Flowchart for Reporting Internal Adverse Events and Unanticipated Problems to UT IRBs

Was the event related to the research?
• Reasonable possibility that the event was caused by research procedures
• Includes events that are definitely or possibly related to the research procedures

Was the event unanticipated?
• Unforeseen given the nature of the research and subject population
• Not described in the protocol, consent form or other information given to participants

Did the event involve risks to subjects or others?
• Includes adverse events, protocol deviations, other problems or events
• May involve physical, psychological, social, legal or economic harms

Report event using the UT Adverse Event Reporting form

Report event at time of Continuing Review

Do not report UNLESS you believe that the event could influence the safe conduct of research. Then use AE form

Do not report