Safety Reporting to the IRB

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UCLA requires researchers to report any unanticipated problems involving risks to subjects or others in a timely manner.

Determining which adverse events or problems need to be reported can sometimes be tricky. Please use the Adverse Events Decision Tree to help you decide whether an adverse event should be reported to the IRB. We encourage you to learn more about safety reporting to the IRB. Please see the following materials for additional guidance:

- OHRPP Post-Approval Reporting (PAR)

- OHRPP Protocol Deviations and Incidents Decision Tree
- OHRPP Reports Decision Tree
- OHRPP Reliance PARs Decision Tree
- OHRP Unanticipated Problem Guidance
- FDA AE Reporting to IRBs Guidance
- FDA Safety Reporting Guidance for INDs
- FDA Mandatory Reporting- Form 3500A
- FDA IDE Reporting

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