

Protocol Deviations and Protocol Violations

Definitions:

A **protocol deviation** is a variance from the approved study protocol that:

- Is generally noted or recognized after it occurs
- Has no substantive effect on the risks to research participants
- Has no substantive effect on the scientific integrity of the research plan or the value of the data collected
- Did not result from willful or knowing misconduct on the part of the investigator(s)

Some examples of protocol deviations are:

- A participant clicks “yes” that they are 18 or older and eligible to participate in the study, however, it is later found after reviewing the date of birth information on the demographic form, that the participant is under the age of 18.
- The study protocol states that all interviews will be conducted in person, however, the RA conducts an interview over the phone. The PI discovered that the interviews had been conducted by phone, rather than in-person, at a weekly research team meeting with the RA.

Reporting: Deviations should be tracked by the investigator and a protocol deviation form completed with a corrective action plan. Protocol deviations must be reported to the IRB via email within 7 working days.

A **protocol violation** is defined as a variance from the approved study protocol that:

- Has harmed or increased harm to one or more research participants
- Has damaged the scientific integrity of the data collected for the study
- Results from willful or knowing misconduct on the part of the investigator(s)
- Demonstrates serious or continuing noncompliance with federal regulations, state laws, or university policies

Some examples of protocol violations are:

- Proceeding with the protocol before obtaining final IRB approval.
- Failing to follow the established criteria or procedures that were approved by the IRB.
- Adding, removing or modifying a research instrument (or adding to an existing instrument) in a survey study without prior IRB approval unless the changes are within a range of anticipated potential changes specified as acceptable within the IRB approval.
- Implementing any change in the protocol without IRB approval.

Reporting: Protocol violations should be reported within one (1) week of the investigator becoming aware of the event

Unanticipated Events / Adverse Events

Definitions:

Unanticipated problems are events that occur which are unexpected and result in new circumstances that increased the risk of harm to participants without directly harming them. In addition, the event may have presented unanticipated risks to others (e.g., the sexual partners of the participants, individuals with whom the participant may come in contact such as family members, research personnel, etc.) in addition to participants. In each case, while the event may not have caused any detectable harm or adverse effect to participants or others, it nevertheless represents an unanticipated problem and should be promptly reported.

Some examples of unanticipated events:

- A research laptop containing research data is stolen
- Complaint from a family member

Reporting: Internal unanticipated problems (but not fatal or life threatening), shall be reported to the IRB within ten (10) working days of the investigator becoming aware of the event. External adverse events (i.e., external sponsor generated safety reports) which are unanticipated problems shall be reported to the IRB within ten (10) working days of their receipt.

An **adverse event** is any physical, psychological, or social harm to participants during the course of research and as a result of participation in the research.

Some examples of adverse events:

- A participant is physically injured and the injury was unexpected (unexpected meaning: its specificity and severity are not accurately reflected in the informed consent document) and related (related meaning: it was more likely than not to have been caused by the research procedures or if it is more likely than not that the event affected the rights and welfare of current participants) to the research.

Reporting: Principal investigators must report to the IRB as soon as possible, but in all cases within ten (10) working

Protocol Deviations/Protocol Violations Flow Chart

