

***Guideline For Researchers***

**REPORTING UNANTICIPATED ISSUES AND ADVERSE EVENTS**

Federal guidelines state, “Researchers shall report to the REB any unanticipated issue or event that may increase the level of risk to participants, or has other ethical implications that may affect participant’s welfare.” (Article 6.15, TCPS2 p.81)

As defined by the TCPS, **Unanticipated Issues** are issues that “occur during the conduct of research that may increase the level of risk to participants or have other ethical implications that may affect participant’s welfare and were not anticipated by the researcher in the research proposal submitted for research ethics review.” (TCPS2 p.197)

**Adverse Events** are defined as occurrences with an undesirable outcome for the participant.

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

* Negative, physical, or allergic reactions to drugs administered in a study
* Physical consequences from dietary manipulations (e.g., fainting)
* Negative physical reactions in volunteers who have chronic diseases (e.g., heart conditions, diabetes)
* 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)
* Equipment failure during an experimental session should also be reported if it resulted in harm to a participant
* Participants showing signs of emotional upset in conjunction with or following interviews or other tasks associated with participation
* Any release, even inadvertent, of research participants' identities or personal information

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To report an Unanticipated Issue or Adverse Event, please first email the Chair of the Research Ethics Board the details. This email should be directed to rebchair@ryerson.ca. This should be followed within 72 hours by the completion and submission of an Adverse/Unanticipated Event Report.

The Adverse/Unanticipated Event Report can be accessed by signing into MyRyerson. After signing into MyRyerson, click on the link to the “Online Ethics Protocol Submission”. You will then be presented with the option of submitting a new protocol or going to other protocols already in progress or approved. Click on this second link and you should be presented with a list of the protocols which you are able to access. Click on the appropriate protocol. When that protocol comes up one of the options available will be the completion of the Adverse/Unanticipated Event Report. Click on the link and complete the report. Once you have completed the report, please submit.

You will receive an automatic acknowledgement that the report has been submitted. Once submitted the report become a permanent part of the protocol record.

The report will be reviewed by a member of the Ryerson REB and you will be notified within one week’s time if the REB has any questions or concerns or if any additional corrective action is required.