An Adverse Event Occurs
The Local PI evaluates the Event

Was the AE EXPECTED?
Yes → STOP
No → The AE is Unexpected

Is the AE RELATED to the research?
No → STOP
Yes → The AE is UNEXPECTED and RELATED

Are subjects placed at GREATER RISK than they were before?
No → STOP
Yes → The AE must be reported to the IRB.

If the AE is serious, the answer is always “Yes”.

AE’s that are expected do not need to be reported.
AE’s that are unrelated do not need to be reported.
AE’s that do not place participants at greater risk of harm do not need to be reported.