Adverse events are the most frequent but not the only type of unanticipated problems. Other reportable events include may require prompt reporting if they are unanticipated problems involving risks to subjects or others.

Examples (see SOP 802):
- change in subject status: incarceration of a subject, pregnancy, becoming a ward of the state
- breach of confidentiality of data
- some types of protocol deviations

Unanticipated Problem
Report promptly to IRB, sponsor and applicable regulatory authority

Report as part of progress report summary at time of continuing review

STOP

Unanticipated Problem
Report promptly to IRB, sponsor and applicable regulatory authority

For more information
- IRB SOP 408: Unanticipated Problems
- IRB intranet page on Reportable Events
https://intranet.research.chop.edu/display/cmtirb/Reportable+Events

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