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 <u>research procedures</u>
- Includes events that are definitely or possibly related to the <u>research procedures</u>



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



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

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

