

University of Waterloo
Office of Research Ethics

Protocol Deviation Report Form

A. Background: Distinguishing between Modifications and Protocol Deviations

Modifications or changes to a study (e.g., procedures) can sometimes occur after it has received ethics clearance. These changes can be anticipated and in some cases, are planned. Such changes generally do not impact or alter the protection of the safety and welfare of research participants. Examples of these types of changes include: addition or deletion of investigators' names; addition of questionnaires or questionnaire items; additional procedures; increased numbers of participants. An Amendment is used by the Principal Investigator (PI) to request ethics clearance of study modifications, and is submitted to Research Ethics. The requested change(s) can be incorporated into the study once the PI on the study receives notification of ethics clearance.

Protocol deviations are changing a study after it has received ethics clearance. Protocol deviations, however, are unanticipated or unintentional and can be minor or major in nature. Minor protocol deviations generally impact administrative and logistical aspects of the study such as study participants missing appointment, change in appointment dates. Major protocol deviations may impact the research protocol, information consent documents or other study materials, and usually cannot be anticipated ahead of time or are often necessary to ensure the safety and welfare of the participants. Examples of major protocol deviations include changes in procedures required to eliminate immediate risk/hazards to participants; enrollment of participants outside the protocol inclusion/exclusion criteria whether agreed to or not by the sponsor; significant deviation in the informed consent process (i.e. use of incorrect version). The Principal Investigator and Faculty Supervisor, in the case of student research, is responsible for reporting any protocol deviations discovered during any stages of the research. Protocol deviations of a major nature must be reported to Research Ethics within 7 days of the deviation. Please attach additional pages to describe this deviation if needed.

Please do not submit handwritten forms. Typewritten forms must be provided. This form is a fillable PDF.

The following sections are to be completed by the PI as indicated on the Research Ethics Application.

B. Study Information

Research Ethics #:

Ethics Clearance Date (D M Y):

Name of Principal Investigator or Faculty

Supervisor's Name:

Name of Principal Investigator or Faculty

Supervisor's Department/School:

Study Title:

C. Protocol Deviation Information

1. Provide a brief description of the protocol deviation including the date(s) of occurrence.

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2. Does the protocol deviation compromise the scientific integrity of the study? Yes No
If **yes**, provide a brief explanation.
3. Did the protocol deviation increase the risk or the possibility of risk to the research participant(s)? Yes No
If **yes**, provide a brief explanation.
4. Was the protocol deviation caused by, or the result of an action of:
- | | | |
|-----------------------|-----|----|
| Sponsor | Yes | No |
| PI | Yes | No |
| Other team researcher | Yes | No |
| Study participant | Yes | No |
- If **yes** to any of the above, indicate what measures have been/will be taken to ensure this, or a similar deviation, will not occur again.
5. As a result of the protocol deviation, will an Amendment be submitted to Research Ethics for a planned change to the study? Yes No

Signature of Principal Investigator: _____

Date: _____

Please print and sign the completed form and send an electronic copy to Research Ethics at reb@uwaterloo.ca

For Research Ethics/REB Use Only Review of Protocol Deviation Report

Action Required: Yes No further action is required

Change(s) are required to:

- Protocol
- Information Consent Document
- Other

Study Disposition:

- Continuation of study permitted
- Continuation of study conditional on change(s) noted above
- Suspension of study pending further review by REB

Julie Joza, MPH
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University of Waterloo

Heather Root, Ph.D
Senior Manager, Research Ethics
University of Waterloo

Date

Date