



**Name:** **Research Ethics Board Policy and Procedures on Adverse Events**

**Policy Number:**

**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

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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.

