UNIVERSITY OF ONTARIO INSTITUTE OF TECHNOLOGY

SOP Title	**200: REB Operations**
Number. Version	**REB SOP 207 Ongoing Review of Approved Research**
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Approved By	**REB**
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1.0 PURPOSE

This section describes the standard operating procedure for the ongoing review and monitoring of research. The process for further follow-up reporting of unanticipated issues and reporting of non-compliance are described in SOP 201 and SOP 210 respectively.

2.0 GENERAL PROCEDURE STATEMENT

In addition to the formally scheduled annual renewal, the REB must receive and review any new information generated throughout the course of the research that might affect the rights, safety and well-being of research participants, with the understanding that unanticipated risks may often be evaluated with only commencement of the research. The REB is responsible for reviewing and evaluating the following:

a. Amendments or changes to research, including protocol deviations;
b. Significant new findings or new information that may adversely affect the safety of the research participants or the conduct of the trial;
c. Adverse events and unanticipated issues posing risks to participants or others; and
d. Renewal requests for ongoing research or a project completion notification when the study has concluded.

3.0 RESPONSIBILITY AND AUTHORITY

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

4.0 SPECIFIC PROCEDURES

4.1 Amendment or Change Request

Changes in approved research may not be initiated without prior REB review and approval except where necessary to eliminate apparent immediate hazards to human participants.
Amendments must be submitted using the *Change Request* (available on IRIS). Amendments must clearly explain the following:

a. What aspects of the protocol, consent form, information sheet and/or recruitment materials are affected. The revised documents must be highlighted on the *Change Request* and as attached, revised document(s).

b. The nature of the proposed change
c. The reason for the proposed change
d. Any increase in risk or discomfort for study participants and why it is required

4.2 Change Request Review Procedure

Amendments may be reviewed under the delegated review procedure at the discretion of the REB Vice-Chair, or designate, provided that the proposed changes are minor or administrative in nature, and/or the amendment does not involve increased risks to the study participants such that the study would no longer meet the criteria for minimal risk as outlined in SOP 204. If the proposed change represents more than minimal risk, it must be reviewed by the full REB at a convened meeting and must meet all REB criteria for approval.

4.3 Protocol Deviations: Unanticipated Conduct

A protocol deviation is an unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the currently approved research protocol or documents.

Examples of protocol deviations include:

a. Breach of confidentiality or privacy such as release of data to unauthorized individuals or data exposure (e.g., computer security breach, documents left unsecured etc.);
b. Deviation from the consenting process;
c. Changes in procedures initiated to eliminate immediate hazards to study participants;
d. Enrolment of participants outside protocol inclusion/exclusion criteria;
e. Inadvertent deviation in specific research intervention procedures or timing of the research intervention

As noted in 4.2 above, the PI should not implement any deviation from, or changes to, the protocol without prior REB approval, except where necessary to eliminate an immediate potential risk to participants, or when the change(s) involves only logistical or administrative aspects of the study (e.g., change in student assistants), change of telephone number, email, etc.). If uncertain, please contact the REB via the Research Ethics Coordinator.

Should a PI implement a deviation from, or a change to, the protocol to eliminate an immediate potential risk to participants without prior REB approval he/she should submit, within two (2) business days, a report notifying the REB of the implemented deviation or change, the reasons for it, and, if appropriate, an accompanying proposed protocol amendment(s) for review and approval, using the *Change Request*.

The report must include at least the following content:

a. A description of the deviation that occurred with an explanation of the circumstances that lead to the deviation and the resulting problem;
b. An explanation of whether or not the deviation increased the risk or the possibility of risk for the research participant(s);
c. A description of the steps taken or that will be taken to correct / address the problem resulting from the deviation, and;
d. A plan for ensuring that a similar deviation does not occur in the future.

4.4 Unanticipated Issues
Unanticipated issues include anything that could significantly affect the conduct of the study or alter the REB's approval to continue the study.

An unanticipated issue is any incident, experience, or outcome that meets the following criteria:

a. Unexpected (in terms of nature, severity, or frequency) given the research procedures that are described in the protocol related documents, and the characteristics of the population being studied;
b. The research places participants or others at a greater risk of harm (including physical, psychological, spiritual, economic, cultural, or social harm) than was previously known or recognized, or that were not described in the original application.
c. Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices, or procedures involved in the research).

4.4.1: Some examples of unanticipated issues include, but are not limited to:

a. A breach of confidentiality or privacy;
b. Problems with the PI or study personnel;
c. Protocol deviations / violations that affect data integrity or the safety of research participants;
d. Termination or suspension of the study by a regulatory authority;
e. Any complaint by a participant that includes a report of an unanticipated risk.

4.5 New Information and Unanticipated Findings:

Regardless of whether a research project is biomedical in nature or behavioural, all UOIT researchers must promptly notify the applicable REB of any information about a study that could affect the rights, safety, and well-being of research participants. In general, only those incidents, experiences or outcomes that require a change to the study procedures, study documents and/or require notifying the research participants shall be reported to the REB.

Notification to the REB of new information that might adversely affect the safety or well-being of the study participants or the conduct of the study must be made within two (2) business days after the PI becomes aware of such information.

4.6 Employees, Staff and Faculty obligations to report

It is the responsibility of the PI, the research team, the staff, or any other employee of this institution to promptly report to the REB any findings, results, occurrence, or new information about a study being conducted at any facility under the jurisdiction of the REB that could affect the rights and welfare of research participants. It is the responsibility of the REB staff and members to act on any such information in order to protect research participants.

4.7 Content of and REB Review of Reports of Adverse/Unanticipated Events/Issues

Reports of unanticipated issues shall be submitted using the *Adverse/Unanticipated Events Notification* and shall include the following**:**

a. A description of the incident, experience or outcome;

b. An explanation of the basis for determining that the incident, experience or outcome represents and unanticipated problem (as defined in 4.3.);
c. The PI's opinion regarding its causality to the study/device procedure;
d. The action taken in response to the unanticipated problem;
e. The outcome of the unanticipated problem;
f. The PI's opinion regarding the implications for continuation of the study; and
g. The PI's opinion regarding the need for any change to study procedures, protocol or consent documents.

4.7.1 REB Review Process of Reported Events:

All Severe Adverse Events, new information, unanticipated events and other events or findings will be reviewed by the REB Chair or designate. If the REB Chair feels that as a result of the unanticipated problem, adverse event report, or any DSMB (Data Safety Monitoring Board) or Sponsor-generated safety report that changes are required to the consent form, or that action is needed to protect the safety of research participants due to the nature or frequency of the reported serious adverse events, the REB Chair may act immediately to suspend approval of the study in question pending review by the full REB. This action will be applicable to the REB. During the convened meeting, the REB will determine whether further action is required.

4.8 Ensuring Prompt Reporting of any Serious or Continuing Noncompliance with the Requirements or Determinations of the REB

The REB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the REB policies, is not in compliance with applicable regulations, or has been associated with unexpected serious harm to participants. All credible reports to the REB of inappropriate involvement of human participants in research must be investigated by the REB Chair.

The suspension or termination of approval of research, or the results of an investigation as mentioned above will be reported by the REB Chair to the appropriate Institutional official(s).

Regulatory authorities or sponsors may also be notified by the REB in accordance with applicable laws, or the terms and conditions of research agreements or contractual arrangements.

4.8.1 Possible actions that could be taken by the REB include but are not limited to:

a. Placing a hold on the study pending receipt of further information from the PI or REB deliberation;
b. Requesting modifications to the protocol, including the inclusion or exclusion criteria to mitigate any newly identified risks;
c. Requesting modifications to the consent form;
d. Providing additional information to past participants;
e. Notifying current participants when such information might affect the participants' willingness to continue to take part in the research and requiring that current participants re-consent for ongoing participation;
f. Altering the frequency of continuing review;
g. Observing the research or the consent process;
h. Implementation of additional procedures for monitoring;
i. Requiring additional training of the PI and research staff; and

j. Termination or suspension of the research.

4.9 Renewal Requests and project completion notification

All approved projects are subject to an annual renewal process. Investigators will receive up to three (3) courtesy renewal reminders approximately thirty (30) days before expiry, seven (7) days before expiry and on the day of expiration. Projects must be renewed with the Renewal Request application (available in IRIS) or closed with the Project Completion Notification (available in IRIS) by the expiry date noted in the approval letter.

Projects not renewed by thirty (30) days post expiry date will be automatically suspended by the REB. Projects not renewed by sixty (60) days post expiry date will be automatically closed by the REB.

For suspended and closed projects, all study activities must cease unless there is an apparent or immediate hazard to one or more of the study participants. A new submission will be required to open a new file if the project has been closed by the REB.