

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

Subject Case Report Forms

HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020 - ALL

Signature Prompt: I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Screening Date of Visit**

**Generated On: 29 Jul 2020 19:34:50**

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Screening visit date

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Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Date of Visit - Step 1**

**Generated On: 29 Jul 2020 19:34:50**

Did the participant complete this visit? Yes   
No

Visit Date \_\_\_\_\_

Did the participant exit/terminate the study at this visit? Yes

If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes

If "Yes", please complete the Adverse Event Log. No

Is the participant taking any concomitant medications that have not been previously reported? Yes

No

If "Yes", please complete the Concomitant Medications Log.

Have any protocol deviations been reported at this visit? Yes

If "Yes", please complete the Protocol Deviations Log. No

Was the participant observed taking the study product? Yes

No

If the participant was NOT observed taking the study product, was it already taken before this visit? Yes

No

Did the participant have any additional procedures at this visit? Yes

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit. No

Is the participant moving to a new step or visit schedule? Yes

No

If yes, please indicate which step or visit schedule. Step 2

Pregnancy Schedule

If the participant is not moving to Step 2 or the Pregnancy Schedule, please specify. \_\_\_\_\_

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**Form: Date of Visit - Step 2**

**Generated On: 29 Jul 2020 19:34:50**

Did the participant complete this visit? Yes   
No

Visit Date \_\_\_\_\_

Did the participant exit/terminate the study at this visit? Yes

If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes

If "Yes", please complete the Adverse Event Log. No

Is the participant taking any concomitant medications that have not been previously reported? Yes

If "Yes", please complete the Concomitant Medications Log. No

Have any protocol deviations been reported at this visit? Yes

If "Yes", please complete the Protocol Deviations Log. No

Did the participant have any additional procedures at this visit? Yes   
No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Is the participant moving to a different step or visit schedule? Yes   
No

If yes, please indicate which step or visit schedule. Step 3   
Pregnancy Schedule   
Seroconverter Schedule

**Week 5 Visit ONLY**

Date of participant's last dose of oral study product \_\_\_\_\_

Time of participant's last dose of oral study product \_\_\_\_\_

**WEEK 33 Visit ONLY or early discontinuation**

Date of participant's last injection \_\_\_\_\_

**WEEK 34 Visit ONLY**

Was Open Label PrEP dispensed at week 34? Yes   
No

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Visit Date: \_\_\_\_\_

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**Form: Date of Visit - Step 3**

**Generated On: 29 Jul 2020 19:34:50**

Did the participant complete this visit? Yes   
No

Visit Date \_\_\_\_\_

Did the participant exit/terminate the study at this visit? Yes

If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes

If "Yes", please complete the Adverse Event Log. No

Is the participant taking any concomitant medications that have not been previously reported? Yes

No

If "Yes", please complete the Concomitant Medications Log.

Have any protocol deviations been reported at this visit? Yes

If "Yes", please complete the Protocol Deviations Log. No

Did the participant have any additional procedures at this visit? Yes

No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Is the participant moving to a Seroconverter Schedule or Pregnancy Schedule? Yes

No

If yes, please indicate which visit schedule. Pregnancy Schedule

Seroconverter Schedule

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Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

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**Form: Date of Visit - Seroconverter Schedule**  
**Generated On: 29 Jul 2020 19:34:50**

Did the participant complete this visit? Yes   
No

Visit Date \_\_\_\_\_

Did the participant exit/terminate the study at this visit? Yes

If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes   
No

Is the participant taking any concomitant medications that have not been previously reported? Yes   
No

Have any protocol deviations been reported at this visit? Yes   
No

Did the participant have any additional procedures at this visit? Yes   
No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Date of Visit - Pregnancy Schedule**  
**Generated On: 29 Jul 2020 19:34:50**

Did the participant complete this visit? Yes   
No

Visit Date \_\_\_\_\_

Did the participant exit/terminate the study at this visit? Yes

If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes   
No

Is the participant taking any concomitant medications that have not been previously reported? Yes   
No

Have any protocol deviations been reported at this visit? Yes   
No

Did the participant have any additional procedures at this visit? Yes   
No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Informed Consent**

**Generated On: 29 Jul 2020 19:34:50**

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Date the participant or guardian marked or signed the study screening and enrollment consent form \_\_\_\_\_

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Did the participant or guardian consent to long-term specimen storage? Yes  No

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Did the participant or guardian consent to future testing? Yes  No

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Did the participant or guardian consent to genetic testing? Yes  No

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Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Inclusion Exclusion Criteria**

**Generated On: 29 Jul 2020 19:34:50**

Did the participant meet all eligibility criteria? Yes   
No

Eligibility status Eligible and enrolled   
Eligible/Not enrolled   
Ineligible   
Incomplete screening

If "Eligible and enrolled", or "Incomplete screening", end of form.

Select reason(s) why participant is ineligible.

- I1. Assigned female at birth
- I2. At enrollment, below 18 years of age
- I3. At enrollment, body weight  $\geq$  50 kg (110 lbs.)
- I4. Willing to provide written informed assent/consent for the study and/or able to obtain written parental/guardian informed consent
- I5. Self-reported sexual activity with a male (oral, anal or vaginal) in the past 12 months
- I6a. Non-reactive / negative HIV test results
- I6b. Absolute neutrophil count  $>$  799 cells/mm<sup>3</sup>
- I6c. Platelet count  $\geq$  100,000/mm<sup>3</sup>
- I6d. Hemoglobin  $\geq$  11g/dL
- I6e. Calculated creatinine clearance  $\geq$  60 mL/minute using modified Schwartz equation
- I6f. Alanine aminotransferase (ALT)  $<$  2.0 times the upper limit of normal (ULN) ( $\leq$  grade 1) and total bilirubin (Tbili)  $\leq$  2.5 x ULN
- I6g. Hepatitis B virus (HBV) surface antigen (HBsAg) negative and accepts vaccination
- I6h. HCV Antibody negative
- I7. Willing to undergo all required study procedures
- I8. Must have a negative beta human chorionic gonadotropin (BHCG) pregnancy test (sensitivity of  $\leq$  25 mIU/mL) performed (and results known) on the same day as Enrollment and before initiating study product

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**Form: Inclusion Exclusion Criteria**  
**Generated On: 29 Jul 2020 19:34:50**

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- 19. Must agree to use a reliable form of long acting contraception, during the trial and for 48 weeks after stopping the long acting injectable, or 30 days after stopping oral study product, from the list:  
Intrauterine device (IUD) or intrauterine system (IUS) that meets <1% failure rate as stated in the product label OR Hormone-based contraceptive that meets <1% failure rate when used consistently and correctly as stated in the product label (implants or injectables only; this excludes combined oral contraception)
- E1. Co-enrollment in any other HIV interventional research study or other concurrent studies which may interfere with this study (as provided by self-report or other available documentation)
- E2. Currently receiving PrEP from a non-study source
- E3. Past or current participation in HIV vaccine trial with exception for participants who can provide documentation of receipt of placebo
- E4. Exclusively had sex with biological females in lifetime
- E5a. In the last 6 months (at the time of screening): self-reported unprotected anal or vaginal intercourse with someone known to be HIV-infected
- E5b. In the last 6 months (at the time of screening): self-reported illicit injection drug use of any kind or stimulant use (including inhaled nitrate, cocaine in any form, methamphetamine, or non-physician prescribed pharmaceutical-grade stimulants)
- E5c. In the last 6 months (at the time of screening): active or planned use of any substance use which would, in the opinion of the site investigator, would hinder study participation (including herbal remedies), as described in the IB or listed in the SSP, and/or Protocol Section 4.4

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Visit: \_\_\_\_\_

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**Form: Inclusion Exclusion Criteria**  
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- E5d. In the last 6 months (at the time of screening): self-report of greater than 5 different sexual partners (anal or vaginal), regardless of use of protection or knowledge of HIV status
- E6. Known history of clinically significant cardiovascular disease, as defined by history/evidence of symptomatic arrhythmia, angina/ischemia, coronary artery bypass grafting (CABG) surgery or percutaneous transluminal coronary angioplasty (PTCA) or any clinically significant cardiac disease
- E7. Inflammatory skin conditions that compromise the safety of intramuscular (IM) injections
- E8. Tattoo or other dermatological condition overlying the buttock region that may interfere with interpretation of injection site reactions
- E9. Current or chronic history of liver disease (e.g., non-alcoholic or alcoholic steatohepatitis) or known hepatic or biliary abnormalities (with the exception of Gilbert's syndrome, asymptomatic gallstones, or cholecystectomy)
- E10. Known history of clinically significant bleeding
- E11. A history of seizure disorder, per self-report
- E12. Medical, social, or other condition that, in the opinion of the site investigator, would interfere with the conduct of the study or the safety of the participant (e.g., provided by self-report, or found upon medical history and examination or in available medical records)
- E13. Plans to move out of the geographic area within the next 18 months or otherwise unable to participate in study visits, according to the site investigator
- E14. Pregnant or currently breastfeeding at the time of screening or intends to become pregnant and/or breastfeed while on study

If "Investigator decision", specify (max. 200 characters): \_\_\_\_\_

If eligible, but participant declined enrollment, specify reason: \_\_\_\_\_

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**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Enrollment**

**Generated On: 29 Jul 2020 19:34:50**

Was the participant enrolled in the study? Yes   
No

Date of Enrollment \_\_\_\_\_  
Was the participant observed taking the first dose? Yes   
No

Date of participant's first dose of oral study product \_\_\_\_\_  
Time of participant's first dose of oral study product \_\_\_\_\_

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**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Demographics**

**Generated On: 29 Jul 2020 19:34:50**

Date of birth \_\_\_\_\_

Age \_\_\_\_\_ Fixed Unit: yrs

Sex at birth \_\_\_\_\_ Male

Female

Race \_\_\_\_\_

Gender \_\_\_\_\_

Mark all that apply.

Gender Female

Gender Nonconforming/Gender Variant

Gender Male

Gender Self-identify

Gender Self-identify Other Specify \_\_\_\_\_

Gender Transgender Female

Gender Transgender Male

Gender Prefer not to answer

How do you identify your sexual orientation? Gay/Lesbian/Homosexual

Bisexual

Queer

Two Spirit

Straight/Heterosexual

Additional category

Not sure

Prefer not to answer

If "Additional category", specify: \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

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**Form: Vital Signs**

**Generated On: 29 Jul 2020 19:34:50**

Were vital signs done? Yes   
No

Date of assessment \_\_\_\_\_ Fixed Unit: cm

Height \_\_\_\_\_ Fixed Unit: cm

Weight \_\_\_\_\_ Fixed Unit: kg

BMI calculated \_\_\_\_\_ Fixed Unit: derived field (kg/m2)

Body temperature \_\_\_\_\_ Fixed Unit: C

Systolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

Diastolic blood pressure \_\_\_\_\_ Fixed Unit: mmHg

Pulse \_\_\_\_\_ Fixed Unit: beats/min

Rate of respiration \_\_\_\_\_ Fixed Unit: breaths/min

Oxygen Saturation \_\_\_\_\_ Fixed Unit: %

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

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**Form: HIV Test Results**

**Generated On: 29 Jul 2020 19:34:50**

Specimen Collection Date \_\_\_\_\_

Was this sample collected for additional testing? Yes   
No

HIV Rapid test result Reactive/Positive   
Non-Reactive/Negative   
Invalid   
Not Done

HIV Laboratory based immunoassay test result Reactive/Positive   
Non-Reactive/Negative   
Invalid   
Not Done

HIV RNA Qualitative test result Reactive/Positive   
Non-Reactive/Negative   
Invalid   
Not Done

Was a viral load done? Yes   
No

Final HIV status Reactive/Positive   
Non-Reactive/Negative   
Additional testing required

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

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**Form: Pregnancy Test Results**

**Generated On: 29 Jul 2020 19:34:50**

Was a pregnancy test done? Yes

No

Date of pregnancy test \_\_\_\_\_

Specimen type (Mark only one): Urine

Plasma

Serum

Pregnancy test result Positive

Negative

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Adverse Event Y/N**

**Generated On: 29 Jul 2020 19:34:50**

Has the participant experienced an adverse event during the study? Yes

No

If "Yes", update the Adverse Event log.

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Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Adverse Event**

**Generated On: 29 Jul 2020 19:34:50**

Date AE reported to site \_\_\_\_\_

Adverse event (AE) \_\_\_\_\_

Onset date \_\_\_\_\_

Visit AE was reported  V102.0 - Day 0/Enrollment

V103.0 - Step 1 Week 2

V104.0 - Step 1 Week 4

V201.0 - Step 2 Week 5

V202.0 - Step 2 Week 6

V203.0 - Step 2 Week 9

V204.0 - Step 2 Week 10

V205.0 - Step 2 Week 17

V206.0 - Step 2 Week 18

V207.0 - Step 2 Week 25

V208.0 - Step 2 Week 26

V209.0 - Step 2 Week 33

V210.0 - Step 2 Week 34

V301.0 - Step 3 Week +8

V302.0 - Step 3 Week +12

V303.0 - Step 3 Week +24

V304.0 - Step 3 Week +36

V305.0 - Step 3 Week +48

V401.0 - HIV Confirmation Visit

V402.0 - HIV Week 12

V403.0 - HIV Week 24

V404.0 - HIV Week 36

V405.0 - HIV Week 48

Interim Visit

V501.0 - Pregnancy

Confirmation Visit

V502.0 - Pregnancy Week 12

V503.0 - Pregnancy Week 24

V504.0 - Pregnancy Week 36

V505.0 - Pregnancy Week 48

Interim Visit Code \_\_\_\_\_

Is the AE still ongoing? Yes

No

If "No", outcome date \_\_\_\_\_

Severity grade  Grade 1 (Mild)

Grade 2 (Moderate)

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

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**Form: Adverse Event**  
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	Grade 3 (Severe)	<input type="checkbox"/>
	Grade 4 (Potentially life-threatening)	<input type="checkbox"/>
	Grade 5 (Death)	<input type="checkbox"/>

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Relationship to study product	Related	<input type="checkbox"/>
	Not related	<input type="checkbox"/>

---

Action taken with study product	Dose not changed	<input type="checkbox"/>
	Dose reduced	<input type="checkbox"/>
	Dose increased	<input type="checkbox"/>
	Drug withdrawn	<input type="checkbox"/>
	Drug interrupted	<input type="checkbox"/>
	Not applicable	<input type="checkbox"/>

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Other actions	<input type="checkbox"/>
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Mark "None" or all that apply.

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None	<input type="checkbox"/>
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---

Medication(s)	<input type="checkbox"/>
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Therapeutic procedure/surgery	<input type="checkbox"/>
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Diagnostic procedure	<input type="checkbox"/>
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Referral	<input type="checkbox"/>
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Other	<input type="checkbox"/>
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If "Other", specify (max. 200 characters): \_\_\_\_\_

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Status/outcome	Recovered/resolved	<input type="checkbox"/>
	Recovering/resolving	<input type="checkbox"/>
	Recovered/resolved with sequelae	<input type="checkbox"/>
	Not recovered/not resolved	<input type="checkbox"/>
	Fatal	<input type="checkbox"/>
	Severity/frequency increased	<input type="checkbox"/>

---

Is this a serious adverse event according to ICH/GCP or protocol guidelines?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>

If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.

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Results in death	<input type="checkbox"/>
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Is life-threatening	<input type="checkbox"/>
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Requires inpatient hospitalization or prolongation of existing hospitalization	<input type="checkbox"/>
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Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

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**Form: Adverse Event**

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Results in persistent or significant disability/incapacity

Is a congenital anomaly/birth defect

Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

SAE/EAE onset date \_\_\_\_\_

Has or will this AE be reported as an EAE? Yes

If "Yes", provide EAE number below. No

EAE number \_\_\_\_\_

Begin number with 4-digit year, followed by 6-digit EAE number (no dashes or spaces). \_\_\_\_\_

Was this AE a worsening of a baseline medical condition? Yes

No

Comments (max. 450 characters): \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Participant Identifier**

**Generated On: 29 Jul 2020 19:34:50**

Participant ID: \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Injection Administration**

**Generated On: 29 Jul 2020 19:34:50**

Reminder: All HIV test results from previous visits and at least one HIV test result from the current visit must be confirmed negative/nonreactive prior to injection/dispensing of study product.

Was an injection given at this visit? Yes   
No

If injection was given:

Injection date \_\_\_\_\_

Needle gauge 21 G   
23 G   
25 G   
Other

If other needle gauge, specify: \_\_\_\_\_

Needle length 1 in   
1.5 in   
2 in   
Other

If other needle length, specify: \_\_\_\_\_

Was complete dose given? Yes   
No

If no, what volume was given? Fixed Unit: ml

Location of injection Right buttock   
Left buttock

Time of preparation for injection \_\_\_\_\_

Time of injection \_\_\_\_\_

If injection was not given:

Indicate if injection was missed, refused, temporarily held, permanently discontinued or other reason why injection was not provided. Injection missed   
Injection refused   
Injection schedule on hold or permanently discontinued   
Other, specify

If Other, specify \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

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**Form: Supplemental HIV Results**

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HIV 1/2 Discriminatory Assay

Mark 'Not Done' OR enter Specimen Collection date and mark result:

Not Done

OR

Specimen Collection Date \_\_\_\_\_

Assay Result

Assay result not provided

HIV Negative

HIV-1 Positive

HIV-2 Positive

HIV-2 Positive with HIV-1

Cross-Reactivity

HIV-1 Positive, Untypable

HIV-1 Indeterminate

HIV-2 Indeterminate

HIV Indeterminate

Other

Other assay result: \_\_\_\_\_

Comments (max. 200 characters) \_\_\_\_\_

Laboratory Reported HIV Interpretation \_\_\_\_\_

Mark 'Not Reported' if not provided by testing laboratory OR mark interpretation:

Not Reported

OR

Interpretation

HIV Negative

HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected.

No laboratory evidence of HIV infection.

HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.

HIV-1 Positive

HIV-2 Positive

HIV-2 Positive - This result is distinct from HIV Positive, Untypable.

HIV Positive

Acute HIV-1 Positive

HIV-1 Negative, HIV-2 inconclusive

Inconclusive

Other

Other interpretation: \_\_\_\_\_

Comments (max. 200 characters) \_\_\_\_\_

HIV DNA \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

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**Form: Supplemental HIV Results**

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Mark 'Not performed/Not reported by Lab' OR enter Specimen Collection date and complete appropriate result field:

Not performed/Not reported by Lab (add comment)

OR

Specimen Collection Date

DNA Result

Detectable DNA result (record below)

Detectable DNA , but below limit of detection (<4.09 copies per million cells)

Detectable DNA, above the reportable range of the assay (>100 copies per million cells)

Undetectable DNA, below limit of detection (<4.09 copies per million cells )

Detectable DNA result:

Fixed Unit: copies per million cells

Comments (max. 200 characters)

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Interim Visit**

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Interim visit date \_\_\_\_\_

Interim visit code \_\_\_\_\_

Was study product use permanently discontinued (scheduled or early) at this visit? Yes   
If "Yes", please complete the Discontinuation of Study Product" CRF. No

Did the participant exit/terminate the study at this visit? Yes   
If "Yes", please complete the Study Termination CRF. No

Were any new adverse events (AEs) reported at this visit? Yes   
If "Yes", please complete the Adverse Event Log. No

Is the participant taking any concomitant medications that have not been previously reported? Yes   
If "Yes", please complete the Concomitant Medications Log. No

Have any protocol deviations been reported at this visit? Yes   
If "Yes", please complete the Protocol Deviations Log. No

Reason for interim visit (Mark all that apply)

AE report or follow-up

ISR report or follow-up   
If checked, please complete the Injection Site Reaction Log.

Report social harm   
If checked, please complete the Social Impact Log.

Additional laboratory testing

Product Hold   
If checked, please complete the Product Hold Log.

Other

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

Were vital signs (such as weight) taken at this visit? Yes   
No

Is the participant moving to a new visit schedule? Yes   
No

If yes, please indicate which visit schedule. Step 2   
Step 3   
Seroconverter Schedule   
Pregnancy Schedule

Mark all forms completed at this visit.

CD4 Test Results/Viral Load

Chemistry Panel

Counseling

Fasting Lipid Test Results

Hematology

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Interim Visit**

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Hepatitis Test Results	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Injection Administration	<input type="checkbox"/>
CASI	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Specimen Collection and Storage	<input type="checkbox"/>
STI Tests	<input type="checkbox"/>
Urinalysis	<input type="checkbox"/>
Physical Exam	<input type="checkbox"/>
Vital Signs	<input type="checkbox"/>
Pill Count Step 1	<input type="checkbox"/>
Pregnancy Test Results	<input type="checkbox"/>
Contraception	<input type="checkbox"/>

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Additional Study Procedures**

**Generated On: 29 Jul 2020 19:34:50**

Select any additional forms completed at this visit.

CD4 Test Results/Viral Load	<input type="checkbox"/>
Chemistry Panel	<input type="checkbox"/>
Hematology	<input type="checkbox"/>
STI Tests	<input type="checkbox"/>
Injection Administration	<input type="checkbox"/>
Fasting Lipid Test Results	<input type="checkbox"/>
Hepatitis Test Results	<input type="checkbox"/>
Participant Receipt	<input type="checkbox"/>
Participant Transfer	<input type="checkbox"/>
Urinalysis	<input type="checkbox"/>
CASI	<input type="checkbox"/>
HIV Test Results	<input type="checkbox"/>
Physical Exam	<input type="checkbox"/>
Counseling	<input type="checkbox"/>
Pregnancy Test Results	<input type="checkbox"/>
Contraception	<input type="checkbox"/>
Supplemental HIV Results	<input type="checkbox"/>

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Specimen Collection and Storage**  
**Generated On: 29 Jul 2020 19:34:50**

Specimen type Plasma   
Dried Blood Spot

Was specimen collected? Yes   
No

If "No", record reason why sample was not collected (max. 200 characters). \_\_\_\_\_

Specimen collection date \_\_\_\_\_

Specimen collection time \_\_\_\_\_

Was sample stored? Stored   
Not stored

If "No", record reason why sample was not stored (max. 200 characters). \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Behavioral Assessment**

**Generated On: 29 Jul 2020 19:34:50**

Was a CASI questionnaire completed at this visit?

Yes

No

If no, please explain: \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: CASI Tracking**

**Generated On: 29 Jul 2020 19:34:50**

CASI collection date \_\_\_\_\_

CASI ID \_\_\_\_\_

- Which questionnaire was completed?
- V102.0 - Day 0/Enrollment
  - V104.0 - Step 1 Week 4
  - V201.0 - Step 2 Week 5
  - V203.0 - Step 2 Week 9
  - V205.0 - Step 2 Week 17
  - V207.0 - Step 2 Week 25
  - V209.0 - Step 2 Week 33
  - V302.0 - Step 3 Week +12
  - V303.0 - Step 3 Week +24
  - V304.0 - Step 3 Week +36
  - V305.0 - Step 3 Week +48
  - V502.0 - Pregnancy Week 12
  - V503.0 - Pregnancy Week 24
  - V504.0 - Pregnancy Week 36
  - V505.0 - Pregnancy Week 48
  - Early discontinuation - Step 3

Were there any problems or issues related to the administration or completion of the questionnaire? Yes   
No

If yes, please describe \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: CD4 Test Results/Viral Load**  
**Generated On: 29 Jul 2020 19:34:50**

ABSOLUTE CD4+

Were Absolute CD4+ collected for testing? Yes   
No

Specimen collection date \_\_\_\_\_

Absolute CD4+ \_\_\_\_\_

Unable to analyze

HIV RNA

Was HIV RNA PCR testing completed? Yes   
No

Specimen collection date \_\_\_\_\_

Operator >   
<   
=

HIV RNA PCR \_\_\_\_\_

HIV RNA PCR target not detected

Detected, less than LLQ or LLD

Detected, greater than the upper limit of quantification

Additional CD4 Test Results or Viral Load data collected

Check this box if another CD4 Test Results/Viral Load form is needed to capture additional testing data

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Concomitant Medications Y/N**

**Generated On: 29 Jul 2020 19:34:50**

Were any concomitant medications taken?

Yes

No

If "Yes", update the Concomitant Medications log.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Concomitant Medications**

**Generated On: 29 Jul 2020 19:34:50**

Medication name \_\_\_\_\_  
Indication \_\_\_\_\_  
Date started \_\_\_\_\_  
Date stopped \_\_\_\_\_

Or \_\_\_\_\_  
Ongoing

Dose \_\_\_\_\_  
Dose units \_\_\_\_\_ Grams   
Micrograms   
Milligrams   
Milliliters   
Capsules   
Drops   
Puffs   
Sachets   
Suppository   
Tablets   
Units   
Unknown   
Other

If "Other", specify: \_\_\_\_\_  
Frequency \_\_\_\_\_ PRN - As needed   
QD - Once a day   
BID - Twice a day   
TID - Three times a day   
QID - Four times a day   
QM - Every morning   
QH - Every Hour   
ONCE - Single dose   
Other

If "Other", specify: \_\_\_\_\_  
Route \_\_\_\_\_ Inhalation   
Intramuscular   
Intravenous   
Other   
Oral   
Rectal

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Concomitant Medications**  
**Generated On: 29 Jul 2020 19:34:50**

Subcutaneous

Topical

Vaginal

If "Other", specify: \_\_\_\_\_

Taken for a reported AE?

Yes

No

If "Yes", select adverse event. \_\_\_\_\_

Taken for a reported Injection site reaction?

Yes

No

If "Yes", select injection site reaction event. \_\_\_\_\_

Select additional injection site reaction, if applicable \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Counseling**

**Generated On: 29 Jul 2020 19:34:50**

Did a counseling session occur at this visit?

Yes

No

Indicate which topic areas were covered during this session. Mark all that apply.

- |                                  |                          |
|----------------------------------|--------------------------|
| Adherence goal setting           | <input type="checkbox"/> |
| Adherence reminder strategies    | <input type="checkbox"/> |
| Barriers to adherence            | <input type="checkbox"/> |
| Communication skills             | <input type="checkbox"/> |
| Product Storage                  | <input type="checkbox"/> |
| Disclosing product use to others | <input type="checkbox"/> |
| Planning for future PrEP use     | <input type="checkbox"/> |
| Pill or injection education      | <input type="checkbox"/> |
| Problem solving                  | <input type="checkbox"/> |
| Social Support                   | <input type="checkbox"/> |
| Parental Support                 | <input type="checkbox"/> |
| Other                            | <input type="checkbox"/> |

If other, please specify: \_\_\_\_\_

Indicate which adherence barriers/challenges were explored during this session. Mark all that apply or only "None could be identified".

- |   |                          |
|---|--------------------------|
| None could be identified  | <input type="checkbox"/> |
| Barriers to return for study visits (e.g., money, transportation, time) | <input type="checkbox"/> |
| Disruption in routine (for example, travel away from home)              | <input type="checkbox"/> |
| Forgetting/no pills available   | <input type="checkbox"/> |
| Job/School commitments  | <input type="checkbox"/> |
| Lack of privacy   | <input type="checkbox"/> |
| Medication side effects   | <input type="checkbox"/> |
| Negative reactions (family, friends, partner)                           | <input type="checkbox"/> |
| Partying/drugs/alcohol  | <input type="checkbox"/> |
| Side effects  | <input type="checkbox"/> |
| Other   | <input type="checkbox"/> |

If other, please specify: \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Discontinuation of Study Product**  
**Generated On: 29 Jul 2020 19:34:50**

Date that study product use ended \_\_\_\_\_

Visit that study product use ended \_\_\_\_\_

- V101.0 - Screening
- V102.0 - Day 0/Enrollment
- V103.0 - Step 1 Week 2
- V104.0 - Step 1 Week 4
- V201.0 - Step 2 Week 5
- V202.0 - Step 2 Week 6
- V203.0 - Step 2 Week 9
- V204.0 - Step 2 Week 10
- V205.0 - Step 2 Week 17
- V206.0 - Step 2 Week 18
- V207.0 - Step 2 Week 25
- V208.0 - Step 2 Week 26
- V209.0 - Step 2 Week 33
- V210.0 - Step 2 Week 34
- V301.0 - Step 3 Week +8
- V302.0 - Step 3 Week +12
- V303.0 - Step 3 Week +24
- V304.0 - Step 3 Week +36
- V305.0 - Step 3 Week +48
- V401.0 - HIV Confirmation Visit
- V402.0 - HIV Week 12
- V403.0 - HIV Week 24
- V404.0 - HIV Week 36
- V405.0 - HIV Week 48
- Interim Visit
- V501.0 - Pregnancy Confirmation Visit
- V502.0 - Pregnancy Week 12
- V503.0 - Pregnancy Week 24
- V504.0 - Pregnancy Week 36
- V505.0 - Pregnancy Week 48

If 'Interim Visit' is chosen, provide interim visit code. \_\_\_\_\_

Primary reason for ending study product use

- Scheduled study product use period completed
- Death
- Participant refused further participation
- Participant is unwilling or unable to comply with required study procedures

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Discontinuation of Study Product**  
**Generated On: 29 Jul 2020 19:34:50**

- 
- Lost to follow-up
  - Investigator decision
  - Participant refused further study
  - product use
  - HIV infection
  - Early study closure
  - Protocol deviation
  - Adverse event
  - Withdrawal of consent by
  - participant
  - Study terminated by sponsor
  - One or more reactive HIV test
  - results or acute HIV infection
  - suspected
  - Participant unable to adhere to
  - visit schedule
  - Use of prohibited concomitant
  - medications
  - Acquired HBV infection
  - Injection site reaction
  - Positive pregnancy test result
  - Low oral adherence - Step 1
  - Other, specify

---

If "Other" is selected, please specify: \_\_\_\_\_

---

If "Adverse event", select applicable adverse event. \_\_\_\_\_

---

If "Use of prohibited concomitant medications", select applicable concomitant medication. \_\_\_\_\_

---

If "Injection site reaction", select applicable Injection site reaction event. \_\_\_\_\_

---

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Protocol Deviations Y/N**

**Generated On: 29 Jul 2020 19:34:50**

Have any protocol deviations been reported?

Yes

No

If "Yes", update the Protocol Deviations log.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Protocol Deviations Log**

**Generated On: 29 Jul 2020 19:34:50**

Site awareness date \_\_\_\_\_

Deviation date \_\_\_\_\_

Has or will this deviation be reported to local IRB/EC? Yes   
No

Has or will this deviation be reported to DAIDS as a critical event? Yes   
No

Type of deviation

- Inappropriate enrollment
- Study product management deviation
- Study product dispensing error
- Conduct of non-protocol procedure
- Breach of confidentiality
- Physical assessment deviation
- Lab assessment deviation
- Use of non-IRB/EC-approved materials
- Informed consent process deviation
- Other

Description of deviation \_\_\_\_\_

Plans and/or action taken to address the deviation \_\_\_\_\_

Plans and/or action taken to prevent future occurrences of the deviation \_\_\_\_\_

Deviation reported by \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Injection Site Reaction Y/N**

**Generated On: 29 Jul 2020 19:34:50**

Has the participant experienced any Injection Site Reactions?

Yes

No

If yes, complete the Injection Site Reaction Log.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Hematology**

**Generated On: 29 Jul 2020 19:34:50**

**Lab Name:** \_\_\_\_\_

**HEMOGRAM**

Was a hematology sample collected? Yes   
No

Hematology collection date \_\_\_\_\_

Hemoglobin \_\_\_\_\_

Hemoglobin severity grade  
Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

Hemoglobin adverse event, if applicable  
Not reportable as an adverse event

Hematocrit \_\_\_\_\_

MCV \_\_\_\_\_

Platelets \_\_\_\_\_

Platelets severity grade  
Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

Platelets adverse event, if applicable  
Not reportable as an adverse event

WBC \_\_\_\_\_

WBC severity grade  
Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

WBC adverse event, if applicable  
Not reportable as an adverse event

**DIFFERENTIAL**

Was a differential done? Yes   
No

Differential collection date \_\_\_\_\_

Neutrophils \_\_\_\_\_

Neutrophils severity grade  
Grade 1 (Mild)   
Grade 2 (Moderate)

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Hematology**

**Generated On: 29 Jul 2020 19:34:50**

**Lab Name:** \_\_\_\_\_

Grade 3 (Severe)

Grade 4 (Potentially  
life-threatening)

Not gradable

Neutrophils adverse event, if applicable \_\_\_\_\_

Not reportable as an adverse event

Lymphocytes \_\_\_\_\_

Lymphocytes severity grade \_\_\_\_\_

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially  
life-threatening)

Not gradable

Lymphocytes adverse event, if applicable \_\_\_\_\_

Not reportable as an adverse event

Monocytes \_\_\_\_\_

Eosinophils \_\_\_\_\_

Basophils \_\_\_\_\_

Atypical lymphocytes \_\_\_\_\_

Comments (max. 200 characters): \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Chemistry Panel**

**Generated On: 29 Jul 2020 19:34:50**

**Lab Name:** \_\_\_\_\_

Was a sample collected for serum chemistries? Yes   
No

Specimen collection date \_\_\_\_\_

**LIVER FUNCTION TESTS**

Alkaline Phosphatase Result \_\_\_\_\_

Alkaline Phosphatase severity grade Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

Alkaline Phosphatase Adverse Event \_\_\_\_\_

Not reportable as an adverse event

AST (SGOT) result \_\_\_\_\_

AST (SGOT) severity grade Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

AST (SGOT) adverse event \_\_\_\_\_

Not reportable as an adverse event

ALT (SGPT) result \_\_\_\_\_

ALT (SGPT) severity grade Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

ALT (SGPT) adverse event \_\_\_\_\_

Not reportable as an adverse event

Total Bilirubin Result \_\_\_\_\_

Total Bilirubin severity grade Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

Total Bilirubin adverse event \_\_\_\_\_

Not reportable as an adverse event

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Chemistry Panel**

**Generated On: 29 Jul 2020 19:34:50**

**Lab Name:** \_\_\_\_\_

**RENAL FUNCTION TESTS**

Creatinine result \_\_\_\_\_

Creatinine severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Creatinine adverse event \_\_\_\_\_

Not reportable as an adverse event

Creatinine Clearance result \_\_\_\_\_

Creatinine Clearance severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Creatinine Clearance adverse event \_\_\_\_\_

Not reportable as an adverse event

BUN result \_\_\_\_\_

Urea result \_\_\_\_\_

**ELECTROLYTES**

Phosphate result (Phosphorous) \_\_\_\_\_

Phosphate severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Phosphate adverse event \_\_\_\_\_

Not reportable as an adverse event

Calcium result \_\_\_\_\_

Calcium severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Calcium adverse event \_\_\_\_\_

Not reportable as an adverse event

**OTHER CHEMISTRIES**

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Chemistry Panel**

**Generated On: 29 Jul 2020 19:34:50**

**Lab Name:** \_\_\_\_\_

CPK (CK) result \_\_\_\_\_

CPK (CK) severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

CPK (CK) adverse event \_\_\_\_\_

Not reportable as an adverse event

Was a fasting sample collected for the glucose testing?

- Yes
- No

Did the participant fast for at least 8 hours prior to blood collection?

- Yes
- No

Glucose result \_\_\_\_\_

Glucose severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Glucose adverse event \_\_\_\_\_

Not reportable as an adverse event

Amylase, Pancreatic result \_\_\_\_\_

Amylase severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Amylase adverse event \_\_\_\_\_

Not reportable as an adverse event

Lipase result \_\_\_\_\_

Lipase severity grade

- Grade 1 (Mild)
- Grade 2 (Moderate)
- Grade 3 (Severe)
- Grade 4 (Potentially life-threatening)
- Not gradable

Lipase adverse event \_\_\_\_\_

Not reportable as an adverse event

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Chemistry Panel**

**Generated On: 29 Jul 2020 19:34:50**

**Lab Name:** \_\_\_\_\_

**Comments (max. 200 characters):** \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Hepatitis Test Results**

**Generated On: 29 Jul 2020 19:34:50**

Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing? Yes   
No

Date of collection \_\_\_\_\_  
Hepatitis B Surface Antigen (HBsAG) Positive/Reactive   
Negative/Non-reactive   
Not Done

Was a sample collected for Hepatitis B Surface Antibody (HBsAb) testing? Yes   
No

Date of collection \_\_\_\_\_  
Hepatitis B Surface Antibody (HBsAb) Positive/Reactive   
Negative/Non-reactive   
Not Done

Was a sample collected for Hepatitis B Core Antibody (HBcAb) testing? Yes   
No

Date of collection \_\_\_\_\_  
Hepatitis B Core Antibody (HBcAb) Positive/Reactive   
Negative/Non-reactive   
Not Done

Was a sample collected for Hepatitis C Antibody (HCAb) testing? Yes   
No

Date of collection \_\_\_\_\_  
Hepatitis C Antibody (HCAb) Positive/Reactive   
Negative/Non-reactive   
Not Done

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Fasting Lipid Test Results**

**Generated On: 29 Jul 2020 19:34:50**

**Lab Name:** \_\_\_\_\_

**SERUM LIPID**

Was a fasting sample collected for the lipid profile? Yes   
No

Did the participant fast for at least 8 hours prior to blood collection? Yes   
No

Date of collection: \_\_\_\_\_

Total Cholesterol result \_\_\_\_\_

Total Cholesterol severity grade  
Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

Total Cholesterol adverse event \_\_\_\_\_

Not reportable as an adverse event

HDL Cholesterol result \_\_\_\_\_

Triglycerides result \_\_\_\_\_

Triglycerides severity grade  
Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

Triglycerides adverse event \_\_\_\_\_

Not reportable as an adverse event

LDL Cholesterol result \_\_\_\_\_

LDL Cholesterol severity grade  
Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

LDL Cholesterol adverse event \_\_\_\_\_

Not reportable as an adverse event

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: STI Tests**

**Generated On: 29 Jul 2020 19:34:50**

Was a urine sample collected for N. gonorrhoea and C. trachomatis testing? Yes   
No

Collection date \_\_\_\_\_

N. gonorrhoea - URINE test result  
Detected   
Non-detected   
Equivocal   
Invalid

C. trachomatis - URINE test result  
Detected   
Non-detected   
Equivocal   
Invalid

**SCREENING, WEEK 33, STEP 3 WEEK +36 ONLY**

Was a vaginal swab sample collected for N. gonorrhoea and C. trachomatis testing? Yes   
No

Collection date \_\_\_\_\_

N. gonorrhoea - VAGINAL SWAB test result  
Detected   
Non-detected   
Equivocal   
Invalid

C. trachomatis - VAGINAL SWAB test result  
Detected   
Non-detected   
Equivocal   
Invalid

Was a sample collected for Syphilis testing? Yes   
No

Collection date \_\_\_\_\_

Syphilis screening test (Non-Treponemal)  
Non-reactive   
Reactive   
Not reported   
Not done

Syphilis titer \_\_\_\_\_

Syphilis confirmatory test (Treponemal)  
Positive   
Negative   
Indeterminate   
Not done

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Urinalysis**

**Generated On: 29 Jul 2020 19:34:50**

**Lab Name:** \_\_\_\_\_

Was a sample collected for urine tests? Yes   
No

Date of collection: \_\_\_\_\_

Protein (Urine) Negative   
Trace   
+1   
+2   
+3   
+4

Protein (Urine) Severity Grade Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

Protein (Urine) Adverse Event \_\_\_\_\_

Glucose (Urine) Negative   
Trace   
+1   
+2   
+3   
+4

Glucose (Urine) Severity Grade Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)   
Not gradable

Glucose (Urine) Adverse Event \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Medical History Y/N**

**Generated On: 29 Jul 2020 19:34:50**

Does the participant have any medical history to report?

Yes

No

If "Yes", update the Medical History log.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Medical History**

**Generated On: 29 Jul 2020 19:34:50**

Date medical history collected \_\_\_\_\_

Description of medical history condition/event \_\_\_\_\_

Is condition/event gradable? Yes   
No

Severity grade Grade 1 (Mild)   
Grade 2 (Moderate)   
Grade 3 (Severe)   
Grade 4 (Potentially life-threatening)

Start date of medical history condition/event \_\_\_\_\_

Is the condition ongoing? Yes   
No

Date medical history/condition ended/resolved \_\_\_\_\_

Comments (max. 200 characters): \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Missed Visit**

**Generated On: 29 Jul 2020 19:34:50**

Target visit date \_\_\_\_\_

- Reason visit was missed
- Unable to contact participant
  - Participant unable to schedule visit within window
  - Participant refused visit
  - Participant incarcerated
  - Participant admitted to healthcare facility
  - Participant withdrew from study
  - Participant deceased
  - Other

If "Other", specify: \_\_\_\_\_

Steps taken to address the missed visit (corrective action plan) \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Physical Exam**

**Generated On: 29 Jul 2020 19:34:50**

Was a physical exam performed? Yes   
No

Date of exam \_\_\_\_\_

**BODY SYSTEM**

HEENT Not done   
Normal   
Abnormal

If "Abnormal", specify: \_\_\_\_\_

Neck Not done   
Normal   
Abnormal

If "Abnormal", specify: \_\_\_\_\_

Lymph Nodes Not done   
Normal   
Abnormal

If "Abnormal", specify: \_\_\_\_\_

Heart/Cardiovascular Not done   
Normal   
Abnormal

If "Abnormal", specify: \_\_\_\_\_

Lung/Respiratory Not done   
Normal   
Abnormal

If "Abnormal", specify: \_\_\_\_\_

Abdomen Not done   
Normal   
Abnormal

If "Abnormal", specify: \_\_\_\_\_

Genitourinary Not done   
Normal   
Abnormal

If "Abnormal", specify: \_\_\_\_\_

Extremities Not done   
Normal   
Abnormal

If "Abnormal", specify: \_\_\_\_\_

Neurological Not done

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Physical Exam**  
**Generated On: 29 Jul 2020 19:34:50**

Normal

Abnormal

If "Abnormal", specify: \_\_\_\_\_

Skin

Not done

Normal

Abnormal

If "Abnormal", specify: \_\_\_\_\_

General appearance

Not done

Normal

Abnormal

If "Abnormal", specify: \_\_\_\_\_

Other system finding

Not done

Normal

Abnormal

If "Other system finding", specify: \_\_\_\_\_

If "Abnormal", specify: \_\_\_\_\_

Comments (max. 200 characters): \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Product Hold Y/N**

**Generated On: 29 Jul 2020 19:34:50**

Does the participant have any clinical product holds to be applied?

Yes

No

If Yes, complete the Product Hold Log

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Product Hold Log**

**Generated On: 29 Jul 2020 19:34:50**

Date of last oral study product use: \_\_\_\_\_

Date of last injection: \_\_\_\_\_

Date when this study product hold was initiated: \_\_\_\_\_

At what visit was this product hold initiated?  V101.0 - Screening

V102.0 - Day 0/Enrollment

V103.0 - Step 1 Week 2

V104.0 - Step 1 Week 4

V201.0 - Step 2 Week 5

V202.0 - Step 2 Week 6

V203.0 - Step 2 Week 9

V204.0 - Step 2 Week 10

V205.0 - Step 2 Week 17

V206.0 - Step 2 Week 18

V207.0 - Step 2 Week 25

V208.0 - Step 2 Week 26

V209.0 - Step 2 Week 33

V210.0 - Step 2 Week 34

V301.0 - Step 3 Week +8

V302.0 - Step 3 Week +12

V303.0 - Step 3 Week +24

V304.0 - Step 3 Week +36

V305.0 - Step 3 Week +48

V401.0 - HIV Confirmation Visit

V402.0 - HIV Week 12

V403.0 - HIV Week 24

V404.0 - HIV Week 36

V405.0 - HIV Week 48

Interim Visit

V501.0 - Pregnancy

Confirmation Visit

V502.0 - Pregnancy Week 12

V503.0 - Pregnancy Week 24

V504.0 - Pregnancy Week 36

V505.0 - Pregnancy Week 48

Interim visit code \_\_\_\_\_

Why is the study product being held?  Reported of use of prohibited concomitant medications

One or more reactive HIV test results or expresses concern about having acute HIV infection

Receiving PEP for potential HIV exposure

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Product Hold Log**  
**Generated On: 29 Jul 2020 19:34:50**

---

	Adverse Event	<input type="checkbox"/>
	Injection Site Reaction	<input type="checkbox"/>
	Positive pregnancy test result	<input type="checkbox"/>
	Hepatitis B infection	<input type="checkbox"/>
	Participant unable/unwilling to comply with the required study procedures, or otherwise might be put at undue risk to their safety and well-being by continuing product use according to the judgment of IoR/designee	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If "Other" is selected, please specify: \_\_\_\_\_

---

If product hold was associated with an adverse event, select the applicable AEs: \_\_\_\_\_

---

If product hold was associated with an injection site reaction, select the applicable ISR: \_\_\_\_\_

---

If product hold was associated with a new or updated concomitant medication, select applicable medication(s): \_\_\_\_\_

---

Will the participant resume study product? Yes

No - Hold continuing for another reason

No - Early termination

No - Permanently discontinued

---

Date participant resumed study product: \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Pregnancy Outcome Log**

**Generated On: 29 Jul 2020 19:34:50**

Is the outcome of this pregnancy obtainable? Yes   
No

If "No", end of form.

How many pregnancy outcomes resulted from this reported pregnancy? \_\_\_\_\_

Outcome date \_\_\_\_\_

Place of delivery/outcome Home   
Hospital   
Clinic   
Unknown   
Other

If "Other", specify: \_\_\_\_\_

Specify outcome Full term live birth (greater than or equal to 37 weeks)   
Premature live birth (less than 37 weeks)   
Stillbirth/intrauterine fetal demise (greater than or equal to 20 weeks)   
Spontaneous abortion (less than 20 weeks)   
Ectopic pregnancy   
Therapeutic/elective abortion   
Other

If "Other", specify: \_\_\_\_\_

Method C-section   
Standard vaginal   
Operative vaginal

Provide a brief narrative of the circumstances (max. 400 characters). \_\_\_\_\_

Were there any complications related to the pregnancy outcome? Yes   
No

If "No", skip to "Were any fetal/infant congenital anomalies identified?".

Delivery-related complications. Mark "None" or all that apply.

None

Intrapartum hemorrhage

Postpartum hemorrhage

Non-reassuring fetal status

Chorioamnionitis

Other

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Pregnancy Outcome Log**

**Generated On: 29 Jul 2020 19:34:50**

If "Other", specify: \_\_\_\_\_

Non-delivery related complications. Mark "None" or all that apply.

None

Hypertensive disorders of pregnancy

Gestational diabetes

Other

If "Other", specify: \_\_\_\_\_

Were any fetal/infant congenital anomalies identified? Mark all that apply. Yes

No

Not assessed

If "No" or "Unknown", go to "Complete the infant items below for live births only." Unknown

Central nervous system, cranio-facial

Central nervous system, spinal

Cardiovascular

Renal

Gastrointestinal

Pulmonary

Musculoskeletal/extremities

Physical defect

Skin

Genitourinary

Chromosomal

Cranio-facial (structural)

Hematologic

Infectious

Endocrine/metabolic

Other

Describe congenital anomaly/defect (max. 200 characters). \_\_\_\_\_

Specify congenital anomaly/defect AE. \_\_\_\_\_

Complete AE Log and EAE Reporting form. \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Pregnancy Outcome Log**

**Generated On: 29 Jul 2020 19:34:50**

Complete the infant items below for live births only. Otherwise, end of form.

Male

Female

Infant sex

Infant birth weight

Fixed Unit: kg

Or

Infant birth weight unavailable

Infant birth length

Fixed Unit: cm

Or

Infant birth length unavailable

Infant birth head circumference

Fixed Unit: cm

Or

Infant birth head circumference unavailable

Infant birth abdominal circumference

Fixed Unit: cm

Or

Infant birth abdominal circumference unavailable

Infant gestational age by examination in weeks

Fixed Unit: Weeks

Infant gestational age by examination in days

Fixed Unit: Days

Or

Infant gestational age by examination unavailable

If unavailable, end of form.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Pregnancy Outcome Log**

**Generated On: 29 Jul 2020 19:34:50**

Method used to determine gestational age

Ballard

Dubowitz

Other

If "Other", specify (max. 200 characters): \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Participant Receipt**

**Generated On: 29 Jul 2020 19:34:50**

Name of receiving study site

Harare - Spilhaus

Johannesburg - Ward 21

Makerere, Kampala, Uganda

Name of transferring study site

Harare - Spilhaus

Johannesburg - Ward 21

Makerere, Kampala, Uganda

Date informed consent signed at receiving site \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Pregnancy History**

**Generated On: 29 Jul 2020 19:34:50**

Date pregnancy history collected \_\_\_\_\_

Has the participant ever been pregnant before? Yes

No

If "No", end of form.

Number of full term live births (>=37 weeks) \_\_\_\_\_

Number of premature live births (Less than 37 weeks) \_\_\_\_\_

Number of spontaneous fetal deaths and/or still births (>=20 weeks) \_\_\_\_\_

Number of spontaneous abortions (Less than 20 weeks) \_\_\_\_\_

Number of therapeutic/elective abortions \_\_\_\_\_

Number of ectopic pregnancies \_\_\_\_\_

Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? Yes

No

If "Yes", specify (max. 200 characters): \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Pregnancy Report**  
**Generated On: 29 Jul 2020 19:34:50**

Date pregnancy reported to site \_\_\_\_\_

Visit at which this pregnancy was reported \_\_\_\_\_

- V101.0 - Screening
- V102.0 - Day 0/Enrollment
- V103.0 - Step 1 Week 2
- V104.0 - Step 1 Week 4
- V201.0 - Step 2 Week 5
- V202.0 - Step 2 Week 6
- V203.0 - Step 2 Week 9
- V204.0 - Step 2 Week 10
- V205.0 - Step 2 Week 17
- V206.0 - Step 2 Week 18
- V207.0 - Step 2 Week 25
- V208.0 - Step 2 Week 26
- V209.0 - Step 2 Week 33
- V210.0 - Step 2 Week 34
- V301.0 - Step 3 Week +8
- V302.0 - Step 3 Week +12
- V303.0 - Step 3 Week +24
- V304.0 - Step 3 Week +36
- V305.0 - Step 3 Week +48
- V401.0 - HIV Confirmation Visit
- V402.0 - HIV Week 12
- V403.0 - HIV Week 24
- V404.0 - HIV Week 36
- V405.0 - HIV Week 48
- Interim Visit
- V501.0 - Pregnancy Confirmation Visit
- V502.0 - Pregnancy Week 12
- V503.0 - Pregnancy Week 24
- V504.0 - Pregnancy Week 36
- V505.0 - Pregnancy Week 48

If "Interim visit", specify Interim visit code \_\_\_\_\_

Date of onset of last menstrual period \_\_\_\_\_

Or

Amenorrheic for past 6 months

Estimated date of delivery \_\_\_\_\_

What primary information was used to estimate the date of delivery? Last menstrual period

Initial ultrasound <20 weeks

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Pregnancy Report**  
**Generated On: 29 Jul 2020 19:34:50**

Initial ultrasound  $\geq$  20 weeks

Physical examination

Conception date by assisted  
reproduction

Other

\_\_\_\_\_  
If "Other", specify: \_\_\_\_\_

Is this the participant's first pregnancy since enrollment in this  
study? \_\_\_\_\_

Yes

No

\_\_\_\_\_  
If "Yes", complete Pregnancy History form. \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Social Impact**

**Generated On: 29 Jul 2020 19:34:50**

Date reported to site \_\_\_\_\_

Concisely describe social impact (max. 200 characters). \_\_\_\_\_

Onset date \_\_\_\_\_

Reported at visit code \_\_\_\_\_

- V101.0 - Screening
- V102.0 - Day 0/Enrollment
- V103.0 - Step 1 Week 2
- V104.0 - Step 1 Week 4
- V201.0 - Step 2 Week 5
- V202.0 - Step 2 Week 6
- V203.0 - Step 2 Week 9
- V204.0 - Step 2 Week 10
- V205.0 - Step 2 Week 17
- V206.0 - Step 2 Week 18
- V207.0 - Step 2 Week 25
- V208.0 - Step 2 Week 26
- V209.0 - Step 2 Week 33
- V210.0 - Step 2 Week 34
- V301.0 - Step 3 Week +8
- V302.0 - Step 3 Week +12
- V303.0 - Step 3 Week +24
- V304.0 - Step 3 Week +36
- V305.0 - Step 3 Week +48
- V401.0 - HIV Confirmation Visit
- V402.0 - HIV Week 12
- V403.0 - HIV Week 24
- V404.0 - HIV Week 36
- V405.0 - HIV Week 48
- Interim Visit
- V501.0 - Pregnancy Confirmation Visit
- V502.0 - Pregnancy Week 12
- V503.0 - Pregnancy Week 24
- V504.0 - Pregnancy Week 36
- V505.0 - Pregnancy Week 48

\_\_\_\_\_ If "Interim visit", specify Interim visit code \_\_\_\_\_

Social impact \_\_\_\_\_ Personal Relationships - Had negative experiences with family, friends, significant others, or sex partners.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Social Impact**

**Generated On: 29 Jul 2020 19:34:50**

- 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.
- Employment - Been turned down for a new job, lost a job, or experienced other problems at work.
- Education - Been turned down by an educational program, told to leave an educational program, or experienced other problems at school.
- Medical/Dental - Been refused medical or dental treatment, or treated negatively by a health care provider.
- Health Insurance - Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.
- Life Insurance - Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance.
- Housing - Had trouble getting or keeping housing, or had other problems related to housing.
- Military/Other Government Agency - Had a problem with the military or any other government agencies.
- Other - Had other problems not covered in the codes above.

\_\_\_\_\_  
If "Other", specify (max. 200 characters): \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Social Impact Y/N**

**Generated On: 29 Jul 2020 19:34:50**

Has the participant experienced any social impacts related to study participation?

Yes

No

If "Yes", update the Social Impact log.

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Study Termination**

**Generated On: 29 Jul 2020 19:34:50**

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Date of study exit \_\_\_\_\_

---

Primary reason for completion/discontinuation

Scheduled exit visit/end of study	<input type="radio"/>
Death	<input type="radio"/>
Participant refused further participation	<input type="radio"/>
Participant is unwilling or unable to comply with required study procedures	<input type="radio"/>
Lost to follow-up	<input type="radio"/>
Investigator decision	<input type="radio"/>
Participant refused further study product use	<input type="radio"/>
Early study closure	<input type="radio"/>
Protocol deviation	<input type="radio"/>
Adverse event	<input type="radio"/>
One or more reactive HIV test results or acute HIV infection suspected - Step 1	<input type="radio"/>
Low oral adherence - Step 1	<input type="radio"/>
Other, specify	<input type="radio"/>

---

If "Other", specify (max. 200 characters): \_\_\_\_\_

---

If "Death", enter date of death. \_\_\_\_\_

---

If "Adverse event", select applicable adverse event. \_\_\_\_\_

---

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Participant Transfer**

**Generated On: 29 Jul 2020 19:34:50**

Name of transferring study site  
Harare - Spilhaus   
Johannesburg - Ward 21   
Makerere, Kampala, Uganda

Name of receiving study site  
Harare - Spilhaus   
Johannesburg - Ward 21   
Makerere, Kampala, Uganda

Visit of last completed contact with participant  
V101.0 - Screening   
V102.0 - Day 0/Enrollment   
V103.0 - Step 1 Week 2   
V104.0 - Step 1 Week 4   
V201.0 - Step 2 Week 5   
V202.0 - Step 2 Week 6   
V203.0 - Step 2 Week 9   
V204.0 - Step 2 Week 10   
V205.0 - Step 2 Week 17   
V206.0 - Step 2 Week 18   
V207.0 - Step 2 Week 25   
V208.0 - Step 2 Week 26   
V209.0 - Step 2 Week 33   
V210.0 - Step 2 Week 34   
V301.0 - Step 3 Week +8   
V302.0 - Step 3 Week +12   
V303.0 - Step 3 Week +24   
V304.0 - Step 3 Week +36   
V305.0 - Step 3 Week +48   
V401.0 - HIV Confirmation Visit   
V402.0 - HIV Week 12   
V403.0 - HIV Week 24   
V404.0 - HIV Week 36   
V405.0 - HIV Week 48   
Interim Visit   
V501.0 - Pregnancy Confirmation Visit   
V502.0 - Pregnancy Week 12   
V503.0 - Pregnancy Week 24   
V504.0 - Pregnancy Week 36   
V505.0 - Pregnancy Week 48

If "Interim visit", specify Interim visit code \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Participant Transfer**

**Generated On: 29 Jul 2020 19:34:50**

---

Date participant's records were sent to receiving study site \_\_\_\_\_

---

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Patient Health Questionnaire**  
**Generated On: 29 Jul 2020 19:34:50**

Over the last 2 weeks, how often have you been bothered by any of the following problems?

Little interest or pleasure in doing things

Not at all

Several days

More than half the days

Nearly every day

Feeling down, depressed, or hopeless

Not at all

Several days

More than half the days

Nearly every day

Trouble falling or staying asleep, or sleeping too much

Not at all

Several days

More than half the days

Nearly every day

Feeling tired or having little energy

Not at all

Several days

More than half the days

Nearly every day

Poor appetite or overeating

Not at all

Several days

More than half the days

Nearly every day

Feeling bad about yourself - or that you are a failure or have let yourself or your family down

Not at all

Several days

More than half the days

Nearly every day

Trouble concentrating on things, such as reading the newspaper or watching television

Not at all

Several days

More than half the days

Nearly every day

Moving or speaking so slowly that other people could have noticed. Or the opposite - being so figety or restless that you have been moving around a lot more than usual

Not at all

Several days

More than half the days

Nearly every day

Thoughts that you would be better off dead, or of hurting yourself

Not at all

Several days

More than half the days

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Patient Health Questionnaire**  
**Generated On: 29 Jul 2020 19:34:50**

Nearly every day

---

PHQ Calculated Total

If you mentioned any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people? Not at all   
Several days   
More than half the days   
Nearly every day

---

In the past year, have you felt depressed or sad most days, even if you felt OK sometimes? Yes   
No

---

Has there been a time in the past month when you have had serious thoughts about ending your life? Yes   
No

---

Have you ever, in your whole life, tried to kill yourself or made a suicide attempt? Yes   
No

---

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Contraception**  
**Generated On: 29 Jul 2020 19:34:50**

Visit

- V101.0 - Screening
- V102.0 - Day 0/Enrollment
- V103.0 - Step 1 Week 2
- V104.0 - Step 1 Week 4
- V201.0 - Step 2 Week 5
- V202.0 - Step 2 Week 6
- V203.0 - Step 2 Week 9
- V204.0 - Step 2 Week 10
- V205.0 - Step 2 Week 17
- V206.0 - Step 2 Week 18
- V207.0 - Step 2 Week 25
- V208.0 - Step 2 Week 26
- V209.0 - Step 2 Week 33
- V210.0 - Step 2 Week 34
- V301.0 - Step 3 Week +8
- V302.0 - Step 3 Week +12
- V303.0 - Step 3 Week +24
- V304.0 - Step 3 Week +36
- V305.0 - Step 3 Week +48
- V401.0 - HIV Confirmation Visit
- V402.0 - HIV Week 12
- V403.0 - HIV Week 24
- V404.0 - HIV Week 36
- V405.0 - HIV Week 48
- Interim Visit
- V501.0 - Pregnancy Confirmation Visit
- V502.0 - Pregnancy Week 12
- V503.0 - Pregnancy Week 24
- V504.0 - Pregnancy Week 36
- V505.0 - Pregnancy Week 48

\_\_\_\_\_  
If 'Interim visit', provide interim visit code

Have there been any changes to your method(s) of birth control since the last visit? Yes   
No

\_\_\_\_\_  
If YES, please complete all sections below that apply. If NO, end form.

Select Concomitant Medication Log line.

\_\_\_\_\_  
Select from the drop-down list 1

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Contraception**

**Generated On: 29 Jul 2020 19:34:50**

Select from the drop-down list 2

Have you had a tubal ligation or hysterectomy surgery since last visit? Yes   
No

If yes, Date of procedure

Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit? Yes   
No

If yes, please update Concomitant Medications and select the medication(s) below.

If yes, select from the drop-down list 1

If yes, select from the drop-down list 2

Have you stopped an oral contraceptive, removed an implant or IUD device since last visit? Yes   
No

If yes, please update Concomitant Medications and select the medication(s) below.

If yes, select from the drop-down list 1

If yes, select from the drop-down list 2

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Contraception - Screening**

**Generated On: 29 Jul 2020 19:34:50**

What type of birth control method are you currently using?

Please update the Concomitant Medications or Medical History form as appropriate.

- |   |                          |
|---|--------------------------|
| None, no birth control.                       | <input type="checkbox"/> |
| Oral Contraceptive pill                       | <input type="checkbox"/> |
| Intrauterine Device (IUD)                     | <input type="checkbox"/> |
| Injectable                                    | <input type="checkbox"/> |
| Contraceptive Patch                           | <input type="checkbox"/> |
| Contraceptive Vaginal Ring                    | <input type="checkbox"/> |
| Implant                                       | <input type="checkbox"/> |
| Other Contraceptive                           | <input type="checkbox"/> |
| Sterilization (Tubal ligation / hysterectomy) | <input type="checkbox"/> |

If Sterilization, end form. If not, select Concomitant Medication

Select Concomitant Medication Log line.

Select from the drop-down list 1

Select from the drop-down list 2

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Pill Count Enrollment**

**Generated On: 29 Jul 2020 19:34:50**

Record the number of pills dispensed at the Enrollment Visit.

Number of pills dispensed \_\_\_\_\_

Comments (max. 450 characters) \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Pill Count Step 1**

**Generated On: 29 Jul 2020 19:34:50**

Date of pill count \_\_\_\_\_

Number of pills the participant presented at this visit. \_\_\_\_\_

Did the participant return any pills at this visit? Yes

If yes, record the number of pills returned at this visit. No

Number of pills returned \_\_\_\_\_

Was the participant dispensed any additional pills at this visit? Yes

If yes, record the number of pills dispensed at this visit. No

Number of additional pills dispensed \_\_\_\_\_

Comments (max. 450 characters) \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Injection Site Reaction**

**Generated On: 29 Jul 2020 19:34:50**

Date reported to site \_\_\_\_\_

Event diagnosis

Injection site abscess

Injection site anesthesia

Injection site bruising

Injection site discoloration

Injection site erosion

Injection site hemorrhage

Injection site itching

Injection site induration

Injection site swelling

Injection site nodule

Injection site pain

Injection site tenderness

Injection site erythema

Injection site warmth

Injection site hematoma

Injection site side

Right buttock

Left buttock

Onset date \_\_\_\_\_

At which visit was this ISR first reported?

V201.0 - Step 2 Week 5

V202.0 - Step 2 Week 6

V203.0 - Step 2 Week 9

V204.0 - Step 2 Week 10

V205.0 - Step 2 Week 17

V206.0 - Step 2 Week 18

V207.0 - Step 2 Week 25

V208.0 - Step 2 Week 26

V209.0 - Step 2 Week 33

V210.0 - Step 2 Week 34

If 'Interim Visit' is chosen, provide interim visit code. \_\_\_\_\_

Is the reaction still ongoing?

Yes

No

If no, provide an outcome date \_\_\_\_\_

Severity Grade

Grade 1 (Mild)

Grade 2 (Moderate)

Grade 3 (Severe)

Grade 4 (Potentially life-threatening)

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**  
**Form: Injection Site Reaction**  
**Generated On: 29 Jul 2020 19:34:50**

Grade 5 (Death)

Action taken with study product

Dose not changed

Dose reduced

Dose increased

Drug withdrawn

Drug interrupted

Not applicable

Other action(s) taken (Select "none" or all that apply)  
None

Medication(s)

Therapeutic procedure/surgery

Diagnostic procedure

Other

Other, specify: \_\_\_\_\_

Status/Outcome

Recovered/resolved

Recovering/resolving

Recovered/resolved with sequelae

Not recovered/not resolved

Fatal

Severity/frequency increased

Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? Yes   
No

If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.

Results in death

Is life-threatening

Requires inpatient hospitalization or prolongation of existing hospitalization

Results in persistent or significant disability/incapacity

Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

SAE/EAE onset date \_\_\_\_\_

Has or will this AE be reported as an EAE? Yes   
No

If "Yes", provide EAE number below. \_\_\_\_\_

Participant ID: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

Visit: \_\_\_\_\_

Visit Date: \_\_\_\_\_

**HPTN084-01\_Version 1.0\_PROD\_BK\_28JUL2020: ALL**

**Form: Injection Site Reaction**

**Generated On: 29 Jul 2020 19:34:50**

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EAE number

Begin number with 4-digit year, followed by 6-digit EAE number  
(no dashes or spaces).

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