TABLE LISTING TIMELINES AND PROCEDURE FOR REPORTING SERIOUS ADVERSE EVENTS/ADVERSE EVENTS (SAE/AE)

Severity:	**Nature:**	**Causality:**	**PI notifying/ reporting requirements:**	**Form to use:**
Local SAE - resulting in death #	Unexpected/ Expected	Regardless of causality	Notify (including CMB of the institution*) within 24 hours. Full report within 7 calendar days.	SAE Reporting Form for both initial notification and full report
Local SAE – life-threatening	Unexpected/ Expected	Regardless of causality	Notify as soon as possible but not later than 7 calendar days. Full report within 8 additional calendar days.	SAE Reporting Form for both initial notification and full report
Local SAE – not life-threatening	Unexpected	Definitely / probably / possibly related	Notify as soon as possible but not later than 15 calendar days.	SAE Reporting Form
Local SAE – not life-threatening	Unexpected	Unlikely / Not related	Provide summary annually. (together with study status report)	
Local SAE – not life-threatening	Expected **but** there is increase in the rate of occurrence which is judged to be clinically important	Definitely / probably / possibly related	Full report within 15 calendar days.	SAE Reporting Form
Local SAE – not life-threatening	Expected	Definitely / probably / possibly related	Provide summary annually. (together with study status report)	
Non-local SAE – fatal or life threatening	Unexpected	Definitely / probably / possibly related	Full report within 30 calendar days.	Available format (e.g. CIOMS)
Local AE	Unexpected	Definitely / probably / possibly related	Provide summary annually (together with study status report)	

*If stipulated by the institution

[All reporting time lines are counted from the day that the PI becomes aware of the event]

 # Reporting Requirements of Local Death in Oncology Research (including Haematological malignancies)

The CIRB has implemented an alternative set of reporting requirements of local death of subjects in oncology research (including haematological malignancies) which will supplement the existing reporting requirement. The CIRB requires all local SAE resulting in death to be reported within 24 hours after investigator is aware of the event, regardless of causality and nature of the event. However in oncology research where treatment-free long-term follow up is required, the CIRB grant separates reporting requirements of local death in three categories.

The reporting requirements of local death in oncology research are outlined below.

Local death occurring 30 days (or less) after last dose	**Local death occurring more than 30 days after last dose** Δ
a. Related/Unrelated (Unexpected or Expected) Notification by PI within 24 hours. Full report within 7 calendar days	**b. Related (Unexpected or Expected)** Report within 7 calendar days
	c. Unrelated (Unexpected or Expected) Continuing Review (together with study status report)

ΔThis should be reported until study closure

For local death occurring 30 days (or less) after last dose, it has to be reported within 24 hours after investigator is aware of the event, regardless of nature and causality. The full report can be submitted within 7 calendar days.

For local death occurring 30 days after last dose, it has to be reported within 7 calendar days after investigator is aware of the event if it is related to the study. If it is not related, it can be reported in the continuing review.