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?

Yes → AE’s that are expected do not need to be reported.

No → STOP

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

Yes → AE’s that are unrelated do not need to be reported.

No → STOP

The AE is Unexpected and RELATED

Are subjects placed at GREATER RISK than they were before?

Yes → The AE must be reported to the IRB.

No → STOP

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

Is it reported in the Informed Consent? If yes, it is expected.