*Forms are subject to change. Check for the latest forms on the Tulane IRB web site.

Tulane University Human Research Protection Program
Protocol Deviation/Violation Reporting Diagram

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

DOES PROTOCOL VIOLATION EXIST?
Rule: An event/problem is a protocol violation if it:
- Is an accidently, intentional, or unintentional change, to, or non-compliance with an IRB approved protocol (after enrollment of 1st subject); AND
- Is not previously approved by study sponsor and IRB: AND
- Increases risks and/or decreases benefit; affects subjects’ rights, safety, or welfare, or the integrity of the data.
*See Tulane’s HRPP SOPs for details

NO

DOES PROTOCOL DEVIATION EXIST?
Rule: An event/problem is a protocol deviation if there is any change, divergence, or departure from the study design or procedures of the protocol that is under the investigator’s control and has not been approved by the IRB.
*See Tulane’s HRPP SOPs for details

YES

PI REPORTS EVENT TO THE IRB
For MAJOR violations, the report is to be provided within 5 working days;
For MINOR violations, the report is to be provided within 10 working days.

YES

The PI must receive IRB approval prior to implementation

NO

DOES PROTOCOL EXCEPTION EXIST?
Rule: Means an impermanent (temporary) protocol deviation that is pre-approved by the sponsor or funding agency (and the FDA, if applicable, for investigational device studies) and the IRB prior to its implementation. Protocol exceptions are generally for a single subject or occasionally, a small group of subjects. The Protocol Exception is usually evaluated by both the sponsor or funding agency (and FDA, if applicable) and the IRB in order to determine that it does not increase the risk to the subject(s) or jeopardize the integrity of the research data.

YES

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