

Protocol Deviation and Protocol Violation Definitions

Protocol Deviation: Accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. Deviations may result from the action of the subject, researcher, or research staff.

A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of a researcher. Examples of a deviation include:

- A rescheduled study visit
- Failure to collect an ancillary self-report questionnaire
- Subject's refusal to complete scheduled research activities

Protocol Violation: Accidental or unintentional change to, or non-compliance with the IRB approved protocol without prior sponsor and IRB approval. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data.

Examples of protocol violations:

- Failure to obtain valid informed consent (e.g., obtained informed consent on a non-date stamped form)
- Loss of laptop computer that contained identifiable, private information about subjects
- Accidental distribution of incorrect study medication or dose
- Not following inclusion/exclusion criteria

See [MMC's SOP RR 404-D](#) for examples of reportable and non-reportable deviations and/or violations.