An untoward event occurs in one or more human subjects engaged in research under auspices of Tulane’s IRB.

Is event unexpected in nature, severity, or frequency?

Is event related (or possibly related) to participation in the research?

Does even suggest that the research places subjects or others at greater risk of physical/psychological harm than was previously known or recognized?

Event is an unanticipated problem. Report to Tulane’s IRB:
- Within 5 working days if serious
- All others, within 10 working days (DHHS 45 CFR 46. 103(b)(5))

- PI still must consider whether event is a protocol violation or deviation, which have different reporting requirements
- PI must still consider whether event is reportable to sponsor as an adverse event
- If SAE involves human gene transfer that has/may result in hospitalization or death, PI must notify NIH within 5 days
- If SAE involves HUD that has/may have caused/contributed to death/serious injury, PI must report to FDA within 5 days

The event is not an unanticipated problem and need not be reported to Tulane’s IRB.