



## 6. Medications

List all drugs taken (or prescribed) before occurrence of SAE

Generic Name	Dose	Frequency	New judgement of causality
1.			Unrelated Poss. related Cannot be assessed
2.			Unrelated Poss. related Cannot be assessed
3.			Unrelated Poss. related Cannot be assessed
4.			Unrelated Poss. related Cannot be assessed

## 7. Other causes of SAE, if unrelated to drugs mentioned in Section 6 above

7a. According to the physician, is this SAE likely to be related to participation in the research?

Yes ☐ No ☒

7b. According to the physician, is this SAE related to any causes other than the research?

This includes the patient's medical history

Yes ☐ No ☒  
Describe

Patient had been lost to follow up for 9 months + defaulted ART before returning already very sick.

## 8. SAE Outcome

☒ Death

→ Date of death

(unknown)

Unknown to date

Ongoing

Improved

Worsened

Recovered

→ Another complementary SAE notification form must be submitted.

→ Date of recovery

Recovered without sequelae  
or

Recovered with sequelae

→ Describe

Probable  
Diagnosis

Stage IV HIV; overwhelming opportunistic infections.

## Physician reporting SAE Complementary Notification

Name MELANIE HILL

Signature [Signature]

Date form completed 20151002