

REPORT OF ADVERSE EVENTS, PROTOCOL DEVIATIONS,
 AND OTHER UNANTICIPATED PROBLEMS

This form is for the mandatory reporting of Adverse Events and Other Unanticipated Problems, as defined below. This information is needed by the REB to ensure that the study is proceeding safely, respectfully, and according to its accepted protocol procedures. If you are unsure whether a Report is required, or if the event gives rise to an imminent threat of harm or breach of data security, please call or email us promptly to discuss.

Phone: (613) 520 2600, ext. 2517 (CUREB A/B); Email: ethics@carleton.ca

This Form must be submitted within **5 days** of the occurrence of the event or finding, or of the PI becoming aware of it.

Complaints received from anyone affected by the study, whether related to the reported event or not, must be promptly reported to the REB by email: ethics@carleton.ca

**Definitions:**

**Adverse Event:** Any untoward occurrence affecting a study participant with a reasonable likelihood of being causally related to a study activity or intervention. For example, a data privacy breach or a situation where a participant faints or suffers distress.

**Material Incidental Finding:** Any unanticipated discovery made in the course of research that is outside the scope of the research but that nevertheless will or may significantly affect a participant’s welfare. For example, a finding of suspected child abuse or that a participant has suicidal ideation, or some possibly significant cardiac abnormality on an ECG.

**Protocol Deviation:** Any change or alteration from the study procedures provided in the REB-cleared study protocol, consent documents, or other study materials. A Protocol Deviation may be deliberate (e.g. to avoid potential harm) or unplanned (e.g. by error or oversight, or in response to unexpected circumstances). For example, by oversight, a participant signs an out-of-date version of the consent form or there is a change of location of a research activity.

**Other Unanticipated Problem:** Any unanticipated event that may increase the level of risk to participants or that may affect participants’ welfare or willingness to continue to participate in the study or that may adversely affect data integrity. An Unanticipated Problem includes also the discovery of any new information that may have any of these effects. For example, that a relevant finding discovered in the published literature restricts some aspect of participant interaction.

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| 1. **Identification of Project and PI**
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| Study Title:  | Ethics Protocol Number: |   |  |
| Date of this report: Click or tap to enter a date. | Academic Supervisor: |   |  N/A [ ]   |
| Lead Researcher Name: |   |
|   | Department: |   |
| Institution: |   |
| Email: |   |

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| 1. **Type of Report**
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* 1. [ ]  Adverse Event

 [ ]  Protocol Deviation

 [ ]  Material Incidental Finding

 [ ]  Other Unanticipated Problem or Relevant New Information

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| 1. **Description of the Event and Response**
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* 1. Date of the event or discovery of the issue, event or finding:

Click or tap to enter a date.

* 1. Where did the event take place?

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* 1. Describe the event or problem, and the effect on any participant, if applicable:

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* 1. What actions, if any, were taken, or will be taken, to address or remedy any adverse consequences for any participant(s)?
	2. Have any participants withdrawn, or been required to withdraw, as a result of the reported event?

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* 1. As a result of this event, describe any proposed change(s) to study procedures to address safety or other ethical issues related to the reported event.

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* 1. Is a Change to Protocol (including an amendment to any Consent Form, recruitment or other materials) needed to properly address this issue or event? If yes, describe Change.

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If Change is required, study activities involving affected participants must be suspended until Change to Protocol is cleared, except to avert significant harm to participants. If this is the case, please explain and submit Change to Protocol Form.

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* 1. Is there any other information or detail relevant to the reported event?

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| 1. **Certification**
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| * 1. By submitting this form, I confirm that the above information is correct and complete.
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| 1. **Comments**
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| * 1. Do you have any comments or suggestions to improve this form?
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