SAINT MARY'S UNIVERSITY SINCE 1802

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Name:	**Research Ethics Board Policy and Procedures on Adverse Events**
Policy Number:	9-1004
Origin:	Research Ethics Board
Approved:	May 18, 2007
Issuing Authority:	University Senate
Responsibility:	Research Ethics Board
Revision Date(s):	n/a
Effective Date:	May 18, 2007

Definition of an Adverse Event

An **adverse event** includes, but is not limited to, a complaint or unexpected event that alters the level of risk for the researcher or participants, or a situation that requires a substantial change in approach to a participant(s) based on the TCPS guidelines. It includes any undesirable experience or response reported by a research participant that is/may be related to his/her experience in the study. The adverse event may be emotional, psychological or physiological in nature.

The following are examples of adverse events that must be reported to the REB:

- Participants showing signs of emotional upset in conjunction with or following interviews or other tasks associated with participation in behavioural or social science studies.
- Any release, even inadvertent, of research participants' identities or personal information.
- Unexpected accidents that occur during the course of a research project, e.g. a participant in an exercise study falling off an exercise bike or treadmill.

Researchers must take reasonable steps to monitor adverse events so that they can take action (if appropriate) to minimize the likelihood that other participants in the study will experience the same outcome.

Reporting of Adverse Events

Researchers have an obligation to report to the Chair of the Research Ethics Board (REB) any occurrence of an adverse event(s) associated with a project that has ethics clearance. This requirement is in adherence with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. The Principal Investigator (or Faculty Supervisor in the case of student research) must notify the Chair and submit the Adverse Event Report (available on-

line at http://www.smu.ca/academic/reb/forms.html)about the occurrence of an adverse event as soon as possible but not later than **one business day** following the event.

The Principal Investigator or Faculty Supervisor is expected to respond to the adverse event immediately and in accordance with the procedures outlined in their original ethics application.

Procedures for an Adverse Event

1. The REB Chair receives an Adverse Event Report from the principal investigator or supervisor of an undergrad or graduate student researcher, or receives an external complaint.
2. Chair decides what immediate action should be taken prior to the next REB meeting. Other REB members may be consulted as needed.
3. Chair informs the researcher(s) in writing of the necessary immediate actions required.
4. Copy of Adverse Event Report and pertinent pages of the related application are included in the next REB meeting agenda package.
5. Chair provides researcher with written feedback from the REB meeting with any additional actions that need to be taken.
6. REB Chair receives written feedback from the researcher about the actions taken.

Saint Mary's University Research Ethics Board ***ADVERSE EVENT REPORT***	
PRINCIPAL INVESTIGATOR: **Email:**	**DEPARTMENT:**
FACULTY SUPERVISOR: **Email:**	**CO-INVESTIGATOR(s):**
REB File #:	**Ethics Clearance Date:**
Title of Project:	
EVENT DESCRIPTION: *(*Attach any relevant documentation.)*	
Description of how the situation was resolved.	
Description of any changes to the research protocol or methodology (please attach relevant materials)	
Should Letter of Information or Consent Form Be Amended? Yes [ ] No [ ] **If yes, please provide copy of amended form indicating where changes have been made.**	
PRINCIPAL INVESTIGATOR'S SIGNATURE: _____ **DATE:**	
Signature of the SMU REB Chair: _____ **Date Received** _____	

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