Commit

**University Research Ethics Board (UREB)**



**REB.FORM.007 | Adverse Event Report**

The principal investigator or faculty supervisor (in the case of student research) has an obligation to *promptly* report to the Chair of the UREB any adverse or unexpected events that occur during the conduct of research. An adverse event includes any undesirable experience, response, or outcome. The adverse event may be emotional, psychological and/or physiological in nature. The principal investigator or faculty supervisor is required to submit this completed Adverse Event form within one (1) business day of the incident.

**Please note:** For events that include privacy breaches that may compromise participants’ confidentiality or anonymity, researchers must submit **REB.FORM. 015** within one business day. All privacy breaches reported to the UREB will be sent to the MSVU FOIPOP Officer for investigation.

|  |
| --- |
| Section A – Report Information |
| 1. Research Ethics Clearance File #:
 | Click or tap here to enter text. |
| 1. Date of this Report:
 | Click or tap to enter a date. |
| 1. Reported completed by:
 | Click or tap here to enter text. |
| 1. Date of the Adverse Event
 | Click or tap to enter a date. |
| 1. Title of Research Study:
 | Click or tap here to enter text. |
| 1. Principal Investigatoror Nominated Principal Investigator (see REB.INFO.001 for definitions) - if different from #3 above
 | Click or tap here to enter text. |
| 1. Email Address (MSVU email only)
 | Click or tap here to enter text. |
| 1. Telephone Number
 | Click or tap here to enter text. |
| \*Please provide your supervisor’s or MSVU Faculty Sponsor’s information below (if applicable) |
| 1. Supervisor
 | Click or tap here to enter text. |
| 1. Supervisor’s Email (MSVU email only)
 | Click or tap here to enter text. |
| 1. Supervisor’s Telephone Number
 | Click or tap here to enter text. |

|  |
| --- |
| Section B – Adverse Event Information |
| 1. Please describe the nature of the adverse event (attach any relevant documentation to this report).

Click or tap here to enter text. |
| 1. Did this adverse event occur to a participant enrolled in your study?
 | ☐Yes ☐No |
| 1. Was the adverse event related to the procedure of the study?
 | ☐Yes ☐NoIf yes, please describe below:Click or tap here to enter text. |
| 1. Is the adverse event beyond that which is described in the “Risks” section of the ethics application and in the Information letter/Consent letter?
 | ☐Yes ☐No |
| 1. Is this type of adverse event likely to occur again?
 | ☐Yes ☐No |
| 1. Describe the event, including details on the physical, emotional, or psychological impact of the adverse event.
 | Click or tap here to enter text. |
| 1. Describe the actions (if any) taken following the identification of the adverse event. How was the situation resolved?
 | Click or tap here to enter text. |
| 1. Is there any plan for follow up contact?
 | ☐Yes ☐NoPlease explain your response below.Click or tap here to enter text. |
| 1. Should any changes be made to the study as a result of this adverse event in order to reduce or eliminate risk to participants?
 | ☐Yes ☐NoIf yes, please attach all relevant documentation to this report **and** indicate below what changes have been made:Click or tap here to enter text. |
| 1. Should the letter of information/consent or consent procedures be amended in light of this event?
 | ☐Yes ☐NoIf yes, please attach the modified letter or form to this report **and** indicate below what changes have been made:Click or tap here to enter text. |
| 1. Should this adverse event be reported to other parties (e.g., sponsors, funding agencies, PHAC)
 | ☐Yes ☐NoIf yes, please explain your response below.Click or tap here to enter text. |

|  |
| --- |
| Section C – Signature and Agreement |
| My/Our signature(s) below confirms that the above information is correct, up-to-date and that no unapproved procedures were used in this study. All events (adverse, unanticipated, privacy breaches) have been reported to the UREB.   |
| Signature of person submitting this report | Name: Click or tap here to enter text. | Date: Click or tap to enter a date. |
| Signature of Faculty Supervisor (if necessary) | Name of Faculty Supervisor: Click or tap here to enter text. | Date: Click or tap to enter a date. |

**Submission Process:**

1. Researchers are asked to submit the application electronically only to ethics@msvu.ca
2. Please note that recruitment and data collection may not begin until a certificate of Research Ethics Clearance has been issued.
3. Researchers may **only** use letters and/or numbers for file names and refrain from using any special characters (e.g., #; &; etc.).
4. All documents must be clearly labeled and reflect how they are referenced in the application.
5. Note - a **maximum of 2 attachments** are permitted for submission– the application (1) and the combined appendices (2)
6. Application packages shall only be accepted in the form of Word documents (\*.doc or \*.docx) or Portable Document Format (\*.pdf)

For details on specific submission criteria, please see [**Guidance Documents**](https://www.msvu.ca/research-at-the-mount/research-ethics/policies-procedures-guidelines/):

* REB.INFO.401 – Faculty & Staff
* REB.INFO.402 – Graduate Students
* REB.INFO.403 – Undergraduate Students

***For UREB Use Only***

|  |
| --- |
| Action Required: ☐Yes ☐No |
| Details of Action Taken:Click or tap here to enter text. |
| Details of Follow-up Action:Click or tap here to enter text. |

***Acknowledgement****:* The University Research Ethics Board wishes to extend its appreciation to the Research Ethics Board(s) at Saint Mary’s University, University of Waterloo, University of Ottawa, and McGill University for permission to embed several aspects of their ethics applications into this current UREB iteration.