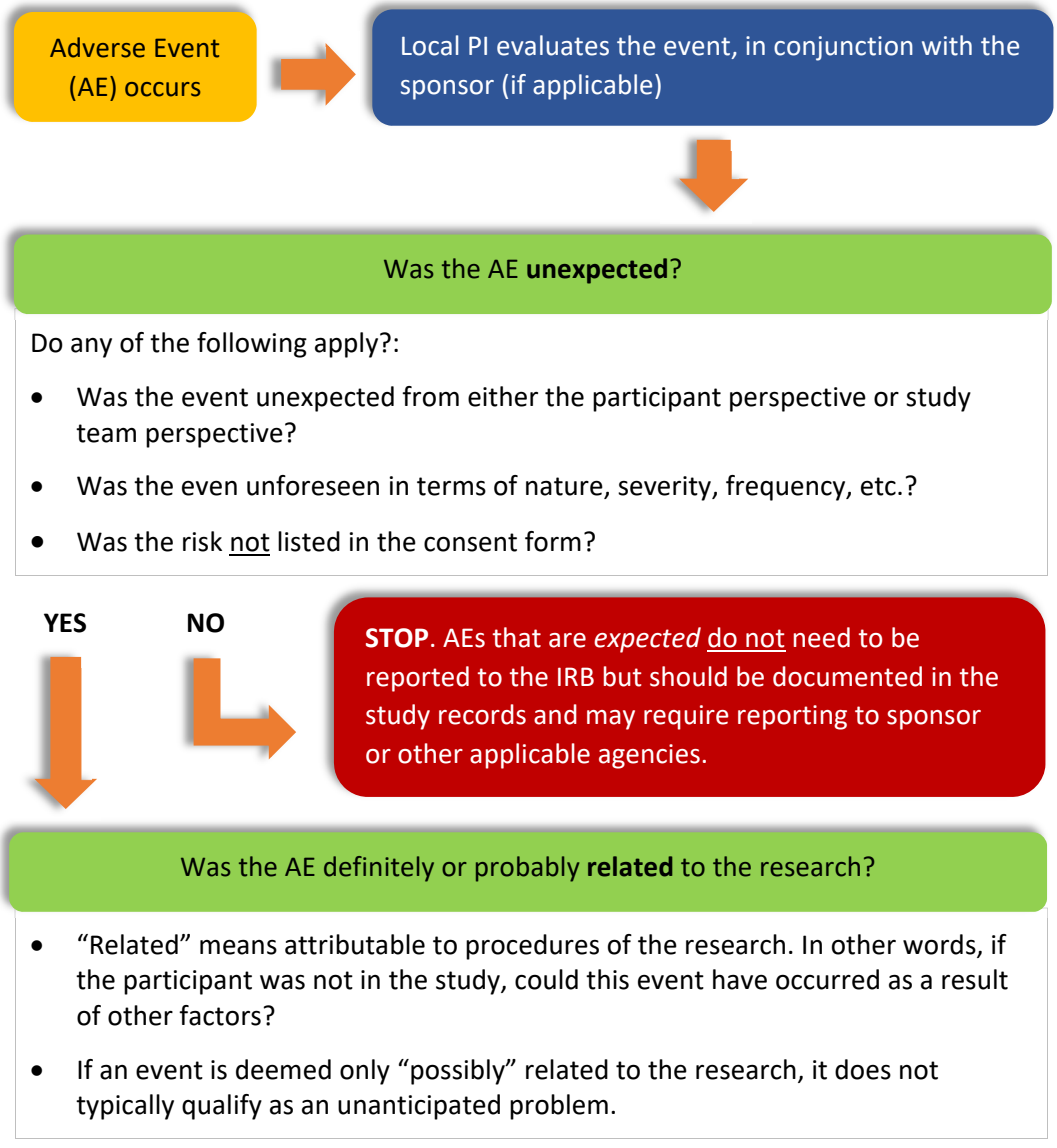
# ADVERSE EVENTS/UNANTICIPATED PROBLEMS ASSESSMENT

Not all adverse events constitute unanticipated problems that need to be reported to the IRB. How do you determine whether or not to submit a report of an adverse event to the IRB? Use the flowchart below to decide whether the event meets IRB reporting requirements.



- If there is not enough information to attribute relatedness to the research, the event likely does not meet IRB's reporting threshold. If future information about the event is discovered, a report form may be necessary at that time.

**YES** **NO**

**STOP**. AEs that are *not related* do not need to be reported to the IRB but should be documented in the study records and may require reporting to sponsor or other applicable agencies.

Are participants placed at a **greater risk of harm** than previously known as a result of the AE?

- This may include physical, psychological, economic or social harm, etc.
- Please consider whether or not the consent form is being updated with a new risk. If so, it is likely participants are placed at a greater risk of harm as a result of the event.

**YES** **NO**

**STOP**. AEs that do not pose a *greater risk of harm* than previously known do not need to be reported to the IRB but should be documented in the study records and may require reporting to sponsor or other applicable agencies.

**This adverse event may represent a possible unanticipated problem and should be reported to the IRB via a report form.**

**Please Note:** Investigators are required to submit possible unanticipated problems to the IRB as soon as possible after the study team learns of the event. The IRB's policy for timeline of reporting is within 10 working days (5 working days for VA).