participant's Concomitant Medications Log.
- **Item 13c:** This item applies only to those participants using oral contraceptives. For participants who do not use oral contraceptives, leave item 17c blank and go to item 18.
- **Item 14a:** If the unexpected bleeding is:
  - menstrual - grade the AE (menorrhagia or menometrorrhagia) using the row for clinical adverse events not identified elsewhere in the DAIDS AE grading table on page 3.
  - non-menstrual - grade the AE (IMB) using the row for intermenstrual bleeding (IMB) in the DAIDS AE grading table on page 13.
  - hemorrhage - grade the AE using the row for hemorrhage (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."

**DO NOT FAX THIS FORM TO DATAFAX**

# HPTN 035

## LDMS Specimen Tracking Sheet

Group: HPTN

Participant ID

-      -   
Site Number Participant Number Chk

Protocol #: 035

Visit Code (Vst)

.

Specimen Collection Date

/     /    
*dd MMM yy*

# of TUBES (or Specimens)	PRIMARY SPECIMEN TYPE	ADDITIVE
<input type="checkbox"/>	Gram Stain Slide ( <b>VAG</b> )	<input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____
<input type="checkbox"/>	GUD Swab ( <b>GLU</b> )	<input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____
<input type="checkbox"/>	Blood ( <b>BLD</b> )	<input type="checkbox"/> EDTA <input type="checkbox"/> No Additive <input type="checkbox"/> Other, specify: _____ Plasma aliquot instructions: <input type="checkbox"/> Enrollment specimen—lab to make at least four (4) 1.0 mL aliquots <input type="checkbox"/> Follow-up specimen—lab to make at least four (4) 0.5 mL aliquots
<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* Receiving Staff

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## LDMS Specimen Tracking Sheet (nonDataFax)

*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.*

*This form accompanies LDMS specimens (in their original specimen collection containers) to the site LDMS entry laboratory. Once the specimens have been entered into LDMS, this form is kept on file at the LDMS entry laboratory. If the site chooses, a copy of this completed form may be made once the specimens have been entered into LDMS and the copy kept in the participant's study notebook. This is not required, however.*

### Item-specific Instructions:

- **Visit Code:** For specimens collected at Screening Part 2 visits and/or Enrollment visits, use the visit code "02.0".
- **# of TUBES (or Specimens):** Record the total number of collected tubes or specimens of the listed primary specimen type that will be entered into LDMS. If no LDMS specimens of the primary specimen type were collected, record "0."
- **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/her initials here.
- **LDMS Data Entry Date:** Record the date the LDMS 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 the form) records his/her initials here.