Module 6: Participant Safety and Adverse Event Reporting

After completing this module, you should understand how to identify, record, and report adverse events in social and behavioral research studies.

Overview of Participant Safety and Adverse Events

An Adverse Event, or AE, is any untoward medical occurrence that happens during the study, but that may or may not be caused by the treatment intervention.

Visit your own IRB's website. How does your institution define an AE?

Note some potential adverse events for your study and the processes you have in place to identify them.

Reporting Adverse Events

How and when you report adverse events to the IRB will depend on both your institutional and sponsor guidelines. In general, be sure to note the date of an incident, whether or not it was expected, its relation to the study, a description of what occurred, what was done to address it, and how it was resolved.

Use the space below to make notes about an adverse event you have encountered in one of your own studies.

Data Safety Monitoring Boards

Data Safety Monitoring Boards review study data, safety reports, and protocol deviations to ensure participant safety and data integrity.

What questions might you bring up at a study meeting to ensure you are following your data safety monitoring plan?

Other Notes

Resources

Unanticipated Problems Involving Risks and Adverse Events Guidance from the U.S. Department of Health and Human Services
http://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/