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 PI Evaluates the Event

Was the AE EXPECTED?

Yes

STOP

No

(The AE is UNEXPECTED.)

Was the AE SERIOUS?
- Death
- Congenital anomaly/birth defect
- Hospitalization
- Life threatening
- Significant or persistent disability/incapacity

Yes

STOP

No

AEs that are expected do not need to be reported

AEs that are not serious do not need to be reported

Yes, It was SERIOUS

Would the SAE have implications for conduct of the study?

Yes

The SAE must be reported to the IRB

Don't Forget: Researchers must submit the serious adverse event reports to the IRB within 24 hours of being informed of the event.

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