UNIVERSITY OF ONTARIO
INSTITUTE OF TECHNOLOGY

SOP Series	SOP 300 Board of Record (BOR)
SOP Title	**SOP BOR 301 Coordinated Initial and Ongoing Review Process for Durham College and the University of Ontario Institute of Technology**
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1.0 PURPOSE

This Standard Operating Procedure (SOP) describes the initial and ongoing review process for research studies involving human participants that have been accepted for ethical review through the Durham College (DC) and The University of Ontario Institute of Technology (UOIT) Board of Record (BOR) coordinated review process.

2.0 GENERAL PROCEDURE STATEMENT

All research projects involving human subjects require Research Ethics Board (REB) approval prior to study initiation at the institution where the research project is led. The BOR coordinated review process will streamline ethics review between DC and UOIT so that an ethics submission is only required at one institution. Under the DC-UOIT BOR coordinated review process, a BOR designation will be assigned to either the DC or UOIT REB. This is a decision that will be mutually agreed upon by each REB. **To qualify for a BOR coordinated review, a project team member (e.g. Principal Investigator or Co-Investigator) must be affiliated with DC and/or UOIT.** REB submissions will be made to the assigned BOR. The BOR that will carry the responsibility for the initial review, approval and ongoing ethical review of the study.

3.0 RESPONSIBILITY

The REB Chairs, Vice-Chairs and REB administrators are responsible for executing this SOP.

4.0 DEFINITIONS

4.1 Board of Record (BOR) is the REB of the institution where the main research activities will be led. The BOR will be responsible for the ethics review, approval and ongoing review of the study. BOR is assigned to DC or UOIT by the REB Chair(s).

4.2 Delegated Research Ethics Board (DREB) is the REB of the institution that defers the ethics review, approval and ongoing review of the study to the BOR.

4.3 REB administrator: Research Ethics Officer at UOIT or Finance and Ethics Compliance Coordinator at DC who provides administrative support and liaises with the research community and REB**.**

4.4 Principal Investigator (PI) is responsible for completing the UOIT or DC REB application. The PI must be affiliated with DC and/or UOIT.

4.5 Project team member can be the PI or Co-Investigator named on the REB application.

4.6 Research activity(ies) are considered participant enrolment, research interventions and data collection.

5.0 SPECIFIC PROCEDURES

5.1 Initial Applications Submitted to the REB

Ethics applications involving DC and UOIT are screened and assessed for risk by the REB administrator upon receipt. If the application has been deemed as minimal risk research by the REB and qualifies for BOR coordinated review, the receiving REB will promptly notify the other REB. If an application has been deemed as above minimal risk by the REB, the project team member will be notified that a separate application must be submitted to other institution.

5.2 BOR Assignment

Once a project has been deemed as eligible to undergo a BOR coordinated review, each REB will work together to assign a BOR. The BOR will be assigned to the REB of the institution where the research will be led. The other institution that defers REB review to the BOR, will be considered as the Delegated REB (DREB) and will accept the decisions of the BOR. To illustrate, if the PI's home institution is DC, and the project will involve participants at UOIT, the BOR will be assigned to DC given that DC is the PI's primary affiliation. In this case, UOIT will be assigned as the DREB. As another example, if the PI is cross appointed with DC and UOIT and the project will involve participants at each institution, a mutual decision will be made between the REBs as to which institution will be assigned as the BOR.

When UOIT is the BOR, the PI will be notified by the REB administrator that the *DC REB External Researcher Institutional Permission Request Form* is required and must be submitted to DC prior to study initiation.

5.3 BOR Review Process and Records Management

The BOR will be responsible for all aspects of the initial and ongoing review of applications undergoing a BOR coordinated review process. The BOR REB administrator functions as the principle point of contact for the researchers and will provide administrative support for the BOR coordinated review process. The application will be reviewed and approved according to the designated BOR's review pathway. All initial and post review activities such as the REB review decision letter, responses to the decision letter, issuing of study decisions, ongoing continuing review and study consultations will be overseen by the BOR. Each REB reserves the right to conduct an independent research ethics review of any research involving humans at any time.

All BOR decisions will be communicated in writing to the PI. Documentation surrounding the initial and post review activities will be managed and retained by the BOR. A copy of the BOR initial study decision letter will be given to the DREB for informational purpose.

5.4 BOR Ongoing Review

The ongoing review, post approval activities (e.g. change requests and yearly progress reports) monitoring and follow-up reporting of anticipated issues and non-compliance will be overseen and managed according to the designated BOR's SOPs and policies.

When DC is the BOR, all ongoing review activities will be managed according to DC's *REB Protocol #404 (Ongoing REB Review Activities).* Likewise, when UOIT is the BOR, ongoing review activities will be managed according to *UOIT's REB SOP 207 Ongoing Review of Approved Research.*

5.5 Monitoring and Review

These procedures will be reviewed as necessary and at least every three years (unless another timeframe is required for compliance purposes). The Chair, Vice-Chair and REB administrators are responsible to monitor and review these procedures.

6.0 REFERENCES

6.1 DC REB External Researcher Institutional Permission Request Form
6.2 UOIT REB SOP 207: Ongoing Review of Approved Research
6.3 DC REB Protocol #404: Ongoing REB Review Activities