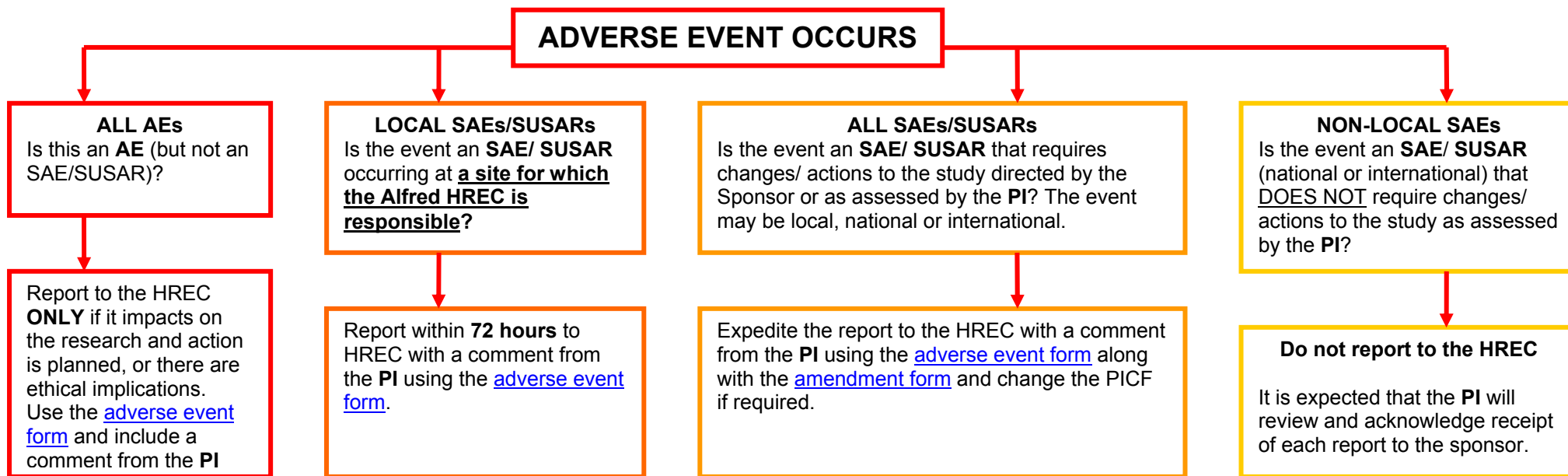


# Reporting Adverse Events to the Alfred Hospital HREC for Clinical Trials

*\*\*It is the responsibility of investigators to identify and report significant safety information to the Ethics Committee\*\**



**Listings of SAEs/SUSARs** (eg. quarterly or six-monthly line listings) should be (a) reviewed by the PI, (b) acknowledged to the sponsor, (c) reported to the HREC (with a comment from the PI) ONLY IF the listing reveals significant information.

**Reports from DSMB or other safety monitors** need to be reported to HREC promptly with a comment by the PI stating the implications of the findings on the trial.

## DEFINITIONS

<b>SUSAR</b> <u>S</u> erious, <u>U</u> nexpected, <u>S</u> suspected <u>A</u> dverse <u>R</u> eaction	An <b>unexpected</b> SAE where there is <b>some degree of probability</b> that the event is related to the drug. This assessment is usually (but not always) made after the data is un-blinded (by the Data Safety Monitoring Board - DSMB) to judge causality.
<b>SAE</b> <u>S</u> erious <u>A</u> dverse <u>E</u> vent	An event that: <ul style="list-style-type: none"> <li>❖ requires hospitalisation/prolongation of existing hospitalisation</li> <li>❖ results in death</li> <li>❖ is life threatening</li> <li>❖ results in persistent or significant disability/incapacity</li> <li>❖ is a congenital anomaly/birth defect; or</li> <li>❖ is a medically important event or reaction</li> </ul>
<b>AE</b> <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)
<b>PI</b> <u>P</u> rincipal <u>I</u> nvestigator	Principal Investigator or a co-investigator delegated this responsibility
<b>Comment from the PI</b>	A statement about the significance of the information, the possible impact on study participants, and action taken or recommended