Other Forms *AS NEEDED*

- Hepatitis Test Results (HEP-1)
- Social Impact Log (SIL-1)
- Sexually Transmitted Infections (STI-1)
- Regimen Hold/Discontinuation Log (RHD-1)
- Concomitant Medications Log (CM-1)
- Adverse Experience Log (AE-1)
- Pregnancy Report and History (PR-1)
- Pregnancy Outcome (PO-1)
- Interim Visit/Contact (IV-1)
- Pharmacogenomic Testing Consent and Sample Collection (PTC-1)
- Missed Visit (MV-1)
- End of Study Inventory (ESI-1)
- Termination (TM-1)
- Participant Transfer (PT-1)
- Participant Receipt (PRC-1)

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Visit Code ☐☐.☐ 1

HPTN 069 (109) HEP-1 (040)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Hepatitis Test Results

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

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

1. HEPATITIS C *(required for Enrollment and as clinically indicated)*

1a. Anti-Hepatitis C Antibody (anti-HCV): ..... *negative* ☐ *positive* ☐

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

2. HEPATITIS B *(as clinically indicated)*

2a. Hepatitis B Surface Antigen (HBsAg): ..... *negative* ☐ *positive* ☐

If positive, complete Regimen Hold/ Discontinuation Log and Adverse Experience Log.

2b. Hepatitis B Surface Antibody (HBsAb): ..... *negative* ☐ *positive* ☐

2c. Hepatitis B Core Antibody (HBCoreAb): ..... *negative* ☐ *positive* ☐

3. Was the Hepatitis B vaccination series recommended? ..... *yes* ☐ *no* ☐ *N/A* ☐

Comments:_____

Hepatitis Test Results (HEP-1)

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

Alternate Collection Date: This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required.

Item-specific Instructions:

- **Item 2:** Participants who are Hepatitis B surface antigen positive at Screening will not be enrolled in the study.

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

HPTN 069 (109) SIL-1 (151)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Social Impact Log

1. Concisely describe social impact:

_____

_____

_____

_____

_____

dd *MMM* *yy*

2. Onset date: ..... ☐☐ ☐☐☐ ☐☐

3. Reported at visit:..... ☐☐ . ☐

4. Social impact code: ☐☐

Social Impact Codes: *See back for definitions.*

01 Personal Relationships	**05** Medical/Dental	**09** Military/Other Government Agency
02 Travel/Immigration	**06** Health Insurance	**10** Other
03 Employment	**07** Life Insurance	
04 Education	**08** Housing	

Social Impact Log (SIL-1)

Purpose: Complete this form when recording the occurrence and resolution of adverse social impacts reported at scheduled visits and those reported spontaneously at any time during the study.

Note: Social impacts are events that the participant thinks are related to participation in this study.

Item-specific instructions:

- **Item 3**: If a participant reports a negative social impact outside of a regularly scheduled visit, complete this Log and the Interim Visit form. Record the same interim visit code on both forms.
- **Item 4:** Use the following definitions to code the social impact:

Code	Definition
01 Personal Relationships	Had negative experiences with family, friends, significant others, or sex partners.
02 Travel/Immigration	Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization.
03 Employment	Been turned down for a new job, lost a job, or experienced other problems at work.
04 Education	Been turned down by an educational program, told to leave an educational program, or experienced other problems at school.
05 Medical/Dental	Been refused medical or dental treatment, or treated negatively by a health care provider.
06 Health Insurance	Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.
07 Life Insurance	Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance.
08 Housing	Had trouble getting or keeping housing, or had other problems related to housing.
09 Military/Other Government Agency	Had a problem with the military or any other government agencies.
10 Other	Had other problems not covered in the codes above.

Visit Code ☐☐.☐ 1

HPTN 069 (109) STI-1 (148)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Sexually Transmitted Infections

Initial Specimen Collection Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

Not done/ Not collected	Alternate Collection Date *dd*	*MMM*	*yy*		*non-reactive*	*reactive*	*equivocal*
☐	☐☐	☐☐☐	☐☐	1. Syphilis screening test	☐	☐	☐

If non-reactive, go to item 3.

1a. Syphilis titer ..... **1:** ☐☐☐☐ **OR** N/A ☐

		negative	*positive*	*indeterminate*
2.	Syphilis confirmatory test	☐	☐	☐

Not done/ Not collected	Alternate Collection Date *dd*	*MMM*	*yy*		*negative*	*positive*
☐	☐☐	☐☐☐	☐☐	3. *N. gonorrhea*–URINE	☐	☐
☐	☐☐	☐☐☐	☐☐	4. *C. trachomatis*–URINE	☐	☐
☐	☐☐	☐☐☐	☐☐	5. *N. gonorrhea*–RECTAL	☐	☐
☐	☐☐	☐☐☐	☐☐	6. *C. trachomatis*–RECTAL	☐	☐
☐	☐☐	☐☐☐	☐☐	7. *N. gonorrhea*–CERVICOVAGINAL	☐	☐
☐	☐☐	☐☐☐	☐☐	8. *C. trachomatis*–CERVICOVAGINAL	☐	☐

Comments: _____

☐☐☐☒ 13-FEB-13

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01 Language

Staff Initials / Date

Sexually Transmitted Infections (STI-1)

General Information/Instructions:

- All participants: Test results from samples collected at the Screening or Enrollment visit may be reported as baseline using visit code “2.0” on the CRF.
- Main study participants: Complete this form at baseline, Week 24, and Week 48.
  - Rectal swabs and urine are collected in all men.
  - Rectal swabs are collected in women who report having had anal sex in the last year (from the time the swab is collected).
  - At sites that have the clinical and laboratory capacity to collect and test cervical or vaginal swabs for GC/CT, this swab should be collected.
  - A woman may opt to self-collect a vaginal swab specimen; if she does, this must be done at the study clinic.
  - For sites that cannot collect and test vaginal or cervical swabs for GC/CT testing, urine should be collected for this purpose.
- Tissue subset participants: Complete this form at baseline, Week 16, and Week 40.

Item-specific Instructions:

- **Item 1a:** If the type of syphilis screening test does not yield a titer, mark the “N/A” box.

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

HPTN 069 (109) RHD-1 (410)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Regimen Hold/Discontinuation Log

1. Date and visit code when this study regimen hold or discontinuation was initiated: *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐ *Visit Code* ☐☐.☐

2. Why is the study regimen being held or discontinued? *Mark only one.*

- ☐ study regimen related toxicity
- ☐ abnormal lab value
- ☐ clinical reasons determined by the investigator
- ☐ Hepatitis B infection

→ *AE Log page #* ☐☐☐

- ☐ one or more reactive HIV test results/possible acute HIV infection
- ☐ reported use of prohibited concomitant medication
- ☐ reported use of post-exposure prophylaxis

→ ***Complete or update Concomitant Medications Log.***

- ☐ request by participant to terminate study regimen
- ☐ participant is unwilling or unable to comply with required study procedures
- ☐ other, specify: _____
- ☐ pregnancy

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

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

In item 5, record the date and visit code on which the participant would have been instructed to resume product use if not being held for another reason.

5. Date and visit code when participant was instructed to resume or permanently discontinue study regimen: *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐ *Visit Code* ☐☐.☐

Comments: _____

Regimen Hold/Discontinuation Log (RHD-1)

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

In the case of temporary regimen holds, do not wait for information about regimen resumption to fax the form—fax this form to SCHARP DataFax as soon as **items 1–3** have been completed. Refax the page once **items 4 and 5** have been completed.

Item-specific Instructions:

- **Page:** Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Regimen Hold/Discontinuation Log pages after faxing, unless instructed by SCHARP.
- **Item 1:** Record the date and visit code at which the clinician initiated the regimen hold/discontinuation. A complete date is required.
- **Item 2:** Mark the box to the left of the reason why the participant is being instructed to hold or permanently discontinue study regimen use. If regimen is being held or discontinued due to an adverse experience, record the page number of the AE Log documenting the regimen hold or permanent discontinuation. If the regimen hold/discontinuation is due to a reason other than the ones listed, mark "other, specify" box and record the reason for the hold/discontinuation on the line provided.
- **Item 3:** Record the date the participant last used study regimen. Use a best estimate if the actual date cannot be determined.
- **Item 4:** Complete this item once study staff have determined that the participant can resume study regimen use or have determined that the participant is permanently discontinued from study regimen use.
    - Mark this item "yes" if study staff instructed the participant that he/she can resume use of study regimen.
    - If the participant was permanently discontinued from study regimen use, mark the "no (permanently discontinued)" box. This box should only be marked on one Regimen Hold/Discontinuation Log page.
    - If the reason for the regimen hold, as recorded in **item 2**, has resolved but there is a concurrent reason for continuing the regimen hold, mark "no (hold continuing/permanently discontinued for another reason)." Complete a new Regimen Hold/Discontinuation Log page if necessary.
- **Item 5:** Record the date and visit code on which the participant was told by a study staff member to resume use of study regimen or to permanently discontinue study regimen use. If "no (hold continuing/permanently discontinued for another reason)" is marked for item 4, in item 5, record the date and visit code that the participant would have been instructed to resume study product use based on resolution of the reason marked in item 2 of the form.

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

HPTN 069 (109) CM-1 (423)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Concomitant Medications Log

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

→ ***Fax to SCHARP DataFax.***

☐ **No medications taken throughout study.** Staff Initials/Date _____

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

1.

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

Indication

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

Date Started ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

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

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

Dose/Units

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

2.

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

Indication

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

Date Started ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

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

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

Dose/Units

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

3.

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

Indication

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

Date Started ☐☐ *dd* ☐☐☐ *MMM* ☐☐ *yy*

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

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

Dose/Units

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

Concomitant Medications Log (CM-1)

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

General Information/Instructions: When to fax this form:

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

Item-specific instructions:

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

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

  - Use "other, specify" for alternate dosing schedules.

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

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

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

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

HPTN 069 (109) AE-1 (460)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐

Site Number Participant Number Chk

Adverse Experience Log

Date Reported to Site

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Adverse Experience (AE)

_____

Record diagnosis (in English) if available. Include anatomical location, if applicable.

2. Onset Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

3. Severity

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

4. Relationship to Study Regimen

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

5. Study Regimen Administration

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

6. Status/Outcome

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

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

→ ☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

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

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

		yes	*no*
8.	Is this an SAE according to ICH guidelines?	☐	☐
9.	Has/will this AE be reported as an EAE?	☐	☐

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

11. Was this AE only related to mucosal sampling?
procedure code

- ☐ yes → ☐☐ *see over for Code List*
- ☐ no
- ☐ don't know

Comments: _____

_____

_____

☐ ☐ ☒ ☐ 14-SEP-12

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0 1
Language

_____
Staff Initials / Date

Adverse Experience Log (AE-1)

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

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

Item-specific instructions:

- **Page:** Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.
- **Item 1:** Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
- **Item 2:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected.
- **Item 3:** To grade the severity of an AE, consult the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Experiences*. Report a Grade 1 AE only if it results in a temporary hold or permanent discontinuation of study medications.
- **Item 4:** Mark the assessment of the relationship between the AE and the study agent. Mark "Related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "Not related" if there is not a reasonable possibility that the AE is related to the study agent. If "Not related," record an alternative etiology, diagnosis, or explanation in the "Comments" field. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
- **Item 5:**
  - ***No change***: Mark if the participant is expected to continue to use study regimen and the AE does NOT result in a study regimen hold or permanent discontinuation.
  - ***Held:*** Mark if the AE results in a study regimen hold. If multiple AEs are reported at the same visit, mark "Held" for the AE(s) that contributed to the regimen hold.
  - ***Permanently discontinued:*** Mark if the AE results in permanent discontinuation of study regimen. If multiple AEs are reported at the same visit, only mark "Permanently discontinued" for the AE that contributed to the permanent discontinuation.
  - ***N/A (not applicable):*** Mark if the AE occurred after the participant had completed all administration of the study regimen, or the study regimen is held or permanently discontinued for a different AE or other reason, or the AE is Grade 5-death.
- **Item 6:**
  - ***Continuing:*** AE is continuing at the time it is reported.
  - ***Resolved:*** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
  - ***Death:*** Mark only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation."
  - ***Severity/frequency increased:*** If an AE increases in severity or frequency after it has been reported on the AE Log, line through the "Continuing" box previously marked and mark "Severity/frequency increased." Record the date of increase in the "Status/Outcome Date." Report the increase in severity or frequency as a new AE. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. Update EAE form if applicable. Note that decreases in severity should not be recorded as new AEs.
  - ***Continuing at end of study participation:*** Mark this box whenever an AE is continuing at the time of participant study termination.
- **Item 6a:** At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant no longer experienced the AE; or the date of the study visit or specimen collection at which the change in status/ outcome is first noted.
- **Item 7:** Indicate all treatments administered for this AE, including treatment provided by a health care professional and participant self-treatment. Do not indicate treatments that were clinically indicated or prescribed, but not administered.
- **Items 8 and 9:** For questions about ICH guidelines and EAE reporting, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2*.
- **Item 11:** Mark "yes" if AE is related only to mucosal sampling; use the Code List below to code the procedure associated with the event. Mark "no" if AE is definitely not related only to mucosal sampling; mark "don't know" if this determination cannot be made with certainty.

01 rectal mucosal sampling	02 cervicovaginal mucosal sampling

Visit Code ☐☐.☐ 1

HPTN 069 (109) PR-1 (440)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Pregnancy Report and History

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

		yes	no	
3.	Has the participant ever been pregnant before?	☐	☐ →	***If no, end of form.***
3a.	Is this the participant's first pregnancy since enrollment in this study?	☐	☐ →	***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:	☐☐

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

Comments:_____

☐☐☐☒ 13-FEB-13

01 Language

Staff Initials / Date

Pregnancy Report and History (PR-1)

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

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

Item-specific instructions:

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

Visit Code ☐☐.☐ 1

HPTN 069 (109) PO-1 (441)

Participant ID

☐☐☐ – ☐☐☐☐☐ – ☐
Site Number Participant Number Chk

Pregnancy Outcome

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

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

2. **OUTCOME #1**

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

2b. **Specify Outcome:** *Mark only one.*

- ☐ full-term live birth (≥ 37 weeks)
- ☐ premature live birth (< 37 weeks)

→ 2b1. **Method:** *C-section* ☐ *vaginal* ☐

- ☐ spontaneous fetal death and/or still birth (≥ 20 weeks)
- ☐ spontaneous abortion (< 20 weeks)
- ☐ ectopic pregnancy
- ☐ therapeutic/elective abortion

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

→ ***If yes, complete AE Log and EAE Reporting form.***

If only one outcome, end of form.

3. **OUTCOME #2**

3a. **Outcome Date** *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

3b. **Specify Outcome:** *Mark only one.*

- ☐ full-term live birth (≥ 37 weeks)
- ☐ premature live birth (< 37 weeks)

→ 3b1. **Method:** *C-section* ☐ *vaginal* ☐

- ☐ spontaneous fetal death and/or still birth (≥ 20 weeks)
- ☐ spontaneous abortion (< 20 weeks)
- ☐ ectopic pregnancy
- ☐ therapeutic/elective abortion

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

→ ***If yes, complete AE Log and EAE Reporting form.***

Comments: _____

☐☐☐☒ 13-FEB-13

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Language

Staff Initials / Date

Pregnancy Outcome (PO-1)

Purpose: This form is used to report the pregnancy outcome(s) of a pregnancy reported post-enrollment. Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that the outcome is unobtainable. A Pregnancy Outcome form is required for each Pregnancy Report and History form that is completed for a participant.

General Information/Instructions: 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.
- **Outcome unobtainable:** If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark the "Outcome unobtainable" box at the top of the page and fax to SCHARP DataFax. Note the rationale on the Comments line.
- **Items 2b and 3b:** Refer to the protocol and applicable version of the *Manual for Expedited Reporting of Adverse Events to DAIDS* to evaluate if the outcome or any maternal complications, as a result of the pregnancy outcome, meets AE and/or EAE reporting requirements. If prior to study termination, a therapeutic/elective 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 item 7, "Treatment."
- **Items 2c and 3c:** If prior to study termination, a woman on study has a baby with a congenital anomaly/ birth defect and the infant does not have his/her own participant ID, report the event on an Adverse Experience (AE) Log. On the AE Log, record "Congenital Anomaly in Offspring" on Item 1, record the Outcome Date as the Onset Date, and note the specific anomaly on the Comments line. Also submit an Expedited Adverse Event Reporting form (EAE).

Visit Code ☐☐.☐ 1

HPTN 069 (109) IV-1 (350)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Interim Visit/Contact

Visit Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

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

- ☐ 1a. in-person visit to report new symptoms
- ☐ 1b. phone call from participant to report new symptoms → ***Complete Adverse Experience Log, if applicable.***
- ☐ 1c. report a social impact
- ☐ 1d. replace EDM device → *new device #* ☐☐☐
- ☐ 1e. pills dispensed → *Maraviroc (MVC)/ placebo* ☐☐☐ *Emtricitabine (FTC)/ placebo* ☐☐☐ *Tenofovir (TDF)/ placebo* ☐☐☐
- ☐ 1f. other, specify: _____

2. Besides this Interim Visit form, what other DataFax study forms were completed at this visit? *Mark all that apply.*

- ☐ 2a. HIV Test Results
- ☐ 2b. Hepatitis Test Results
- ☐ 2c. Follow-up Complete Blood Count
- ☐ 2d. Follow-up Laboratory Results
- ☐ 2e. Specimen Storage–All Participants
- 2f. Tissue Subset Specimen Storage **NO LONGER APPLICABLE**
- 2g. Tissue Subset Follow-up Lab Results **NO LONGER APPLICABLE**
- 2h. Tissue Subset Urine Sample Collection **NO LONGER APPLICABLE**
- ☐ 2i. CD4+/Viral Load Results
- ☐ 2j. Regimen Hold/Discontinuation Log (new) → 2j1. How many **new** Regimen Hold/ Discontinuation Log pages were completed for this visit? *# of pages* ☐☐
- ☐ 2k. Adverse Experience Log (new) → 2k1. How many **new** AE Log pages were completed at this visit? *# of pages* ☐☐
- ☐ 2l. Social Impact Log (new) → 2l1. How many **new** Social Impact Log pages were completed for this visit? *# of pages* ☐☐
- ☐ 2m. Other, specify: _____
- ☐ 2n. Sexually Transmitted Infections
- ☐ 2o. Pregnancy Test Results
- ☐ 2p. Pregnancy Report and History
- ☐ 2q. Pregnancy Outcome

Comments: _____

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Staff Initials / Date

Interim Visit/Contact (IV-1)

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

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

Visit Code ☐☐.☐ 1

HPTN 069 (109) PTC-1 (020)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Pharmacogenomic Testing Consent and Sample Collection

1. Did the participant consent to pharmacogenomic testing? ..... *yes* ☐ *no* ☐ → ***If no, end of form.***

Specimen Collection Date

dd *MMM* *yy*

☐☐ ☐☐☐ ☐☐

2. Blood for pharmacogenomic testing: *stored* ☐ *not stored* ☐ *not done/ not collected* ☐

Reason not stored or not collected: _____

Comments: _____

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Staff Initials / Date

Pharmacogenomic Testing Consent and Sample Collection (PTC-1)

General Information and Instructions: Complete this form once for each participant at enrollment; for those participants enrolled under version 2.0 of the protocol, complete this form after the participant consents and provides a sample OR refuses to consent to the sample collection. If consent and sample collection take place at different visits, the visit code recorded on the CRF must be for the sample collection date.

Visit Code ☐☐.0 1

HPTN 069 (109) MV-1 (463)

Participant ID

☐☐☐-☐☐☐☐☐-☐

Site Number Participant Number Chk

Missed Visit

Form Completion Date

☐☐ ☐☐☐ ☐☐

dd *MMM* *yy*

1. Target Visit Date: *dd* ☐☐ *MMM* ☐☐☐ *yy* ☐☐

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

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

_____

Comments: _____

_____

_____

_____

Missed Visit (MV-1)

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

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

Item-specific Instructions:

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

HPTN 069 (109) ESI-1 (489)

Participant ID

Site Number – Participant Number – Chk

End of Study Inventory

Form Completion Date

dd MMM yy

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

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

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

		page #		*no pages submitted*
3a.	Adverse Experience Log (AE-1)	☐☐☐	**OR**	☐
3b.	Concomitant Medications Log (CM-1)	☐☐		
3c.	Pre-existing Conditions (PRE-1)	☐☐		
3d.	Social Impact Log (SIL-1)	☐☐	**OR**	☐
3e.	Regimen Hold/Discontinuation Log (RHD-1)	☐☐	**OR**	☐

Comments:_____

End of Study Inventory (ESI-1)

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

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

Item-specific instructions:

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

HPTN 069 (109) 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. participant unable to adhere to visit schedule

☐ 2e. participant relocated, no follow-up planned

☐ 2f. investigator decision, specify: _____

☐ 2g. unable to contact participant

2h. HIV infection **NOT APPLICABLE FOR THIS PROTOCOL.**

2i. Inappropriate Enrollment **NOT APPLICABLE FOR THIS PROTOCOL.** → *End of form.*

☐ 2j. invalid ID due to duplicate screening/enrollment → ***End of form.***

☐ 2k. other, specify: _____

☐ 2l. early study closure → ***End of form.***

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

3a. Record AE Log page: ☐☐☐ **OR** Specify: _____

Comments: _____

☐☐☐☒ 01-JUN-12

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Staff Initials / Date

Termination (TM-1)

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

General Information/Instructions: If a participant is terminated prior to completing all study regimen administration, complete a Regimen Hold/Discontinuation form.

Item-specific Instructions:

- **Item 1:** A complete date is required.
- **Item 2:** Mark only the primary reason for termination.
    - **Item 2a:** Scheduled exit visit/end of study: Only mark 2a if the participant completes the protocol-defined final visit.
    - **Item 2b1:** At a minimum, the month and year are required.
    - **Item 2l:** Early study closure: Only mark 2l when instructed by SCHARP.
- **Item 3a:** Record the page number of the Adverse Experience Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the “specify” line. If termination is associated with a reactogenicity symptom that is not documented on an AE Log, record the symptom on the “specify” line.

HPTN 069 (109) PT-1 (465)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Participant Transfer

Form Completion Date

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

dd *MMM* *yy*

1. Name of transferring study site: _____

2. Name of receiving study site: _____

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

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

dd *MMM* *yy*

Comments: _____

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Participant Transfer (PT-1)

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

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

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

Item-specific instructions:

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

HPTN 069 (109) PRC-1 (466)

Participant ID

[ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ]

Site Number Participant Number Chk

Participant Receipt

Form Completion Date

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

dd *MMM* *yy*

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

1. Name of receiving study site: _____

2. Name of transferring study site: _____

3. Date informed consent signed at receiving study site: [ ][ ] [ ][ ][ ] [ ][ ]

dd *MMM* *yy*

Comments: _____

Participant Receipt (PRC-1)

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

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

Item-specific instructions:

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