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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.

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 to the Research Office and Ethics.

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| **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 For example, by oversight, a participant signs an out-of-date version of the consent form or there is a change of location of a research activity.**Other Unanticipated Problem:** Any unanticipated event that may increase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. |

N.B.: All boxes below can expand to accommodate your text.

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| --- |
| 1. **Identification of Project and PI**
 |

Ethics file number:

Research Project title:

Date of this report: Click or tap to enter a date.

Academic Supervisor:  [ ] N/A

Lead Researcher Name:

Department:

Institution:

Email:

|  |
| --- |
| 1. **Type of Report**
 |

[ ]  Adverse Event

[ ]  Protocol Deviation

[ ]  Material Incidental Finding

[ ]  Other Unanticipated Problem or Relevant New Information.

 Please specify:

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

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* 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)?

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* 1. 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 even

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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.

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

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| 1. **Attestation**
 |
| [ ]  I agree to abide by the ethical guidelines and procedures of Saint Paul University Research Ethics Boards, of the [*Tri-Council Policy Statement (TCPS 2)*](http://pre.ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html), of my profession or discipline, as well as of the institution in which the research is undertaken. I am aware of my responsibility to be familiar with these standards. I further agree to notify the appropriate Research Ethics Board of any substantive change in the use of data in this research and to comply with requests made by such REB during the life of this research. |

Signature:       Date: Click or tap to enter a date.

Printed Name:

Signature:       Date: Click or tap to enter a date.

Printed Name:

Signature:       Date: Click or tap to enter a date.

Printed Name:

**Submit to:**

Research Office and Ethics

Saint Paul University (Guigues Hall)

223 Main Street, Room 166

Ottawa, Ontario
K1S 1C4

Email: mkouachi@ustpaul.ca

Phone: (613) 236-1393 ext. 2323