
ALFRED ETHICS COMMITTEE GUIDELINES: REPORTING PROTOCOL DEVIATIONS / VIOLATIONS

DEFINITIONS

There is no official definition of a protocol deviation or violation, but the following may serve as a guide.

- A protocol violation is a failure to comply with the final study protocol as approved by the Ethics Committee. A violation is a serious non-compliance with the protocol that can result in the exclusion of a patient or their results from the study and in some cases a charge of research misconduct.
- A protocol deviation is a less serious non-compliance with the approved study protocol. A protocol deviation presented in advance of the event may be considered acceptable by the sponsor (if any) and the Ethics Committee.

REPORTING PROTOCOL DEVIATIONS / VIOLATIONS TO THE ETHICS COMMITTEE

Researchers should provide written details to the Ethics Committee of protocol violations or deviations when:

- there are safety or ethical implications for the participant(s)
- the scientific integrity of the study is affected (normally the sponsor will advise on this)
- the protocol methodology causes the protocol deviation/violation to occur (eg. exclusion criteria too strict)
- the conduct of the study causes the protocol deviation/violation to occur (eg. rotating staff not detailing consent procedures in patient notes)

Researchers should provide the following details to the Ethics Committee using the [Protocol Deviations / Violations Report Form](#):

- project number and name
- name and signature of the principal researcher
- details of the deviation/violation
- the impact of the deviation/violation on patient safety and/or scientific integrity
- evidence of acceptance of the deviation by the sponsor, if relevant
- what steps have/are to be taken to avoid a recurrence

Please note:

- if any changes to the project/protocol are required, an amendment should be submitted to the Ethics Committee
- the Ethics Committee is under no obligation to approve a protocol deviation presented in advance

FURTHER INFORMATION

Ethics Office
w: www.alfredresearch.org
e: research@alfred.org.au
t: +613 9076 3619
f: +613 9076 8841

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