



Protocol Deviations and Violations

Protocol Deviation- A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IRB. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the IRB using the standard reporting form.

Any change, divergence, or departure from the study design or procedures of a research protocol that affects the subject's rights, safety, or well being and/or the completeness, accuracy and reliability of the study data constitutes a protocol violation. Changes or alterations in the conduct of the trial which do not have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data are considered minor protocol deviations.

Protocol Violation- A protocol violation is a deviation from the IRB approved protocol that may affect the subject's rights, safety, or well being and/or the completeness, accuracy and reliability of the study data.

If the deviation meets any of the following criteria, it is considered a protocol violation. Example list is not exhaustive.

I. The deviation has harmed or posed a significant or substantive risk of harm to the research subject.

Examples:

- A research subject received the wrong treatment or incorrect dose.
- A research subject met withdrawal criteria during the study but was not withdrawn.
- A research subject received an excluded concomitant medication.

II. The deviation compromises the scientific integrity of the data collected for the study.

Examples:

- A research subject was enrolled but does not meet the protocol's eligibility criteria.
- Failure to treat research subjects per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)
- Changing the protocol without prior IRB approval.
- Inadvertent loss of samples or data.



III. The deviation is a willful or knowing breach of human subject protection regulations, policies, or procedures on the part of the investigator(s).

Examples:

- Failure to obtain informed consent prior to initiation of study-related procedures
- Falsifying research or medical records.
- Performing tests or procedures beyond the individual's professional scope or privilege status (credentialing)

IV. The deviation involves a serious or continuing noncompliance with federal, state, local or institutional human subject protection regulations, policies, or procedures.

Examples:

- Working under an expired professional license or certification
- Failure to follow federal and/or local regulations, and intramural research or CC policies
- Repeated minor deviations.

V. The deviation is inconsistent with the NIH Human Research Protection Program's research, medical, and ethical principles.

Examples:

- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

Minor Protocol Deviation- A minor protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IRB and which DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.