**St. Clair College Research Ethics Board**

*Adverse Event Report*

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| **Submission Instructions**In the event of Adverse Event or Unanticipated Event, the Investigator is required to immediately notify St. Clair College Research Ethics Board (REB) using this form. If notice is not provided within fifteen (15) days of the event, the College’s REB is allowed to suspend approval for the submitted research proposal.Changes to consent or research protocol must be submitted in writing using the Amendment Form.  |

An Adverse Event is any unfavorable change in current health status (including mental, emotional or psychological) of a person participating in a research study. This change may or may not be causally related to the study protocol.

An **Unanticipated Event** is any unfavourable or unintended occurrence during the course of a research study which may have immediate or potential implications for participants.

1. **TITLE OF RESEARCH PROJECT**

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Original Approval Date:

Previous Renewal Date:

**2. INVESTIGATOR INFORMATION**

**Investigator:**

|  |  |
| --- | --- |
| Title (e.g., Dr., Ms., etc.):        | Name:       |
| Department:       |
| Mailing address:       |
| Phone:        | Institutional E-mail:       |

**Level of Project**

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| --- |
| Faculty Research [ ]   |
| Post-Doctoral Research [ ]   |
| Student Research: Doctoral [ ]  Masters [ ]  Student Number       |

 **Faculty Supervisor/Sponsor:**

|  |  |
| --- | --- |
| Title:        | Name:       |
| Department (or organization if not affiliated with St. Clair College)       |
| Mailing address:       |
| Phone:        | Institutional E-mail:       |

**3. DESCRIPTION OF ADVERSE/UNANTICIPATED EVENT**

**Date of event**:

a) What action (if any) has been taken, or will be taken, by the research site, and by whom?

b) What action (if any) has been taken, or will be taken, by the research team?

**4. LOCATION**

a) Did the event occur at St. Clair College? Yes**[ ]** No**[ ]**

If **Yes**, specify precise location of event (building, room #, etc.)

Has the College been informed of the event? Yes[ ]  No[ ]

b) If the event occurred off-site, specify the location where the event occurred:

Has anyone from the site been notified? Yes [ ]  (who)       No [ ]

5. IMPACT

Please describe the impact of this information on the study and on St. Clair College (if any)

**6. STATEMENT OF PRINCIPAL INVESTIGATOR**

I am aware of and understand the circumstances and/or information related to the adverse/unanticipated event referred to on this form. I have assessed the significance of this event with respect to participants involved in this research and as a result, I believe that:

The study should continue without change to the protocol: Yes [ ]  No [ ]

**7. SIGNATURES**

**My signature certifies that the above information is correct.**

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|  Signature of Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:        |

 AND (if applicable):

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| --- |
|  Signature of Faculty Supervisor/Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:        |

NOTE: We cannot process the form until all the signatures are in place.

Acknowledgement: The following was adapted from the University of Toronto with their permission.