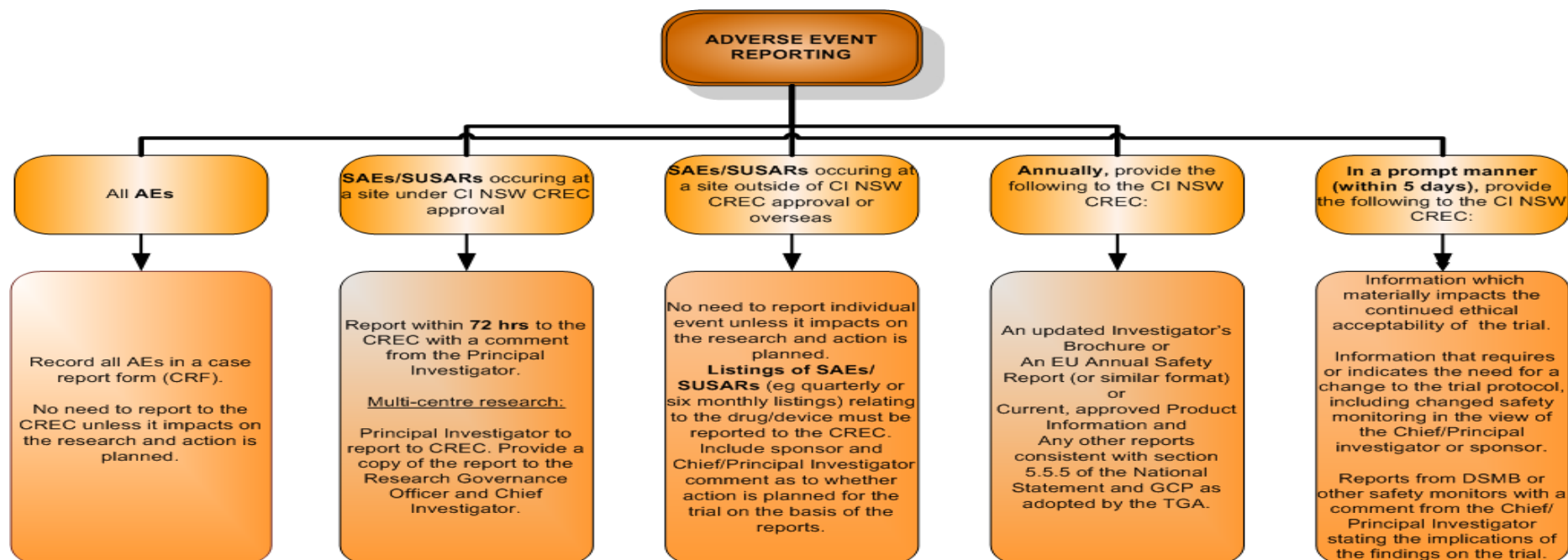


## Adverse Event Reporting to the Cancer Institute NSW Clinical Research Ethics Committee

ALL REPORTS MUST BE SUBMITTED ACCORDING TO THIS FLOW CHART



### 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 which is <b>probably</b> related to the drug. This assessment is made after the data is un-blinded (by the DSMB) to judge causality.
<b>SAE</b> <u>S</u> erious <u>A</u> dverse <u>E</u> vent	An event resulting in: <ul style="list-style-type: none"> <li>➤ Hospitalisation/prolongation of hospitalisation</li> <li>➤ Death/congenital abnormality</li> <li>➤ Life threatening/medically important</li> <li>➤ Persistent disability</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>Unexpected Adverse Event</b>	Not defined in the current Investigator Brochure/Product Information.

CI NSW Adverse Event Reporting Flowchart Apr 2010;  
NHMRC AHEC Position Statement May 2009