

February 28, 2020

Dear research community,

The Ontario Tech Research Ethics Board (REB) is pleased to share with you updates on new initiatives to streamline and facilitate the ethics review process, and to provide important notifications about the REB.

In this issue, you will find:

## Important notifications:

- Non-peak REB submission period
- 2018-2019 REB annual report available
- Reminder: Updated Tri-Council Policy Statement 2, 2018
- Major change: New requirements for research consent forms
- New submission tools for researchers
- Ongoing recruitment of new REB members
- New REB Twitter account
- New Standard Operating Procedure on Process for Consideration or Appeal of Decisions of the REB
- IRIS user resources and training

### **New initiatives:**

- REB application
- Pre-approvals for standing practices in research projects
- Board of Record Research Ethics Review Agreements with Ontario Shores and Lakeridge Health REBs

### Services and education:

- REB consultations
- Research ethics education
- New education e-module on vulnerable circumstances

## Important notifications

## Non-peak REB submission period

The REB encourages early planning of REB submissions to minimize unforeseen delays with project startups. We are currently in an off-peak submission period, which makes this a good time to submit an application to the REB.

## Important notes:

- The standard time for communicating results about the review is within 20 to 30 business days after the original ethics application is accepted.
  However, some applications may take longer due to the additional information or clarifications the REB may require.
- July to November is the peak REB submission period. Submitting
  applications during this period may result in extended review turnaround
  times. The REB strongly encourages researchers to apply to the REB
  during the non-peak submission period.

## 2018-2019 REB annual report available

Each year, the REB publishes a report to inform Ontario Tech faculty members, research staff and other interested groups of the REB's activities throughout the year. This year's report covers the REB's activities from July 1, 2018, to June 30, 2019, fiscal year. You can access it on the <u>Annual Reports page</u> of the REB website.

### Reminder: Updated Tri-Council Policy Statement 2, 2018

In June 2019, Canada's Secretariat on Responsible Conduct of Research released the Tri-Council Policy Statement 2, 2018 (TCPS 2 (2018)), which replaced TCPS 2 (2014) as the official research ethics policy of the federal research agencies (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council (SSHRC)). The REB encourages researchers to consult with the new version of the TCPS 2 when creating REB submissions.

Visit the Government of Canada's Panel on Research Ethics website to:

- Read the announcement about the release of TCPS 2 (2018).
- See a summary of the revisions published in TCPS 2 (2018).

## Major change: New requirements for research consent forms

In October 2019, the REB posted the revised research consent form on its website. Since then, the consent form has been piloted in a number of new REB submissions, with research users providing their feedback. The REB has made additional changes to the consent form based on this feedback, and in alignment with standards set out by current guidelines, policies, regulations and research ethics best practices.

Effective February 28, all REB submissions that involve Ontario Tech leading the research activities (e.g. research recruitment, or when the primary student population is recruited from Ontario Tech) must use the new consent form template found on the Resources page of the REB website. In cases where departures from the consent form template are required, the spirit of the template can be followed and the consent principles outlined in the TCPS 2 must be considered for alterations to the consent requirements.

### New submission tools for researchers

The Ethical Merit Assessment Form and the IRIS pre-submission REB application checklist are available on the <u>Resources</u> page of the REB website. Researchers can use these helpful tools to guide their research ethics submissions. In particular, they can use the Ethical Merit Assessment Form to self-assess their submissions to ensure the research ethics themes and principles of the TCPS 2 are considered in their ethics applications to facilitate with the review and approval.

Researchers are also highly encouraged to use the IRIS pre-submission REB application checklist to ensure applications are complete before they are submitted to the REB.

### Ongoing recruitment of new REB members

REB members play a critical role in ensuring the success of timely and ethically sound research ethic reviews. The REB continually seeks expressions of interest for appointment to the REB for general memberships (three-year term, renewable). Applicants must have knowledge of the TCPS 2 (2018) and current research experience involving human participants.

Interested applicants should send a current CV (condensed) to researchethics@ontariotechu.ca. Questions about the REB, or the position, can also be directed to the Research Ethics office at 905.721.8668 ext. 3693.

### **New REB Twitter account**

Researchers and other members of the research community can follow <a>®OntarioTechREB</a> on Twitter for news, announcements, events, and

developments surrounding research ethics at the university.

## New Standard Operating Procedure on Process for Consideration or Appeal of Decisions of the REB

A new Standard Operating Procedure (SOP) on the Process for Consideration or Appeal of Decisions of the REB is available on the <u>REB documents web page</u>. The SOP describes the REB's reconsideration and appeal process for unfavorable decisions the REB makes on proposals involving human participants or human biological materials. This procedure has been set out in accordance with the TCPS 2 (2018).

As a first step, the REB encourages ongoing collegial and collaborative discussions with the Principal Investigator (PI), the REB Chair/Vice-Chair and/or REB administration relating to the submission of research proposals. If there is a disagreement between the PI and REB over a decision regarding a research proposal that cannot be resolved through collaborative discussions, the PI is entitled to a reconsideration by the REB. If the reconsideration does not resolve the disagreement, the PI may appeal the REB decision in accordance with these procedures (Article 6.19, TCPS 2 (2018)).

## IRIS user resources and training

The Office of Research Services (ORS) offers many <u>online resources</u> to help you use the Integrated Research and Innovation System (IRIS) portal, including guidelines on registering for an IRIS account, and frequently asked questions about the system. The ORS can also provide in-person training sessions and demonstrations on how to use IRIS.

To book a training session or demonstration, contact the IRIS support administrator at <a href="mailto:iris@ontariotechu.ca">iris@ontariotechu.ca</a>.



#### **REB** website

The REB website has a new look. <u>Visit the website</u> for up-to-date information about the REB, and to access the most recent templates.

### **REB** application

The REB is in the process of revising and peer-reviewing a new REB application. The application will include new questions that align with current standard practices and regulations related to research involving human participants. The

REB currently seeks researchers to pilot the new application for future submissions and to provide feedback on the application.

The original REB application is still accessible and available for use in the IRIS research portal until the new REB application is finalized and replaces the original.

## Pre-approvals for standing practices in research projects

The REB is currently working on a pre-approval process that will allow researchers to seek approval for a standard research procedure that can be applied across similar studies (e.g. in the case of multi-research studies that conduct standard research procedures involving specialized equipment, recruitment of a unique population, and/or standard data collection procedures).

The application process will require the completion of a pre-approval application and a stand-alone document (e.g. Standard Operating Procedure or protocol) that will describe in detail the standard research practices. The REB will review the pre-approval application. Once approved, researchers can append the process to subsequent REB applications. This will eliminate the need to answer the same questions about methods each time a new REB application is submitted. This process is currently under development and more information will follow in the next few months.

# Board of Record Research Ethics Review Agreements with Lakeridge Health and Ontario Shores REBs

The ORS and the Ontario Tech REB are in the midst of developing a Board of Record (BoR) agreement and standard operating procedures between:

- Ontario Tech REB and Lakeridge Health REB.
- Ontario Tech REB and Ontario Shores Centre for Mental Health Sciences REB.

Under the BoR review process, the ethics review will be streamlined between studies involving Ontario Tech and Lakeridge Health, or Ontario Tech and Ontario Shores, where only one ethics submission is required at one institution. The aim is to have an executed agreement and standard operating procedures finalized by the end of this year. Watch for more updates in the near future.

## Services and education

#### **REB** consultations

In-person or remote consultations are available to all researchers and students who need help with their REB submissions. REB consultations include discussions on:

- How to submit to the REB.
- Human ethics advice.
- Interpreting the content of the REB application.
- Applicable legislations.
- Procedures and/or policies.
- Assessing the level of risk for your study and determining which REB application to use.

REB consultations can facilitate and streamline the ethics review and approval process; researchers are encouraged to seek a consultation before applying to the REB.

Contact <u>researchethics@ontariotechu.ca</u> or 905.721.8668 ext. 3693 to schedule a consultation.

### Research ethics education

REB representatives are available to give presentations or facilitate class discussions about research ethics. Contact <a href="mailto:researchethics@ontariotechu.ca">researchethics@ontariotechu.ca</a> or 905.721.8668 ext. 3693 to set up a time.

### New educational e-module on vulnerable circumstances

Do you find it challenging to understand and apply the concept of vulnerable circumstances in research contexts?

The concept of vulnerability is central to international and national research ethics guidelines and policies, which help REBs determine whether the risks and benefits are appropriately balanced in research proposals. Research proposals involving vulnerable populations require greater care and attention, as the participation of these populations in research may lead to vulnerable circumstances such as inadvertent exploitation and/or long-term consequences.

The Canadian Association of Research Ethics Boards created an e-module on vulnerable circumstances that will help researchers and REB members understand this abstract concept and apply it in real-life research contexts.

Key learning objectives and outcomes:

- Understand that all human participants are potentially vulnerable because of the shifting circumstances in their daily lives, or because of the risks they may encounter when participating in research.
- Explore how the concept of vulnerability has developed in light of historical events, and how key research ethics documents such as the Nuremberg Code were created in their wake.
- Explore the tension between the concepts of 'vulnerable circumstances' and
   'vulnerable populations,' and why it is valuable to struggle with that tension (including
   the confrontation of exclusion, paternalism or 'disablism,' even when these behaviours
   stem from good intentions).

To request the institutional code for the e-module, contact <u>researchethics@ontariotechu.ca</u> or 905.721.8668 ext. 3693.

The REB is committed to frequent and open communication with the research community about upcoming initiatives, updates and important notifications. In addition, we welcome any feedback or comments you may have.

Sincerely,

Ontario Tech REB researchethics@ontariotechu.ca