An Adverse Event Occurs

The Local PI evaluates the Event

Was the AE EXPECTED?

The AE is Unexpected

Is the AE RELATED to the research?

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

Are subjects placed at GREATER RISK than they were before?

The AE must be reported to the IRB.

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

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.

STOP

STOP

STOP