ST JOSEPH'S HEALTH CENTRE TORONTO

Excerpt from Research Ethics Board Standard Operating Procedure

4.2 Safety Reporting

Investigators must promptly report to the REB:

- Deviations, from, or changes to, the protocol that serve to eliminate immediate hazards to the trial subjects
- Changes that increase the risk to subjects and/or significantly affect the conduct of the trial
- Any new information that may adversely affect the safety of the subjects or the conduct of the trial
- All adverse events

An adverse event is an unexpected or normally avoidable event that negatively affects, or would reasonably be expected to have the potential for negatively affecting the patient's health and/or overall well-being, and which event occurred in the course of research and/or health care treatment and is not due directly to the natural course of the patient's illness or underlying condition.

If an SJHC subject experiences a serious adverse event or if the principal investigator or local study lead become aware of any new information that may adversely affect the safety of the subjects or the conduct of the trial, the principal investigator or local study lead must notify the REB within 48 hours (or within two working days). If an external subject experiences an adverse event the principal investigator must notify the REB within 10 working days.

Any and all such reports must contain the following information:

- REB Study number
- Title of protocol
- Name of principal investigator
- Subject identifier (study number/reference of subject)
- Date and location of the event
- Description of the event (nature of injury or other adverse occurrence, assessment of severity and assessment of event's relationship to the study)
- Handling of/response to the event
- Any proposed changes in the protocol or the consent form as a result of the event
- To whom else the event has been reported

- Signature of the principal investigator

The REB may ask the Principal Investigator to provide additional information.

For further information regarding one's responsibilities with regards to adverse events which occur at SJHC please see SJHC policy Communication of Adverse Events to Patients and Substitute Decision Makers, Policy #SJ-04-01-19 and for institutional responsibilities regarding the reporting of critical incidents please see SJHC policy Management of Critical Patient Related Incidents #SJ03-03-06 and Incident Report #SJ03-02-01.

Note:
Please find External and Internal Safety Report Forms on the REB webpage:
http://www.stjoestoronto.ca/teaching-and-education/research-ethics-board/

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