

SOP Title	REB Operations Suspension and Termination of Research Involving Human Subjects for Administrative Non-Compliance
Number	REB SOP 211
Version Date	September 18, 2019
Approval Date	October 23, 2019
Approved By	REB

PURPOSE

1. This standard operating procedure (SOP) describes the Research Ethics Board (REB) procedures for responding to suspension or termination of research involving human subjects for administrative non-compliance.

As per article 6.14 of the Tri-Council Policy Statement (TCPS) 2 and the UOIT REB SOP 207, continuing ethics review consisting of an annual report (Renewal Request) or end-of-study report (Project Completion Notification) must be reported to the REB prior to study expiry. Failure to submit yearly reports prior to the expiry date will result in administrative non-compliance. Consequences of administrative non-compliance include suspension or termination of REB approval and freezing access to research funds for funded projects.

DEFINITIONS

2. For the purposes of these procedures the following definitions apply:

“Non-compliance” means not following policies and procedures as outlined in the most recent TCPS 2, and/or institutional REB policies, procedures, 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.

“REB designate” is the Research Ethics Officer or Research Ethics Assistant who is responsible for the coordination of activities related to research involving humans and provides support to the REB.

“Principal Investigator (PI)”, is the person who is a University member and leads a research project. The PI is also responsible for overseeing all aspects of the research project.

“University” means the University of Ontario Institute of Technology (Ontario Tech).

“Suspension” means ethical approval of the research is suspended, resulting in the temporary cessation of all study related activities. This applies to all research involving humans.

“Termination” means ethical approval of the research is permanently revoked and all study-related activities must cease. This applies to all research involving humans.

SCOPE AND AUTHORITY

3. These procedures apply to all research involving humans carried out under the authority of the University. The REB Chair, REB Vice-Chair and REB designate are responsible for executing this Procedure. This Procedure applies to all funded and unfunded research projects involving human subjects.
4. The REB Chair, or successor thereof, is responsible for overseeing the implementation, administration and interpretation of these Procedures.

PROCEDURES

5. Study suspensions for administrative non-compliance

- a. Prior to study expiry, the REB designate will send three courtesy renewal reminder notices to the Principal Investigator (PI) requesting for a submission of annual report (Renewal Request) or end-of-study report (Project Completion Notification) before the study expires.
- b. If the PI does not submit renewal requests or project completion notifications to the REB prior to study expiry, the study will result in suspension of REB approval by the REB Chair, Vice-Chair or designate immediately upon study expiry.
- c. The REB will inform the PI promptly in writing of study suspension.

- 5.1. The REB Chair, Vice-Chair or designate is authorized to suspend research for administrative non-compliance.

6. Studies renewed or closed during suspension

6.1. Renewals

- a. Renewals requests submitted to the REB during suspension are reviewed by the REB Chair, Vice-Chair or designate.
- b. The REB will issue continued approval at the REB's discretion if a satisfactory rationale is provided for the administrative non-compliance.
- c. For studies granted continued approval, the REB will renew the study until the anniversary date of the following year.
- d. The REB will promptly inform the PI of the continued approval.

6.2. Closures

- a. For Project Completion Notifications submitted to the REB during study suspension, the application will be reviewed by the REB Chair, Vice-Chair or designate for closure and the study will be permanently closed at the request of the PI.
- b. The REB will promptly inform the PI of study closure.

7. Study terminations for administrative non-compliance

- a. For studies with suspended REB approval of more than two weeks from date of expiry, these are reviewed at the next convened REB meeting where a decision is rendered to terminate the study. The decision will reflect a majority vote from the REB members.
- b. Post-meeting, the REB will provide written notification to the PI that REB approval is permanently terminated due to administrative non-compliance.
- c. For funded research projects, the institutional head of the Office of Research Services (ORS) or delegate are notified of study termination for follow up action and communication with applicable departments.

- 7.1.** The REB Chair, Vice-Chair or designate is not authorized to terminate research for administrative non-compliance; rather, study termination requests must be reviewed at a REB meeting where a decision is rendered.

MONITORING AND REVIEW

- 8.** These procedures will be reviewed as necessary and at least every three years (unless another timeframe is required for compliance purposes). The REB Chair, or successor thereof, is responsible to monitor and review these Procedures.

9. REFERENCE

- 9.1.** Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans
- 9.2.** REB SOP 207 Ongoing Review of Approved Research
- 9.3.** REB SOP 210 Non-compliance