Researchers shall report to the REB any unanticipated issue or event that may increase the level of risk to participants or that has other ethical implications that may affect participants’ welfare.

|  |  |
| --- | --- |
| REB File Number: |  |
| Title: |  |
| Principal Investigator: |  |
| Funder: |  |

When did the event occur, and when did the study team learn about the event?

|  |
| --- |
|  |

When did the study team learn about the event?

|  |
| --- |
|  |

Describe the event.

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|  |

Describe the actions taken following the event.

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|  |

Indicate the actions that will or have been taken to prevent such an event from occurring in the future.

Changes to the protocol –submit [Amendment Request Form](https://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/ethicsforms.html)

Modification of consent/assent form(s) - submit [Amendment Request Form](https://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/ethicsforms.html)

Suspension of enrolment of new participants

Temporary study suspension

Study termination – Submit [Closure Form](https://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/ethicsforms.html)

No corrective measures are proposed (provide justification below)

Other

Provide details of all corrective action(s).

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|  |

Does this incident require reporting to another Research Ethics Board?

Yes  No

If yes, where?

If the event involved a privacy breach, has the [Executive Director, University Governance](https://www.uregina.ca/president/executive-team/ed-governance-univ-secretary/privacy/breach.html) been contacted?

Yes  No

Will participants be notified? Provide a copy of communications.

Yes  No

**Declaration by Principal Investigator (or Supervisor for student projects)**

***All information provided is accurate and complete. An Amendment Request Form will be submitted for any changes made to the protocol.***

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Signature of Principal Investigator Date (MM/DD/YY)