

# OnCore Communication Memo

## Memo #: 9 – Reportable event IRB numbers

**To:** All CTO OnCore Users  
**From:** System Administrator  
**Effective Date:** 11/5/13

**Purpose:** To establish consistency when entering IRB numbers into SAEs entered in OnCore. This will assist in cross referencing IRB reportable events and SAEs for accuracy.

**Notes:** When an SAE is entered into OnCore and meets the criteria for immediate reporting to the IRB (unexpected and possibly, probably, or definitely related to the research), the corresponding IRB Reportable Event number must be entered into the SAE. If a follow up report is sent to the IRB and a new RE number is generated, this number must also be added.



Additional SAE Identifiers

Identifier Type*	Identifier*	Identifier Owner
<input type="text" value="AdEERS"/> <input type="text" value="IRB"/>	<input type="text"/>	<input type="text"/>

No information entered

Complete and Lock Submit Clear Close

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Here's an example of an SAE that was reported to the IRB initially, then a follow up was done (you can see there are two IRB reportable event numbers), but this was actually 1 event. (Event number 1501 was a follow up to event 1500). This is CORRECT.



Event No.	Event Date	Follow-Up No.	Arm Code	Hospitalization	Death Occurred (days)	Additional Identifiers	Toxicity   Grade   Attribution
1500	05/16/2012		1	Y		IRB: RE00002767	Respiratory failure 4 InvTx: Possible Tocilizumab: Unlikely Disease: Unlikely
1501 (1500)	05/16/2012	1	1	Y	With...	IRB: RE00002777	Multi-organ failure 5 InvTx: Possible Tocilizumab: Possible Disease: Possible Respiratory failure 4 InvTx: Possible Tocilizumab: Possible Disease: Possible

New

**If an event does not meet the immediate reporting criteria, then no Reportable event number is needed. It will be reported with the CPR.**