Research Safety

- Safety Reporting to the IRB
- Safety Committee Resources

Safety Reporting to the IRB

UCSD 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 sample 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:

- OHRP Unanticipated Problem Guidance
- FDA AE Reporting to IRBs Guidance
- FDA Safety Reporting Guidance for INDs
- FDA Mandatory Reporting- Form 3500A
- FDA IND Regulations
- FDA IDE Regulations

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UCSD Human Research Protection Program (HRPP)

Post Approval Reporting. The Principal Investigator is responsible for submitting to the IRB ongoing reports of events that may adversely affect the safety of participants or the conduct of the research, and any information relevant to the conduct of the approved research. The types of events and information that may need to be reported to the IRB include, but are not limited to:

- Adverse Events
- Violations, Deviations, and Incidents

- Updated Study Safety Information

An unanticipated problem is an event or outcome that meets the following criteria: 1) unexpected; 2) related or possibly related to participation in the research; and 3) places subjects or others at a greater risk of harm than was previously known or recognized. All unanticipated problems need to be reported to the IRB via webIRB, though not all adverse events, violations, incidents or deviations are unanticipated problems. For details, please see the Fact Sheet or SOPP on the IRB website.

UCSD Environment, Health & Safety

Training & Outreach. In-class and online training courses are available to assist you in meeting regulatory training requirements along with videos, publications and other resources to help promote safety on campus.

Forms and Templates. Additional resources, including sample forms, templates, and examples are available via the UCSD EH&S Blink website.

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