

9 Protocol Exceptions & Deviations

Protocol exceptions and deviations must be reported to the IRB.

9.1 Exceptions

A protocol exception is a one time, intentional action or process that departs from the IRB-approved protocol.

It is the responsibility of the Investigator to report exceptions to the IRB. The IRB will perform an expedited review of the Request for Protocol Change form submitted by the PI along with documentation of sponsor justification and approval. Exceptions must be approved by the sponsor and IRB before being implemented.

Exceptions may not increase risk or decrease benefit, affect the participants' rights, safety, welfare, or affect the integrity of the resulting data.

9.2 Deviations

A protocol deviation is defined as a violation that is unanticipated and happens without any prior agreement (eg, protocol visit scheduled outside protocol window, blood work drawn outside protocol window, etc.)

It is the responsibility of the PI not to deviate from the protocol approved by the IRB, except to avoid an immediate hazard to the participant. The PI must submit an amendment request to the IRB and receive written approval prior to implementation of any change to the protocol.

Deviations that increase risk, have potential to recur, or are undertaken to eliminate an immediate hazard would be considered an Unanticipated Problem and should be handled according to Section 8.

When a sponsor requests that the IRB be notified of a deviation, the completed form will be forwarded to the IRB chair or designate for review of the Request for Protocol Change form submitted by the PI.

Deviations may be ruled by the IRB to constitute non-compliance resulting in suspension of IRB approval.

9.3 Reporting & Review

Deviation/Exception Reports are to be completed for those events that qualify as a protocol deviation or exception. These reports should be filed with the IRB Office. The IRB Office will forward the report to the IRB Chair or designate for review. An acknowledged report will be sent back to the PI for the study file. The Chair may choose to place any deviation or exception on the agenda of the next convened IRB meeting for discussion. The PI may be asked to appear at that meeting to answer any questions or clarify issues for the IRB.