

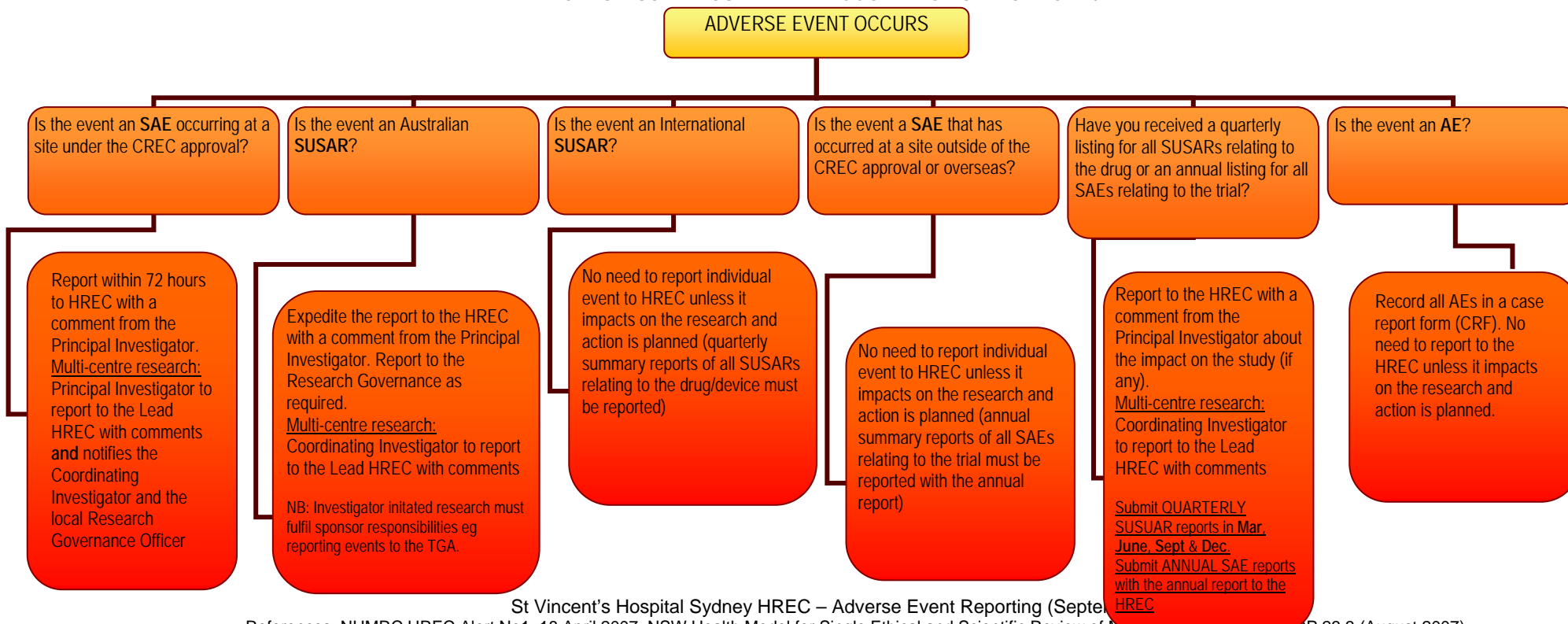
Adverse Event Reporting to the Cancer Institute NSW Clinical Research Ethics Committee

For Human Research Ethics Committees to be able to protect the safety of clinical trial participants, sufficient information about adverse events must be provided in context.
Supplying this information is a condition of ethical approval.

Step 1: Is the event an SAE? **Step 2:** Is it unexpected? **Step 3:** Is it related to the drug/device? **If yes to all 3 = SUSAR**

SUSAR - <u>S</u> erious, <u>U</u> nexpected, <u>S</u> suspected <u>A</u> dverse <u>R</u> eaction	An SAE which is probably related to the drug and is unexpected . This assessment is made after the data is un-blinded (by the DSMB) to judge causality.
SAE - <u>S</u> erious <u>A</u> dverse <u>E</u> vent	An event resulting in: <ul style="list-style-type: none"> ❖ Hospitalisation/prolongation of hospitalisation ❖ Death/congenital abnormality ❖ Life threatening/medically important ❖ Persistent disability
AE - <u>A</u> dverse <u>E</u> vent	Any untoward event that does not necessarily have a causal relationship with the treatment. These may be expected (defined in the Investigator Brochure)
Unexpected Adverse Event	Not defined in the current Investigator Brochure/Product Information

ALL REPORTS MUST BE SUBMITTED ACCORDING TO THIS FLOW CHART



St Vincent's Hospital Sydney HREC – Adverse Event Reporting (September 2007)
 References: NHMRC HREC Alert No1, 18 April 2007; NSW Health Model for Single Ethical and Scientific Review of Medicines (2007) OP 23.3 (August 2007)