Reporting of Adverse Events

Application Type	Adverse Event Occurred at	Refer to Flow Chart
Multi-site Reviewing[1] OR Single Site[2]	Alfred Health	A
Multi-site Reviewing	External Site	B
Multi-site Accepting[3]	Alfred Health	C

[1] Our Committee is the Reviewing HREC and reviewed and approved the application submitted under the streamlined process for multiple sites.

[2] Our Committee reviewed and approved the single-site application submitted outside of the streamlined process for one site.

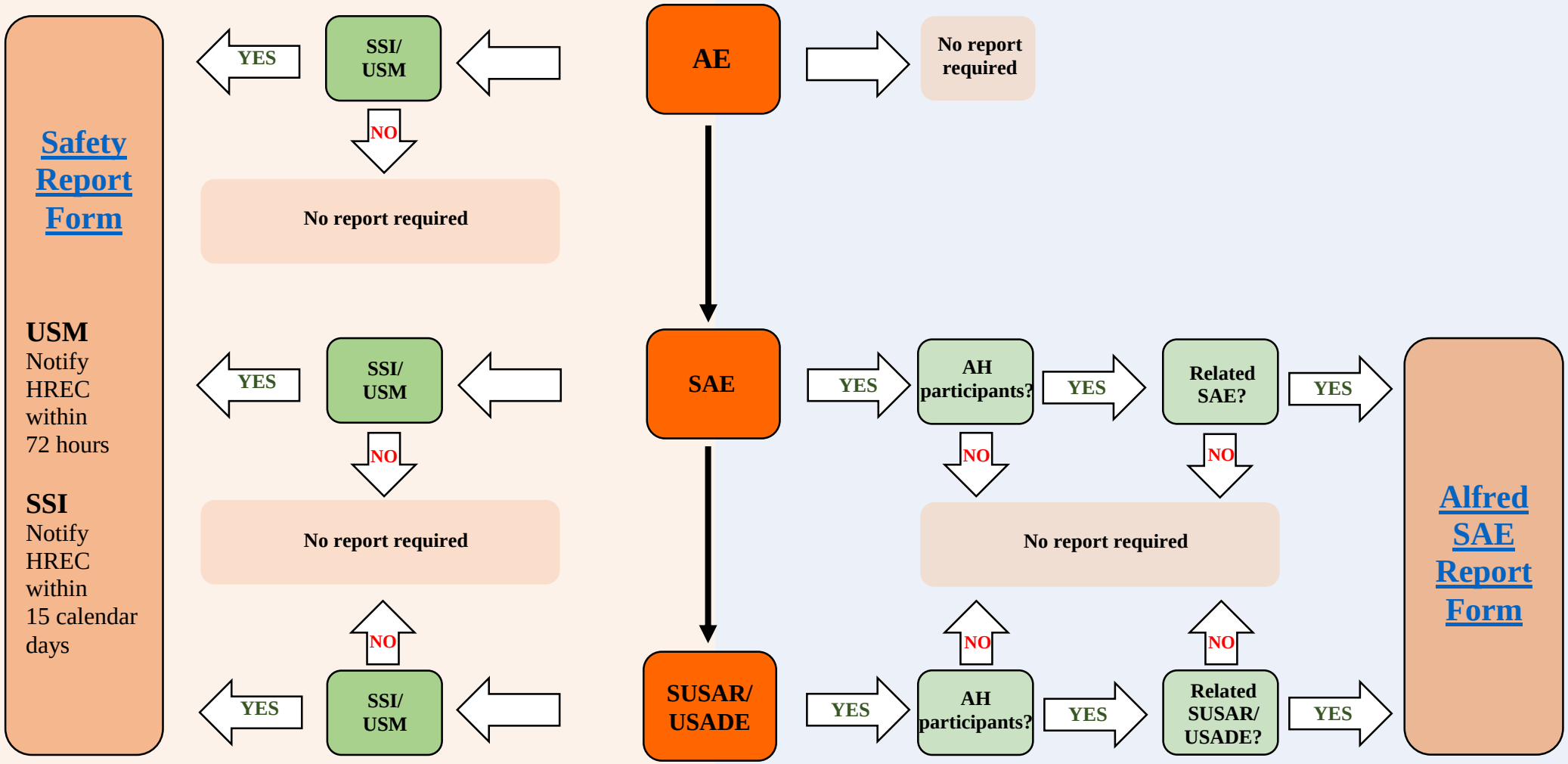
[3] Another Committee is the Reviewing HREC and reviewed and approved the application submitted under the streamlined process. Alfred Health as an Accepting Site has accepted the ethics review and has given site-specific authorisation.

A

Reporting Adverse Events to

The Alfred Hospital Ethics Committee (Ethics)

Alfred Health (Governance)



\+ Annual Safety Report Form or other documentation (refer to EC guideline)

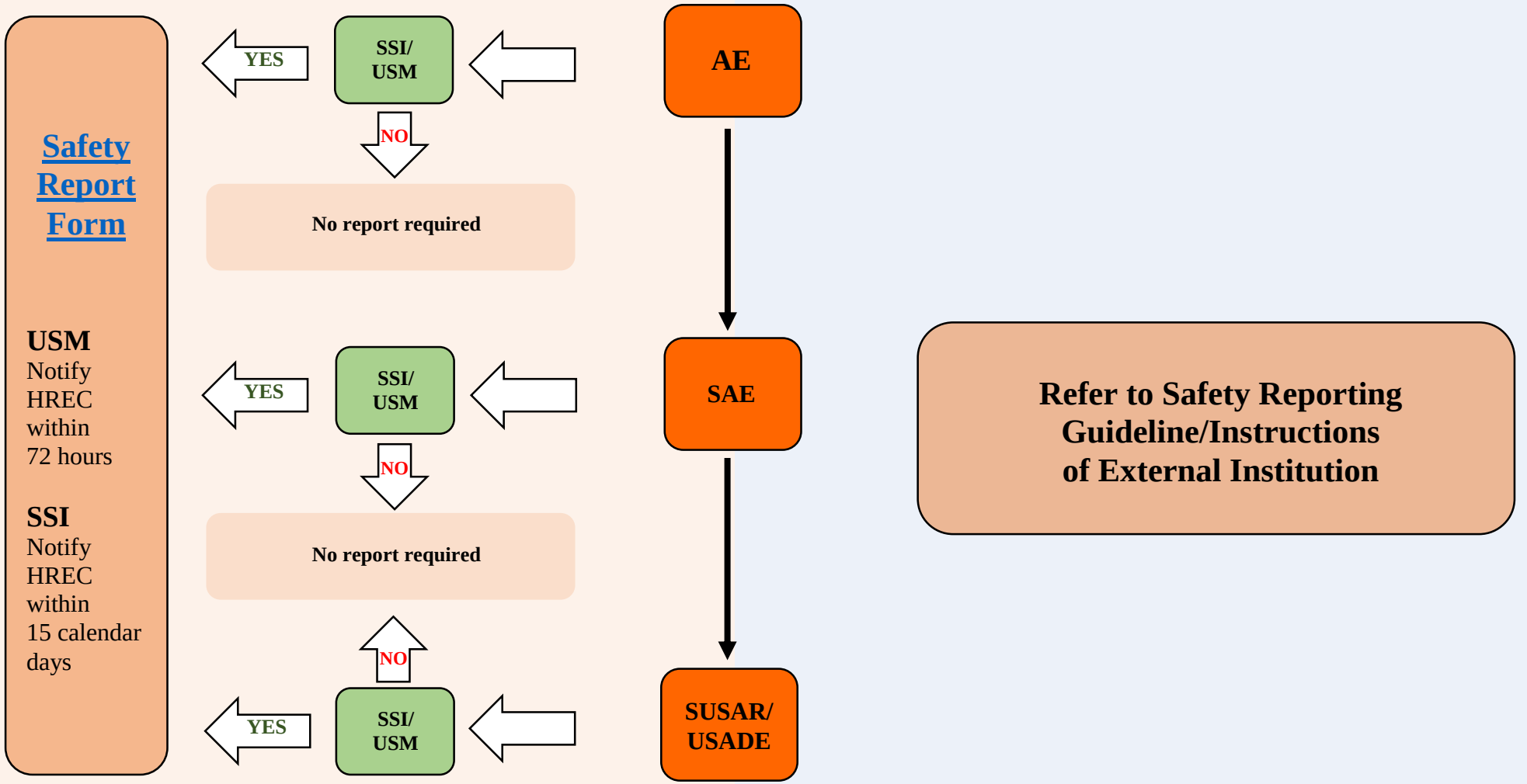
\+ Events ≠ SAEs, but are unexpected or (possibly) related and suggest greater risk of harm for participants or others than was previously recognized, email research@alfred.org.au in timely manner

B

Reporting Adverse Events to the

Alfred Hospital Ethics Committee (Ethics)

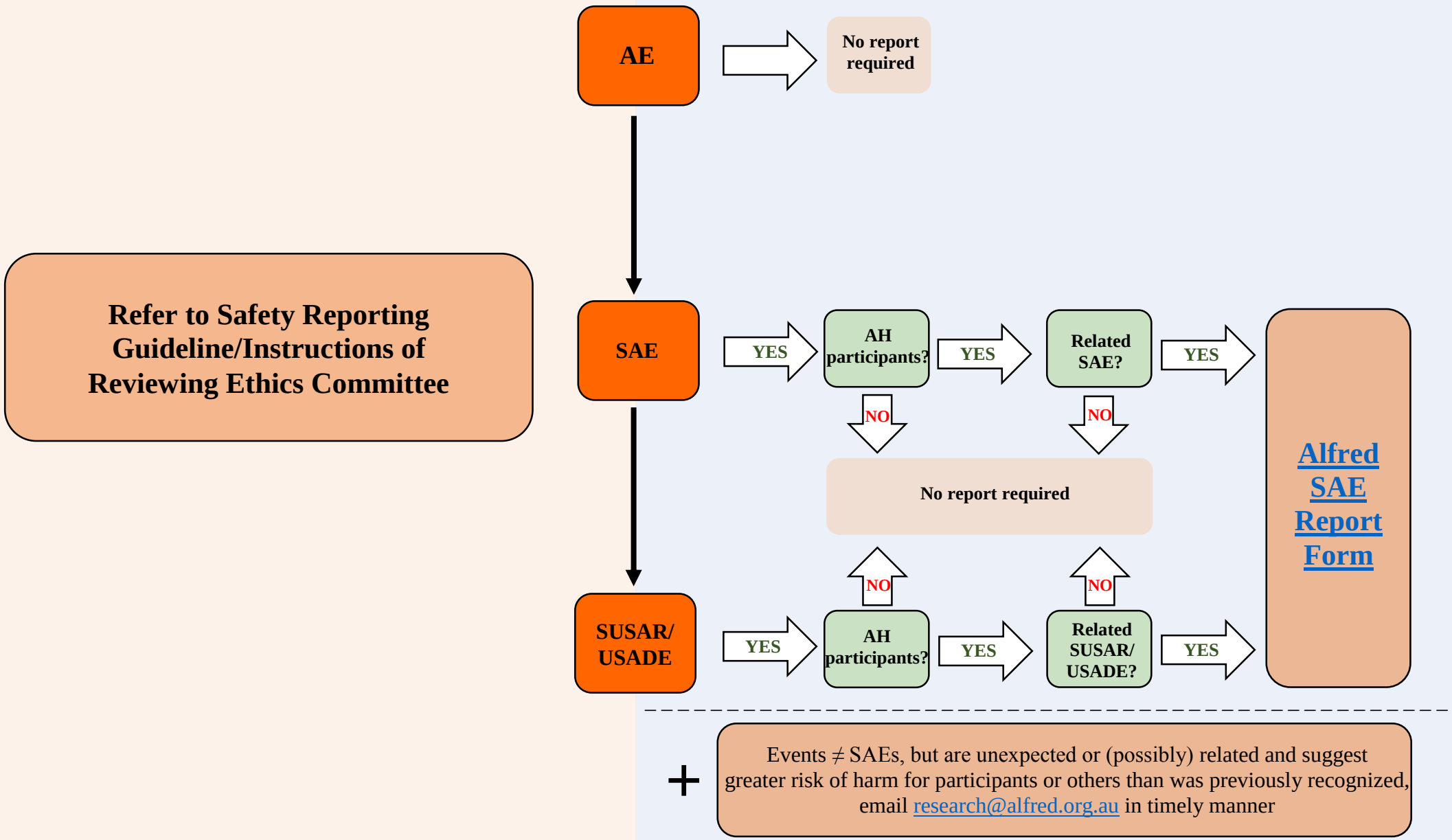
External Institution (Governance)



\+ Annual Safety Report Form or other documentation (refer to EC guideline)

C

Reporting Adverse Events to

The Reviewing Ethics Committee (Ethics)

Alfred Health (Governance)