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. Unanticipated problems are problems that (1) are not expected given the nature of the research procedures and the subject population being studied; and (2) suggest that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

Determining which adverse events or problems need to be reported can sometimes be tricky. Please use the Internal event, internal deaths, external event flowcharts 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:

- UCLA Policy
- 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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