

Brandon University Research Ethics Committee (BUREC)
Standard Operating Procedure

Reporting Unanticipated Issues and Events

Excerpt from the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2-2018)*:

Reports of Unanticipated Issues – Article 6.15:

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 participants' welfare.

Definitions:

Unanticipated Issues:	Issues that occur during the conduct of research; may increase the level of risk to participants or have other ethical implications that may affect participants' welfare; and were not anticipated by the researcher in the research proposal submitted for research ethics review.
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Application (BUREC):

Over the course of the implementation of the approved research project, issues may arise that the researcher did not anticipate when originally submitting the research for ethics review. Unanticipated issues include unexpected reactions by participants to a researcher intervention (e.g., unintended stimulation of traumatic memories, unforeseen side-effects of a medication or natural health product), as well as unavoidable single incidents (e.g., a translator not available for a day, or a failure to follow correct research procedures for one participant on one occasion). They may be minor or serious in magnitude, with short- or long-term implications.

Any unanticipated issue that increases the level of risk to participants or has other ethical implications should be reported to the BUREC without delay. Fatal or life threatening events must be reported to BUREC immediately, at maximum 7 days

following the event. Changes that are necessary to eliminate an immediate risk(s) to the participants may be implemented as needed, but must be reported to the BUREC at the earliest opportunity. If the incident or issue has immediate implications for the safety of participants, the BUREC may withdraw ethics approval, which would require that the research be halted or modified until the matter can be addressed. It may require submission of a revised research proposal for BUREC review. Any change in the status of the ethics certificate, i.e. temporary suspension, is at the discretion of the Chair of BUREC. Failure to report an unanticipated issue or event is considered non-compliance and is subject to the *Brandon University Research Ethics Committee (BUREC) Non-Compliance Policy and Procedures*.

Minor deviations for the research (e.g., a slight increase or decrease of testing time, a wording adjustment on a question) should not require immediate reporting to the BUREC, but may be summarized in annual status reports. In some types of qualitative research, for example, emergent design, the research design evolves over time, so adjustments to the research are to be expected and need not be reported to the BUREC, unless they alter the level of risk or have other ethical implications for participants.

The report to the BUREC should include a description of the unanticipated issue or event, including details of how the researcher(s) dealt with the situation. The point in reporting is to enable the BUREC and the researcher to better protect participants. Depending on the nature of the issue, and in consultation with researchers, BUREC may require that the researcher adjust their procedures to prevent its recurrence during the research project.

Any person(s) can submit an unanticipated issue or event report, and also any person(s) may consult with the Chair of BUREC to determine if an occurrence is to be categorized as an unanticipated issue or event, warranting an official report.

Unanticipated Issue or Event Reporting and BUREC Review Procedures:

Unanticipated issues and events shall be reported to BUREC as soon as possible. Any person may report such event or issue to BUREC. Fatal or life-threatening reportable events shall be reported to BUREC immediately, at maximum 7 days following the event. Failure to submit a report to BUREC constitutes non-compliance and is subject to the *Brandon University Research Ethics Committee (BUREC) Non Compliance Policy and Procedures*.

At the discretion of the BUREC Chair, the ethics certificate may be temporarily suspended while BUREC investigates the event or issue. A majority representation of BUREC shall meet within 7 business days of receipt of the unanticipated issue and event report. The Committee may ask the Principle Investigator to attend the meeting to provide additional information or verify facts outlined in the submitted report.

When reviewing a report of an unanticipated issue or event, the BUREC shall assess the appropriateness of any proposed corrective or preventative measures by the sponsor and/or PI, consider any additional appropriate measures that may or may not have been identified or proposed by the sponsor and/or PI, and consider whether the affected research still satisfies the requirements for BUREC approval. In particular, the BUREC shall consider whether risks to research participants are still minimized and reasonable in relation to the anticipated benefits to the research participants, and the importance of the knowledge that may reasonably be expected to result.

The BUREC shall consider whether some or all of the research participants should be notified of the unanticipated issue or event (i.e., if it may affect the participant's willingness to continue participation in the research).

Finally, the BUREC shall make a determination on whether termination of the research or the research site is warranted.

The BUREC may request corrective actions or substantive changes that might include:

- Changes to the research protocol to be initiated by the principal investigator prior to obtaining BUREC approval to eliminate apparent immediate hazards to research participants;
- Modification of inclusion or exclusion criteria to mitigate the newly identified risks;
- Implementation of additional procedures for monitoring research participants;
- Suspension of enrolment of new research participants;
- Suspension of research procedures on currently enrolled participants;
- Modification of informed consent documents to include a description of newly recognized risks; and/or
- Provision of additional information about newly recognized risks to previously enrolled research participants.

BUREC shall submit a report to the Vice-President (Academic & Provost) on each Unanticipated Issue/Event Report received, with a summary of the Committee's findings and decisions. The Vice-President (Academic & Provost) may be obligated to submit a report to the Secretariat on the Responsible Conduct of Research.

Please note, the following are synonymous terms for the purposes of this Standard Operating Procedure: "unanticipated issues", "unanticipated problems", "unanticipated events".

Additional Resources:

- *Tri-Council Policy Statement: Ethical Conduct on Research Involving Humans (TCPS2-2018)*

Approved by BUREC – December 2018

Revisions Approved by BUREC – June 29, 2020