

# SERIOUS ADVERSE EVENT (SAE) REPORTING FLOW CHART – What to report to the IRB

You've received a serious adverse event report today. What do you do?

## Review the report to determine whether the event is considered **SERIOUS**

**DEFINITION:** An event is considered “serious” if it meets any of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in congenital anomaly/birth defect
- Results in persistent or significant disability/incapacity
- May jeopardize the subject’s health, and may require medical, counseling, or surgical intervention to prevent any of the above
- Results in criminal or civil liability, or damaging to the subject’s financial standing, employability, or reputation.

**NO**

Do not submit to the IRB

**YES**

## Review the report to determine whether the event is considered **UNEXPECTED**

**DEFINITION:** An event is considered “unexpected” when it’s specificity or severity are inconsistent with risk information previously reviewed and approved by the IRB in terms of nature, severity, frequency, and characteristics of the study population. These approved documents include:

Sponsor or local protocol - Consent Form - Investigator Brochure - Package Insert - Device Information

**NO**

Do not submit to the IRB

**YES**

## Review the report to determine whether the event is considered **PROBABLY RELATED**

**DEFINITION:** An event is considered “probably related” to the research procedures if, in the opinion of the investigator and/or the sponsor (the sponsor’s assessment supersedes the investigator’s), the research procedures more likely than not (greater than 50% likely), caused the harm. Terms not considered probably related:

Cannot be ruled out - Possibly related - May be related - Casual relationship

**NO**

Do not submit to the IRB

**YES**

Submit to the IRB