ADVERSE EVENTS FLOWCHART

Not all adverse events need to be reported to the IRB. So, how do you determine whether or not to submit a report?

Adverse Event (AE) Occurs

The local PI evaluates the event

Was the AE UNEXPECTED?

No

STOP

AE’s that are EXPECTED do not need to be reported.

Yes

The AE is UNEXPECTED

Is it more likely than not that the AE is related?

No

STOP

AE’s that are UNRELATED do not need to be reported.

Yes

The AE is UNEXPECTED and RELATED

Is the AE RELATED to the research?

No

STOP

AE’s that are UNRELATED do not need to be reported.

Yes

Are subjects placed at GREATER RISK than they were before?

No

STOP

AE’s that DO NOT place participants at GREATER RISK of HARM do not need to be reported.

Yes

The AE must be reported to the IRB.

Don’t Forget: Investigators are required to submit the AE report to the IRB as soon as possible after the PI learns of the event, but in all cases, within 10 working days.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.