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

HPTN 052 (096) IAE-1 (421)

Index ID

___ - ___ - 0 0 - ___

Site Number | Index Number | Partner | Chk

Index Adverse Event Log

Date Reported to Site

___ ___ ___

dd *MMM* *yy*

1. Adverse Event

_____

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

2. Onset Date

___ ___ ___

dd *MMM* *yy*

1a. Indicate if diagnosis is confirmed or probable: ☐ Confirmed ☐ Probable

3. Severity

- ☐ Grade 3 - Severe
- ☐ Grade 4 - Life-threatening
- ☐ Grade 5 - Death

3a. Is this AE serious according to ICH guidelines? *yes* ☐ *no* ☐

4. Relationship to ART Study Product

- ☐ Definitely related
- ☐ Probably related
- ☐ Possibly related
- ☐ Probably not related

→ *Record related study medications in item 10.*

- ☐ Not related

Record reason why AE is "not related" in Comments below.

5. ART Study Product Administration

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

6. Status/Outcome

- ☐ Continuing
- ☐ Resolved
- ☐ Death
- ☐ Severity/frequency increased *Report as new AE.*
- ☐ Status changed to reportable HIV/AIDS associated event
- ☐ Continuing at end of study participation

6a. Status/Outcome Date

Leave blank if Status/Outcome is "Continuing."

___ ___ ___

dd *MMM* *yy*

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

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

8. Has/will this AE be reported as an EAE? ..... *yes* ☐ *no* ☐

9. This AE was first reported at visit: ___ . ___

Visit code required (regular or interim).

10. Record the medication and relationship codes for each study medication that is definitely, probably, or possibly related to the AE *(see item 4 above)*:

Medication codes (Med Code): Please refer to the SSP appendices for a complete list.
Relationship to ART Study Product (Rel Code): 1 – Definitely related, 2 – Probably related, 3 -- Possibly related, or 4 – Probably not related.

10a. Med Code	10a1. Rel Code	10b. Med Code	10b1. Rel Code	10c. Med Code	10c1. Rel Code	10d. Med Code	10d1. Rel Code
☐☐	☐	☐☐	☐	☐☐	☐	☐☐	☐

Comments: _____

☐ ☒ ☐ ☐ 16-JAN-13

0 1

Language

Staff Initials / Date

Index Adverse Event Log (IAE-1)

Any Adverse Event (AE) reported by the participant or clinically observed, regardless of whether or not it is related to study product, must be documented any time during study participation.

Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency.

Page: Number pages sequentially throughout the study, starting with 001. Do not repeat page numbers. Do not renumber any AE Log pages after faxing, unless instructed by SCHARP.

Adverse Event (AE): Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE Log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."

Onset Date: At minimum, month and year are required. Record one of the following, as appropriate:

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

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

Diagnosis: Use the AACTG Appendix 60 to determine whether the diagnosis is confirmed or presumptive.

Relationship to Study Product: If the AE is related to multiple products, mark the relationship box for the product most closely related to the AE.

- ***Definitely related:*** The exposure to study product and the onset of the AE are related in time; a direct association between the study product and the AE can be demonstrated (i.e., the AE shows a pattern consistent with previous knowledge of the study product).
- ***Probably related:*** The exposure to study product and the onset of the AE are reasonably related in time; the AE is more likely explained by the study product than by another cause but cannot be considered "definitely related."
- ***Possibly related:*** The exposure to study product and the onset of the AE are reasonably related in time but relationship does not meet criteria for being defined as "probably related"; the AE could be due to another equally likely cause.
- ***Probably not related:*** There is another more likely cause of the AE.
- ***Not related:*** The exposure to study product and onset of the AE are not considered to be reasonably related in time, or there is another obvious cause of the AE.

Study Product Administration: Mark the administration box for the product most closely related to the AE. Mark N/A if the AE occurred after the participant stopped taking the study product, the study regimen is held for a different AE, or the AE is Grade 5 - Death.

Status/Outcome:

- ***Continuing:*** AE is continuing at the time it is reported.
- ***Resolved:*** Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
- ***Death:*** Mark this box only if the severity of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation."
- ***Severity/frequency increased:*** If an AE increases in severity or frequency after it has been reported on the AE Log, line through the "Continuing" box previously marked and mark "Severity/frequency increased." Record the date of increase in the "Status/Outcome Date." Report the increase in severity or frequency as a new AE. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. Note that decreases in severity should not be recorded as new AEs.
- ***Changed to reportable HIV/AIDS associated event***: If an AE later meets the criteria of an HIV/AIDS event, line through the "continuing" box and mark "...reportable HIV/AIDS associated event." Record the date of the change in the "status/outcome date." Record the event on the HIV/AIDS Associated Events log.
- ***Continuing at end of study participation:*** Mark this box whenever an AE is continuing at the time of participant study termination.

Status/Outcome Date: At minimum, month and year are required. Record one of the following, as appropriate:

- the date on which the participant no longer experienced the AE; or
- the date of the study visit or specimen collection at which the change in status/outcome is first noted.

AE Revisions and Updates:

- If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE page #" (specify page number of diagnosis AE).