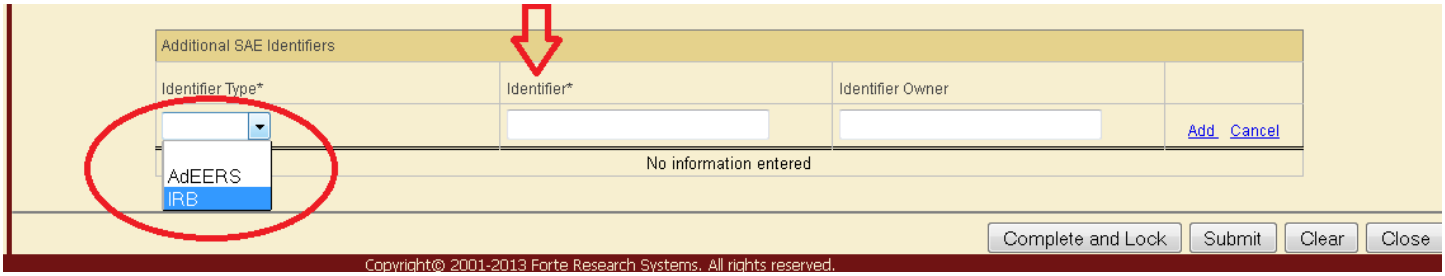
OnCore Communication Memo

Memo #: 9 – Reportable event IRB numbers

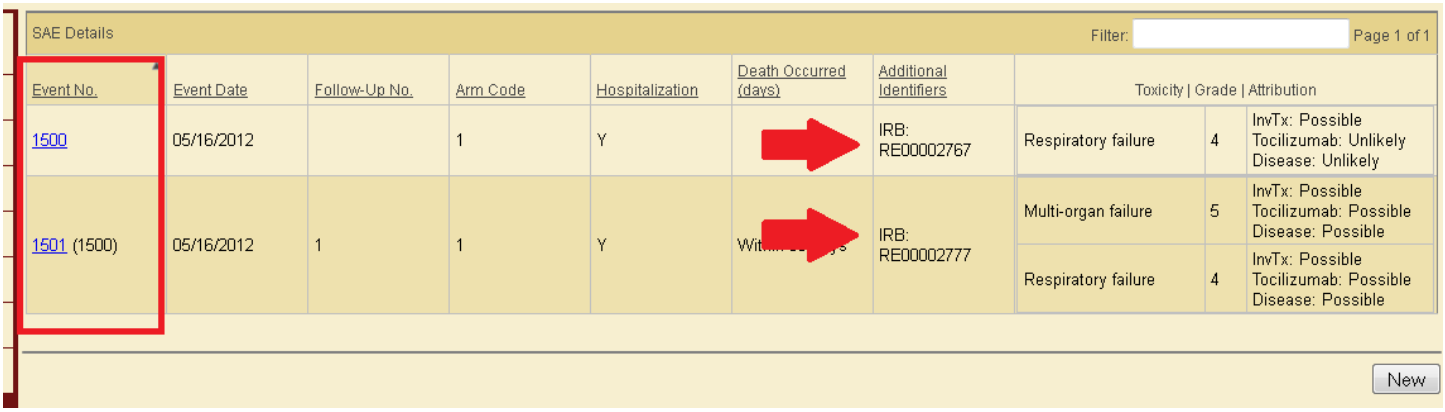
To: All CTO OnCore Users
From: System Administrator
Effective Date: 11/5/13

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.



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.



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