Decision Tree for Reporting Unanticipated Problems and Adverse Events in Research to the IRB and CRB

A problem occurs during a research project

Is the AE "SERIOUS" as defined by FDA?
  i.e., Did the AE result in or need medical or surgical intervention to prevent death, a life-threatening experience, inpatient hospitalization, prolongation of hospitalization, persistent or significant disability or incapacity, congenital anomaly or birth defect, or jeopardy to a subject

Does the problem or event involve RISKS to SUBJECTS?

Does the problem or event involve RISKS to ANYONE ELSE (e.g., subjects’ family members, research personnel, others)?

Was the problem or event ANTICIPATED as to NATURE, SEVERITY, and FREQUENCY, as described in the protocol, consent document, or other materials approved by IRB?

Is the problem or event RELATED or POSSIBLY RELATED to the research or can the event be considered a NEW risk?

If medical costs incurred

Track this event and submit to IRB during annual review

The problem or event MUST BE REPORTED PROMPTLY to the IRB.

The problem or event MUST BE REPORTED PROMPTLY to the CRB.

No

Yes

No

Yes

No

Yes

No

Yes

Yes

2/27/2020