

Guidelines for Non-Compliance (REB Approved - May 2005)

Non-compliance refers to any departure from relevant research policies as outlined by the *Tri-Council Statement: Ethical Conduct for Research Involving Humans and/or the Brock University Faculty Handbook*, whether deliberate or inadvertent and, in particular, those that relate to the following issues:

- Breach of research ethics and/or protocol
- Misconduct in research or scholarship
- Financial mismanagement of public funds

The following outlines REB procedures in the case of breach of research ethics and/or protocol.

- Allegations/complaints regarding non-compliance should be directed to the Research Ethics Officer (REO) who will, in turn, advise the REB Chair and Vice-Chair. In instances where the Chair and/or Vice-Chair are unavailable or have a conflict of interest, a designate shall be appointed by the Research Ethics Officer. For example, when circumstances warrant, the Vice Chair may be asked to assume the duties of the Chair, and a senior (experienced) REB member may be asked to assume the duties of the Vice-Chair.
- Allegations of non-compliance usually shall be submitted in writing to the REO by the person(s) making the allegation.
- Allegations sent from anonymous sources or via a third party may be considered, but only if all relevant facts are publicly available or otherwise independently verifiable.
- Parties making allegations over the telephone will be asked to provide follow-up contact information and informed that a written statement may be requested at a later date.
- The REO shall issue an acknowledgment of receipt to the source of the allegation and inform the REB Chair and Vice Chair within three working days of receiving the allegation.
- The REO shall conduct an investigation by reviewing existing files, contacting the source of the allegation to obtain any further details required, and contacting the researcher(s) for information. Results of the investigation will be provided to the REB Chair and Vice Chair.

The level at which non-compliance issues are dealt with shall reflect the actual, potential or perceived harms involved. The REO, REB Chair and Vice-Chair shall review the allegation and evidence and decide on an appropriate course of action, which may include the following options:

- a) Dismissing and/or not pursuing the allegation any further;
- b) Undertaking to resolve the matter directly with the investigator(s) and faculty supervisor and any third parties involved (e.g., REB members, research participants, and community members). See Level 1 and Level 2 below; and
- c) Referring the matter to the Associate Vice-President (VP) Research for investigation. See Level 3 below.

Level 1: The REB considers the non-compliance issue to be minor resulting in actual, potential or perceived harms that are considered to carry no more than minimal risk.

Examples include, but are not limited to, the following:

- Failure to submit appropriate supplemental documentation when requested
- Any deviation from protocol, without REB clearance of revision or modification, where the resulting actual, potential or perceived harms are considered to carry no more than minimal risk

The course of action taken for Level 1 non-compliance issues will be as follows:

- REO, REB Chair and Vice-Chair will establish a realistic schedule for resolving the situation, including meeting with the investigator(s) and faculty supervisor (if relevant). Whenever possible, an educative approach will be taken. Actions will be determined to rectify any harm that may have been perceived or experienced by participants or community members.
- REO will produce a report of proceedings, which will be sent to the REB Chair, Vice Chair, Investigators and Faculty Supervisor (if relevant)
- VP will be notified and receive copies of all correspondence but generally will not be involved in the case.
- A summary report will be given at the next full REB meeting.

Non-compliance issues not resolved at Level 1 to the satisfaction of the REO, REB Chair, and/or Researcher and faculty advisor (if relevant) will consequently advance to Level 2.

Level 2: The REB considers the non-compliance issue to be serious in nature resulting in actual, potential or perceived harms that are considered to carry more than minimal risk.

Examples include, but are not limited to:

- ***Issues that cannot be resolved to the satisfaction of the REO, REB Chair, and/or Researcher and faculty advisor (if relevant) at Level 1.***
- Failure to obtain ethics clearance prior to starting researching involving human participants

- Any deviation from protocol, without REB clearance of revision or modification, where the resulting actual, potential or perceived harms are considered to carry greater than minimal risk
- Failure to disclose, or incomplete disclosure of the potential risk of research to REB and/or research participants
- Intentionally providing incorrect or misleading information to the REB and/or research participants
- Intentional violation of the basis principles of the Tri –Council Policy Statement and/or Brock University Ethics Policy

The course of action taken for Level 2 non-compliance issues will be as follows:

- The case will be brought to full REB review where an effort will be made to resolve the matter with the investigator(s), faculty supervisor (if relevant), and any third parties involved (e.g., research participants, community members). Attempts will be made to establish a realistic schedule for resolving the situation, including requesting that the Investigator(s) develop a remedial plan and implement corrective measures.
- VP will be notified and receive copies of all correspondence but generally will not be involved in the case.

If the researcher and faculty advisor (if relevant) are not satisfied with the decision of the REB at this level they may direct an appeal to the Research Ethics Board Appeals Committee.

Decisions of the Research Ethics Board Appeals Committee shall be final and binding in all respects for any appeal from a decision of the REB (see FHB 8.3.7).

Non-compliance issues not resolved at Level 2 to the satisfaction of the REO and REB will consequently advance to Level 3.

Level 3: If the non-compliance issue meets any of the following criteria, it will be referred to the VP Research:

- a) The issue cannot be resolved to the satisfaction of the REO and REB Chair at Level 2;
- b) The issue is particularly serious or sensitive;
- c) The issue involves misconduct in research/scholarship; and/or
- d) The issue involves breach of contract or financial mismanagement of public funds.

Sanctions resulting from issues of non-compliance that may be imposed by the REB include, but are not limited to, the following:

- a) Temporary suspension of research activity until satisfactory corrective measures are in place;
- b) Termination of research activity;
- c) Reporting cases of possible illegal or unethical conduct to the appropriate authorities.