Commit

**University Research Ethics Board (UREB)**



**REB.FORM.008 | Unanticipated Research Event Report**

An unanticipated research event is generally any unintended occurrence(s) during the course of the research that had, or may have, an impact on participants. This includes, but is not limited to, confidentiality breaches, complaints, violation of approved protocols, or unfavourable participant reactions. 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 unexpected events that occur during the conduct of research. The principal investigator or faculty supervisor must submit the completed Unanticipated Research Event Report within **five (5) business** days 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 (1) business day. All privacy breaches reported to the UREB will be sent to the MSVU FOIPOP Officer for investigation.

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| 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 Unanticipated Event: | Click or tap to enter a date. |
| 1. Title of Research Study (if different from REB file) | Click or tap here to enter text. |
| 1. **Principal** Investigator or Nominated Principal Investigator (see REB.INFO.001 for definitions) - if different from #3 above | 1. 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. |

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| Section B – Unanticipated Event Information | |
| 1. Please describe the nature of the unanticipated event (attach any relevant documentation to this report).   Click or tap here to enter text. | |
| 1. Did this event occur to a participant enrolled in your study? | Yes  No |
| 1. Was the event directly related to a procedure of the study? | Yes  No  If no, please describe below:  Click or tap here to enter text. |
| 1. Is the event beyond that which is described in the “Risks” section of the ethics application and in the information Letter/consent Form? | Yes  No |
| 1. Is this type of event likely to occur again? | Yes  No |
| 1. Describe the event, including details on the physical, emotional, or psychological impact of the unanticipated event. | Click or tap here to enter text. |
| 1. Describe the actions taken following the identification of the unanticipated event. How was the situation resolved? | Click or tap here to enter text. |
| 1. Is there any plan for follow up contact? | Yes  No  Please 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 event in order to reduce or eliminate risk to participants? | Yes  No  If 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 Information Letter, Consent Form, or consent procedures be amended in light of this event? | Yes  No  If 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 event be reported to other parties (e.g., sponsors, funding agencies, PHAC) | Yes  No  If yes, please explain your response below.  Click or tap here to enter text. |

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| 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 completing this report | Name:  Click or tap here to enter text. | Date: Click or tap to enter a date. |
| **Faculty Supervisor or MSVU Sponsor (if required)**  In the case of student research, as Faculty Supervisor, my signature below indicates that I have read and approved the application and proposal, deem the project scientifically valid and worthwhile, and agree to provide continuing and thorough supervision of the student(s). I will ensure that the level of risk inherent to the project is balanced by the level of research experience that the student researcher has. I will provide appropriate oversight to ensure that the research will be conducted in accordance with MSVU UREB's policies/procedures and that it adheres to this cleared protocol and consenting process. | | |
| Signature of Faculty Supervisor | 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](mailto: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***

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| 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 Ottawa and McGill University for permission to embed several aspects of their ethics applications into this current UREB iteration.