

SOP Title	200: REB Operations
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1.0 PURPOSE

This standard operating procedure (SOP) affirms the standards of ethical research conduct, describes the policies and procedures for responding to reports of ethical non-compliance, and defines the actions the REB may take as a result of its review of reports of ethical non-compliance.

2.0 GENERAL PROCEDURE STATEMENT

UOIT pledges to promote and uphold the highest ethical standards in the conduct of human research. All members of the University community (e.g., faculty, staff, students, visiting scholars, adjuncts, etc.) are required to comply with UOIT Policies and Procedures, applicable guidelines and regulations (national and international), and the requirements and determinations of the REB.

All members of the University community share the responsibility for reporting incidences of non-compliance.

A researcher may decide to voluntarily suspend or to terminate some or all research activities; however, this is not considered a suspension or termination of REB approval.

3.0 RESPONSIBILITY AND AUTHORITY

The Chair, Vice-Chair and the REB Administration are responsible for executing this SOP.

This SOP applies to all UOIT REB members. The REB is responsible for determining whether any information received throughout the course of the research requires consideration of the suspension or termination of REB approval of a research protocol. The researcher is responsible for notifying the REB and the institution of any suspensions or terminations of research and for providing a detailed explanation for the action.

4.0 DEFINITIONS:

- I. **Non-compliance:** not following policies and procedures as outlined in the most recent TCPS and/or UOIT REB policies, procedures, or communications and/or the researcher's approved REB protocol.

Non-Compliance can range from Administrative Non-Compliance (continuing to conduct research that has expired) to Adverse Non-Compliance, placing participants at an increased

level of risk, resulting in an adverse event involving a participant (i.e., leaving data unsecured). Note that examples provided are for illustrative purposes only.

- II. **Suspension:** ethical approval of the research is suspended, resulting in the temporary cessation of all recruitment, data collection, data analysis, and data reporting **including publication. This applies to all primary and secondary use of data.**
- III. **Termination:** ethical approval of the research is permanently revoked and all study-related activities must cease, including recruitment, data collection, data analysis, and data reporting **including publication. This applies to all primary and secondary use of data.**
- IV. **Study Closure:** direct or indirect contact with human participants relating to data collection has ceased. Other activities related to data analysis, data reporting, and publication may continue.

5.0 SPECIFIC PROCEDURES:

The REB Chair, Vice-Chair or designate is not authorized to terminate research; however, he/she is authorized to suspend research and is responsible for reporting any suspensions to the full REB at the next convened meeting. The REB is authorized to terminate the ethical approval of the research following its review at a convened meeting. If deemed necessary, the Chair or designate will notify the Manager of the Office of Research Services to ensure compliance with the Tri-Council Agreement on the Administration of Agency Grants and Awards by Research Institutions and any other relevant institutional policies and procedures.

The Research Ethics Coordinator is responsible, when applicable, for reporting all terminations of UOIT approvals to the regulatory authorities in accordance with applicable laws, or the terms and conditions of research agreements or contractual arrangements.

5.1 Allegations of Non-compliance

When an allegation of non-compliance is referred to the REB, the REB Chair will assess the allegation to determine its accuracy. The Chair may use any of the following methods to gather the required information:

- Conduct an initial review alone;
- Convene a subcommittee (comprised of the Vice-Chair and Research Ethics Coordinator) of the REB to conduct a review;
- Seek guidance from University counsel (such as Risk Management or independent legal counsel)

5.2 The Chair or Vice-Chair will produce a written report of the findings and evidence. All documents will be reviewed by the REB at the next full board meeting. The researcher will be given an opportunity to address the board at this time. The REB will determine the appropriate way to remedy the non-compliance as outlined in Section 5.3. The REB reserves the right to obtain more information before rendering a final decision.

5.3. The actions the REB may take include, but are not limited to, the following:

- Request modifications to the research protocol;
- Request the notification of past and/or current participants;

- Require that current participants re-consent to participation;
- Request modification of the continuing review schedule;
- Initiate or increase monitoring of the research;
- Suspend the research;
- Terminate the research;
- Refer the matter to other organizational entities (e.g., legal counsel, risk management, institutional official)

5.3.1 The REB file will include a description of the nature of the event, the findings, actions taken, and plans for continued investigation or action, if required.

5.3.2 The REB Chair or Vice-Chair will notify the researcher in writing of the results of the investigation and of any remedial actions required by the REB. When a decision of non-compliance has been rendered, the Chair or Vice-Chair will forward the letter to the researcher. A copy of this letter will be sent to the researcher's Dean. The letter will outline the decision of the REB and actions to be taken by the researcher. It will also include a request for the researcher to respond in writing within ten (10) business days. If the researcher does not agree with the decision or the REB, he/she has the opportunity to request to appeal the decision, also within ten (10) business days.

5.3.3 If remedial actions are required, the study will remain suspended until these conditions are satisfactorily met. Under normal circumstances, the UOIT REB will not review or grant approval for research that has been conducted without prior approval. All conditions must be met in cases of termination before any subsequent submissions from the researcher will be considered for REB review.

5.3.4 Appeal of a Termination: In the event that a researcher would like to appeal a decision by the REB, the appeal will be brought before UOIT's Appeal Board at Trent University. All documentation would be forwarded to Trent's REB for review. UOIT ethical approval of a study under appeal will remain suspended until a decision is rendered by the Appeals Board.