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

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

Yes

(The AE is UNEXPECTED AND RELATED.)

Are subjects placed at greater risk than they were before?
(If the AE is serious, this answer is always “YES”.)

Yes

The AE must be reported to the IRB

No

STOP

Don’t Forget: Researchers are required to submit the serious adverse event reports to the IRB within 24 hours and adverse events within 5 business days.

AEs that are related do not need to be reported

AEs that are unrelated do not need to be reported

AEs that do not place participants at greater risk of harm do not need to be reported

For more information, contact the NSU Institutional Review Board at (954) 262-5311