

Institutional Review Board

Reporting of an Adverse Event or Unanticipated Problem(s) or Event(s)

Adverse events include, but are not limited to, death, injury, individuals' loss of income, incurring expenses related to the research, and/or experiencing anxiety as a result of the research.

Unanticipated problems could include having a breach of security of your data. For example, if you misplaced your raw data or had your computer hacked, you might encounter a security breach.

Unanticipated events might include change in principal investigators or study site; additional time needed to complete your research; and/or any other alteration of the study subsequent to the IRB's approval of the initial proposal.

All researchers are expected to address any problem immediately in order to protect the safety of research participants. Researchers should also report the following information to the IRB within three business days.

1. Name of Researcher(s), Faculty Advisor, if applicable
2. Email and phone contacts
3. Title of study
4. Date event occurred
5. Date event recognized by researchers
6. Describe the event, including location.
7. Has this event occurred before? If so, please explain.
8. Did this event involve a breach of confidentiality? For example, did you misplace data or was your computer hacked? If so, please explain.
9. What actions have you taken or will you take in response to this problem/event?