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?

No

Does the problem or event involve RISKS to SUBJECTS?

No

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

Yes

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?

No

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

No

Track this event and submit to IRB during annual review

Yes

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

Yes

If medical costs incurred

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