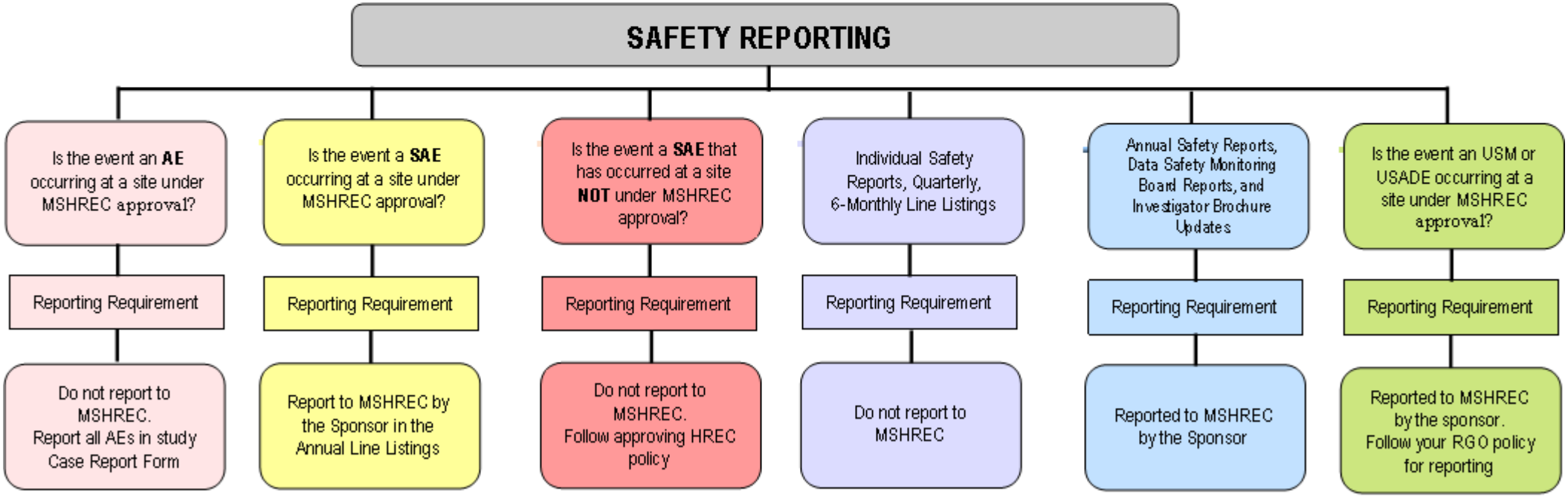
Adverse Event Reporting to the Metro South Human Research Ethics Committee (MSHREC) for Commercially Sponsored Clinical Trials

Pharmaceutical Study:			
Step 1: Is the event a SAE	**Step 2:** Is it unexpected and poses a significant safety risk	**Step 3:** Is it related to study drug	**If yes to all = USM**
Device Study:			
Step 1: Is the event a SAE	**Step 2:** Is it unexpected	**Step 3:** Is it related to the device	**If yes to all = USADE**
Definitions:			
SAE — Serious Adverse Event	A SAE is an event resulting in: Hospitalisation/Prolonged Hospitalisation / Life threatening/Medically important / Death/Congenital abnormality / Persistent disability		
USM — Urgent Safety Measure	An USM is a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety. **Note:** *This type of significant safety issue can be instigated by either the investigator or sponsor and can be implemented before seeking approval from HRECs or RGOs.*		
USADE—Unanticipated Serious Adverse Device Effect	An USADE is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report. **Note :** *Anticipated serious adverse device effect (ASADE) is in effect which by its nature, incidence, severity or outcome has been identified in the current version of the risk analysis report.*		



References:
Framework for Monitoring: Guidance for the National Approach to Single Ethical Review of Multi-Centre Research, Jan 2012
National Statement on Ethical Conduct in Human Research (2007) (Updated 2018)
Safety monitoring and reporting in clinical trials involving therapeutic goods, November 2016