



Brandon University Research Ethics Committee (BUREC) Non-Compliance Policy and Procedures

POLICY as per the *Brandon University Policy on Research Involving Humans and the Brandon University Research Ethics Committee (BUREC) Policies and Procedures:*

Brandon University requires that all faculty members, staff, and students adhere to the BUREC Policies and Procedures. The University considers non-compliance and the inappropriate treatment of human participants to be a serious offence, subject to penalties, including, but not limited to, formal written documentation included permanently in one's personnel file, suspension of ethics certifications, withdrawal of privileges to conduct research involving humans, and/or disciplinary action. All acts of non-compliance will be reviewed on a case by case basis by BUREC, and may involve the Vice-President (Academic & Provost). Any actions taken will take into account the severity of non-compliance.

CATEGORIZATION OF NON-COMPLIANCE:

Instances of non-compliance are categorized as follows:

- One-Time, Minor Incident
- Repeated Minor Incident
- One-Time, Serious Incident
- Repeated Serious Incident

Violations may be a one-time, minor or serious incident, or may be repeated incidents indicating a more chronic issue of non-compliance. The following list provides examples of instances of non-compliance; this list is not intended to be an exhaustive list:

Description of Non-Compliance Offense	Seriousness or Degree of Offense
1. Conducting human participatory research without prior approval from BUREC, unless otherwise exempt from REB review as per the <i>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2-2014)</i> , the <i>Brandon University Policy on Research Involving Humans</i> , and the <i>Brandon University Research Ethics Committee (BUREC) Policies and Procedures</i> ;	<i>Serious Incident: see Procedures – Exceptions to the Above – b)</i>
2. Failing to follow the approved research ethics protocol;	<i>Serious or Minor Incident</i>
3. Failing to report an adverse event;	<i>Serious or Minor Incident</i>

4. Failing to submit an <i>Amendment to a Previously Approved Ethics Application</i> should a procedure or research instrument be revised.	<i>Serious or Minor incident</i>
5. Failing to fulfill the continuing research ethics review requirements, including submitting an <i>Annual Progress Report</i> or <i>Final Report</i> at the conclusion of the project, as outlined in the <i>Brandon University Research Ethics (BUREC) Policies and Procedures</i> , including Annual Reports and Final Report.	<i>Minor Incident (may be one-time or repeated)</i>

RIGHTS AND RESPONSIBILITIES:

BUREC has the right and responsibility to:

1. Determine the category of incident (minor or serious);
2. Suspend ethics certifications for one, any, or all active protocols;
3. Provide a written report on the violation, including such details as the category of incident, the finding of any investigation, and the decision of BUREC, to the Vice-President (Academic & Provost) for further consideration.

PROCEDURES:

The following procedures shall be observed for each category of non-compliance (i.e. one-time minor incident, repeated minor incident, one-time serious incident, repeated serious incident):

1. Any person can inquire about, or report a violation of an ethics protocol to BUREC at any time. BUREC shall investigate the claim of non-compliance by corresponding with the individual/persons reporting the incident and, subsequently, the Principal Investigator. The identity of the person(s) reporting an incident of non-compliance shall remain confidential to the BUREC, except beyond such reasonable limits as required by natural justice or the law.
2. Written notification shall be sent by BUREC to the Principal Investigator (PI) with a request for the PI to provide, in writing, an explanation of the alleged violation and/or justification for having not followed policy, to be received within 10 business days.
3. A meeting shall be scheduled at the earliest possible time between the BUREC or a BUREC sub-Committee consisting of at least the Chair and two members of the Committee, and the PI. Subsequent meetings may be necessary as additional facts concerning the incident emerge and such meetings may or may not require the attendance of the PI.
4. Should evidence of non-compliance be demonstrated, the ethics certification for the protocol under review may be immediately suspended.
5. BUREC or the BUREC sub-Committee shall determine the actions to be taken, which may include (but are not limited to) written notification to the PI outlining their responsibilities when

conducting human participatory research and any requirements to be undertaken to reactivate the ethics certification for that protocol.

6. BUREC shall submit a report on the investigation of non-compliance to the Vice-President (Academic & Provost) for further review and action as applicable, as per the Brandon University *Policy on Academic Integrity and the Responsible Conduct of Research, Scholarship and Creative Work*. A copy of all documents pertaining to the policy violation shall be kept in the applicable ethics file for the duration of the file retention as per Brandon University Policy and/or Tri-Agency Policy.

Exceptions to the above:

- a) For minor instances of non-compliance in which an Annual Progress Report is not submitted by the noted deadline, or a Final Report is not received at the conclusion of the protocol, a meeting may not be required (as outlined above). For these specific instances, BUREC shall immediately suspend the ethics certification and send correspondence to the PI requesting the applicable report. Upon receipt of the Annual Progress Report or Final Report and the approval of the report by BUREC, the suspension shall be lifted for that protocol. However, for repeated minor incidents of this nature, the procedures outlined above shall be applied.
- b) For serious instances of non-compliance in which a report is received of human participatory research being conducted without prior approval from BUREC, unless otherwise exempt from REB review, the investigation is deferred to and the responsibility of the Vice-President (Academic & Provost).

REACTIVATION OF A SUSPENDED PROTOCOL:

Ethics certification may only be reactivated if and when the actions imposed by the Committee and/or the Vice-President (Academic & Provost) have been fulfilled by the PI and reviewed and approved by BUREC.

APPEAL:

The appeal process provides researchers with the opportunity to seek reconsideration of a non-compliance decision where evidence suggests that an error occurred during the process as outlined above. The decision of the BUREC and/or the Vice-President (Academic & Provost) can only be appealed by the PI named in the ethics application. An appeal of the non-compliance decision must be based on a compelling demonstration of a procedural error in the review of the non-compliance occurrence, which may include failure to consider evidence, the consideration of evidence which can be proven to be false, or evidence indicating real bias on the part of the BUREC.

Notice of appeal must be filed with the Vice-President (Academic & Provost) within twenty-one (21) working days of notification of the decision. The Appeal Committee shall be comprised of one (1) academic dean elected by and from the Deans' Council, one (1) academic member elected by and from the Senate Research Committee and one (1) external member who has no current affiliation with the University, mutually agreed upon by the two internal members. The external member shall Chair the Committee and shall normally hold the rank of full professor or equivalent at an AUCC member

Canadian university. If the two Brandon University members of the Committee cannot agree up on a Chairperson within ten (10) working days, he/she shall be chosen by the Executive Committee of Senate. The appeals committee shall determine its own procedures, taking into account relevant Brandon University policies. The Appeals Committee shall normally hear the appeal within fifteen (15) working days of the appointment of the Chair. The decision of the Appeal Committee is final, but does not restrict access to remedies that may be sought in accordance with grievance and arbitration processes. (As per the Brandon University *Policy on Academic Integrity and the Responsible Conduct of Research, Scholarship and Creative Work*).

Other Relevant Policies:

- *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2-2014)*
- *Brandon University Policy on Research Involving Humans*
- *Brandon University Research Ethics Committee (BUREC) Policy and Procedures*
- *Brandon University Policy on Academic Integrity and the Responsible Conduct of Research, Scholarship and Creative Work*

Approved by BUREC – February 27, 2017

Approved by JAC – March 2017

Approved by SRC – April 19, 2017

Approved by Senate – May 16, 2017